International Comparison of Ten Medical Regulatory Systems

Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa and Spain

Han de Vries, Paul Sanderson, Barbara Janta, Lila Rabinovich, Fragiskos Archontakis, Sharif Ismail, Lisa Klautzer, Sonja Marjanovic, Bhanu Patruni, Samir Puri, Jan Tiessen

RAND EUROPE

The study does not necessarily reflect the opinions and views of the UK General Medical Council nor is it bound by its conclusions.

The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

RAND® is a registered trademark.

Preface

This study was commissioned by the General Medical Council (GMC) to provide an evidence base on the systems of medical regulation in place in the countries of origin of doctors seeking to enter the UK and obtain registration to practise. The countries selected for analysis by the GMC are the countries of origin of the ten largest groups of non-UK qualified doctors registered in the UK: Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa and Spain.

RAND Europe is an independent not-for-profit policy research organisation that aims to improve policy and decision making in the public interest, through research and analysis. RAND Europe's clients include European governments, institutions, NGOs and firms with a need for rigorous, independent, multidisciplinary analysis. This report has been peer-reviewed in accordance with RAND's quality assurance standards.

For more information about RAND Europe or this document, please contact Lila Rabinovich.

RAND Europe
Westbrook Centre
Milton Road
Cambridge CB4 1YG
United Kingdom
Tel. +44 (1223) 353 329

Contents

List of Figures

List of Tables

Acknowledgements

Glossary

ÄAppO	Approbationsordnung für Ärzte (Medical Licensure Act)
A.c.L.T.I.	Associazione contro le Leucemie e i Tumori nell'Infanzia (a national level patient organisation in Italy)
ADIP	Greek Authority of Quality Assurance
AFMC-CEE Kerala	All India Entrance Test (executed while graduating after 12th grade and applying for university)
AICE	Associazione Italiana Contro l'Epilessia (a national level patient organisation in Italy)
AIIMS Delhi	All India Entrance Test (executed while graduating after 12th grade and applying for university)
A.I.L	Associazione Italiana contro le Leucemie (a national level patient organisation in Italy)
AIP	Associazione Italiana Parkinsoniani (a national level patient organisation in Italy)
AIPGE	All India Entrance Test (executed while graduating after 12th grade and applying for university)
AIPMT Delhi	All India Entrance Test (executed while graduating after 12th grade and applying for university)
AISM	Associazione Italiana Sclerosi Multipla (a national level patient organisation in Italy)
	A.L.A – Associazione Nazionale Famiglie Contro il Cancro Associazione Nazionale Italiana Lotta A.I.D.S. (a national level patient organisation in Italy)
A.J.K	Azad Jammu and Kashmir (the southernmost entity controlled by the Pakistani part of the former princely state of Jammu and Kashmir)
ÄK	Ärztekammern (chamber of doctors)
ANLAIDS	Associazione Nazionale per la Lotta contro l'AIDS (a national level patient organisation in Italy)

ANT	Associazione Nazionale Tumori (a national level patient organisation in Italy)
BÄK	Bundesärztekammer (German Medical Association)
BÄO	Bundesärzteordnung (Medical Practitioners' Act)
BDS	Bachelor of Dental Surgery (in India and Pakistan)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
BO	Berufsordnungen (professional codes)
CGCOM	Consejo General de Colegios Oficiales de Médicos de España (General Council of Official Colleges of Doctors)
CME Scheme	Continual Medical Education Scheme
CEU	Continuing Education Unit
DCI	Dental Council of India
DH	Department of Health
D. M	Doctor of Medicine
DMS	Directorate of Medical Services (Nigeria)
DOATAP	Hellenic National Academic Recognition Information Centre
EC	European Commission
ECFMG	Educational Commission of Foreign Medical Graduates in South Africa
E.C.M.	Educazione Continua in Medicina (program responsible for the continuous medical education in Italy)
EEA	European Economic Area
ELOT	Greek organisation for accreditation
EMRO	WHO Eastern Mediterranean office
EMS	Egyptian Medical Syndicates
ENPAM	Ente Nazionale di Previdenza e Assistenza in Favore dei Medici iscritti agli albi professionali (organisation dealing with the provincial medical associations for doctors in Italy)
ESY	Greek National Health System
FNOMCeo	Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri (an umbrella organisation for medical regulations in Italy)
FTP	Fitness to Practise
GHQ Hospitals	General Headquarter Hospitals

GMC	General Medical Council
GP	General practitioner
HEIs	Higher Education Institutions
HPCSA	Health Professionals Council of South Africa
IKA	Greek social insurance fund
IMA	Indian Medical Act
IMPP	Institute für medizinische un pharmazeutische Prüfungsfragen (Institute for Medical Exam Questions)
KAUM	Komisja Akredytacyjna Akademickich Uczelni Medycznych (Commission for Accreditation of Medical Universities in Poland)
KESY	Greek Central National Health Council
MBBChir	Degree awarded upon graduation from medical school (i.e. after six years of medical training)
MBBS	Bachelor of Surgery and Bachelor of Medicine
MBChB	Basic Dental Degree Certificate
M. Ch	Master Chirurgiae
MCI	Medical Council of India
M. D.	Doctor of Medical
MDCN	Medical and Dental Council of Nigeria
MDS	Dental Council of India's post graduation program
MIR	a test of 250 multiple choice questions for access to places of special medical education in Spain
MoHE	Ministry of Higher Education
MoHP	Ministry of Health and Population
M. S.	Master of Surgery
NARIC	Hellenic National Academic Recognition Information Centre
NGO	Non Governmental Organisation
NHRM	National Rural Health Mission
NHS	National Health Service
NIL	Naczelna Izba Lekarska (Polish Chamber of Doctors and Dentists)
NMA	Nigeria Medical Association
NQAAA	National Assurance and Accreditation Agency

NWFP	North-West Frontier Province of Pakistan
OGA	Greek social insurance
PASOK	Greek Socialist Party
PMA	Pan-Hellenic Medical Association
PMDC	Pakistan Medical and Dental Council
QAAP	Quality Assurance and Accreditation Project
RMC	Regional Medical Court
RMPD	Registered Medical and Dental Practitioners
SAMDC	South African Medical and Dental Council
SAPC	South African Pharmacists' Commission
SMAC	South African Medical Council
SMC	The Supreme Screener for Professional Liability and the Supreme Medical Court
SPL	Screen for Professional Liability
SSN	Servizio Sanitario Nazionale (Italian regional based NHS)
USAID	United States Agency of International Aid
WHO	World Health Organisation
WO	Weiterbildungsordungnen (specialised training regulations)
ZVS	Zentralstelle für die Vergabe von Studienplätzen (Administer of the admissions for medical schools)

Executive summary

The core objective of this study is to provide the UK General Medical Council (GMC) with an evidence base on medical regulation in other countries which can be utilised in developing policy and practice regarding overseas doctors who seek registration to practise within the UK. These doctors may be from within the European Economic Area (EEA) or be classified as International Medical Graduates (IMG).

In accordance with the GMC's requirements the study provides analysis of the medical regulatory systems in ten countries: Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa and Spain. Medical professionals from these countries represent the largest groups of non-UK qualified doctors registered with the GMC. The number of registrants in the UK from each country is indicated in brackets below[1]:

- Egypt (2,755)

- Germany (3,672)

- Greece (1,682)

- India (26,589)

- Italy (1,731)

- Nigeria (3,192)

- Pakistan (7,340)

- Poland (1,937)

- Spain (1,082)

- South Africa (7,167)

The assurance of quality of care and patient safety are important concerns for the GMC and (partly) depend on the regulation of the medical profession. As the core regulator of the doctors in the UK, the GMC seeks to understand how the medical regulation of medical professionals in other countries compares to medical regulation in the UK, and whether any differences could potentially affect quality of care and patient safety. Understanding these differences might also assist the GMC in developing specific policies to facilitate the smooth transition of non-UK trained medical professionals into the UK

---

[1] Data for February 2009.

medical system and easier adjustment into a new medical regulatory regime. In addition, this evidence base may help the GMC engage more effectively with other medical regulators, particularly those in the countries of origin of non-UK qualified doctors practising, or wishing to practise, in the UK.

The main findings of the study are set out below.

The structure, remit and values of medical regulation vary in significant ways between the countries examined

The countries surveyed have developed a number of different medical regulatory systems and, while all have departments of health, the development of standards and codes of ethics together with responsibility for the regulation of individual doctors has been devolved to other organisations. These range from a unitary state authorised body such as the Egyptian Medical Syndicate (EMS), the Medical and Dental Council of Nigeria (MDCN), the Pakistan Medical and Dental Council (PMDC), or the Health Professionals Council of South Africa (HPCSA), to the decentralised polycentric Spanish, Indian, German and Italian systems. In some of the countries with decentralised systems (most notably India and Spain) lack of coordination and of a harmonised approach to regulation between the local authorities is of concern and discussions are taking place to develop strategies to overcome these problems.

The extent to which regulation is combined with representation again varies. The EMS also represents Egypt's doctors and has considerable dominance while the MDCN and the HPCSA (and its constituent professional boards) are solely statutory regulators, representation being the function of, respectively, the Nigerian and South African Medical Associations. To devolve regulatory functions to representative bodies must always risk the suspicion of conflict of interest. For instance, the vast majority of the documentary output (and one might speculate, resources and thus effort) of Spanish Provincial Colleges of Doctors appears to be heavily geared towards supporting doctors rather than the protection of patients.

In terms of their remit, the medical regulatory organisations in the countries surveyed set as their primary objectives a combination of registering/licensing medical practitioners, setting standards for the profession, promoting best practice and patient safety, promoting fair access to healthcare and regulating medical education. There are some local variations. The MDCN has responsibility for homeopathy and alternative medicine, reflecting the practice of native medicine in the country. In devolved systems the bodies that represent groupings of provincial medical associations (e.g. the central General Council of Official Colleges of Doctors in Spain) may have some additional regulatory responsibilities in respect of their organisational memberships.

Purpose may also be driven by circumstances. In Greece, the relatively low rate of pay accorded to public sector doctors has led doctors regularly to charge or solicit bonus payments directly from patients. This is considered a major disciplinary offence but remains common. In South Africa the experience of apartheid has influenced regulatory objectives with a focus on equal medical treatment irrespective of race.

Nevertheless, there is a core set of regulatory functions to which all medical regulators subscribe with few exceptions. The issue is really one of the effectiveness of the regime and

its capacity and resolve to attain its stated objectives. The influence of the medical profession itself on the regulatory process is a real concern in Egypt and the failure of the Greek state to enforce its own law on doctors demanding commissions is worrying. While some of the informants interviewed for this research did indeed comment on this issue further research is needed to investigate the implementation of medical regulations in the countries surveyed.

The values of medical regulation in the countries examined are variously stated or implied. If explicit they may be expounded in legislation or set out within codes of ethics. As with regulatory purpose, there are a set of core values to which most regulators subscribe. They are expressed however in a multitude of different ways. Most can be grouped, however, into those relating to respect for patients, for scientific knowledge and for colleagues. For instance, the German doctors' code, the *Berufsordnung*, requires doctors: to preserve and enhance the trust between doctors and patients; to ensure, in the interest of the whole population, the quality of doctors' work; to persevere the freedom and the reputation of the medical profession; to encourage worthy behaviour and to prevent unworthy behaviour of doctors. There are a few additional values arising out of culture or tradition. In Egypt the first part of the code of ethics is an oath to God and there are references to Islam and pan-Arabic aspirations contained within the detail of the code, while in South Africa there is a strong emphasis on education as means of protecting the public.

Most of the values set out in the preamble to legislation or in codes of ethics are stated in aspirational terms rather than possessing any instrumental orientation, which is to say that, for example with respect to patients none referred explicitly to reducing the risk of harm. In fact there seemed very little emphasis on the concept of regulation or the measurement and reduction of risk amongst the European countries studied or elsewhere in the world. There was therefore no evidence of any real use or understanding of some of the regulatory strategies familiar to UK regulators such as better regulation, smart regulation or risk-based regulation. This may reflect cultural and linguistic differences and indeed different political imperatives, rather than being indicative of a substantive difference to UK understandings of regulation in respect of aims and objectives.

Registration with a medical regulatory body before doctors start practicing is a formal requirement in all the countries examined – with the exception of a small number of autonomous regions in Spain

In all the countries studied, registration with a medical regulatory body is a formal requirement before medical doctors start practising. The only exceptions are a small number of autonomous Spanish regions (which include Andalucía and Asturias) where medical graduates are not required to register before starting to practise medicine.

In most of the countries in this study, medical regulatory authorities do not formally distinguish between registration and licensing processes, and registration alone may be sufficient to entitle doctors to practise. In Germany, Egypt and Italy, however, registration and licensing are separate. In Egypt, registration is controlled solely by the EMS, whereas licensing for public sector doctors is the preserve of the MoHP. Doctors cannot apply for a licence with the MoHP until they have registered with the EMS. Similarly, a two stage process is to be found in Germany; doctors first need to obtain the licence to practice issued by *Länder* authorities and later register with the local chamber of doctors.

Application to the Ministry of Health is also a prerequisite to register with the medical associations in Italy. The distribution of responsibility between two regulators in Egypt, Germany and Italy, although a formal requirement, does not in practice have significant implications for the process of registering doctors in those countries.

From the perspective of medical regulation, the more interesting aspect is the centralisation versus decentralisation of the regulatory process; the countries in this study represent either one or the other model. In Germany, Spain, Poland, Italy and Greece doctors need to register with the regional office, in the province/geographical area where they intend to practise, although their licence may be valid for the whole country. In other countries, such as India, Pakistan, South Africa and Egypt, one centralised registration office exists serving all doctors wishing to practise medicine in these countries.

Another variation between analysed countries is in relation to the types of registration granted by registration bodies. In some countries, such as Italy or Egypt, doctors are granted a full licence for life. In other countries, registration is either renewable or various types of licences are granted depending on the seniority, knowledge and skills of the applicant. More details about variations in the type of registrations are presented in the table 0-1.

Table 0-1: Type of registration/licences

	Type of registration / licences
Egypt	Full for life.
Germany	Two main types: 1. full, indefinite licence to practise (Approbation); 2. limited, temporary permission to work as a doctor.
Greece	Full for life. Must be renewed each year.
India	Depending on qualifications: provisional registration (valid for one year only) and a full registration.
Italy	Indefinite licence.
Nigeria	Provisional and full registration, limited or temporary registration, registration as specialist.
Pakistan	Depending on qualifications: provisional, basic medical, basic medical with postgraduate qualifications.
Poland	Two main types: 1. provisional licence valid for 5 years; 2. full permanent licence.
SA	Six main registration categories: student, intern, public service, supervised practice, education and independent practice.
Spain	Full for life; compulsory in most – but not all - autonomous regions

The research suggests that management of the registration process is more consistent and possibly easier to control in countries with centralised regulatory structures, such as India, Pakistan, Egypt and South Africa. Integrity is also maintained in systems where regional authorities are responsible solely for the administration and implementation of national strategies (for example in Poland or Germany). However, in counties where regional

regulatory authorities have greater autonomy, such as Spain and to a certain degree Greece, it is more difficult to achieve internal (national) consistency. The more independent role of regional associations in establishing and applying their own regulations means that regulatory requirements can vary significantly within a single country.

Assessing medical qualifications can be more complex for those countries with large numbers of individuals unlawfully practising medicine, most notably India and Pakistan. In these countries, it is estimated that the number of individuals practising medicine without a formal qualification is nearly equal to the number of officially qualified and recognised doctors suggesting regulations may not be applied with the same vigour as they are in the UK.

An important aspect that differentiates medical regulatory models analysed in this study also relates to the requirement (or lack of a requirement) to re-register or renew a registration or licence. In many countries, once a registration or licence is granted doctors remain on the register for as long as their fees allow, which could be for life. This means that the regulatory authorities have only limited oversight of doctors on the register and little knowledge of the extent to which their qualifications and skills are updated.

Finally, an important factor when analysing medical registration and licensing is the real purpose of registration. In countries such as Germany, Poland or Spain registration entitles registrants to additional benefits (for example pensions, legal advice in case of complaints and continuous professional development (CPD) courses). For that reason, the benefits of registration with a medical authority may be expressed to a great extent in terms of benefit to the doctor in contrast to the UK where the primary goal of medical registration is to protect patients and ensure compliance with standards.

The requirements for a licence to practise medicine are relatively similar across all analysed countries

Conditions to be granted a licence to practise medicine are relatively similar across all analysed countries. In general, applicants have to meet the following conditions:

- Be of a citizen of a country where they apply for a licence (or EEA national in case of European countries);

- Have full entitlements to public rights;

- Have a medical university (or equivalent) degree;

- Be of professional good standing, and;

- Pay a registration fee.

Some countries impose additional requirements. For example, doctors registering in Italy, Spain and Greece need to produce a document certifying that they are resident in the area of the relevant regional registration authority, whereas in Poland in order to be granted a permanent registration doctors need to pass a national medical exam.

Within the EU, community law formally prohibits imposing any additional requirements on EU candidates moving to another member state country, including language testing. However, in some of the countries examined doctors are required to sign a declaration stating that they possess a level of language that would allow them to practise medicine in

that country, or that language requirement is tested during the recruitment process. Within the EU, this can only be a requirement for non-EEA graduates.

In all of the analysed countries, there are additional medical or linguistic requirements imposed on non-EEA applicants for medical registration. Often, candidates are examined on their medical knowledge and skills, and often they are also tested on their fluency in the language spoken in the country where they are registering.

Revalidation is uncommon in the ten countries examined

None of the countries we examined have a formal system for revalidation similar to the one being developed in the UK although some have a form of re-registration. These include Egypt, Germany, Greece, Italy, Pakistan and Spain. Only in Poland is some form of revalidation (recertification) required, although there are no direct sanctions if a doctor does not get recertified.

In India, re-registration requirements vary by state, with some states (e.g. Delhi, Maharashtra) issuing registrations for a stipulated period of time (generally 5 years) with the requirement to renew thereafter (although renewal is purely administrative). Some countries, such as Egypt, South Africa and Spain, are currently developing proposals for a revalidation system. In Egypt, the proposed process would use a points system, and be tied explicitly to Continuous Professional Development (CPD).

Even though revalidation processes are not widespread across the ten countries, in some the issue is increasing in importance on the policy agenda as they consider introducing such systems in the future. For most of these countries, however, it is difficult to assess how advanced the development of such systems is at the moment, or how long it would take for them to be fully implemented.

It is not clear why revalidation is not more widely established. The costs of revalidation may be high, but it could be argued that revalidation will prevent certain (costly) fitness to practise procedures and ensure patient safety.

All countries surveyed have a code of medical ethics which follows a relatively uniform pattern

All the surveyed countries have a code of medical ethics. These may be established by act of parliament or ministerial decree after consultation with the medical profession (Egypt, Greece, Poland) or developed and instated by a national medical association - sometimes as a template for regional association (Germany, India, Italy, Nigeria, Pakistan, South Africa, Spain). In Germany the regional chambers of doctors set their own individual codes based on the nationally developed *Muster-Berufsordnung*.

The standards contained therein are detailed in the country reports but include sections on the imperative to preserve life and health and other duties to patients, dealings with colleagues and the public or society at large. Many also contain standards relating to HIV, abortion, organ donation, genetics, CPD, and even adoption and 'truth-telling' (Pakistan). Most include definitions of malpractice and set out the potential disciplinary procedures to be faced. Of especial interest is the Egyptian code which is in three parts. The first part is a religious oath, the second focuses on the duties of doctors, the third on special treatments such as gender reassignment and drug testing.

The content of the codes follows a relatively uniform pattern with the exception of religion and special treatments. If research being carried out elsewhere suggests that the details of regulation such as the content of the doctor's home country code of ethics affects their perceptions of their duties when employed in other domains then a detailed line by line comparison may be useful.

Standards may be fully codified in a dedicated act of parliament or decree (Egypt, Greece) but more frequently are developed by national or regional medical associations. These associations are usually brought into being by statute and thus have quasi-judicial status in terms of monitoring and disciplining their members (Pakistan, South Africa). Some go further. The MDCN disciplinary panel has the formal status and powers of a high court of the federal republic. All standards have some sort of statutory framework.

While all the codes are either statutory or instated by a statutorily authorised body perhaps the real question is the extent to which codes of practice – and indeed regulations as a whole – are applied, a question a follow on research project may want to address.

In terms of developing the code there was no evidence of any requirement for periodic review except in Nigeria, and no formal consultation processes were evident although it should be noted that surveying each individual regional and local medical association was beyond the scope of this project.

The extent to which patients and the public (as well as doctors) are aware of the relevant code of medical ethics is difficult to discern

Credible information on dissemination of the codes is hard to obtain. Most are set out in full or summary form on websites although not all are easy to locate (Egypt). By law, every hospital in Greece must have an office for citizens' rights to deal with patients' complaints which would suggest that the medical code of practice ought to be available. This is also the case in South Africa where the code, the Patient's Rights Charter and the Batho Pele Principles (an initiative to enhance the quality and accessibility of government services) is readily available on the internet and is posted in every hospital. Poland also makes a virtue of disseminating information on ethics, using medical journals, print media, TV and radio. In Nigeria distribution of copies of the code is seen as a way of disseminating not only best practice but also information on what patients ought to expect of their medical practitioners. Poland is probably typical in that there is, in theory, a good deal of information available to patients on their rights but in practice the extent to which they are aware of and understand these rights remains unclear.

Only South Africa describes its process of code development as 'iterative and stakeholder inclusive.' Certainly the public in most countries are rarely consulted on such matters, if at all, and there is doubt as to the extent to which patients really know the content of the relevant code of ethics even as it relates to their own rights in respect of dealings with medical practitioners. This suggests standards and codes of practice may not be foremost in the minds of medical practitioners in their dealings with their patients.

All countries examined have disciplinary procedures in place - but there is substantial variation in the bodies responsible

While the term fitness to practise (FTP) is common in the UK medical regulatory system, similar (but not necessarily identical) regulation appears under different names in other

countries. For example, in Poland, this type of regulation is referred to as "Professional liability", while in Germany at least two procedures would fall under the FTP label, the "Berufsrechtliches Verfahren" (Procedures under the professional code) used to enforce the professional code, and a procedure by the *Länder* authorities to revoke the licence.

Although all countries have disciplinary procedures there is substantial variation in the structure of the bodies handling them. In some countries, there is only one organisation, for example Egypt, where all procedures are carried out by the (EMS), India through the Medical Council of India (MCI) and Pakistan through the Pakistan Medical and Dental Council (PMDC).

In other countries, parallel tracks exist. In Germany, there are procedures under the professional code of the association of doctors and under federal licensing law.

Still in other countries, such as Egypt, there are geographical distinctions where FTP procedures can either be at national or local level, or in Greece where procedures start at the hospital level, and may be escalated to a regional medical chamber with final appeal to the national Supreme Medical Disciplinary Board.

Finally, in some countries even though the medical council is the formal body responsible for FTP, its role appears to be marginalised in practice, because the ministry of health (such as in Pakistan) might play an important role as well.

The table 0-2 compares the different types of sanctions (shown as 'X') that can be imposed in each of the 9 countries for which we have data.

Table 0-2: Types of sanctions in FTP cases*

	Warning	Admonition	Suspension	Removal	Public statement of blame	Fine
Egypt	X	X	X	X	X	X
Germany	X	X	X	X	X	X
Greece		X	X	X		
India			X	X		
Italy	X	X	X	X		
Nigeria			X	X		X
Pakistan		X	X	X		
Poland	X	X	X	X		
South Africa	X			X		
Spain				X		

* In the cases of Spain, South Africa and India, no evidence could be found on whether other types of sanctions than those marked in the table are used in FTP cases. For those countries, reliable evidence could only be found on the use of the sanctions marked with an X.

However, the local definition of FTP, the institutional level at which FTP cases are heard (local, regional, national) and the penalties levied can vary greatly.

Unfortunately, we were only able to retrieve data on the flow and quantity of FTP procedures for a limited set of countries. This in itself is an interesting finding, as one would expect that with thorough record-keeping these figures should be readily available for any countries having FTP or disciplinary procedures. The figures reveal in important point though: the odds of a formal judgment after a complaint has been received can vary tremendously between countries. It is an open question whether this could be due to the fact that FTP panels in some jurisdictions are more likely to come to a judgment, that judgments across countries differ, or that the number of complaints received is much higher in some countries.

All countries examined have structures in place to regulate and quality assure medical education - but the bodies responsible for these functions vary across countries

All countries examined here have some structures in place to regulate and/or quality assure medical education. However, the bodies responsible for these functions vary from country to country. While in some (India, South Africa, Pakistan) the formal regulation of medical education is primarily the remit of the medical regulatory body, in others responsibilities are shared between medical councils, local authorities, and ministries or health and/or education (Spain, Poland, Germany, Egypt, Greece). Regulatory and quality assurance activities in these countries variously included: setting of curricula, administering entry exams, issuing degrees, conducting inspections of and issuing accreditations to medical schools, and other duties.

The evolution of medical education regulation and quality assurance is at different stages in some of the countries, and faces different challenges. In Pakistan, for example, one of the key concerns regarding the regulation of medical education is that many new private medical schools were started by professionals who are members of the regulatory body, thus compromising the transparency and reliability of regulatory and quality assurance processes. In Egypt, there are growing calls – including from international bodies such as the World Health Organisation (WHO) – to centralise some of the functions of medical education, such as the setting of curricula which is still the preserve of individual medical schools.

The regulation and quality assurance of medical education appeared to be a relatively uncontroversial issue in most of the countries. With the notable exceptions of Pakistan and Egypt, which face distinct challenges in this area, in other countries the regulation and quality assurance of medical education did not seem to raise particular concerns. It is apparent from our research that the countries examined here have different approaches towards the regulation and quality assurance of medical education but, unlike other areas of medical regulation, there is little sense of growing international convergence in this area, or of a need for such convergence.

Approaches to continuous professional development (CPD) vary widely – but the attention paid to CPD by regulators is increasing

In most countries CPD is part of the medical code of practice, but the organisations that promote CPD vary from country to country. In Spain and Germany, for example, CPD is one of the main areas of activity of the provincial medical colleges and regional chambers of doctors, which often provide training courses and related services. In others, such as South Africa, standards and the promotion of continuous professional development is

done primarily by the HPCSA, which randomly audits about 10% of all doctors every year to check on their compliance with the South African CPD requirements. However, other bodies such as ministries and scientific societies are also involved. In Egypt, the regulation or promotion of CPD is rudimentary although talks of a system of CPD are quite advanced. The proposed system, administered by the MoHP, would be based on credits, to be accumulated year-on-year, to ensure that training is kept up to date. There are concerns, however, regarding the country's capacity to implement such a system in practice.

The divergence in the CPD systems in the ten countries examined in this report is of great interest. This issue appears to be increasing in importance on the policy agenda in many of the countries examined. Our research suggests that the extent to which CPD is rooted within the regulatory structures of the medical field varies significantly. South Africa is a notable case in which the debate on CPD is highly advanced and systems to ensure CPD among professionals have been developed and implemented. While the implications of this are uncertain, it is possible that the prominence of CPD in the different countries to some extent shapes doctors' perceptions of and attitudes towards it.

The differences in the medical regulation systems of these countries has a number of policy implications for the GMC

This report provides a wealth of information on medical regulation in ten other jurisdictions. As highlighted in the introduction to the report, this information aims to contribute to an evidence base to inform GMC policy and practice. It may help frame and inform approaches to dealing with some of the more salient challenges facing the GMC when dealing with non-UK qualified doctors.

For example, improvements in communication with other regulators could be beneficial. At present the GMC may not know if a doctor who applies to practise in the UK has previously been removed from a register overseas.

More challenging for the GMC is the issue of how medical practitioners make the transition from their own jurisdictions into the UK regulatory system, and the processes of adjustment they undergo. How can the GMC facilitate this? One way could be to engage non-UK qualified doctors more actively in understanding, and embracing, the GMC's standards and codes of ethics and practice. According to our research, in many of the countries examined the regulator may be focusing too little on the patient and quality of care, and too much on the interests and welfare of the professional. It may be useful therefore to ensure that newly-arrived doctors are made aware of the *detail* of what a patient-centred approach means and what it therefore implies for everyday medical practice.

Some issues and debates that have occupied the GMC for some time may be only just emerging in some countries, if present at all. For example, our research indicates that revalidation processes are in place in only a few countries. The new regulations around licensing and revalidation that will come into place shortly in the UK will probably embody concepts that are unfamiliar to some incoming doctors.

These examples are intended to provide an indication of the way in which the information presented in this report might be used to support policy and practice development.

Introduction

1.1 Objective of this study

The core objective of this study is to provide the UK General Medical Council (GMC) with an evidence base on medical regulation in other countries, which can be utilised in developing policy and practice on graduates from the European Economic Area (EEA) as well as International Medical Graduates (IMG) (i.e. those who qualified outside the UK) seeking or obtaining registration within the UK. The study aims to:

- Increase the GMC's understanding of the values, structures and operations of non-UK medical regulators;

- Help the GMC identify similarities and differences between medical regulation in the UK and in other regulatory jurisdictions;

- Provide an evidence base on international medical regulation that can inform the GMC in the development of policies and procedures for supporting and working with EEA and IMGs, and;

- Develop a body of regulatory contacts to facilitate collaboration globally.

In accordance with the GMC's requirements, the study examined the medical regulatory system in ten countries: Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa and Spain. Medical professionals from these countries represent the largest groups of non-UK qualified doctors registered with the GMC. The approximate number of registrants in the UK from each country is indicated in brackets below[2]:

- Egypt (2,755)

- Germany (3,672)

- Greece (1,682)

- India (26,589)

- Italy (1,731)

- Nigeria (3,192)

---

[2] Data for February 2009.

- Pakistan (7,340)

- Poland (1,937)

- Spain (1,082)

- South Africa (7,167)

The assurance of quality of care and patient safety are important concerns for the GMC and (partly) depend on the regulation of the medical profession. As the core regulator of the medical profession in the UK, the GMC seeks to understand how the medical regulation of medical professionals in other countries compares to medical regulation in the UK, and whether any differences could potentially affect quality of care and patient safety. Understanding these differences might also allow the GMC to develop specific policies to facilitate the smooth transition of medical professionals trained abroad into the UK medical system and easier adjustment into the new medical regulatory regime. In addition, this evidence base can help the GMC engage more effectively with other medical regulators, particularly those in the countries of origin of non-UK qualified doctors practising, or wishing to practise, in the UK.

1.2   Motivation and Background

The international migration of doctors is a growing phenomenon worldwide. In general, geographical proximity, shared language, customs and educational curricula are the factors influencing the choice of a destination country for migrating doctors, with historical links (such as colonial rule) still affecting mobility directions.[3] In Europe, nearly all countries report increased in-flows of medical professionals, although the migrant doctor's profile significantly differs across EU member states. While doctors from EU countries constitute more than a half of all non-UK qualified doctors in Austria, Portugal and France, nearly three quarters of internationally-trained medical practitioners in the UK are from outside the EU, mainly from the former British colonies.[4]

For a long time the NHS has been reporting healthcare staff shortages that affect the efficiency of the system and service delivery. Notwithstanding recent investment in medical education the number of students at British medical schools, and consequently the supply of doctors, has consistently failed to match NHS requirements - with UK-qualified doctors

---

[3] Buchan, J. 2006, 'Migration of health workers in Europe: policy problem or policy solution?' [in:] Dubois, C. A., McKee, M., Nolte, E. (eds.): 'Human resources for health in Europe' [in:] *European Observatory on Health Systems and Policies Series*, Maidenhead, New York: Open University Press; World Health Organisation, 2006, *Health Worker Migration in the European Region: Country Case Studies and Policy Implications*, Copenhagen; Wiskow, Christiane, 2006. *Health worker migration flows in Europe: Overview and case studies in selected CEE countries – Romania, Czech Republic, Serbia and Croatia*, International Labour Office, Geneva.

[4] Garcia-Perez, M. A., Amaya, C. and A. Otero, "Physicians' migration in Europe: an overview of the current situation", *BMC Health Services Research* 2007, 7: 201. and Bourassa Forcier, M., Simoens, S. and A. Giuffrida, "Impact, regulations and health policy implications of physician migration in OECD countries", *Human Resources for Health*, 2004, 2:12

only supplying around 80% of total need.[5] According to Department of Health (DH) statistics, the total number of registered doctors increased by 48% between 1986 and 1995, whereas the proportion of doctors who qualified in the UK fell from 61% to 42%. Data for the period between 1995 and 2000 also provides information on the trajectory of medical workers migratory trends. While the proportion of European Economic Area (EEA) doctors working in the UK remained at about 6%, the proportion of non-EEA trained doctors on the GMC register increased from 23% to 26% over the same period.[6]

The international recruitment of medical professionals was, and to a certain extent still is, part of an explicit British government policy to assist in increasing the number of NHS workers. The DH stated that "international recruitment is a sound and legitimate contribution to the development of the NHS workforce".[7] As a result, the NHS is one of the main recruiters of overseas-trained healthcare workers and reports the highest level of inflows of IMGs among all EU member states. In total, non-UK trained doctors make up approximately 33% of all NHS doctors.[8]

Immigration policy and regulations for accreditations of medical qualifications are two of the key factors shaping the inflow of non-UK qualified doctors to the UK. Although the traditional colonial links still play an important role in the provision of medical workforce, the free movement of people in Europe with unrestricted access to the labour markets as well as mutual recognition of professional qualifications increases the mobility of workers in the EEA area.

There are some fluctuations over time in the number of non-UK qualified doctors from particular countries practising in the UK. Irish doctors, having a long tradition of migrating to Britain and working in the NHS structures, are no longer among the top ten suppliers. On the other hand, there is a growing trend in the provision of doctors from the EU new accession countries, such as Poland. While in the pre-accession years there were on average 20 new GMC registrations issued to Polish doctors annually, the number of Polish-trained doctors on the GMC register has grown significantly in the last years with more than 2,300 new registrations from 2004 to 2006.[9] Although there is an increase in the number of registrants from EU countries, non European-trained doctors still make up

---

[5] Johnson, J., 2004. *Speech of the chairman of Council of the BMA*, 28 June 2004, London: British Medical Association. Available from: http://www.bma.org.uk/ap.nsf/Content/ARM04chCouncil. Last accessed 3rd April 2008.

[6] MWSAC, 1997, "Planning the medical workforce'', third report, Medical Workforce Standing Advisory Committee, <www.doh.gov.uk/medical/mwsca3.htm>, in: Raghuram, P. and E. Kofman, "The state, skilled labour markets, and immigration: the case of doctors in England", *Environment and Planning A*, 2002, v. 34, pp. 2071-2089.

[7] Department of Health, 2004, *Code of practice for NHS employers involved in international recruitment of healthcare professionals*, London, p. 7.

[8] Buchan, J. 2006, 'Migration of health workers in Europe: policy problem or policy solution?' [in:] Dubois, C. A., McKee, M., Nolte, E. (eds.): 'Human resources for health in Europe' [in:] *European Observatory on Health Systems and Policies Series*, Maidenhead, New York: Open University Press.

[9] This information was drawn from the GMC registration office (Janta, B. (2007) *Experiences of Polish medical doctors working in the United Kingdom*, University of Cambridge MPhil dissertation thesis).

a large proportion of the medical professionals registered with the GMC, with doctors from former British colonies, such as India, Pakistan and South Africa constituting the highest share of overseas-trained doctors practising in the UK.[10]

Studies have shown that the medical labour market for overseas doctors is highly differentiated in the UK. Non-EEA doctors are more likely than their European counterparts to be employed at the higher medical grades (27% and 7% respectively), however, they are also more commonly concentrated in non-consultant career grades, such as staff grades[11] and trust doctor posts, meaning that they have limited options to advance their career.[12]

1.3 Research Questions

Our study addressed two main research questions:

1. What are the main characteristics of the medical regulatory systems in the ten countries examined here?

2. What are the implications for GMC policy stemming from these similarities and differences?

The first question is the main question of the study and directly addresses the GMC's request to learn more about the similarities and differences between medical regulation systems across the world, compared to the UK. The second question aims to provide an answer to the first question in a policy-relevant perspective, and facilitate the GMC's desire to develop appropriate policies and procedures. The project also produced a typology of medical regulatory systems, to facilitate identification of similarities and differences with the UK, and an understanding of the values, approaches and workings of medical regulation outside the UK.

1.4 Structure of the report

We discuss the method used to answer our research questions in Chapter 2. Chapters 3 to 12 contain a description of the medical regulatory system in each of the ten countries: Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa, and Spain.[13] Each of these chapters is structured to follow the typology (presented in appendix A). Chapter 13 summarises the key findings from the ten country case studies, and briefly

---

[10] Raghuram, P. and E. Kofman, "The state, skilled labour markets, and immigration: the case of doctors in England", *Environment and Planning A*, 2002, v. 34, pp. 2071-2089.

[11] In 2000, 66% of all doctors working at the staff grade positions were from non-EEA countries.

[12] Raghuram, P. and E. Kofman, "The state, skilled labour markets, and immigration: the case of doctors in England", *Environment and Planning A*, 2002, v. 34, pp. 2071-2089.

[13] It is worth noting that not all the chapters contain information on every heading of the typology, as there were differences in the extent and quality of the information that could be drawn from the desk research and interviews for each of the regulatory jurisdictions examined here.

discusses their implications for understanding medical regulation in other jurisdictions. Here again we follow the structure of the typology. Finally, we discuss conclusions and recommendations in Chapter 14.

Research approach

Our approach to the research comprised four main steps. First, we developed a typology of medical regulatory systems. Second, we characterised the medical regulatory system of each of the ten countries according to this typology, based on available documents and key informant interviews. Third, we conducted a cross-country analysis to draw key messages and issues of particular interest to the GMC. In a fourth and final step we draw conclusions and implications for the GMC, and recommendations for further research. The approach to each of these four steps is described in this chapter.

2.1 Development of a Typology of Medical Regulation

We started by developing a typology of medical regulation, which would allow us to characterise medical regulatory systems in a structured way. The typology can also be used as a tool for the GMC to effectively compare other medical regulatory systems to that in the UK.

To develop this typology, we conducted a brief review of the literature on medical regulation and developed an interview protocol. We then interviewed 20 GMC staff across all major disciplines in medical regulation, including:

- medical regulation and quality assurance
- fitness to practise
- clinical assessment and international graduates
- medical education
- governance
- public and patient involvement
- standards & ethics
- registration

Based on the literature and interviews, we developed a 3-level hierarchical typology of medical regulatory systems, which was used as a tool to draw information from each of the medical regulatory jurisdictions examined in this study. The typology is presented in Appendix A. By providing a common structure to all the countries studied, the typology ensured consistency and comparability.

2.2 Data collection: Literature review and key informant interviews

We developed a questionnaire based on the typology and identified within each of the ten countries the main organisations and governmental bodies responsible for medical regulation. For most countries, we interviewed key informants within some of these organisations by telephone. In a few cases it was difficult to identify and schedule interviews with key informants and we had to rely on other contacts. To provide some idea about the background of our interviewees and their familiarity with the topic, we give the following examples:

- Vice president of National Health Council

- Member of disciplinary committee of a Medical Association

- President of Association of General and Private Medical Practitioners

- Head of the International Relations/Cooperation team of the Chamber of Doctors and Dentists

- CEO of Medical Sector NGO

- Secretary-General of the Medical Council

- WHO consultant for quality and accreditation

- Member of the Continuing Professional Development Council

- Member of Human Rights and Ethics Committee

In addition to the key informant interviews, we collected information on medical regulatory systems in each of the ten countries through desk-based research, particularly looking at information provided by relevant organisations and governmental bodies on the internet, in legal documents and in any other literature on medical regulation available online.

It is worth noting that because of the significant variation in the type and quality of information available for each of the countries, the country chapters are significantly different to each other. While they all address the same research questions, and are organised with broadly the same structure, they are heterogeneous in style, length and content.

2.3 Comparative analysis

To compare medical regulation across the ten countries, we analysed similarities and differences across the countries within each subsection of the typology, and briefly examined the implications of these for the GMC's understanding of different medical regulatory systems.

2.4   Conclusions and recommendations

As a final step, we summarised some of the key messages emerging from the cross-country comparative analysis and discussed some of the implications for the GMC. Finally, based on our analysis and findings, we provide recommendations for further research.

CHAPTER 3 **Medical regulation in Egypt**

3.1 Overview

There are currently around 200,000 doctors registered to practise in Egypt.[14] A survey conducted by the WHO in 2005 found that around 68,500 practised wholly in public hospitals administered by the Ministry of Health and Population (MoHP).[15] The disparity in these two figures reflects the considerable extent of private healthcare provision in Egypt, where up to 60% of healthcare expenditure is supported by out-of-pocket contributions.

Medical regulation in Egypt involves fairly basic systems of registration, licensing, and oversight of medical education establishments. The core regulatory functions in the medical field in Egypt are carried out by the Ministry of Health and Population (MoHP), the Egyptian Medical Syndicate (EMS) and to some extent by the medical schools, many of which house large hospitals.

---

[14] The availability of general descriptive information on the medical regulatory system in Egypt is good, contained usually in broader reports on the organisation and financing of the health system that have been produced by international bodies, in particular the WHO. Similarly, formal, legal documents on the regulatory system are freely available in Arabic on the website of the Egyptian Medical Syndicate (information in Arabic was translated into English by the case study author). However, statistical data to support these general perspectives is much harder to obtain: the most recent figures available are for 2005, some are contradicted by data presented in other sources, and anything we state for the years since 2005 comes directly from key informant interviews for which independent verification is necessarily more difficult to obtain. Two key informant interviews were conducted for this case study: one with a professor at an American University specialising in the Egyptian medical system (in particular on quality assurance), and the other with a member of the Egyptian Medical Syndicate. The first was conducted in English, the second in Arabic. Interviews were a vital source of information for this case study, particularly in shedding light on disparities between the system as it is represented in legislation and official government documents, and as it is actually implemented on the ground.

[15] Figure based on most recent survey of membership of the Egyptian Medical Syndicate, conducted in 2005 for a WHO study on the health system in Egypt. WHO EMRO report: *Health System Observatory: Egypt* (2006), online at: http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Health%20system%20reform.pdf (accessed October 2008).

3.2 Structure and nature of medical regulation

3.2.1 Purpose of the medical regulatory system

The dual purpose of the medical regulation system in Egypt is to:

1. Ensure that doctors practise in the fields in which they are formally qualified; and,

2. To provide a system of values and an ethical code upon which medical practice is based.

3.2.2 Drivers and influential events

While tacit codes of ethics have been in place to help govern medical practice in Egypt since at least the colonial period, regulatory practices were not enshrined in law until 1945. The current regulatory system is based in large measure on the stipulations laid down in Law 54, which provided for the establishment of the EMS. This was one of a series of laws passed in 1969 calling for the establishment of professional 'syndicates' to help govern the health system in Egypt. Similar organisations were formed for dentists and nurses, among others. The aims of all of these syndicates fell roughly into line, and included:

- "Improving the practice of the profession scientifically and socially and raising its standard, which entails maximum benefit to the syndicate's members and to citizens in general;

- Endeavouring to render treatment opportunities available to all citizens especially in rural areas and for those on low incomes;

- Cooperating with the doctors' syndicates in other Arab states, in serving the Arab nation, as well as working towards constituting a Union for Arab doctors;

- Reinforcing relations with dentists in Asia, Africa, Latin America and the rest of the world's states;

- Participating in the development of policies concerning medical education, the improvement of its curriculum and the technical training of doctors;

- Assisting in the provision of work opportunities for the syndicate's members;

- Mobilizing the members' capacities in order to actualise the medical mission to address the health problems of the population, so as to render healthcare a secured right for all citizens, whether in the form of protection or treatment".

There is now widespread recognition that the medical regulatory system in Egypt is in need of reform. A key driver for recent improvements in medical regulation has come from government. In 1998, the MoHP launched a major health system reform initiative with the publication of its *Egypt health service analysis and future status* report. This document included a specific commitment to improve regulatory systems in the health sector. Key features of the reform programme are:

- 'To redefine the role of the MoHP to develop its regulatory functions, notably to establish quality norms and standards and to establish a mechanism of accreditation and licensure to enforce these standards, and to consolidate multiple public health programs;

- To strengthen the program for training and retraining of family healthcare doctors, nurses and health professionals, with greater emphasis on preventive healthcare;

- To decentralise management of the government health delivery system to the governorate and district level, and introduce greater managerial autonomy at the level of individual medical facilities;

- To rationalise public investment in health infrastructure and health manpower based on Governorate and District Health Plans that identify the actual needs and availability of resources to sustain the investments."[16]

International aid agencies have also played an important role in driving the implementation of reforms since 1998, usually as major donors. Key actors have included the United States Agency for International Development (USAID), the European Commission (EC), the World Bank and the African Development Bank. They have also provided considerable financial support for the implementation of improved accreditation structures in higher education. The World Bank has played a particularly important role in this context. A $50 million loan in 2002 to support programmes of reform for higher education included support for an initiative that launched a Quality Assurance and Accreditation Project (QAAP) as part of the Ministry of Higher Education (MoHE).[17]

The role of patients and their representative interest groups is however limited in influencing medical regulation. Some changes occurred as a result of a scandal and media storms but these are rare occurrences.

3.2.3 Values within medical regulation

The laws governing professional syndicates include key statements of values for members. For EMS, a key article of Law 54 states that "a member should have the traditions and honour of his profession in mind while performing his duties". The law also requires doctors not to engage in "commercial activities or any other occupation that may be contrary to the dignity of the profession". Furthermore, doctors are required to take the following oath: "I swear by God Almighty to perform my duties according to the rules of faith and honour, and to keep the secrets of the profession and execute its rules of conduct and respect its traditions".[18]

Risk of harm to patients as a basis for medical regulations in Egypt is only evident through the oath sworn by medics when they have registered and are admitted formally to the profession. One interviewee suggested that serious discussion on the need for improved patient safety were only just beginning to emerge in Egypt. A certain expectation remains that in their actions doctors will be guided by a moral compass – the oath is preceded by a brief invocation of religious faith (Islamic) as an important guide to medical practice.

---

[16] WHO EMRO report, *Health System Observatory: Egypt* (2006). Online at: http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Health%20system%20reform.pdf (accessed October 2008).

[17] See: http://www.qaap.net/about_us.htm (accessed October 2008)

[18] Translated from the Arabic text of law 54.

It is important to note that the law does not include any explicit value statements regarding conduct towards patients.

3.2.4 Interactions between regulatory bodies

While the MoHP, EMS and medical schools all have a role in administering medical registration, licensing and regulation in Egypt, remits are not clearly defined and there is some overlap between organisations. Partly as a result of this confusion over administrative remits, standard-setting in the Egyptian medical system is patchy. On the other hand, the establishment of a standard-setting unit in the MoHP in 2002 – providing guidance on both health technologies and medical practice – suggests that there is an awareness of this deficit. Its early activities have included substantial work on family health.

The Egyptian Medical Syndicate

The EMS is Egypt's association of doctors, and is by far the most powerful professional association in the health sector. It is also the administrator of a large-scale health insurance model, the Medical Union, which includes the four medical syndicates (doctors, dentists, pharmacists and veterinarians). The plan services members of the syndicates, their spouses, children, retirees and widows/widowers of deceased members. Although core functions are held within the central office, the EMS also has 28 branch offices, one in each country governorate. These offices mostly administer continuing education programmes for doctors.

The EMS currently has three main areas of responsibility: (1) registration of all doctors in Egypt; (2) administration of continuing professional education post-registration; and (3) administration of Fitness to Practise (FTP) proceedings against individual doctors.

The Syndicate currently has around 200,000 registered members, including doctors practising abroad. Around 60,000-70,000 of these practise abroad in the Middle East, Europe, North America and Australasia. The Syndicate registers, on average, 12,000 new doctors every year.

The Ministry of Health and Population

The MoHP theoretically has the regulatory capacity to design and implement national standards. Formally, its functions include: (1) capital investment in the health system; (2) health care facility accreditation, through an autonomous body that collaborates with the MoHP Quality Assurance Unit; (3) licensing of all doctors practising in Egypt; and (4) regulation of health insurance.

There is an important administrative distinction between the jurisdictions of the MoHP and EMS in that, although both organisations formally regulate medical practice in the public sector, the MoHP is currently solely responsible for regulating practices in private clinics.[19] This represents a potential administrative problem since doctors operating in the private sector are not required to register with the Ministry. They must merely secure an appropriate licence for the clinic in which they practise.

---

[19] Mona El-Nahhas, 'The doctors' dilemma', *Al Ahram Weekly*, 20th-26th June 2002. Online at: http://weekly.ahram.org.eg/2002/591/feat2.htm (last accessed January 2009).

3.2.5 Funding arrangements for medical regulatory bodies

Funding for quality and accreditation initiatives in Egypt has historically been dominated by contributions from international aid agencies working in the country. For basic registration and licensing functions, however, funds come from the MoHP, the EMS and the medical schools. Some of the yearly government funding to the MoHP is channelled into a Quality Unit. The EMS, on the other hand, is a membership organisation for doctors and receives very limited statutory funding. It is supported principally by subscriptions from its members – currently of approximately LE 150 per annum (equivalent to around £18).

3.3 Registration process and requirements

3.3.1 Registration and licensing process

Medical registration and licensing is granted for life following completion of a registration year of practice, after graduation from medical school. Responsibility for registration and licensing are held by different actors. Registration is controlled solely by the EMS. Licensing is the preserve of the MoHP. All doctors wishing to practise in Egypt require *both* registration and a licence to practise. Doctors cannot apply for a licence with the MoHP until they have been registered at the EMS.

In the first instance registration with the EMS at this stage is as a General Practitioner. After specialist training doctors can register as specialists although this does not formally change the status of a doctor's licence. More recently nurses and midwives have also been required to register with the MoHP. It is uncommon for registration and licensing applications to be rejected.

3.3.2 Registration for overseas doctors

Unlike the situation in the UK, Egypt has for some years enjoyed a relatively healthy doctor-citizen ratio compared with other countries in its income band (i.e. middle-income countries). The medical education system in Egypt produces enough qualified doctors. Opportunities for those qualified outside Egypt are in relative short supply. It is far more common for Egyptian doctors to move abroad in search of work than the other way round. Almost all practising doctors in Egypt are graduates of the Egyptian system, which is partly explained by the fact that Egyptian medical schools were until recently regarded as among the best in the Middle East (although according to one of the interviewees this is no longer the case).

If an Egyptian hospital wishes to invite a doctor trained abroad to practise, securing special permission from the Syndicate is a requirement.

3.4 Standards & ethics

While a regulatory code of ethics is now in place, and basic norms of medical practice are governed by the Syndicate Law, one interviewee suggested that "standards of practice are questionable" in reality. One of the interviewees suggested that there is now a National Code of Medical Ethics (set down by ministerial decree in the past few years). However,

no evidence of such a code can be found on any government websites, nor could the interviewee give explicit detail on its contents. It therefore seems unlikely that patients would have a clear awareness of their "rights. It was also difficult to establish whether a patients' rights movement exists in Egypt.

3.5 Fitness to practise (FTP) and related disciplinary procedures and sanctions

Since there is no rolling system of checks and evaluations for medical practitioners, FTP in Egypt tends to take the form of disciplinary proceedings and imposition of sanctions where evidence of malpractice has been found. Formally, all disciplinary proceedings against practising doctors are handled by the EMS, in accordance with its governing law. The EMS disciplinary body was established on the premise that: "Any member would be tried before the disciplinary body who: violates the provisions of this law or the morals of the profession and traditions; abstains from executing the decisions of the general assembly, the syndicate's board, the assemblies at the governorates, or the boards of the branch governorates; commits actions violating the profession's honour or degrades it; or commits negligence in a work related to his profession."[20]

3.5.1 Definition of FTP

FTP is not formally defined either in Syndicate law or the National Code of Medical Ethics. Instead, it is judged against the doctor's efforts to uphold the values expressed in the Law and Code, as outlined earlier in the case study.

3.5.2 Penalties and implications of violations at minimal levels

According to Syndicate law, a scale of sanctions can be applied according to the severity of the case:

1. Notice;

2. Warning;

3. Public statement of blame;

4. A fine of LE 200 (approximately £25) to be paid to the treasury of the syndicate;

5. Suspension from the syndicate for a period not exceeding a year; and finally,

6. Loss of the syndicate membership, which also entails revocation of the licence held with MoHP. In this instance, the doctor is not allowed to practise until or unless he/she is reinstated at the Syndicate.

3.5.3 Formal disciplinary proceedings

In those instances where proceedings are called, they may be heard either at national level or at local (branch) level. The doctor concerned is permitted to continue practising throughout the period during which a complaint is under consideration (which may last up to 1-2 years); the Syndicate has no legal authority to bar a doctor from practising during this period.

---

[20] Translated from the text of law 54.

Investigations into charges made against individual members are heard before a specially convened committee at a national or local branch of the Syndicate. Members of the committee typically include the Syndicate's deputy chairman, a member of the Administrative Prosecutor's office at the governorate level, and either the syndicate's General Secretary or the branch secretary. The investigation committee, the defendant and indeed those lodging the complaint may calls witnesses to support their respective cases.

Formal disciplinary proceedings, by contrast, are led by specially convened panels consisting of five participants. Three of these participants are judges; the other two are doctors chosen by the Syndicate – one to represent the doctor charged with misconduct, the other to represent the patient. The Syndicate chooses its two representatives on the panel from its core membership body, with the head of the panel typically being the individual who has been a member of its Council for longest. The charges considered by the disciplinary panel are normally decided on the basis of the findings of the investigation committee. In practice, its role appears to be one of effectively rubber-stamping the findings of the investigation committee. Final decisions are recorded both with the EMS (at national level) and with the MoHP.

All disciplinary proceedings – whether investigative or final – are conducted as closed sessions. Typically, there is a 'contest' period of 60 days during which the defendant can appeal against the findings of a case. If no successful appeal is lodged, the punishment recommended by the disciplinary committee stands. It is extremely rare for doctors to be permanently struck off. Public hospitals may independently take the decision to suspend a doctor in cases of malpractice, but one interviewee felt that in general terms employment law in Egypt makes this very difficult for public sector employers. In the private sector, on the other hand, the same interviewee suggested a much greater willingness to dismiss doctors accused of malpractice.

3.5.4 Disciplinary vs. criminal proceedings

Criminal proceedings may be brought against a doctor in cases of malpractice, but this only occurs if the patient concerned or their family decide to sue.[21] The Syndicate is quickly involved in all such cases as a representative of the doctor concerned, and action will typically lead to an investigation committee being set up.

3.5.5 Prevalence

In general terms, it is unusual for complaints to move to formal proceedings against an individual doctor. For example, in 2007, some 705 complaints were received by the Syndicate from all sources. Of these, 542 were found to be without basis, or inappropriate for consideration by the Syndicate and not pursued. 163 were referred to specially convened investigative committees, and of these, 27 were passed on to formal disciplinary committees. Formal judgements were passed in only 20 cases in 2007, imposing varying degrees of punishment on the doctors concerned.[22]

---

[21] The Egyptian legal system retains some aspects of *Shari'a* provision in this area.

[22] All figures provided by a key informant from Egypt.

3.6 Medical education

The medical education system in Egypt is dominated by 23 medical schools: 18 in the public sector and five private institutions. The capacity of these institutions (in terms of the number of graduates that they turn out annually) currently stands at 26,318.

3.6.1 Education trajectory

Enrolment in higher education in Egypt is managed solely through the total score of the secondary school graduation examination and certificate (the *thanawiyya 'amma*) – there are no interviews for prospective university candidates. Entrants into medical school are normally among the highest scorers because of the perceived desirability of medical qualifications.

There are currently 49 colleges of medical education across the public, private and non-profit sectors, with 116,326 students enrolled at the last count (in 2005). Of these, 23 are specialist medical schools. However, there has been growing concern that the medical school system is heavily oversubscribed, and particularly that there is now a 'glut' of trained medical professionals on the market. As a result, the government has upheld a recent call from the EMS to cut the number of entrants into medical schools across the country by 14% in 2008. This is an unprecedented move, and its impact on the health system in Egypt is difficult to predict.

3.6.2 Undergraduate education

The medical education system in Egypt roughly follows the trajectory of the British system. This includes three years of pre-medical training, leading to an undergraduate qualification (a BSc), followed by a further three years of clinical training. Upon graduation from medical school (i.e. after six years of university training) candidates are awarded an MBBChir.

The undergraduate education system for medicine is currently undergoing substantial reform. Historically, curriculum setting has been the preserve of the medical schools, who have often done so independently. However, there is now recognition that setting curricula should be a centralised, collaborative effort between the MoHP and the MoHE. Reforms to the undergraduate medical education system have been adopted to give undergraduates experience in providing clinical care from an earlier stage, with a much stronger community and family focus. However, these reforms have not been fully implemented yet, partly because of a lack of capacity. The proposed new regime will require trainers to operate in those governorates where training capacity is poor. Furthermore, training centres will need to be established to support this new initiative. Overall, the new reforms are an attempt to move towards a more facilitative, problem-based learning style, rather than a didactic one.

3.6.3 Further education, specialisation and career progression

Once candidates have graduated from medical school, they participate in a registration year. This requires graduates to spend one to two months in each department of a state hospital, on rotation.

Historically, once formal registration had been granted, trainee medics could specialise in one of two years of compulsory work in a state hospital.[23] Upon completion of this three-year post-qualification training programme, doctors were free to practise as specialists in the public or private sector. Recent reforms have changed this system. Further education and specialisation post-qualification in Egypt is now split between two streams. On one hand, doctors may follow a formal academic track, leading to tenure at one of the Universities/teaching hospitals in Egypt. On the other, they may pursue a recently introduced professional qualification administered by the MoHP.

Formal postgraduate education (i.e. within the university system) in Egypt roughly follows the British system, with one important exception: doctors must obtain a Diploma in their chosen area of specialty before taking a Masters. Typically, Diplomas are completed in two years. Masters degrees take a further 2-3 years. PhDs are awarded after 3-4 years of postgraduate study, as they are in Britain. Career progression in academic medicine is closely tied to these qualifications, and academic doctors are unlikely to be promoted to consultant status without a PhD. In general, a Masters degree is enough to secure Junior Lecturer status; a PhD will elevate the holder to Senior Lecturer.

For those seeking further specialisation without an academic career, the MoHP has recently established a Fellowship qualification, which includes a range of specialist clinical skills and general skills such as teamwork and communication. This qualification was introduced about 10 years ago, with the first graduates emerging in the early 2000s. It is not considered equivalent to a PhD by the Supreme Council of Universities in Egypt because it does not include a thesis. The Fellowship programme is currently administered by the Egyptian Board of Medical Specialisation, an off-shoot of the MoHP, with approval from the Arab Board of Medical Specialisation. While this qualification does not seem to be introducing more rigour into the process of promotion in MoHP hospitals, one interviewee suggested that in general terms, promotion was based on seniority and experience rather than ability demonstrated in this way.

3.7   Continuing education and revalidation

Continuing education is perceived as a key weakness in the Egyptian health system. Indeed, a recent WHO report held that "continuing education for all categories of health worker continues to be fragmented and uncoordinated". The choice of whether to pursue continuing education is regarded as an individual decision and there are no formal structures for encouraging it at present. The impact of this relative lack of training provision appears to be that knowledge and skills among the health workforce in the country are a major problem.[24]

However, there are moves underway to address this, as part of efforts to introduce a system of revalidation. According to one of our interviewees, these developments come partly in

---

[23] See: http://student.bmj.com/back_issues/1001/life/384.html (accessed October 2008).

[24] See: http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Human%20resources.pdf (accessed October 2008).

response to declining demand for Egyptian-trained doctors elsewhere in the Arab world, where it is perceived that standards of training in Egypt are in decline.

Under current proposals being discussed by the EMS and MoHP, revalidation of all practising doctors in Egypt would occur every five years, based on a points system. This would be tied explicitly to Continuous Professional Development (CPD), with an expectation that 250 points' of credit hours would be accrued over a five year period to ensure revalidation. Furthermore, doctors would need to ensure that they consistently earn 50 points' worth of credits each year. It is expected that around 80% of points awarded would be for further education in the doctor's speciality; the remaining 20% would cover generic skills such as communication and teamwork. Sanctions for failures to meet the 250 point requirement in any five-year period are still under discussion. However, it is not yet clear how revalidation will be implemented in practice.

3.7.1 Quality assurance in the medical education system

Until early 2000s, there was no formal quality assurance of medical schools. Medical schools were free to set their own curricula, examine their students, and were not expected to bid for formal accreditation. Since 2001, with the establishment of QAAP, there has been a move towards a system of accreditation in higher education. This includes medical education. The National Quality Assurance and Accreditation Agency (NQAAA) conducts inspections on a rotating basis, but it is not clear how far this impacts on medical schools. There is also no formal requirement for accreditation before degrees can be awarded.

The WHO regional office for the Eastern Mediterranean (EMRO) has been assisting Egypt in developing a system of national accreditation for medical education since early 2000s. As a result of this partnership, national accreditation standards were introduced in 2006, though an accrediting body that will focus specifically on the health sector has not been established yet. A move towards external accreditation was planned from 2007, but it appears that this has not been put in place yet. An important further driver in the education field has been QAAP, which has the following objective for maintaining/improving quality in higher education: "Ensuring the quality, continuous improvement, and efficient performance of Egyptian higher education institutions, so that the community can have confidence that the calibre of their graduates fulfil international recognised standards."[25] QAAP's objectives include:

- Developing a National Quality Assurance and Accreditation system for higher education institutions (HEIs)

- Establishing a National Quality Assurance and Accreditation Agency (NQAAA)

- Raising awareness on the importance of a culture of quality in both HEIs and the community

- Ensuring that university graduates can compete nationally, regionally, and internationally

---

[25] See: http://www.qaap.net/about_us.htm (accessed October 2008).

- Establishing national standards

How far new systems of accreditation have penetrated the medical education system in Egypt is difficult to determine. One interviewee told us that "there are serious efforts in medical schools to improve medical education", he went on to say that "[university hospitals] are in the first stage of implementing quality standards…there is a long journey ahead of them and serious work needs to be undertaken to ensure appropriate implementation". He highlighted particular problems in the areas of quality facilities and systems for universities seeking accreditation.

Medical regulation in Germany

4.1 Overview

Medical regulation in Germany is characterised by a division of tasks between the federal and the *Länder*[26] level of government and a strong tradition of self-regulation within the medical profession with the German Medical Association and the Chambers of Doctors playing important roles.[27]

4.2 Structure and nature of medical regulation

Medical regulation in Germany takes place in a complex governance system, characterised by a division of tasks between the federal and the *Länder* level and a strong tradition of self-regulation within the medical profession.

4.2.1 Regulatory bodies and their interaction

The main actors within German medical regulation are the Federal Ministry of Health (*Bundesministerium für Gesundheit*, BMG), the *Länder* ministries responsible for health and other *Länder* agencies on the one side, and the bodies of the system of medical self-administration on the other side. These are the German Medical Association

---

[26] Throughout this country report, the German states are referred to as *Länder*.

[27] This case study on medical regulation in Germany is based on four main sources of evidence. First, we conducted key informant interviews. The research team interviewed two representatives from the federal ministry of health and one interview with a representative of the German Medical Association. The interviews were conducted in German. We also conducted a review of the relevant regulations, both on the federal and state level. These regulations are only available in German and information retrieved was translated to English by the authors. Third, to overcome the lack of published reports and academic literature on the subject of medical regulation in Germany, the research team reviewed the websites of the involved institutions at the federal and state level, looking for descriptions of the key processes as more in depth analysis and statistics. Finally, statistical information was gathered. The institutional fragmentation of the German system of medical regulation results also in a fragmentation of data sources; thus, there is no comprehensive, federal data on many of the questions raised in this study. The most comprehensive statistics is the German Medical Association's annual physician statistics, but which does not cover any aspects of licensing or FTP procedures. Overall, the evidence collected for the study allowed for a comprehensive account of the institutional structures and key procedures, but has been not sufficient to assess the softer aspects of regulation, such as perceptions of the regulatory systems and the dynamics of change beyond the formal procedures.

(*Bundesärztekammer, BÄK*), a federal-level umbrella organisation and independent chambers of doctors (*Ärztekammern*) in the *Länder*.[28] Due to the diversity of these bodies, no information about the budget for medical regulation is available.

Federal Ministry of Health (Bundesministerium für Gesundheit, BMG)

The BMG is responsible for the regulation of the medical professions in Germany by setting uniform standards for medical education. In conjunction with the *Bundesrat*, it introduced the Medical Licensure Act (*Approbationsordnung für Ärzte, ÄAppO*), which specifies the education trajectory and additional licensing requirements for doctors. This Act is based on the Federal Medical Practitioners' Act (*Bundesärzteordnung, BÄO*), which regulates the Licensure of Doctors.

Länder ministries

The implementation of medical regulations is carried out by the administrations of the *Länder*, with details on the implementation varying from one *Länder* to another. In most cases, the intermediate authorities or authorities subordinated to ministries (agencies) are responsible.[29] The main responsibilities of the *Länder* are to administer the first and second medical exams and to issue and revoke licences for doctors. To ensure a uniform application of standards, the *Länder* founded and financed a specialised institute – the Institute for Medical Exam Questions (*Institut für medizinische und pharmazeutische Prüfungsfragen, IMPP)* – which devises exam questions and partly administers the exams. Although operating on a federal level, this institution does not belong to the federal government. Finally, the *Länder* governments and parliaments have also established a legal framework for the self-administration of doctors by introducing special regulations relating to the professional code and the chambers of doctors (*Berufsordnugen*, and *Heilberufsgesetze/Kammergesetze*).

German Medical Association

Doctors' self-administration in Germany is coordinated by the German Medical Association (BÄK), which also provides professional representation and serves as an interest group for 413,696 doctors.[30]

As the joint association of the 17 State Chambers of Doctors in Germany and thus an organisational combination of public-law corporations, the BÄK is an unincorporated association. The individual doctor is only indirectly a member of the BÄK via compulsory membership of his or her local medical association. The BÄK plays an active role in the opinion-forming process in relation to health policy in society, and in legislative procedures.

Postgraduate training of doctors has been delegated to the self-administration of the medical profession at the *Länder* level, and is covered by specific specialised training

---

[28] There are 17 chambers of doctors, one in each *Länder*, with the exception of North Rhine-Westphalia which is, due to its size, split into two chambers.

[29] In Lower Saxony, however, the competent authority for the implementation of medical regulation is a specialised association, the *Niedersächsischer Zweckverband zur Approbationserteilung*.

[30] Data from 31 December 2007.

regulations (*Weiterbildungsordnungen, WO*). To ensure, however, a certain level of uniformity, the BÄK developed federal model training regulations (*Musterweiterbildungsordnung*) that have been endorsed by the German Medical Assembly (*Bundesärztetag*), the "parliament" of the German medical profession. These model regulations are followed closely by the *Länder* chambers of doctors in their specialised training regulations.[31] The *BÄK* also developed a model professional code (*Muster-Berufsordnung*), which is closely followed by the individual *Länder* chambers in the development of their own professional codes.

Chambers of doctors

The chambers of doctors (*Ärztekammern, ÄK)* are the main bodies of medical self-administration. Membership is mandatory for each doctor and doctors have to pay an annual contribution, which varies according to their income. The *ÄKs'* tasks are defined by the respective *Länder*; however three areas of responsibility are of particular importance for this study:

1. The *ÄK* are responsible for the specialised training of doctors by setting standards and holding the oral exams at the end of the specialised medical training. In addition, they define the requirements for continuous education each doctor has to meet, and offer special training courses.

2. The *ÄK* pass binding professional codes (*Berufsordnungen, BO*) that define the rules of good conduct and duties of doctors, and they enforce those standards with their own procedures.[32] The *BOs* usually follow closely the model adopted at the federal level.

3. The *ÄK* run arbitration/mediation procedures to facilitate out-of-court settlements between patients and doctors.

Other organisations

Besides these main regulatory bodies, a number of organisations are involved in medical regulation. They include:

*   the Association of Statutory Health Insurance for Doctors (*Kassenärztliche Vereinigungen*)

*   health insurance companies

*   medical schools and universities.

Finally, although not within the legislative sphere and thus not regulatory bodies, it should be noted that courts, and in particular administrative courts, are of importance in the application of medical regulation.

---

[31] Interview BMG.

[32] The *BOs* are passed by the democratic decision-making bodies within the chambers and need approval by the *Länder* authorities.

4.2.2 Purpose of medical regulation

To define the purpose of medical regulation, a closer look at the individual regulations is necessary. The two federal regulations *BÄO* and *ÄAppO* aim to ensure that only doctors with the required medical education and qualifications are granted a licence to practise and to ensure common standards for medical education in Germany. Specialised training regulations passed by the *ÄK* ensure a uniform professional standard is applied to specialised medical training; furthermore, the regulations define several medical specialisations, which limit the exercise of specialism in the medical profession.

Finally, the professional codes passed by the *ÄK* define the standards of good (ethical) conduct and duties of doctors, including, for example, the duty to engage in continuous education.

4.3 Registration process and requirements

In Germany, two steps of licensing and registration are necessary to work as a doctor, as well as a third if a doctor wants to set up his own practice within the public health insurance system, which is, however, outside the scope of this report. First, a doctor has to apply for a licence to practise with the *Länder* authorities; secondly she/he must register with the local chamber of doctors.

4.3.1 Licence to practise

The German law differentiates between two types of licences to practise, regulated in federal law (*BÄO, ÄAppO*)

- Full, indefinite licence to practise (*Approbation*).

- Limited, temporary permission to work as a doctor *(Berufserlaubnis).*

- Both licences are issued (and revoked, if necessary) by the *Länder* authorities. In general the full licence to practise has to be granted after application if, the applicant:[33]

    o is a German, EU or EEA citizen or citizen of a third country with which special agreements exist

    o has not been found guilty of a behaviour that shows that he or she is not worthy to be a doctor

    o is fit to practise in health terms

    o has obtained his or her medical degree in Germany or obtained an equivalent degree in an EU member state or an EEA country, or a third country with which special agreements exist, or is trained in a country outside the EU and can prove that he/she has three years of professional experience as a medical professional and/or earned an equivalent degree

    o has the German language skills required for the exercise of the profession.

---

[33] Federal Medical Practitioners' Act (*BÄO*) §3 para 1.

In effect citizens from the EU, the EEA and countries with special bilateral agreements are considered legally equal to German citizens, and thus have a right to receive a licence if they meet requirements. Citizens of a third country with which no special agreement exists can receive a full licence to practise medicine only if they can prove that their degree is equivalent to a German qualification or, if the authorities cannot verify the qualification, if they can pass a test to demonstrate their knowledge. There is no systematic test of German language skills for applicants.

The application procedure is in writing and applications require the following documents:

- an abbreviated curriculum vitae

- a birth certificate and a marriage certificate

- evidence of nationality

- an official certificate of good conduct which must not have been issued more than one month before submission of the application

- a declaration as to whether criminal court proceedings or a public prosecutor's preliminary investigation is pending against the applicant

- a medical certification, which may not be older than one month, which states that the applicant is not unsuitable for the practice of medicine because of health reasons

- the medical examination certificate (the original or a certified copy that has been officially translated).

Reaccreditation/revalidation of the licence is not required.

For non-German applicants, some licensing authorities (Berlin) require applicants to meet the authority in person.

In cases where the preconditions for a full licence are not met, doctors can apply for a temporary licence, which cannot exceed four years, unless the doctor meets one of the several exemption criteria. The precondition for granting a temporary licence is that a doctor has completed his or her medical studies; however no proof of equivalence is explicitly required.

There are no national data sets available on the total number of licences and permits to practise granted, as these activities are implemented at the *Länder* level. Based on the number of medical students graduating each year and the number of recognitions, it is estimated that between 9,000 and 10,000 full licences are granted by the 16 *Länder* authorities every year. [34]

If a licence is refused, applicants have the right to appeal against the decision before the competent administrative courts in the *Länder.*

---

[34] Interview BMG.

4.3.2 Registration with the chamber of doctors

The second prerequisite to practise as a doctor is to be a member of the local chamber of doctors. Upon receiving the licence, doctors are obliged to become a member of the local chamber of doctors and pay annual membership contributions, which vary in relation to earnings. Each chamber keeps an updated register of its members, including their current employment (medical or non-medical) and contact data. The chambers of doctors also run a specific, mandatory pension scheme for doctors. As members of a chamber, doctors are also subject to the professional code issued by that chamber.

In 2007 there were a total of 413,696 registered doctors in Germany, of which 98,784 were not practising clinical medicine.

4.4 Standards & ethics

As a result of the complex regulatory environment, professional and ethical standards for the medical profession are codified in various regulations. The federal law, *BÄO* and *ÄAppO,* mostly regulate the formal requirements for becoming (and remaining) a doctor. The *Länder* regulations create the framework for the self-administration of doctors. The specialised training regulations of the chambers of doctors define the medical specialisations, while professional codes (*Berufsordnung*) define the duties of a doctor and the ethical standards of medical practice. Additionally, recommendations and guidelines for therapy given by the respective medical societies are of practical relevance as they create standards and define the standard of care under civil law.

This section will concentrate on the professional code of the chambers of doctors. The *Berufsordnung* is passed by the assembly of the chamber of doctors (*Deligiertenversammlung*), which consists of representatives elected by all members of the chamber. The references made here refer to the *Berufsordnung*[35] of the Berlin chamber of doctors. As this follows a standard template, regulations in all other *Länder* are very similar.

Following a version of the Hippocratic Oath binding every member of the *Ärztekammer*, the *Berufsordnung* is structured in three main sections: a Preamble (A), the regulation of professionalism (B) and Rules of conduct (C), detailed below.

The **preamble** states the general purpose of the regulations and rules set down in the *Berufsordnung*:

- To preserve and enhance the trust between doctors and patients.

- To ensure, in the interests of the whole population, the quality of doctors' work.

- To preserve the freedom and the reputation of the medical profession.

- To encourage worthy behaviour and to prevent unworthy behaviour of doctors.

This preamble is followed by the regulations of professionalism, which also consist of four main sections. Section 1 contains the basic rules defining the principles of behaviour (Article 1). This includes the obligation of a doctor to serve the health of the individual

---

[35] Translation by the authors

and the population as a whole, and the very purpose of the medical profession: to preserve life and health, to reduce suffering and to help the dying. Furthermore it states the duties of a doctor, such as continuous education, quality assurance and the duty to report the adverse effects of medication. Within this section, two articles are of particular interest to this research project, namely continuous education and quality assurance (details on these are provided later in this chapter).

Section 2 defines the rules of the patient-doctor relationship in particular cases, including rules such as professional confidentiality or the duty to document treatment accurately. Within this section, again two articles are of particular interest to this research project, namely the principles of treatment, the rules of conduct, and the duty to inform a patient about treatment. Details of this are provided below:

- **Principles of treatment and rules of conduct (Article 7):**

  1) Every treatment given must respect human dignity and take into account the personality, the will, and the rights of the patient, in particular her/his right to right to self-determination.

  2) Doctors must respect the right of patients to choose and change the doctor that provides the treatment. On the other hand, the doctor is free to refuse to provide treatment to a particular patient, unless the patient is in an emergency situation or the doctor is under any other legal obligation to provide treatment. The attending doctor should normally not refuse the wish of a patient to get a second medical opinion from another doctor or to be referred to another doctor.

  3) A doctor is not allowed to carry out treatment, and in particular provide advice, solely via letters, newspapers or magazines, or exclusively through other (electronic) means of communication.

  4) Relatives and other persons are allowed to be present during examination and treatment, if both the attending doctor and the patient agree.

- **Duty to inform the patient about the treatment (article 8):** Before carrying out treatment, the doctor requires the patient's consent. Prior to obtaining consent, the doctor must inform the patient in person about her/his condition and the potential risks of the proposed treatment.

Section 3 deals with the ethics of special medical interventions, research and abortion. Finally, Section 4 establishes the rules of cooperation within the medical profession, as well as the economic regulations on setting up a surgery, etc.

The *Berufsordnung* concludes with a summarised set of rules of conduct for doctors, such as contact with patients, the principles of medical treatment, conduct towards other medical professions, the protection of the human embryo and procedural rules on cross-border activity. Within this section, three rules are of particular interest to this research project:

1. **Interaction with patients** – The standards of professional conduct require that in their conduct towards patients doctors:

- respect patients' dignity and right to self-determination

- respect patients' privacy

- provide clear and appropriate information on:

  - the assessment of a patient's state of health

  - the proposed diagnostics and therapy, and respective alternatives

  - the patient's right to refuse suggested diagnostics and therapies

- respect patients' situations

  - remain professional and fair when there is disagreement with a patient

  - pay appropriate attention to communication from patients and responds in a professional way to criticism from patients.

2. **Principles of treatment** – Administering the therapy requires the thorough execution of the necessary medical treatments according to best medical practice. This also includes:

  - involving other doctors if a doctor's own competency is not sufficient to carry out the necessary diagnostics and therapies

  - referring a patient to other doctors for continuation of treatment, without unnecessary delay

  - not refusing the wish of a patient to seek a second medical opinion

  - producing treatment documentation in a timely fashion.

3. **Rules of conduct towards non-medical staff** – Correct professional conduct requires that a doctor does not discriminate against non-medical colleagues and in particular respects all relevant employment regulations.

Changes to the professional code for doctors are made in accordance with the decisions of the German medical assembly. The last major revision of the professional code was carried out in 1997. Since then minor changes have been made to respond to emerging challenges.[36] The code is available on a number of websites, but it is difficult to assess the extent of patient awareness and understanding.

No systematic studies have been conducted into the perceptions doctors have of the regulatory bodies, including the regional chambers of doctors, thus any assessment is necessarily anecdotal. In general, doctors have contact with their respective chambers for various reasons, particularly for matters concerning specialised medical training and continuous medical education. As chambers represent the professional interest of the doctors and doctors participate in electing their delegates, it is likely that chambers of doctors are seen as more than enforcers of the professional code.

---

[36] See Fuchs and Gerst Medizinethik in der Berufsordnung. *Entwicklungen der Muster-Berufsordnung.* Bundesärztekammer: http://www.baek.de/page.asp?his=1.100.1142., last accessed December 2008.

4.5   Fitness to practise and related disciplinary procedures and sanctions

In Germany there is no direct equivalent to the FTP procedure that exists in the UK. There are, however, two similar processes in place, one for each legal framework doctors are operating within:

- Procedures under the professional code (*Berufsrechtliches Verfahren).*

- Procedures under the federal licensing law.

In addition, there are procedures for patients in cases of treatment errors. Patients can choose to either appeal to an arbitration board, located at a chamber of doctors in the *Länder*, or sue the doctor before a civil court. In the case of bodily harm caused by negligence, patients can lodge a complaint against a doctor under criminal law. The criminal court has the power to disqualify a doctor from practising medicine.

4.5.1   Procedures under the professional code

If the chamber of doctors has been made aware of any evidence suggesting that a doctor has acted in breach of the professional code, the elected board of the chamber can initiate an enquiry into the alleged breach.[37] The enquiry is led by an investigator that is usually proposed by the chamber and then appointed by the *Länder* supervisory authority for a four-year period. When the investigation is complete, the board of the chamber takes a decision on how to proceed:

- In cases where the breach of the code is minor, the chamber can issue a warning (*Rüge)*, which can entail a penalty fee of up to € 5,000 to be paid to a charity.

- In cases where the evidence suggests a serious breach of the professional code, legal proceedings are passed on to the administrative courts. The administrative courts have special chambers dealing with issues relating to the professional code. These chambers also involve doctors, nominated as lay judges by the chamber of doctors. In the lower administrative courts, the chamber (*Kammer für Heilberufe)* consists of two professionals and three lay judges. In the higher administrative courts, three professional judges and two lay judges take the final decision (*Senat für Heilberufe).*

If a doctor is found guilty the courts can impose sanctions under the professional code. The licence to practise is, however, only indirectly affected by those sanctions, as it is not granted as part of the professional code. The five types of sanctions are:[38]

- warning

- formal admonition

- financial penalty of up to € 50,000

---

[37] The description of the proceedings under the professional code is based on the legal situation in Berlin. Similar arrangements are however in place for all other 16 chambers of doctors. See e.g. the website of the Berlin chamber of doctors for further details (http://www.aekb.de/35_Recht/08_Berufsrechtliches/05_BODurchs.html).

[38] Berlin Law on the Chamber of Doctors (*Berliner Kammergesetz*) § 29.

- suspension of the right to vote in the chamber

- statement that the doctor is unworthy or unreliable as a doctor.

The statement of unworthiness and unreliability is the strongest sanction the chambers can adopt, as it will usually result in the withdrawal of the licence to practise under federal law. This is discussed in the next section. If proceedings against a doctor have also started under criminal law, proceedings under the professional code are suspended until the criminal case is complete.

4.5.2 Procedures under the federal licensing regulation

Under federal law (*BÄO, Article. 2*) a licence must be revoked if the doctor has "been guilty of a behaviour that shows that he is unworthy or unreliable to be a doctor". Furthermore, the licence can be revoked if a doctor's state of health is adversely affecting his/her FTP. In addition, the licence can be suspended (*BÄO, Article 6)* when a criminal investigation against a doctor is ongoing; or when a doctor is (temporarily) physically unfit to practise; or when it transpires that a doctor does not have the language skills required for practising his/her profession in Germany. While the licence is suspended the doctor is not allowed to practise.

The revocation of the licence is carried out by the *Länder* authorities, often as a result of a previous procedure under criminal or civil law, or as a consequence of an investigation under the professional code. Most decisions to withdraw a licence will, be settled in court, as doctors tend to challenge the decisions of the authorities. Defendants can appeal against the decision to withdraw a licence in both the lower and the higher administrative courts, both on procedure as well as on judgement.

4.5.3 Arbitration procedures

In cases of treatment errors, the chambers of doctors also provide an extrajudicial arbitration procedure. There are currently eight arbitration offices in Germany.[39] The arbitration process can be initiated by any of the following three groups, although participation is on a voluntary basis:

- patients or their representatives

- doctors

- the liability insurers.

The main aim of arbitration is to achieve a common understanding on the factual basis of the case. To achieve this external experts are appointed to assess the case. The arbitration

---

[39] A number of north German chambers of doctors established the North German arbitration office (*Norddeutsche Schlichtungsstelle*) in Hanover, thus there are fewer arbitration offices than chambers of doctors, (see http://www.norddeutsche-schlichtungsstelle.de)

process does not result in sanctions. The arbitration office is staffed with both lawyers and doctors. Overall, the arbitration process consists of the following steps: [40]

1. Application for arbitration;

2. The arbitration board screens the facts of the case and collects evidence from the treating doctor, as well as from hospitals and health insurers to assess the case.

3. If the matter is complex, the arbitration board decides to contract an external expert opinion. Based on the evidence already available a task description for an external opinion is developed. At this stage all participants are allowed to request changes to the task description.

4. Once the external opinion is completed, the legally and medically trained members of the arbitration board assess the opinion and make a concluding statement on the liability. If the complainant accepts the findings of the arbitration board, the patient and the liability insurer agree on the level of compensation.

The result of the arbitration is non-binding and the parties are free to pursue the case before the courts if they do not agree with the arbitration outcome. So far arbitrations have been rather successful in avoiding court proceedings – an evaluation conducted in 2007 using 2002 data, showed that only 11% of cases were settled in court following the arbitration process. Figure 4.1 below shows the overall number of arbitration cases from 1976 to 2007. From 1990 onwards, the figures also include the East German *Länder* of Brandenburg, Mecklenburg-Vorpommern, Sachsen-Anhalt und Thüringen.

Figure 4-1: Annual number of arbitration procedures, Germany

---
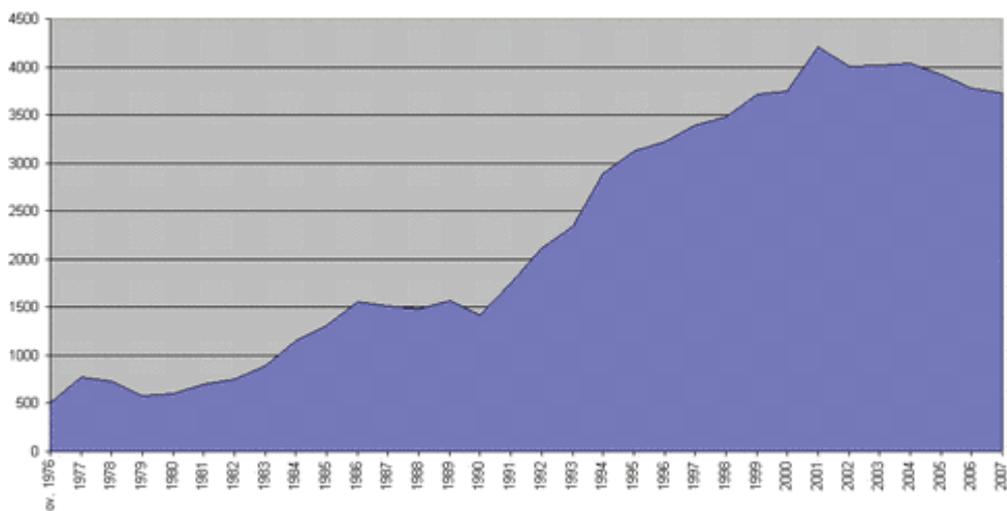
[40] See http://www.norddeutsche-schlichtungsstelle.de

4.6   Medical education

4.6.1   Education trajectory

Admission

Admission to medical schools is jointly administered by the *Zentralstelle für die Vergabe von Studienplätzen* (ZVS), a central organisation operated by the *Länder*, and medical schools. There is a uniform nationwide admissions procedure that stipulates that 20% of available places are offered according to applicants' final score in the *Abitur* (the highest secondary school diploma, comparable to A-levels). A further 20% of places are allocated according to a waiting list. Medical schools allocate the remaining 60% according to their own criteria such as candidate interviews. The details of the selection process differ between medical schools.[41]

Basic medical training

Medical training comprises

- university studies in medicine of not less than six years that include continuous practical training (practical year) for forty-eight weeks (Article 3 *ÄAppO*). It consists of three 16-week work placements in internal medicine, in surgery, in general practice, or another elective subject

- first aid training (Article 5 *ÄAppO*)

- a three-month period providing nursing care (Article 6 *ÄAppO*), which students have to make either prior to university studies or before the first part of the medical examination

- a four-month clinical elective (*Famulatur* pursuant to Article 7 *ÄAppO*) in between the first part of the medical examination and the practical year, split between two months in a hospital, one month in a practice or out-patient unit and one additional month in either or both

- a medical examination that must be taken in two parts (Article 1 para 3 *ÄAppO*).

Medical training is normally divided into a pre-clinical and a clinical stage. To allow for the development of innovative and alternative study courses, Article 41 of the *ÄAppO,* stipulates that model study programs can differ from some otherwise binding provisions of the *ÄAppO*.[42]

---

[41] See www.zvs.de

[42] Model study programmes can differ in the following aspects: The medical examination may consist of just part two of the medical examinations, which is taken after at least six years of medical studies; The nursing service, the training in first aid and the clinical traineeship may be completed at a different time than the one prescribed by the normal program of studies. The practical year need not be completed in the manner prescribed by § 1 Paragraph 2 Sentence 1 Number 1. The universities may involve suitable hospitals, medical practices and other institutions providing out-patient medical care in every part of the training. This requires a

The first state medical examination takes place after two years of study and concentrates on natural sciences (physics, physiology, chemistry, biochemistry/molecular biology, biology and anatomy) and theoretical principles (medical psychology and sociology). After the first part of the medical examination and before the practical year universities test clinical subjects such as internal medicine, surgery, obstetrics and gynaecology, paediatrics, pharmacology, pathology, etc.[43] Course credits are a precondition for admission to the practical year (*Praktisches Jahr*). The second state medical examination takes place after six years of study.

The state exams are jointly administered by the *Länder* authorities and IMPP. Thus, uniform question across all *Länder* are used in the multiple-choice part of the exam. At the autumn 2008 exams, around 13.7% of students failed the first written exam (15.6% in autumn 2007) and 4.9% the second written exam, (5.7% in autumn 2007).[44]

A certificate in the form prescribed by Schedule 12 to *ÄAppO* is issued to candidates who have passed the second medical examination. It is a medical diploma attesting to the completion of university studies of medicine in line with the provisions of EU law and subject to mutual recognition in the member states of the EEA.

Approbation

After successfully passing the final exam, medical graduates apply to the *Länder* authorities for their doctor's licence (*Approbation*) if they are German or EU citizens, or citizens of a third country with which either Germany or the EU have a special agreement. Once the licence has been granted, graduates receive the licence to practise medicine and the professional title of doctor (*Arzt*).

Doctor of Medicine

The professional title *Arzt* is independent from the academic degree of Doctor of Medicine ("Dr. med."). Holding the degree of "Dr. med." is not required for practising in the medical profession or for specialist training. The title is awarded after successfully completing and defending a scientific dissertation. Many students opt to write their thesis during the second stage of their studies. The requirements for obtaining a doctor qualification are established in the doctoral degree regulations of medical faculties and university departments.

Specialised medical training

After graduating, most doctors move on to specialised medical training. The responsibility for postgraduate training has been delegated by the *Länder* to the chambers of doctors in the *Länder*, but the requirements have been to a large extent standardised through the implementation of a model specialised training regulation.

---

corresponding study regulation on the part of the university concerned, an evaluation of the model study course, provisions on duration, on the discontinuation of the model and crediting as students move into regular studies. The first such course has been piloted at the Charité Berlin. Several more pilot projects are ongoing.

[43] See Medical Licensure Act (*ÄAppO* §27(1)) for a complete list of subjects.

[44] See the website of the Institute for Medical Exam Questions www.impp.de

Specialised medical training takes four, five or six years, depending on the specific training regulation for each subject. Training is conducted in an authorised hospitals operated by universities or other healthcare institutions accepted by the chambers of doctors under the supervision of a person authorised to conduct specialised medical training. To some extent specialist training comprises additional mandatory courses, which take place outside the teaching hospital. After meeting all the requirements, doctors need to pass an exam with the regional chamber of doctors before they are permitted to use the specialist title.

Recent reforms have been adopted which make it mandatory for doctors to hold a specialist degree before they can set up a practice within the public health insurance systems.

4.6.2 Funding
As higher education is the responsibility of the *Länder*, medical education is funded by the respective *Länder* governments, which also maintain the medical schools and university hospitals. Some, but not all, recently introduced tuition fees.

Doctors pursuing specialist medical training are employed full-time and remunerated as assistant or junior doctors (*Assistenzarzt*).

Continuing education is partly financed by fees paid to doctors and by the mandatory annual contributions paid to the chambers of doctors.

4.6.3 Quality assurance
Medical education takes place in university hospitals and is thus subject to the normal quality-assurance processes that apply to the healthcare system. In addition, medical schools are under the supervision of the ministries of education in the *Länder* which ensure compliance with standards. Additionally, the results of nationwide exams provide a good quality benchmark. The *IMPP* publishes exam results by university, as well as by medical subject within a university.

4.6.4 Continuous medical education
The German professional code obliges doctors to undertake continuous medical education to maintain and develop the necessary professional knowledge to practise as a doctor. In addition, it obliges doctors to demonstrate to the chamber of doctors that they undertake continuous medical education.

Medical regulation in Greece

5.1 Overview

The regulation of the medical profession in Greece is the remit of five bodies: the Central National Health Council ("KESY"); regional/city-based medical chambers, and the Greek Medical Association which acts mostly as a coordinating and supervising body to the regional chambers; the Ministry of Health and Social Solidarity; the Ministry of Education (responsible for university hospital doctors and higher education); and the Ministry of National Defence (partially responsible for military doctors). [45]

5.2 Structure and nature of medical regulation

Medical regulation in Greece is a responsibility shared between a number of different bodies, including the Central National Health Council, medical chambers and ministries. More details on this are provided in Table 5-1.

Most medical professionals in Greece are employed in the public sector. Data on healthcare employment can be found in Table 5-1.

---

[45] The information and data for this case study were obtained from a range of sources. Written sources included the official websites of several institutions, such as the Greek Ministry of Education (www.ypepth.gr) and Ministry of Health (ww.mohaw.gr), international organisations (WHO), articles published in the peer-reviewed journals and other non-published circulated material (both in English and Greek). Sources in Greek were translated into English by the case study author. Interviews were conducted with a senior official from the Ministry of Health, and a Greek university professor researching Health and Welfare Services. The authors also had a number of shorter discussions with Greek medical practitioners with knowledge of the issues around regulation. The availability of quantitative data for Greece is limited, and as a result some of the figures presented in this case study are not very recent.

Table 5-1: Greek National Health System (ESY) employment data

Health employment	1982	1992	1999
Practising doctors	25,909	38,738	46,124
Female practising doctors	6,736	11,234	15,373
Practising specialists	16,197	24,889	31,120
Practising dentists	8,007	10,403	12,152
Practising pharmacists	5,082	7,834	8,767*
Practising nurses**	21,050	36,505	41,151

Source: OECD Health Data 2002
*1998 data
** Registered and Assistant nurses
Data for employees of both the public and the private healthcare sector

Doctors that work in private practice are grouped as follows:

- doctors providing services on an exclusively private basis, the cost of which is fully covered by patients

- doctors employed part-time by the Greek National Health System (ESY)

- doctors working in polyclinics of insurance organisations

- ESY doctors providing afternoon outpatients' services within ESY hospitals two days per week.

5.2.1 Interaction between different regulatory bodies

The regulation of the medical profession[46] in Greece is within the remit of five bodies:

- the Central National Health Council (KESY)

- regional/city-based medical chambers and the Greek Medical Association which acts mostly as a coordinating and supervisory body to the regional chambers

- the Ministry of Health and Social Solidarity

- the Ministry of Education (responsible for university hospital doctors and higher education)

- the Ministry of National Defence (partially responsible for military doctors).

The discussion and evidence provided in this chapter reflects this structure of combined responsibility for medical regulation in Greece.

Central National Health Council

The Central National Health Council (KESY) was established in an advisory capacity to the Ministry of Health and Social Solidarity on health policy and research issues following

---

[46] Regarding dental care, apart from numerous regional dental chambers there are at national level the Hellenic Dental Association (www.eoo.gr) and the Greek Orthodontic Society (www.grortho.gr).

the 1983 reforms.[47] KESY functions as an adviser to the health minister and is composed of:

- three representatives from the Pan-Hellenic Medical Association (PMA)

- 14 representatives from the health professions trade unions and university faculties

- two senior officers from the Ministry of Health

- two governors of the biggest social insurance funds - the Greek social insurance fund (IKA) and the Greek social insurance (OGA) - and the Chairman of the National Drug Organisation

- three members appointed by the Minister of Health and Welfare from the scientific and social fields.

The chairman of KESY is elected by the medical members of the Council. Several councils and committees work under KESY. Until now KESY has not produced innovative policies and programmes for the Greek National Health System nor has it established those new regional bodies foreseen by the 1983 legislation. Due to its medically oriented composition, KESY has focused mainly on the medical field, at the expense of the other professions and the wider interests of the healthcare system[48].

The medical chambers

Currently, there are 58 regional chambers.[49] The medical chambers are responsible for setting medical and ethical standards, medical registration and revalidation processes, fitness to practise (FTP) and other related disciplinary procedures and sanctions.

Athens Medical Chamber is a good example to explore in greater depth, as it is the chamber with the greatest number of registered doctors, and, as a result, is the most influential. According to recent data 25,000 active members doctors are registered with the Athens Medical Chamber. Founded in 1923, the Athens Medical Chamber is a professional, self-governing body of medical practitioners.

Every medical practitioner has to be a member of a medical chamber in order to practise medicine in Greece. Registration with a chamber depends exclusively on the location where the doctor wishes to practise medicine. Membership is restricted to one medical chamber. To move practice to another region a doctor has to cancel registration in the chamber located in the region of origin, and re-register in the region of destination.

5.2.2 Purpose and values of medical regulation

The purpose and values of medical regulation in Greece can be assessed by analysing the aims and objectives of institutions involved in the medical regulatory system and, in particular, those of the regional medical chambers.

---

[47] Mick Carpenter (2003) "On the Edge: The Fate of Progressive Modernization in Greek Health Policy", *International Political Science Review* Vol. 24, No. 2, 257–272.

[48] See: www.euro.who.int/document/e72454.pdf (last accessed January 2009).

[49] See: http://www.pis.gr/medassociations/index.html (last accessed January 2009).

In principle, the objective of regional medical chambers in Greece is to supervise the practice of the medical profession (since most of the principles of professional ethics binding medical professionals are determined by national law) and ensure the compliance of the medical code of good practice.

However, in practice, medical chambers mainly represent and protect the medical profession and actively engage in lobbying activities and discuss funding issues with the government. The chambers also deal with FTP issues, which are discussed in more detail in section 5.6.

Patients' safety and rights are important aspects of the legislation for the medical profession. However, the direct responsibility to protect patients' safety is not within the remit of the KESY, the medical chambers or the Greek Medical Association. The Ministry of Health and Social Solidarity has a broad remit to protect patients' safety, but in practice it acts as a private lawyer representing and protecting patients in the event of medical malpractice. Recent events, such as the case of a 30-year-old patient who suffered serious medical negligence, are receiving increasing media attention and have contributed to growing public and policy-makers awareness of medical misconduct and negligence.[50]

5.2.3 Funding arrangements

Healthcare in Greece is funded mainly through the central government budget (general taxation, 30.4% in 2000), the social insurance funds (25.9% in 2000 from employers' and employees' contributions), private health insurance (2.3% in 2000) and out-of-pocket payments for the remaining 41.5%[51].

Legislation involving medical regulation is proposed mostly by the Ministry of Health and Social Solidarity. The Ministry of Education and the Ministry of National Defence are also key stakeholders and clearly all actions involving these three ministries are publicly funded. Unfortunately, medical regulation activities constitute only a small fraction of the activity areas of these respective ministries, thus it is rather difficult to estimate the combined annual budget of bodies responsible for medical regulation.

5.3 Registration process and requirements

5.3.1 Registration and licensing process

All doctors wishing to practise in Greece are required to register with regional medical chambers. Their registration must be renewed each year.

Registration takes place following completion of the medical degree or the medical specialty, at which point doctors must register with a medical chamber (in the region in which they wish to practise) which provides them with automatic licensing to practise medicine.

---

[50] See: www.enet.gr/online/online_print?id=96109740 (last accessed January 2009).

[51] Nikolentzos, A. and N. Mays (2008) "Can existing theories of health care reform explain the Greek case (1983-2001)?" *Journal of European Social Policy* 2008; 18(2); 163-176.

Greek and EU doctors wishing to register are required to present the following documents:

- Medical school degree;

- DOATAP certificate (for recognition of degrees awarded by non-Greek institutions)[52];

- Application form to the regional medical chamber;

- Proof of knowledge of Greek language and medical terminology (applicable to doctors qualified in the EU countries).

There are some further requirements in the case of non-EEA applicants (such as residence permit).

5.4   Revalidation

Doctors registered with the medical chambers are not obliged by law to revalidate their licence. In addition, there are no obligations towards doctors to retrain. The main exception is when a doctor interrupted the practice of medicine for a period of five consecutive years, in which case he/she is obliged by law to serve a year in a hospital (or other public medical centre) as mandated by the Ministry of Health.

After the completion of the degree there are very few controls or inspections of doctors' performance. In the past, there was a regular review process for professionals working in hospitals that took place every three years. However, following the establishment of the Greek National Health System (ESY) in 1983 there was a transitional period during which no controls or inspections took place. Following the 2001 reforms and subsequent legislation, the revalidation process was intended to start again, using new criteria and methods and conducted either on a local (hospital) basis or at the national (KESY) level, but this has not yet happened.

The main forms of Continuous Professional Training are postgraduate degree (such as a Masters degree or a PhD) or participation in conferences and medical symposia. There is no structured life-long learning programme and it is up to the individual to obtain further qualifications and keep up to date with developments in the profession.

---

[52] In order to be able to register in Greece, medical graduates trained in countries outside the EEA almost always have to take several exams and go through the processes of the Hellenic National Academic Recognition Information Centre (NARIC) (also known as DOATAP, or "Δ.Ο.Α.Τ.Α.Π."). The Hellenic NARIC is a statutory body governed by public law, responsible for the recognition of university or technological degrees that are granted by accredited Higher Education Institutions overseas. It is based in Athens and is overseen by the Ministry of Education.

5.5   Standards & ethics

5.5.1 Content

The content of medical standards and ethics in Greece is specified in Greek law – the Law of Medical Profession[53] and the Medical Code of Ethics[54]. These laws set out a number of aspects for the regulation and practice of the medical profession. Some of the main points of the legislation that specifically concern medical standards and ethics include the following:

- The doctor is obliged to practise conscientiously her/his profession and should behave with the dignity and goodwill that the medical profession demands.

- The doctor should respect the "Hippocratic Oath" and practise medicine as a vocation.

- The doctor should respect human life and has the right to abstain from operations to which he/she is conscientiously opposed.

- The doctor should, in the course of practising medicine, enjoy complete ethical and scientific independence.

- The doctor should make sure that he/she assures quality, safety and efficiency in the course of practising medicine. This should include the doctor's commitment to continuous learning, a cross-scientific attitude and professional cooperation.

- The doctor is obliged to provide full information to the patient and should also protect the patient's privacy and confidentiality.

In 2000, the National Bioethics Commission was founded. The Commission consists of nine prestigious scientists selected by the Prime Minister. The Commission is an independent advisory body of experts; it deals with enquiries requested by public authorities, and can also initiate enquiries of its own. Specifically, the Commission:

- investigates the ethical, social and legal issues that arise from scientific advances in biology, biotechnology, medicine and genetics;

- outlines, in collaboration with the respective ministries, proposals of general policy and provides specific recommendations on related issues;

- collaborates with international organisations and represents Greece in international fora;

- informs the public on issues related to biotechnological advances and the impact of their applications, promoting public awareness and dialogue.

The Commission also has the responsibility to coordinate other relevant committees at a national level. More details can be found in the Commission's founding law and the rules

---

[53] See: http://www.isth.gr/?page=2628 (last accessed January 2009).

[54] Medical Code of Ethics (in Greek): http://www.mohaw.gr/ministry/nomothesia/kdikas-iatriks deontologias/files/K-MEDCODE-PAP-1.pdf (last accessed January 2009).

of procedure. The General Secretariat of the Government supports the Commission on a financial and administrative level.

5.5.2 Process and actors involved in the development of standards

The Hellenic Parliament has the power to make amendments to the Medical Code of Ethics. The latest revisions to the document were passed at the Parliament's meeting on 8 November 2005.

5.5.3 Patient involvement and complaints

Patients' involvement is considered in Greek law. According to law 2889/2001 every hospital must have: a) an office for "citizens' rights"; b) an office for "patients' reception"; and c) an office for "quality control". Many hospitals run such services together. These offices are obliged to examine and answer patients' complaints, to run questionnaires and conduct research to examine patient satisfaction, and to implement systems of quality control. Complaints are usually solved by an oral compromise between the doctor or the nurse, the patient or his/her relatives and the hospital administration (although officially such processes should involve written replies, in a more bureaucratic procedure).

In addition to these provisions for quality assurance, ELOT (Greek Organisation for Accreditation) has recently worked with the Ministry of Health to formulate a hospital certification system. There is also a National Committee on Patients' Rights, with limited power, which has not yet published annual data on its activities and outcomes.[55]

5.6 Fitness to practise (FTP) and related disciplinary procedures and sanctions

5.6.1 Content/substantive characteristics

Disciplinary Boards are formed of medical professionals registered in their regional medical chamber. These boards are qualified to judge cases of alleged misconduct by its members, and to carry out disciplinary proceedings.[56]

Disciplinary Boards of the regional medical chambers can impose three types of sanctions:

- Admonition;

- Suspension of licence to practise;

- Withdrawal of licence to practise.

The Supreme Medical Disciplinary Board, located in Athens, has the remit to judge appeals against the decisions of regional Disciplinary Boards.[57]

---

[55] Merakou K. and E. Tragakes (1999) "Development of Patients' Rights Legislation", European Journal of Health Law, Volume 6, Number 1, 1999 , pp. 71-81(11).

[56] Rowe, A. and M. García-Barbero (2005) *Regulation and licensing of physicians in the WHO European region,* WHO Regional Office for Europe.

[57] Ibid.

Relevant disciplinary bodies also operate in every ESY hospital and Regional Health Authority, under the auspices of hospital or regional Medical Scientific Committees, which include Medical Bioethic Groups within ESY hospitals. However, no data or information on procedures and outcomes has yet been published by any of these bodies.

The ESY hospital disciplinary board/committee is the first instance for cases against doctors. Where cases cannot be settled within the hospital, they are passed on to the regional medical chamber (and possibly to the Ministry of Health at the same time). More serious cases can be referred directly to the criminal courts via the district attorney.

If a case is not settled by ESY, patients can contact the regional medical chamber where the doctor is registered for the regional disciplinary committee to process the case. Patients can also contact the national Greek Medical Association which invariably will direct them to the regional chamber, since the national body is not supposed to take disciplinary action. Usually, this process is not very effective and obliges many patients to go to the police and pursue a proper legal action through court. In the event of a doctor being found guilty, the chamber can withdraw his/her licence to practise medicine. Doctors undergoing professional disciplinary proceedings retain their licence and right to practise medicine until the final verdict of the medical court is reached.

In addition to cases of medical negligence and malpractice, the receipt of out-of-pocket payments from patients can be subject to disciplinary action. According to Greek law, it is considered a major disciplinary offence for of Greek ESY doctors to "accept a bonus and especially any compensation or property grant, for any medical service provided". However, this is common practice.

Out-of-pocket payments tend to be high, mainly comprising direct and informal payments for dental or primary healthcare, or for ESY hospital care. Informal payments are to a certain extent symptomatic of a number of structural issues in the Greek medical system, including: the inability of the Greek state to guarantee comprehensive medical provision for the whole population; the characteristics of health insurance coverage in Greece; the desire of doctors for supplementary income; and, some scholars argue, patients' desire to express their gratitude to their doctor.[58]

5.6.2 Involvement and role of external actors

The main external (i.e. non-medical) actors in disciplinary processes are the patients who have been victims of medical malpractice and the insurance/health funds that have been established in order to meet high costs in the event of medical malpractice towards any of their contributors.

---

[58] Nikolentzos, A. and N. Mays (2008) "Can existing theories of health care reform explain the Greek case (1983-2001)?", *Journal of European Social Policy* 2008; 18(2); 163-176.

5.7   Medical education

5.7.1   Education trajectory

The education trajectory on medical education in Greece includes the following main steps:

- completion of undergraduate degree;

- application for professional permit to practise follows to the regional (of the prefecture) health-office;

- internship (i.e. "*Agrotiko*");

- post-graduate studies or opening of private office.

Undergraduate medical education lasts for 12 semesters (six years) and the study programme is practically the same in all of the medical schools. Most of the undergraduate programme is carried out at the theoretical level; the exception are courses of "basic medical specialties" (i.e. pathology and surgery) which include obligatory presence in hospitals. The proportion of the whole course given over to the teaching of basic medicine is approximately five-sixths, with the remaining one-sixth dedicated to practical medical skills.

The undergraduate programme includes a three-month practice, usually in a ESY hospital. After graduation, medical graduates have to undertake a 12-month internship ("*agrotiko*") which is almost always located in rural areas, in health centres and local surgeries.

Practical training in medical settings is not compulsory if the person wishes to pursue a career in the private sector (although doctors practising privately also need to register with the respective medical chamber). Nevertheless, the majority of people do opt to undertake the 12-month internship. One of the reasons for this is that following the completion of the undergraduate education the internship is a good way to enter the labour market and have a modest income.

After obtaining the university degree and the internship, those interested in post-graduate education can opt to do specialist training, which can be between four and seven years depending on the specialty. Specialist training is carried out within a university or a regional or district or specialist hospital, i.e. exclusively within a public medical setting, and is assessed by university professors with a final exam.

5.7.2   Examinations and qualifications

Like in other European countries there is strong competition to secure a place in medical programmes. Normally, medical schools are required to accept candidates with the highest grades.

The numbers of students admitted to medical school in Greece every year are modest but so far the country has produced enough doctors to meet the needs of the Greek health

system. For example, after the final entry exams in 2008, 801 successful high-school graduates enrolled in medical school in Greece for the academic year 2008–09.[59]

5.7.3 Funding

Medical education is funded from public money in Greece, thus students enrolled in medical schools do not have to pay any fees for their study. This is standard practice for all public higher education in Greece, which is free of charge.

5.7.4 Quality assurance

Quality assurance of Greek medical schools falls within the remit of the Ministry of Education. Processes of quality assurance in medical education in particular, and all higher education in general, are extremely slow because there is strong opposition from the faculty members and students to the quality assurance processes proposed within the Bologna Process' standards. However, almost 50 out of 200 university departments around Greece have already submitted their internal evaluation process to the national Authority of Quality Assurance (ADIP), run within the Ministry of Education, while all others are obliged to do so by the end of the 2009 Easter semester.

---

[59] Data from the Ministry of Education at http://www.ypepth.gr/docs/90__epityxontes_080828.xls (last accessed January 2009).

Medical regulation in India

6.1 Overview

Medical regulation in India is characterised by a complex governance structure, with bodies at the federal and state levels sharing responsibilities. The Medical Council of India (MCI) and the Dental Council of India are the bodies responsible for setting the standards of medical education, maintaining the medical register and accrediting the medical and dental colleges. In addition to the MCI, each state in India has its own medical council, which oversees the profession's medical code and standards of good conduct. The state councils maintain the state's register of doctors and promotes Continuous Professional Development (CPD) among its members.

6.2 Structure and nature of medical regulation

India has a fairly well established medical regulatory system with responsibility split between national and state bodies.[60] The Medical Council of India (MCI) and the Dental Council of India are responsible for setting the standards of medical education, maintaining the medical register and accrediting the medical and dental colleges. In addition to the MCI, each state in India has its own medical council, which oversees the profession's medical code and standards of good conduct, maintains the state's register of doctors, and promotes CPD among its members.

The MCI is a statutory body which was established in February 1934 under the Indian Medical Act 1933. This act was repealed in 1956 and replaced by the Indian Medical Council Act 1956; amendments to this act were made in 1958, 1964, 1992, 1993, 2003, 2004 and 2006.

---

[60] The information used for the Indian case study is mostly from the annual reports published by the Medical Council of India and all the rules and regulations laid out on their website. In addition, this information was validated, and further information was gathered, through a number of short discussions with medical professionals in the country. These discussions helped shed light on and provided a clear understanding of the workings of the medical regulatory system in India and the complexities of a system decentralised to the state level.

The other medical regulatory bodies are the Central Council of Indian Medicine, which regulates the practice of traditional Indian medicine such as Ayurveda, and the Central Council of Homoeopathy, which regulates the practice of homeopathy in India.

The MCI has created a regulatory system which has well defined and detailed processes for administrating registration, setting out codes of ethics, developing standards and identifying needs for medical education, and implementing programmes for CPD. However, the decentralised nature of the system makes it difficult to assess its effectiveness, which can vary significantly from state to state (India has 28 states and seven union territories). The best-performing states appear to fare quite well in the following aspects:

- Effectively managing the process of registration and renewal;

- Promoting CPD for registered doctors;

- The overall quality of medical education.

On the other hand, concerns have been expressed in some states regarding:

- The significant under-supply of doctors, leading to quackery;

- The implementation of standards particularly in relation to the code of ethics and the way that private medical colleges are inspected;

- The lack of adequate feedback mechanisms from patient to doctor.

6.2.1 Purpose, values and drivers

The stated functions of the MCI include:

- Carrying out inspections of medical schools with a view to maintaining proper standards of medical education in India;

- Granting permission to establish new medical colleges and new courses (including postgraduate courses) and to increase the number of places on a course;

- Recognising (or rejecting) the validity of Indian Qualifications and foreign qualifications obtained abroad;

- Registering doctors;

- Maintaining the All India Medical Register.

The structure of the MCI is set out in Section 3(1) of the Indian Medical Council Act 1956. The Council is composed of the following members:

- One member from each state (but not union territories), to be nominated by the central government in consultation with the state government;

- One member from each university's medical faculty, to be elected by members of the university;

- One member from each state in which a state medical register is maintained, to be elected by fellow registered members;

- Seven members who possess the appropriate medical qualifications, to be elected by their fellow professionals who possess these same qualifications;

- Eight members to be nominated by the central government. [61]

In addition to the MCI, which operates at a central level, each state in India is required by the 1956 Act to have its own separate medical council. These serve the primary purpose of overseeing the registration of doctors, as well as the profession's medical code and standards of good conduct in the respective state. Allowing for minor variations from state to state, the main functions of the state medical councils include the following:

- Overseeing the code of conduct of the medical practitioners registered with the council, and taking action against doctors that fall within the jurisdiction of the state who contravene such codes of good practice;

- Promoting CPD among their members, including providing assistance in this matter to members of the council facing financial hardship;

- Maintaining the state register.

6.2.2 Funding of the MCI

The MCI does not receive any direct funding from the central government; however, it sometimes receives a grant from the central government which may vary from year to year. The bulk of its revenue comes from the fees collected from inspections and registrations. The MCI spent about Rs. 6 million (approximately £80,000) on salaries, travel, contingencies and other allowances in 2006–2007.[62]

6.3 Registration process and requirements

Only candidates who successfully complete a Bachelor of Surgery and Bachelor of Medicine (MBBS) or Bachelor of Dental Surgery (BDS) from a recognised university or college are eligible for registration with the MCI. Candidates who complete the four-and-a-half year MBBS course can apply for provisional registration (valid for one year) provided they pass the screening test, after which they can complete the internship and apply for a full registration. Candidates can register directly with the MCI or with the state medical council.

Indian citizens educated abroad wishing to register as medical professionals in India need to pass a screening exam conducted by the MCI as specified in the Screening Regulations, 2002. There is no immediately available information on the requirements for doctors educated abroad who are not Indian citizens.

---

[61] See: http://mciindia.org/know/mci/mci_activities.htm (last accessed November 2008).

[62] See: http://mciindia.org/helpdesk/how_to_start/inspection_fees.htm (last accessed January 2009).

Statistics from 31 March 2007 show that the total numbers of registered doctors in the country was 675,334.[63] The average annual number of registrations is around 28,000.

6.4 Revalidation / Re-registration

In some of the state medical councils, especially those of Delhi, Maharashtra and other major cities, registrations are only issued for a stipulated period of time (typically five years) and thereafter need to be renewed. As this is only an administrative procedure it is not essentially a revalidation. By contrast, in some other states registration is issued only once, on a permanent basis. After obtaining the registration, should the professional obtain any higher degree, he/she must register the additional qualification with the MCI or the respective state medical council.

6.4.1 Problem of quackery

Due to India's huge population and growing economy, the demand for health care is rising rapidly, and the existing number of registered professionals is inadequate to deal with this increased demand. This is leading to the spread of quackery, which is one of the most serious challenges facing the medical regulatory system in India. The supreme court of India states that "any person who does not have knowledge of a particular system of medicine but practises in that system is a mere pretender of medical knowledge or skills": in other words, a quack.

K.K. Kohli, who chairs the anti-quackery committee of the Delhi Medical Council, stated that:[64]

> *"India has more fake than genuine doctors. In Delhi alone there are around 40,000. In the teeming slums where up to a third of the capital's population of 14 million live, requests for directions to a doctor will lead to one of many dingy clinic-shacks, where a man who looks more prosperous than his neighbours plies his trade with a stethoscope, a thermometer and a big pile of pills."*

This quotation highlights the extent and seriousness of the quackery problem in India. Various steps are now being taken to increase public awareness of the extent of the quackery problem. Faced with the need to raise awareness of the importance of professional healthcare, especially in rural areas, the Ministry of Health and Family Welfare commissioned a programme in 2005 called the National Rural Health Mission (NHRM), whose primary objectives are the improvement of health infrastructure and facilities to make healthcare more accessible in rural areas. In addition to the NHRM there are a considerable number of non-governmental organisations that help provide better healthcare, especially in rural areas.

---

[63] http://mciindia.org/tools/ann_reports/index.htm (last accessed December 2008).

[64] See: http://www.economist.com/world/asia/displaystory.cfm?story_id=10727817 (last accessed December 2008).

6.5   Standards & ethics

The MCI's Code of Ethics Regulations, 2002 sets out the standards of professional conduct, etiquette and ethics for registered medical practitioners.

Chapter 1 to Chapter 7 of the Code of Ethics Regulations, 2002 sets out the regulations in each of the following areas:

1. Code of medical ethics

A doctor shall:

- Uphold the dignity and honour of his profession with the prime objective of rendering service to humanity;

- Maintain good medical practice;

- Keep detailed medical records;

- Prominently display his registration number;

- Use the generic names for drugs as far as possible;

- Provide the highest quality of patient care;

- Expose any unethical conduct encountered.

2. Duties of doctors towards their patients

- Exercise patience and sensitivity, and uphold patient confidentiality;

- Give an honest prognosis (the doctor should neither exaggerate nor minimise the gravity of a patient's condition).

3. Duties of doctors in consultations

- Avoid unnecessary consultations;

- Ensure that the benefit of the patient remains the main priority of a consultation;

- Strive to be punctual for consultations;

- All statements to the patient or his representatives should take place in the presence of the consulting doctors, except as otherwise agreed;

- No decision should prevent the attending doctor from making changes to a patient's treatment if any unexpected developments occur, but the reasons for the variations should be discussed/explained during subsequent consultations.

- Provide a written case summary when referring patients to specialists;

- Provide information on fees and other charges prior to the treatment.

4. Responsibility of doctors to each other

- No insincerity, rivalry or envy should be indulged in;

- Careful appointment of locums wherever necessary;

- Respecting another doctor's cases.

5. Duties of doctors to the public and to the paramedical profession

- Doctors as citizens: *Doctors, as good citizens possessed of special training should disseminate advice on public health issues;*

- Public and community health: *Doctors, especially those engaged in public health work, should enlighten the public concerning quarantine regulations and measures for the prevention of epidemic and infectious diseases;*

- Pharmacists and nurses: *Doctors should recognise and promote the practice of different paramedical services such as pharmacy and nursing as professions and should seek their cooperation wherever required.*

6. Unethical acts

- Advertising: *Soliciting patients directly or indirectly by a doctor, by a group of doctors or by institutions or organisations is unethical;*

- Patent and copyrights: *A doctor may patent surgical instruments, appliances and medicine or copyright applications, methods and procedures. The benefits of such patents or copyrights should be made available in situations involving a large population;*

- Running an open shop: *A doctor should not run an open shop for the sale of medicine, for dispensing prescriptions prescribed by doctors other than him, or for the sale of medical or surgical appliances. It is not unethical for a doctor to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a doctor for a patient should explicitly state the proprietary formulae as well as the generic name of the drug;*

- Rebates and commission: *A doctor shall not give, solicit, or receive nor shall he offer to give, solicit or receive any gift, gratuity, commission or bonus in consideration of or return for the referring, recommending or procuring of any patient for medical, surgical or other treatment;*

- Secret remedies: *The prescribing or dispensing by a doctor of secret remedial agents of which he does not know the composition, or the manufacture or promotion of their use is unethical and as such is prohibited;*

- Human rights: *The doctor shall not aid or abet torture nor shall he be a party to either infliction of mental or physical trauma or concealment of torture inflicted by some other person or agency in clear violation of human rights;*

- Euthanasia: *Practising euthanasia shall constitute unethical conduct. However on specific occasions, the question of withdrawing supporting devices to sustain cardio-pulmonary function even after brain death, shall be decided only by a team of doctors and not merely by the treating doctor alone.*

7. Misconduct

The following actions count as professional misconduct:

- Violation of the regulations;

- Adultery or improper conduct;

- Conviction by a Court of law for criminal offences;

- Performing sex determination tests (in connection with a possible termination);

- Falsifying professional certificates, reports and other documents.

Circumstances may and do arise from time to time which do not fall within any of these categories. In such instances, the MCI and/or the state medical councils have to consider and decide upon the facts brought before them.

Each state medical council oversees and implements these regulations within its own state judiciary.

The MCI received 732 complaints relating to ethical matters during the year 2006–2007. Out of these 732 complaints, 293 were referred to the relevant state councils/authorities for necessary action, 58 are awaiting clarification or further details from complainants and/or comments from the doctors in question, while 381 complaints have been resolved.

The appropriate council may prevent a doctor from performing the relevant procedure or practice until the complaint has been settled or dismissed.

6.5.1 Disciplinary proceedings

Chapter 8 of the Code of Ethics Regulations 2002 sets out the rules relating to sanctions and disciplinary action:

> *"It is made clear that any complaint with regard to professional misconduct can be brought before the appropriate Medical Council for disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate Medical Council would hold an enquiry and give opportunity to the registered medical practitioner to be heard. If the medical practitioner is found to be guilty of committing professional misconduct, the appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicised in local press as well as in the publications of different Medical Associations/ Societies/Bodies."*

An amendment in the Consumer Protection Act 1986 gives patients the right to sue or file a case against a doctor; this can be either a civil or a criminal case, depending on the nature of and seriousness of the issues.

6.6 Medical education

Graduate Medical Education Regulations, 1997 and Postgraduate Medical Regulations, 2000 laid out by the MCI govern the entry requirements, phasing and curriculum of medical education.

6.6.1 Entry requirements for medical education

The undergraduate degree for medicine in India is the Bachelor of Medicine and Bachelor of Surgery (MBBS) and for dental education it is the Bachelor of Dental Surgery (BDS).

There is a range of exams, at national or state level, which candidates seeking to be admitted to medical college can sit. Eligible candidates in each state must obtain aggregate marks of at least 50%.[65]

The MBBS course is of four and a half years and is followed by one year of Compulsory Rotating Residential Internship. The course is divided into three phases:

- Phase 1 (two semesters): Pre-clinical subjects, including human anatomy, physiology (including bio-physics), biochemistry and an introduction to community medicine (including humanities);

- Phase 2 (three semesters): Para-clinical and clinical subjects. Para-clinical subjects include pharmacology, pathology, microbiology forensic medicine (including toxicology) and part of community medicine. Clinical subjects during Phase 2 (and also Phase 3 – see below) are medicine and its associated specialties, surgery and its allied specialties, obstetrics and gynaecology and community medicine;

- Phase 3: Continuation of clinical subjects. Medicine and its associated specialities include training in general medicine, paediatrics, respiratory medicine, dermatology, genito-urinary medicine, psychiatry, radiology and infectious diseases. Surgery and its associated specialties include training in general surgery, orthopaedic surgery (including physiotherapy and rehabilitation), ophthalmology, otorhinolaryngology, anaesthesia, dentistry and radiotherapy, etc. The obstetrics and gynaecology training include family medicine and family welfare planning.

To obtain a degree, a candidate must obtain an aggregate pass mark of at least 50% in each subject, with a minimum of 50% in the theory examinations (including the oral examinations) and in the practical/clinical examinations. Furthermore, candidates are required to pass all subjects in each phase before proceeding to the next phase. After successfully completing the course, candidates are awarded a provisional MBBS degree and may register provisionally as a medical professional. This registration is valid for one year. They can also start the year-long Compulsory Rotating Residential Internship. At end of the Internship they are evaluated on proficiency of knowledge, responsibility, capacity to work in a team, and other parameters. To be successful they should obtain a score of at least 3 (average) on a scale of 0–5 (with 0 being poor and 5 being excellent).

There are a number of postgraduate degrees for medical education in India, including Master of Surgery (MS) and Master Chirurgiae (M.Ch.); in addition, institutes offer diplomas in various other fields. Postgraduate degrees generally span three years and sometimes more, with the exception of diplomas, which take only two years. The cost of medical education can vary significantly between states and between colleges.[66]

---

[65] See: http://mciindia.org/know/rules/rules_mbbs.htm (last accessed December 2008).

[66] See: http://timesofindia.com/articleshow/2279230.cms (accessed November 2008).

6.6.2 Quality assurance

Maintaining standards in medical education is one of the major statutory requirements of the MCI. For this purpose, the Council carries out inspections of medical colleges both at undergraduate and postgraduate levels. Accreditation of all the recognised colleges by the MCI/DCI, and annual reviews, are mandatory. Inspections must also be carried out prior to increasing the number of places for students on a particular course.

There is currently an intense debate in India regarding the quality of medical education. Researchers and others have observed that "while the graduates generally possess reasonably sound knowledge of medical science, they are often found deficient in the performance of clinical skills and problem-solving, which form the core of clinical competence".[67] A related issue is the growing concerns about the extent to which medical school graduates are aware of their ethical, moral and legal responsibilities (ibid). Much of the focus of this debate is on the curriculum, and on the MCI's recommendations for reform such as a move towards both horizontal (e.g. anatomy-physiology-biochemistry) and vertical (e.g. anatomy and surgery) integration.

6.6.3 Continuous medical education

In 1985 a Continuing Medical Education Cell was set up in the MCI to gain from expertise and to utilise the services of Indian doctors settled in the USA for the improvement of continuing medical education and patient care in India.

The MCI has been the nodal agency to co-ordinate these schemes. For the CME Scheme, an annual grant in-aid under the Plan Budget is released by the central government, Ministry of Health and Family Welfare. The Programmes initially drew on the expertise of Indian doctors practising in the USA. In 1993, with the increase in the popularity and importance of the programmes, the scheme was extended to include NRI (Non-Resident Indian) doctors from the UK and Canada as well.

The central government Ministry of Health and Family Welfare approved the proposal of the MCI for increasing the financial assistance for an approved CME programme. A total of 133 CME Programmes were held successfully by various medical institutions/associations in the country during the year 2006-2007.

---

[67] Sood, R. and Adkoli, BV (2000) Medical education in India – problems and prospects, *Journal Indian Academy of Clinical Medicine* 1:3.

Medical regulation in Italy

7.1 Overview

Italian medical regulation is governed by state laws, regulations, administrative actions and formal acts that are all implemented by the provincial medical associations or "orders" (*Ordini dei Medici Chirurghi e degli Odontoiatri*), who carry out regulatory and administrative functions at a regional level. There are a number of organisations involved in medical regulation, including the Ministry of Health, the Italian regions and independent provinces, the provincial medical associations (given the federal system in Italy, there are more than 100, one for each province) and their national umbrella organisation.

7.2 Structure and nature of medical regulation

Italy has a regionally-based national health service (*Servizio Sanitario Nazionale* – SSN).[68] At a regional level, the organisation of public healthcare provision is the responsibility of the respective regional administration.

Medical regulation and the bodies involved in this are governed by state laws. Regulations, administrative actions and formal acts are all implemented by the provincial medical associations who carry out regulatory and administrative functions at a regional level. Some key Acts regulating the medical profession are: the Civil Code (Art. 2229); Law no. 233 of 13 September 1946; Law no. 1378 of 8 December 1956; Law no. 409 of 24 July 1985; and Law no. 471 of 31 October 1988.

---

[68] The information for the Italian case study is based on input by three of the key stakeholders of the Italian healthcare system: the Ministry of Health, a provincial order that provided a relatively recent report that included a summary of key issues of interest for our case study, and the National Federation of Medico-Surgical and Dental Orders (Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri (FNOMCeo). The stakeholders preferred to respond in writing (the Ministry in English, FNOMCeo in Italian). Given the time-sensitive nature of the analysis and the gap regarding required information, a significant part of the information in the case study has been retrieved via desk research. Information by the stakeholders and information found on the world wide web were most of the time in Italian and were translated into English by the authors. Concrete statistical information, for example on the cost of medial regulation, as well as some more detailed information on the interpretation of clauses in the deontological code (e.g. on the motivation for disciplinary procedures) was hard to obtain due to the complexity of the system, the lack of a central data collection, or the lack of access to this information.

The main organisations involved in medical regulation are the Ministry of Health, the Italian regions and independent provinces, the medical associations (given the federal system in Italy, there are more than 100, one for each province), and their national umbrella organisation, the National Federation of Medico-Surgical and Dental Orders (*Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri* – FNOMCeo). Although numerous bodies are involved in medical regulation, it is the provincial associations and the FNOMCeo that are of central importance.

7.2.1 Purpose of medical regulation

According to the Ministry of Health (*Ministero del Lavoro, della Salute e delle Politiche Sociali*), the objective of medical regulation is to ensure qualified professionals provide a quality service and protect the public's health. The values underpinning the rules include a commitment to science, humanity and collaboration between the professionals involved. More detail can be found in the Code of Ethics (*Codice di Deontologia Medica*) issued by the FNOMCeo.[69]

The regulation of the medical profession is the remit of the provincial medical associations (Law 233/46 and DPR 221/50) which have the disciplinary power to deal not only with professional malpractice, but also with any aspect of the conduct of registered doctors (including private conduct, as discussed in more detail in section 7.2).

As is the case with the Spanish regulatory system, many aspects of medical regulation are decentralised to the provincial/regional level, even though the code of ethics is established at national level by FNOMCeo.

Although reducing the risk of harm to patients is not an explicit objective of the regulatory system, FNOMCeo has several times stated its concern to government that more attention should be paid to the development of efficient policies ensuring the safety of patients and quality of treatment. FNOMCeo is also seeking to promote a positive culture towards clinical risk and the safety of patients amongst health professionals. In addition, article 14 of the code of ethics stresses the importance of the reporting and assessment of mistakes to improve the quality of treatment.

7.2.2 Drivers and influential events

According to research in 1944 "something similar to a national health service" was proposed in Italy, "but it was not until 1978 that this proposal received parliamentary approval".[70] Until that time "Italy's healthcare system was based on a plethora of health insurance funds (*casse mutue*) serving different employment categories." Although health coverage of the population was high, it was not universal. Moreover, the "entitlements and contribution levels varied widely, and there was a north-south divide in the levels of provision". Health insurance funds often had to be bailed out by the state to avoid bankruptcy. This was mainly caused by the separation of the responsibilities of financing (provided by the funds), and spending (undertaken by the hospitals). But there was a

---

[69] http://portale.fnomceo.it/Jcmsfnomceo/cmsfile/attach_5917.pdf

[70] George France and Francesco Taroni (2005) "The Evolution of Health-Policy Making in Italy", *Journal of Health Politics, Policy and Law*, Vol. 30, Nos. 1–2, pp. 169-187.

strong opposition to reform by doctors, "who raised the spectre of socialised medicine," and by insurers and the funds themselves.

The same research highlights two crucial exogenous drivers for reform.[71] First is the decentralisation of government, which would see the regions and municipalities standing to gain from a national health service. According to both the constitution and the reform proposals, the system would be administered at local level, while the financing would be a central responsibility. A second fact was the political rise of the Left. Against this background, the SSN (*Servizio Sanitario Nazionale* – National Health Service) was finally established. This brought universal healthcare entitlements, standardised benefits, and replaced the autonomous funds with local health authorities (*Unità Sanitarie Locali*) under municipal and regional authority.

It soon became evident that the greatest challenge for the SSN was the often "wasteful and inefficient use of financial, human, and physical resources", which was partly a result of the tension between central planning and local control of the budget, as well as of the strong reliance on contracting independent service providers. The crucial momentum for reforms was again spearheaded by two exogenous factors: a bribery scandal that brought down all the main political parties, due to their involvement, and the collapse of the *lira* (Italian currency). This led to the appointment of a coalition government that introduced healthcare reforms in 1992. The reforms aimed at "macroeconomic stabilisation and microeconomic efficiency"; the focus was on fostering "managerialism and competition", and redistributing responsibilities and authority within the healthcare sector. The "municipalities were sidelined in the running of the SSN" and the regions were given greater power in exchange for their approval of tighter budget constraints.

Under the centre-left government that took office in 1996, a third major healthcare reform was introduced in 1999. This time the focus was less on cost-containment and more on "reaffirming the original goals of universalism, comprehensiveness, and public funding of the SSN". This reform occurred against "a widespread dissatisfaction with the 1992 reform, alleged to have encouraged a narrow cost-paring mentality and to have generated a democratic deficit, as well as an inadequate role for doctors and local authorities." Consequently, the objectives of the 1999 reforms included empowering doctors at local level. Doctors retained their right to self-regulate in exchange for accepting spending limits set by central government. These reforms also introduced "compulsory continuing education for all SSN staff, including salaried doctors." A controversial measure was that "doctors employed by the SSN [were compelled] to choose, on a once-and-for-all basis, between undertaking their private practice within public facilities or elsewhere", with the first option leading to a substantial salary increase, and those choosing the latter being "excluded from holding senior posts in the SSN."

Recently a further proposal for a new law that would modernise the Italian healthcare system in a variety of aspects was put forward by the last centre-left government under Prime Minister Prodi. If adopted, the law would foster, among other practices, the involvement of employees in the management of healthcare organisations; greater transparency in the process of appointing, faster processing of claims for compensation for

---

[71] *Ibid.*

the victims of medical malpractice, patient involvement in the evaluation of healthcare services provided by the SSN, and increased specialist training for doctors. Furthermore, the reform proposal foresees the establishment of a national system of guidelines to ensure appropriateness, quality and safety in the areas of diagnostics, clinics, and therapies.[72]

7.2.3 Extent of patient involvement

There is little evidence of institutionalised patient involvement in the area of medical regulation in Italy. The FNOMCeo refers to the principle of informed consent, which is closely related to the right to healthcare that is enshrined in the Italian constitution (Art. 32 and 13), and is also restated in Article 35 of the Code of Ethics that obliges the respective doctor to fully inform the patient about a treatment before obtaining consent to carry out that treatment. The reform proposal put forward by the former Prodi government also provided for patient involvement in the assessment of the Italian healthcare system.

In spite of little formal provision for patient involvement in medical regulation, patient organisations are at the forefront of public debate on healthcare issues. They are often organised around a specific illness (such as cancer) or specific issues (such as disability). Some operate at regional level, and some such as *Alzheimer Italy*, the *Association against Leukaemia and Tumours in Childhood*, the *Italian Association against Epilepsy*, and others, at a national level.[73]

7.2.4 Funding arrangements

An annual payment is necessary to maintain membership to a medical association. The size of the fee varies but is typically around 150 Euros per annum.

Every doctor registered with a provincial medical association is also obliged to pay a contribution to the ENPAM (*Ente Nazionale di Previdenza e Assistenza in Favore dei Medici iscritti agli albi professionali* – the national organisation for the welfare of doctors). This fee consists of two parts: one fixed base fee, which is the same for all doctors registered, and a second part which depends on the specific activity of the doctor (calculated on the basis of his or her income; currently 12.5% of his/her income). These contributions are used mainly for doctors' pensions, and other contributions such as the payments for doctors on maternity leave.

7.2.5 Interaction between different regulatory bodies

As mentioned in Section 7.1, several organisations are involved in medical regulation in Italy. The relationships among competent agencies are regulated by law.

The Ministry of Health establishes the fundamental principles, and self-regulatory activities are performed under the supervision of the ministry, which is assisted in many of its activities by the *Istituto Superiore di Sanità*. A commission within the ministry

---

[72] See: http://www.ministerosalute.it/dettaglio/pdPrimoPianoNew.jsp?id=3&sub=1&lang=it (last accessed November 2008).

[73] For more information on patient associations in Italy see http://www.assomedici.it/assopazienti.htm (last accessed November 2008).

(*Commissione Nazionale per la Formazione Continua*) is responsible for the elaboration of the programme for continuous medical education (*Educazione Continua in Medicina –* ECM).

Given the federal structure of Italy, the regions and independent provinces are responsible for applying the fundamental principles established by the ministry at a national level. Italian law delegates central regulatory and administrative functions to the regional medical associations which are responsible for keeping the register of doctors up to date, establishing the code of conduct, and disciplining their members. At national level these activities are coordinated by the umbrella association, FNOMCeo.

Medical education (along with all university-related issues) is the responsibility of the Ministry of Education (*Ministero dell'Istruzione, dell' Università e della Ricerca*) (more on this below).

Responsibilities do overlap on occasion; for example, hospitals have disciplinary authority over their staff, including doctors, and medical associations have disciplinary authority over doctors registered with them. However, there seem to be mechanisms in place to foster collaboration, and FNOMCeo stresses that it has good relations with the other bodies involved in the medical regulatory process in Italy.

7.3   Registration process and requirements

7.3.1   Registration and licensing process

According to a WHO report[74] the Ministry of Health is responsible for the licensing of doctors, while registration and disciplinary matters are carried out by the medical associations. According to the report:

> *There is one licence to practise issued by the Order following approval of qualifications by the Ministry (which delegates this to the Universities). The University issues Specialist Diplomas which must be registered with the Order. Applications are made in the first instance to the Ministry of Health and then to the appropriate Provincial Order for Registration. The licence issued is valid for the whole of Italy, not only for the province in which the person in registered.*

The licence is issued on a permanent basis, with no time limit attached to it.

For Italian nationals evidence of the following needs to be provided when applying to an association for registration and authorisation to practise:

- Italian citizenship;

- civil status (full entitlement to civil rights and privileges);

---

[74] Alan Rowe and Mila García-Barbero (2005) *Regulation and licensing of physicians in the WHO European Region*, Division of Country Support of the WHO Regional Office for Europe (available at: http://www.euro.who.int/document/e87789.pdf , last accessed December 2008).

- Certificate of professional good standing;

- University or other appropriate institution diploma of completion of medical studies, state examination and internship period;

- Ministerial approval of certificates of medical training and status relevant to entitlement to practise;

- Certificate of residence in the area of the relevant provincial order.

People trained in other EU countries are entitled to register to practise medicine in Italy; the right to practise is in accordance with the relevant European Directives that have been incorporated in Italian Laws nos. 217/78 and 409/85. In addition to the documents required of Italian citizens, those trained in other EU member states must provide a certificate of registration as a doctor in the country from which they came as well as a certificate of professional good standing issued in that country.

For non-EU nationals the following documentation is required[75]:

- Birth certificate;

- Certificate of nationality or equivalent document;

- Certificate of civil status;

- Extract from the legal record;

- Evidence of professional qualifications (diplomas etc.).

Documents issued by the national competent authorities of the applicant must be authorised by the Italian consular or diplomatic services and endorsed by the Ministry of Foreign Affairs (Art 7 DPR 221/50).

Nationals of countries with which Italy has bilateral agreements need to provide evidence of Italian language proficiency through an interview organised by FNOMCeo. EU applicants are not required to prove language proficiency.

According to the latest information from the FNOMCeo there are currently 388,166 doctors (including 54,954 dentists) registered in Italy.

7.3.2 Doctors educated abroad

According to Piccolo (2008)[76], a study conducted by ENPAM and FNOMCeo found that in 2004 out of 365,652 doctors 12,525 (3.5%) were non-Italian nationals. Of these, 7,772 doctors were male and 4,753 female. The majority were between 41 and 50 years of age. A breakdown according to regions and countries of origin showed that in 2004 3,829 of doctors came from an EU member state (1,034 from Germany, 649 from France, 646 from Greece, 256 from Belgium, 207 from Poland and 206 from the United Kingdom). A

---

[75] EU applicants have to submit the required documentation to the Italian Ministry of Health that has to provide its approval or refusal within 30 days.

[76] Stefania Piccolo (2008) "La difficile integrazione dei medici stranieri", *M.D. Medicinae Doctor* - Year XV Number 8, p. 14 (available at: http://www.passonieditore.it/md/08/Riflettori.pdf, last accessed November 2008).

further 2,040 came from other non-EU European countries (760 from Switzerland, 437 from the former Yugoslavian countries, 389 from Romania and 204 from Albania). Some 1,590 came from Africa, 2,524 from the American continent (602 from the USA, 575 from Venezuela, 526 from Argentina, 226 from Brazil and 169 from Canada), 2,328 doctors from Asia, 713 from Iran, 334 from Lebanon, 328 from Jordan, 311 from Syria, and 280 from Israel. The provincial associations with the highest number of non Italian doctors were in Rome (1,855) and Milan (1,035). [77]

According to an OECD study (2008), Italy has a very high number of doctors per capita (around 600 doctors per 100,000 of population in 2005). A third of these work in the public health service. The OECD paper states that "competition is fierce for public-sector employment, and young doctors suffer from a high unemployment rate and often face a long job search before finding regular employment." Further, the paper finds that "overall, the short-term employment outlook for doctors in Italy is not promising. In 1998, for example, of doctors who had received their degree in 1995, only 45.2% were working, and 36.1% had left the labour market (they do not pay their contribution to the medial order, thus they cannot work as medical practitioners)" (Istat, 2000). In 1999, more than 10% of doctors enrolled in the FNOMCeo were not working as doctors (i.e. they were not contributing to the doctors' pension system, ENPAM). There is a shortage of qualified specialists in certain sectors, such as anaesthesia and radiology. The aging of the medical labour force will cause an increase in retirements in the next decades. In paediatrics, the number is expected to halve from 2015 to 2030 if the current enrolment and turnover trends continue. Even with Italy's low fertility rate this is expected to cause a shortage in the sector.

The OECD paper also mentions the fact that the public sector does not offer a lot of stable job opportunities, favouring short-term contracts, and that the local health authorities' staff budget has fallen by 2% from 2004 to 2007 as drivers for Italian doctors to go abroad.

7.4   Revalidation

There is no process of revalidation within the medical profession in Italy. Once doctors obtain their medical degrees and are registered with their respective association they are not subject to any additional regulatory processes until they retire.

7.5   Standards & ethics

Although implementing and monitoring disciplinary procedures is the responsibility of the individual provincial medical associations, the *Codice Deontologico* (Code of Ethics) is established at a national level by the FNEMCeo. The latest version was published in 2006.

The code includes principles regarding doctors' relationships with patients, doctor-patient confidentiality, the quality of medical care, a doctor's duty regarding organ donation,

---

[77] Jonathan Chaloff (2008) *Mismatch in the formal sector, expansion of the informal sector: immigration of health professionals to Italy*, OECD Health Working Paper No. 34 provides similar data.

abortion and the prolongation of life, assisted reproductive treatment, clinical experiments (also on animals), and other issues.

Each provincial association is responsible for ensuring that registered doctors uphold the standards of professional conduct set out in the code. In cases of alleged malpractice or any misconduct that might have a bearing on the standing of the medical profession (including private conduct), it is the responsibility of the association to pursue disciplinary proceedings.

The Code of Ethics sets out the doctor's obligation to:

- Protect life; protect the physical and psychological wellbeing of the individual; and alleviate pain while respecting the freedom and dignity of the patient, without consideration of gender, age, ethnicity, religion, nationality, social condition, and ideology, in peace and war times;

- Support and promote preventative medicine, healthy work practices and individual and public health;

- Promote efficacy of treatment, as well as the non-discriminatory access to, availability, use of and quality of treatments;

- Provide health assistance in urgent cases, and offer support to the respective authority in the event of a catastrophe;

- Uphold confidentiality with respect to patient information and within the limits of the law (confidentiality with respect to patient information does not end with the death of the patient);

- Take into account the dignity of his/her professional status, and obtain informed consent from the patient if applying non-conventional treatments;

- Comply with data-protection regulations relating to personal data and sensitive data;

- Ensure the safety of patients and prevent clinical risk;

- Not abuse his professional status;

- Not perform euthanasia;

- Update his/her knowledge and participate in continuous training;

- Not take on tasks beyond his/her professional knowledge and capacity;

- Respect fundamental human rights;

- Avoid conflicts of interest.

This is just a selection of obligations mentioned – the code lists more, and provides further information on the standards of good conduct. Failure to abide by the principles established by the code constitute a disciplinary fault as specified in the general statutes of the FNEMCeo and are dealt with by the provincial medical association.

The code is continuously revised to reflect developments. The code is published and promoted by the provincial medical associations and by FNOMCeo through meetings, round tables, national conventions, and specific courses of continuing education. Furthermore, the code is published on the FNOMCeo website, which patients can access freely. Patients are also informed about their rights by the association for consumer protection, with which FNOMCeo has a working relationship.

Pre-evaluation (accreditation) and continuous evaluation (quality control) are also applied, in order to ensure the ethical, qualitative, economical, effective and equal provision of services by healthcare professionals and healthcare institutions.

The concepts of clinical governance and quality improvement of services, in which patients, healthcare providers, and healthcare professionals are the main actors, are gaining in importance in developments in medical regulation. Another important actor relevant to quality assurance is the Agency for Regional Services (*Agenzia nazionale per i servizi sanitari regionali*) that is intended to support the regions in the follow up to this innovative concept of quality improvement.

The Italian Society for the Quality of Healthcare Services (*Società Italiana per la Qualità dell'Assistenza Sanitaria*) produced recommendations for patient safety in January 2007; this triggered a programme on this topic by the Ministry of Health, linked to the *Agenzia nazionale per i servizi sanitari regionali*. The FNOMCeo has at the same time made available an e-learning course on patient safety for healthcare providers on the web.

7.6   Fitness to practise (FTP) and related disciplinary procedures and sanctions

Disciplinary procedures are used for violations of the rules of good conduct which might harm the standing of the medical profession, and of the standards established in the Code of Ethics. The provincial association in which an individual doctor is registered is responsible for the disciplinary procedure and the decision on sanctions. The procedure can be started *ex-officio* or in response to a complaint. Public hospitals can initiate a disciplinary procedure against a doctor who is a staff member and will collaborate with the provincial medical associations in the process.

Disciplinary procedures for malpractice are mostly initiated by patients or by a magistrate; they can, however, also be triggered by the Ministry of Health or initiated by the medical associations themselves. Complaints must in the first instance be sent to the medical association which examines the claim and decides whether to undertake a disciplinary procedure. The doctor is also obliged to inform the medical association of any initiative that may cause him/her to act against the rules laid down in the Code of Ethics.

If the complaint originates from the Ministry of Health the hearing is conducted by the Central Commission for Health Professions (*Commissione Centrale per gli esercenti le professioni sanitarie*). This body comprises one Counsellor of the State (*Consigliere di Stato*), who chairs the commission, a member of the Superior Council of Health (*Consiglio Superiore di Sanità*), a health ministry official, an inspector (*ispettore generale medico*), and eight health professionals (*liberi professionisti*).

However, most cases are the responsibility of the president of the relevant provincial medical association who verifies the circumstances and collects the necessary information on the case. A date is then set for a hearing to which all interested parties are invited. In the hearing the doctor cannot be represented or assisted by a lawyer or a technical expert. The doctor is encouraged to attend in person but is not obliged to do so. The hearing is not public.

The association may adopt the following sanctions:

- Warning;

- Admonition;

- Suspension of the right to practise for a period of one to six months;

- Removal from the register (withdrawal of right to practise).

The decision of a suspension or a removal is communicated nationally to all other Italian provincial medical associations.

According to Art. 42, in the event of a doctor being found guilty by a court of a crime punishable by the Penal Code, the doctor is automatically struck off the register.

Appeals

Appeals can be made to the Central Committee of FNOMCeo within 30 days of the announcement of the disciplinary decision by the association (this appeal has a suspending effect). After these thirty days the doctor has the option of appealing to the Central Commission for Health Professions (based in the Ministry of Health).

The decision of the Central Commission can be appealed in the Supreme Court (Art. 68 DPR 221/50); this appeal does not, however, suspend the earlier decision.

In 2008 there were 88 disciplinary procedures against health professionals. As a result of these, 57 doctors were given precautionary suspensions of the right to practise (*sospensioni cautelari*), 29 were suspended at the end of the disciplinary procedure, and two doctors were removed from the register (withdrawal of right to practise). In 2007, the total number of procedures was 82.

7.6.1 Re-registration

If removed from the register, the doctor can re-register after five years if his/her behaviour in these five years was impeccable[78]. The re-registration is, however, only on the request of the doctor him/herself and does not take place automatically *ex-officio*.

7.7 Medical education

7.7.1 Education trajectory and qualification requirements

Medical education takes place in universities; according to the ministry of health, this has an average length of five years across all health professions. Having completed their

---

[78] We were not able to find further details on how the behaviour is assessed.

university studies, some professionals (such as physiotherapists) are already qualified to practise professionally. Others (such as doctors) must pass a state examination and enrol in the relevant regional medical association. Continuous Professional Development is obligatory for all health professionals.

After successfully completing secondary school, an entrance exam must be passed to gain admission into medical school. Each year a decree by the Ministry of Education, Universities and Research (*Ministero dell'Istruzione, dell' Università e della Ricerca*) establishes how many student places are available for medicine. For 2008/2009, 7,945 places were allocated to medicine within all Italian universities (ministerial decree of 1 July 2008). At the same time (and in addition to the 7,945) a further 398 study places were set aside for non-EEA students. Admission depends on test scores. The exam tests knowledge of the following subjects: chemistry, physics, biology, mathematics, logic, and general culture.

A university medical degree in Italy takes six years; five years of course work and a one year an internship (the sixth year of the university degree). According to Italian law, after completion of the university degree and prior to practising, a doctor is required to take a state exam consisting of a three-month internship and a written test, and enrol on the medical register.

Students pay for their own education. There are, however, merit-based scholarships for low-income students. The average cost for the six years of university education (tuition and material) is estimated to be about 20,000 Euros. After completing a university degree a doctor can apply for a place in specialist medical education. These places are publicly funded.

Undergraduate and specialist education is entrusted fully to universities. Both theoretical (5,500 hours of theoretical education) and practical education are provided and supervised by the university. The university is also responsible for issuing the university diploma, and for the qualification exam that is necessary to practise as a doctor. In addition the university is responsible for the entrance exam for specialist training. It is possible to use hospitals for the practical element of the medical training; this is, however, still subject to the control of the university.

In order to pursue a specialisation, another practical and written entrance exam is required. Places for specialist training are very limited and a variety of admission criteria are applied (including the entrance exam results, results of university exams, elective courses attended, performance in internships). Depending on the specialisation, training takes another three to six years.

Participation in continuing professional development (*Educazione Medica Continuata*) is a requirement for every doctor and dentist and is uniform throughout Italy. CPD is certified by the provincial medical associations. A commission within the Ministry of Education (*Commissione Nazionale per la Formazione Continua* – National Commission for Continuous Professional Development) is responsible for the continuous medical education programme.

Medical regulation in Nigeria

8.1 Overview

The primary medical regulatory body in Nigeria is the Medical and Dental Council of Nigeria. However, a number of other bodies share responsibility for the regulation of the medical profession in Nigeria, including federal and state government agencies.

8.2 Structure and nature of medical regulation

The main actors involved in medical regulation in Nigeria are the following bodies[79]:

- Medical and Dental Council of Nigeria (MDCN) – the primary regulator

- Nigerian Medical Association (NMA) – a semi-voluntary association of all medical and dental practitioners in Nigeria, up to eight of whose members sit on the MDCN council board[80]

- the federal government (through the federal Ministry of Health)

- state governments (via state ministries of health)

- National Postgraduate Medical College of Nigeria.

Medical and Dental Council of Nigeria (MDCN)

The primary medical regulatory body in Nigeria is the Medical and Dental Council of Nigeria (MDCN). It is a statutory regulatory body set up by law. Its stated purpose is "to

---

[79] The information presented in the Nigeria case study is predominantly based on the written data sources available on the Medical and Dental Council of Nigeria's and The Nigerian Medical Association's websites. These documents included some general description of the medical regulatory system in Nigeria as well as some official regulatory and policy documents, such as *The Red Book* presenting the code of medical ethics and code of practice. Data from written sources is supplemented by an interview with a senior official of the Association of General and Private Medical Practitioners of Nigeria. The interview findings were then validated through short discussions with Nigerian doctors working in and outside Nigeria, and in one instance, with a former dean of medicine from a teaching hospital in southeast Nigeria. All information and data were available in English.

[80] Nigerian Medical Association (NMA): www.nigeriannma.org/index.htm (last accessed January 2009).

regulate the practice of Medicine, Dentistry and Alternative Medicine in the most efficient manner that safeguards best healthcare delivery for Nigerians".[81]

The Act (Medical and Dental Practitioners Act Cap 221 [now Cap M8] Laws of Federation of Nigeria 1990 and amendment Viz Decree No. 79 of 1992) sets up the MDCN and charges the council with the following responsibilities:

1. determining the standards of knowledge and skill to be attained by persons seeking to become members of the medical or dental profession and reviewing those standards from time to time as circumstances may permit

2. securing in accordance with provisions of this Law the establishment and maintenance of registers of persons entitled to practise as members of the medical or dental profession and the publication from time to time of lists of those persons

3. reviewing and preparing from time to time a statement as to the code of conduct which the Council considers desirable for the practice of the professions in Nigeria

4. performing the other functions conferred on the Council by this Law

5. supervising and controlling the practice of homeopathy, and other focus of alternative medicine (naturopathy, acupuncture and osteopathy)

6. making regulations for the operation of clinical laboratory practice in the field of pathology, which includes histopathology, forensic pathology, autopsy and cytology, clinical cytogenetics, haematology, medical microbiology and medical parasitology, chemical pathology, clinical chemistry, immunology and medical virology.[82]

Since its inception in 1963, the MDCN has published certain documents as guidelines for registered practitioners and those who want to become members of either profession. These documents include:

- *The Red Book: Guidelines on the Minimum Standards of Medical and Dental Education in Nigeria*

- *Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria*.

The Council is empowered to make rules of professional conduct and to establish the Medical and Dental Practitioners Disciplinary Tribunal and Medical Practitioners Investigating Panel for the enforcement of these Rules of Conduct.[83] The MDCN is, therefore, responsible for setting, maintaining and ensuring the standards for doctors' education (in particular, basic training), registration, licensure, and disciplinary issues.

---

[81] Medical and Dental Council of Nigeria (MDCN): www.mdcnigeria.org (last accessed January 2009).

[82] Copied from http://www.mdcnigeria.org/Downloads/20M8.pdf (last accessed January 2009).

[83] Medical and Dental Council of Nigeria. *The Red Book: Guidelines on the Minimum Standards of Medical and Dental Education in Nigeria*. Revised edition. Abuja: Medical and Dental Council of Nigeria, 2006; Medical and Dental Council of Nigeria. *Rules of Professional Conduct for Medical and Dental Practitioners*. Lagos: Medical and Dental Council of Nigeria, 2004; interview with the President of the Association of General and Private Medical Practitioners of Nigeria, on 26 November 2008.

The Nigerian Medical Association (NMA)

The Nigerian Medical Association is a quasi-voluntary association of all medical doctors and dentists. It shares the same objectives as the MDCN, as stated in the Codes of Ethics and Conduct, and commands the allegiance of all doctors and dentists in the land. It is the largest medical association in the West African sub-region. It has over 35,000 members from 36 state branches and the branch from the Federal Capital Territory. About 70% of the doctors associated with the NMA practise in urban areas where only 30% of the Nigerian population reside.

The governing body of the NMA is the National Executive Council. It has full powers to act on its behalf in the period between the Annual Delegates' Meetings in accordance with the provisions of the Constitutions of the Association.

Under the Medical and Dental Practitioners Act CAP 221 Laws of the Federation of Nigeria from 1990 and subsequent acts, any registered medical and dental professional has the right to become a member of the Association on payment of the annual fee. There are six main categories of members: ordinary members, life members, honorary members, associate members, student members and distant members.

The NMA is involved in many of the government's activities; however, it is only formally consulted by the government on an ad-hoc basis and it has to press for its participation. At present, the NMA is mainly involved in influencing health policy formulation in an ad-hoc manner. It plans to be more explicitly involved in all aspects of policy formulation, especially in the planning stages, and is currently actively involved in talks with the federal Ministry of Health to make this happen.

Federal and State Ministries of Health

Nigeria is a country of 36 states and a Federal Capital Territory (Abuja). Partly subsumed by the federal Ministry of Health are state ministries of health. Within this structure, a Directorate of Medical Services (DMS) operating with both federal and state ministries of health is currently responsible for regulating the professional performance and maintenance of the standard of quality of practice of all healthcare practitioners, including medical doctors, within their own jurisdiction. The federal government and federal Ministry of Health influence the composition of the MDCN since the president, in consultation with the Nigerian Medical Association (NMA), appoints the chairman and several members of the MDCN.

National Postgraduate Medical College of Nigeria

The teaching of specialist skills is essentially the prerogative of the West African Colleges [84] and the National Postgraduate Medical College of Nigeria.[85] Regulation of the maintenance of specialist skills seems to be a work-in-progress, although the postgraduate colleges may provide some oversight. The current system tends to deal more with

---

[84] Medical and Dental Practitioners Act CAP M8 2004 under the Laws of the Federation of Nigeria. Available at www.mdcnigeria.org; West African College of Surgeons (WACS): www.wacs-coac.org (last accessed January 2009).

[85] West African College of Physicians (WACP).

registration, licensure and disciplinary actions than with routine monitoring for professional quality assurance. Continued medical education for maintenance of skills has been in the works for a while but is yet to be fully implemented.

8.2.1 Values within medical regulation

The extent of patients' involvement in medical regulation has been described by an interviewee as marginal. Although the MDCN and the federal Ministry of Health use public announcement channels to educate the general public on their rights as healthcare consumers (for example patients are given instructions on how to file complaints against professionals or institutions) this type of initiative is still rare.

Although at the moment of induction all qualified doctors subscribe to the Hippocratic Oath, part of which deals with religion, nationality, race, party politics and social standing as elements that should not intervene between a doctor's duty and the patient, according to our interviewee medical regulation in Nigeria is not specifically concerned with the aspects of race, ethnicity, religion, disability, age and gender. These attributes are only looked at in an administrative sense where the age of the professional might be taken into account for ability to register.

8.2.2 Funding arrangements

The involvement of several organisations in the regulation of medical professionals in Nigeria makes it extremely hard to calculate the combined budget of the medical regulatory bodies. Some of the money comes from public sources, and some funding comes directly from the registration and licensing fees paid by doctors.

8.3 Registration process and requirements

The main issues regarding the registration of medical professionals in Nigeria are dealt with in the registration department of the MDCN. This department processes the registration of doctors including issuing provisional, full and limited/temporary registration, issuing documents confirming additional qualifications, and issuing annual practising licences and certificates of good standing for doctors going abroad.[86]

Nigerian registration guidelines state that "a person shall not hold an appointment or practise as a medical practitioner or dental surgeon, unless he/she is registered with the Council" and that "any person who practises medicine or dentistry anywhere in Nigeria without being appropriately registered with the Council contravenes the law as does his/her employer".[87] Registration is valid upon payment of an annual registration fee. Registration is a necessary condition for legal medical practice in Nigeria.

There are several types of medical registration in Nigeria.

1. Provisional registration. This type of registration is granted to a newly qualified medical practitioner to undertake an internship under the supervision of registered

---

[86] www.mdcnigeria.org (last accessed January 2009).

[87] www.mdcnigeria.org (last accessed January 2009).

consultants or specialists in a hospital approved by the MDCN for the internship training. This registration lapses automatically when the registered practitioner is signed off from the internship. Every medical graduate is required to complete an internship within two years of graduation. This type of registration does not entitle the practitioner to set up and run an independent practice on his own.

2. Full registration. This type of registration is granted after the satisfactory completion of the internship and it confers the legal right to practise independently.

3. Limited or temporary registration. This type of registration is issued to expatriate practitioners. It has a specific period of validity tied to specific employment. Any change of employment invalidates the registration and the practitioner must then re-register.

4. Registration as a specialist. Every practitioner who has acquired a specialist qualification after undergoing the requisite training is required by law to be registered with the Council as a specialist before he can practise as a specialist.

All doctors registering with the MDCN need to physically present themselves before the registration board when they register for the first time. The MDCN publishes an annual register of medical and dental practitioners.

8.3.1 Applications from doctors trained in other countries

Doctors who obtained their medical education and training in the recognised Commonwealth medical institutions and a number of other countries have their qualifications automatically recognised on par with doctors trained in Nigerian medical schools, and these individuals follow the same registration requirements as Nigeria-trained doctors.

Additional requirements are applied to non-Nigerian nationals and Nigerian doctors trained overseas. These doctors need first to apply for temporary registration and later undergo an assessment examination.

In order to be granted temporary registration doctors need to present the following documents:

- a letter of good standing from the medical registration authority in the country of origin;

- a copy of the basic medical or dental degree certificate Bachelor of Surgery and Bachelor of Medicine (MBBS) or Basic Dental Degree Certificate (MBChB);

- the name and address of the institution where the basic medical or dental degree certificate (MBBS or MBChB) was obtained, including the website and email address;

- a copy (or copies) of additional qualification certificate(s) and the name and address of the institution(s) where this/these was/were obtained, including website and email address (if applicable);

- completed application forms (for Temporary Registration and Practising Licence) with three recent passport photographs; the Temporary Registration form should be endorsed with the official stamp from the doctor's country of origin embassy and from the employer in Nigeria;

- a letter of appointment from the employer in Nigeria;

- evidence of having been previously registered in the home country;

- expatriate quota (from the Nigeria Immigration office);

- a resident/work permit (from the Nigeria Immigration office);

- a certified English translation of any document in other languages;

- a certified bank draft of all the appropriate payment fees required;

- a photocopy of the page that shows the date of entry in the doctor's international passport endorsed by the immigration office.

A non-Nigerian doctor without an additional qualification (i.e. a specialist degree) is required to sit and pass the Council's assessment examination before he/she is registered with the Council. The examination consists of a multiple choice questions paper covering all aspects of basic and clinical sciences in medicine, a short answer question paper, a long essay question paper, a clinical examination comprising long and short cases or objectives structured around clinical examination, some practical examination, oral examination and an English language paper for non-English-speaking graduates from medical schools whose language of instruction is not English. All basic and specialist degree certificates need to be verified before temporary registration is granted by the Council.

8.4 Revalidation /competence assurance

According to the regulations of the MDCN, all doctors practising in Nigeria need to update their knowledge and skills to enhance their ability to render appropriate service to patients.[88] Participation in continuing professional development programmes is a mandatory requirement for licence renewal and the MDCN has decided to enforce this during the licence renewals for each year. The main aim of this process is to enhance the competence of all doctors, and to ensure their knowledge remains relevant and up to date. The MDCN has authorised several institutions and organisations to organise continuing medical and dental education, and these bodies involve inter alia training institutions, teaching and specialist hospitals, voluntary agencies, postgraduate medical colleges, foundations, professional societies and some overseas professional societies and institutions. The MDCN has also established a Continuous Professional Development accreditation committee to review the content, duration and scope of each programme with a view to allocating appropriate credit units.

---

[88] This section is based on the information from the following websites: www.nigeriannma.org/index.htm and www.mdcnigeria.org (last accessed January 2009).

The curriculum for continuing medical education covers basic medical and clinical sciences, and accredited programmes include workshops, seminars, scientific conferences, update lectures and website learning. One hour of a programme counts towards one credit unit. The current regulation requires a medical doctor to obtain a minimum of 36 credit units in every two years to be eligible for continued licensing. A minimum of 12 units and a maximum of 24 units must be obtained yearly. All doctors renewing their licence need to pay the practising fees, which vary according to the type of licence held by a doctor.

All doctors are advised to seize this opportunity to keep abreast of rapid developments and expansion in medical knowledge, skills and equipment.

8.5   Standards & ethics

One of the statutory functions of the MDCN is "to renew and prepare from time to time a statement on the Code of Conduct which the Council considers desirable for the practice of the professions in Nigeria".[89] *Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria* was first published in 1963. It was revised in 1995. In January 2004 a new edition was published as *Code of Medical Ethics in Nigeria*. The Council recommends that every medical practitioner should familiarise himself/herself with the provisions of this code, so that he/she may practise the profession with dignity and a clear conscience, within the limits of the provision of the code and without ethical violations. The code is intended to enhance the image of the profession, increase public confidence in practitioners and offer protection to the conscientious practitioner. "Code of Medical Ethics" should also serve as an information booklet for medical students, medical teachers and all other individuals who seek information on aspects relating to the medical and dental professions in Nigeria.

Code of Medical Ethics in Nigeria covers the following key issues:

1. the general regulation of medical and dental practitioners in Nigeria, including the doctors' oath, the legal basis for medical practice, and general principles of the ethics, rights and responsibilities of members of MDCN;

2. professional conduct;

3. malpractice;

4. improper relationships with colleagues or patients;

5. aspects of private medical or dental practice;

6. self-advertisement and related offences;

7. conviction for criminal offences.

The code also contains some rules guiding doctors in biomedical research involving human subjects and other forms of medical research.

---

[89] http://www.mdcnigeria.org/mandateframe.htm (last accessed January 2009).

All doctors are required to obtain copies of *Guidelines on Registration* and *Code of Medical Ethics in Nigeria* (formerly *Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria*).

Every member of the medical profession in Nigeria must agree to abide by the dictates of the Doctors' Oath, the modern version of the Hippocratic Oath, which is the foundation of the profession's code of ethics.

8.6 Fitness to practise and related disciplinary procedures and sanctions

All registered doctors in Nigeria in all areas of their professional conduct and relationships with their patients and other persons should be guided and bound by the rules contained in the codes of conduct and ethics. Any registered practitioner who, after investigation and trial, during which he is given every opportunity to defend his actions and conduct, has been shown to have conducted himself in such a manner which would be regarded as disgraceful or dishonourable by his fellow professional professionals of good repute and competency, is found to have contravened these rules by the Disciplinary Tribunal of the Medical and Dental Council of Nigeria and shall be guilty of professional misconduct. The list of acts that constitute professional misconduct is not exhaustive because the profession demands the highest ethical standards from its members.

The duty of investigating cases of professional misconduct is vested in the Medical and Dental Practitioners Investigating Panel. Once the panel concludes, after due investigation, that there is substance in the allegation against a practitioner, the matter is remitted to the Medical and Dental Practitioners Disciplinary Court for trial. At the trial, the practitioner is given an opportunity to defend his/her actions and conduct. Should the tribunal find the practitioner guilty of professional misconduct as alleged in the charge made against him, the tribunal can impose penalties for failing to maintain the standards set out in the code of conduct, or for any form of misconduct in any of the following ways:

1. admonishing the practitioner;

2. suspending the practitioner from medical practice for a period not exceeding six months;

3. striking the practitioner's name off the relevant register.

When a doctor is found guilty of a recurrent professional negligence (i.e. two or more incidents) he or she does not have the option of being admonished. He shall be suspended from practice for a period not less than six months. A practitioner who is habitually negligent in a professional capacity could have his name struck off the relevant register.

A registered practitioner who was informed by the Investigating Panel of the necessity for his appearance before the panel, for whatever reason, shall attend relevant hearings as and when invited, and is required to duly notify the appropriate official of the panel and obtain the necessary clearance before travelling out of Nigeria. The MDCN may also inform medical councils in other jurisdictions of the disciplinary proceedings against doctors who decide to practise medicine in another country.

The Medical and Dental Practitioners Disciplinary Tribunal has the status of a High Court of the Federal Republic of Nigeria and practitioners who appear before it, whether as complainants, defendants or witnesses, whether or not they are also represented by a lawyer, must conduct themselves as they would before a high court.

Any conviction by a court of competent jurisdiction, whether or not such act has resulted from professional practice, is regarded as professional misconduct. When a registered medical practitioner is given a prison sentence by any court in Nigeria, the Medical and Dental Practitioners Disciplinary Court may strike off the practitioner's name from the medical register. In every case where a practitioner is found guilty by the Medical and Dental Practitioners Disciplinary Tribunal, the sentence given will be published in the *Gazette of the Federal Republic of Nigeria* and also as a paid advertisement in each of four national newspapers. The outcomes of other investigation proceedings are normally not announced to the public, unless the media were involved in the early stages of the investigation process. According to our interviewee, the level of trust that characterises doctors' attitudes towards regulators and their acceptance of outcomes of investigations are moderate to high.

8.7   Medical education

Medical education in Nigeria is regulated by the MDCN.[90] It is responsible for:

1. coordinating the Continuing Medical Education programme;

2. coordinating, accrediting and supervising the statutory Internship programme;

3. assessing and accrediting medical schools' training programmes;

4. reviewing *Guidelines on the Minimum Standards of Medical and Dental Education;*

5. accreditation and orientation of doctors trained abroad.

Standards of medical education in Nigeria are described in *Guidelines on the Minimum Standards of Medical and Dental Education in Nigeria*. These standards were first published in 1975 and later revised in 1993. The document is currently being revised by the present Council.

In undergraduate medical programmes subjects are taught in two main stages: basic medical and basic clinical science. Basic medical science courses include: human biology (including anatomy, histology and physiology), organic chemistry/biochemistry, genetics, medical sociology and psychology. Basic clinical sciences include: medical biology (pathology), morbid anatomy or histopathology, microbiology and immunology, haematology, chemical pathology, epidemiology, biostatistics including computer appreciation, and environmental health.

In some medical schools subjects are taught in the traditional pattern under the pre-clinical and clinical programmes with definite time allotments to each area, and the latter taking at

---

[90]   hhttp://www.mdcnigeria.org/Downloads/Copy%20of%20Guideline%20on%20minimum%20standard-Red%20book.pdf (last accessed January 2009).

least 36 months. Other medical schools have a more integrated pattern in which there is a definite overlap between the two and students may begin to be exposed to the clinical area from their first year. The Council requires a minimum of 18 calendar months of instruction, excluding holiday periods, for the completion of Basic Medical Science courses.

University Authorities of Nigeria and the MDCN have joint responsibility in ensuring that the standards of the institutions intended for the training of medical students in Nigeria are adequate for the purpose of training medical professionals. Basic and specialist education in Nigeria is very much embedded within teaching and general hospitals owned by the federal and state governments; these hospitals are central to the healthcare system. The realities of the Nigerian situation are that almost immediately after graduation the Nigerian doctor is required to assume professional responsibilities that greatly exceed those that his/her counterpart in more developed countries would be expected to carry out immediately after graduation. Therefore it is important that medical schools prepare students for the reality that graduates will face when starting their professional career as medical practitioners.

The MDCN is also involved in the accreditation and monitoring programmes of all medical schools in Nigeria. The Council lays down the guidelines on minimum standards and procedures for assessing the compliance with these established guidelines in the operation of the medical schools.

Medical regulation in Pakistan

9.1 Overview

The Pakistan Medical and Dental Council (PMDC) stands as the main medical regulatory body responsible for regulating the country's medical profession.[91]

9.2 Structure and nature of medical regulation

The Pakistan Medical and Dental Council, the main medical regulatory body in the country, principally invests its efforts in:

- Setting national standards for medical education;

- Keeping a register of medical practitioners;

- Accrediting medical colleges for quality of facilities, numbers of teachers and such like – and particularly regarding growing number of private medical colleges.

While Pakistan's medical regulatory framework is comprehensive, gaps between theory and practice are notable, particularly in the investigation of medical negligence and in combating quackery. This is partly attributable to the PMDC's narrowly focused remit and powers, but note must also be taken of the challenges inherent in operating such as system in a heavily populated country (170 million) with a large informal economy, lax central government administration, and an embedded practice of patronage.

9.2.1 Purpose, Values and Drivers

After gaining independence in 1947, Pakistan initially based its medical education on the *Indian Medical Council Act* (1933). The promulgation of the *PMDC Ordinance* (1962) was the most significant moment of subsequent reform, and aside from a necessary revision to

---

[91] The information and data for the case study on Pakistan was mainly available through the Pakistan Medical and Dental Council (PMDC) website. Although this is aimed principally at students, it constituted a solid base of information for this study. The PMDC has an extensive website with a wealth of regulations and some statistics, including various policy and regulatory documents. Other sources included relevant local press articles, and studies by Pakistani NGOs and academics on the subject. Data from written sources were supplemented by information obtained in two interviews, one with a former Government health advisor, and the second one with the CEO of a non-governmental organisation working in the medical field in Pakistan, with extensive knowledge of medical regulation in the country.

this document following Pakistan's territorial dismemberment in the 1971 war, this document remains the PMDC's foundational mission statement to this day. Its stated purpose is to:

> …*consolidate the law relating to the registration of medical practitioners and dentists and constitute the [Medical and Dental Council] in Pakistan in order to establish a uniform minimum standard of basic and higher qualifications in medicine and dentistry.*[92]

PMDC's mandated role has changed little since then – its current scope of activities include:

- Establishing minimum standards for basic and postgraduate qualifications;

- Keeping a list of all registered medical professionals;

- Accrediting medical colleges and inspecting them to ensure PMDC regulations are followed;

- Determining necessary qualifications/experience for teachers at these colleges;

- Deciding whether doctors coming to Pakistan from abroad are suitably qualified;

- Enforcing its Code of Medical Ethics against incidents of professional negligence.[93]

The PMDC is structured around a series of committees that broadly mirror its responsibilities[94] Despite this wide array of stated functions, in practice, the PMDC has a narrowly interpreted remit that is focussed on producing high calibre medical professionals and in managing Pakistan's medical colleges. What has changed notably over the last decade is the increasing number of private medical colleges opening across the country – a trend that the PMDC has struggled to keep up with. A doctor's practical connection with the PMDC ends when they qualify. Doctors only actively seek contact when they want to set up lucrative private medical colleges, and then they need to court PMDC favour.

As noted in an independent research report on Pakistan's health sector: "Pakistan does not have an institutional mechanism for quality control, hospital accreditation or provider credentialing except for the Pakistan Medical and Dental Council, which serves the role of registration only."[95].

---

[92] "PMDC Ordinance Act 1962", p. 672 (www.pmdc.org.pk/pmdcord.pdf, last accessed October 2008).

[93] See: www.pmdc.org.pk/what_it_does.htm (last accessed October 2008).

[94] These include: Executive Committee; Standing Recognition Committee; Curriculum Committee; Disciplinary Committee; Postgraduate Medical/Dental Education Committee; Committee of Rationalization of Teaching Faculty Requirements & Inspection; National Examination Board; Journal Committee; Committee to Suggest Measures to Combat Quackery; Committee to review proposed amendments in the Ordinance. (www.pmdc.org.pk/how_it_works.htm, last accessed October 2008).

[95] "Pakistan's health sector: does corruption lurk?" (Section 3.5) http://www.u4.no/training/incountry-open/pakistan-materials/health-sector-corruption-pakistan.pdf

Gaps and inadequacies in exercising these functions will be detailed in relevant sections later in this document.

9.2.2 **Funding of the PMDC**

PMDC receives no grants or aid from the federal government and thus appears to be self financing. It collects fees from students (see section 9.3.1), and can collect fees from the medical colleges it inspects. In addition:

> *The Council is authorised to receive, for the purpose of its expenses, benefactions and fees from Governments, institutions, private persons and bodies, and the proceeds of the sale of reports and other publications.... Such funds of the Council as are in excess of current requirements may, on a recommendation by the Registrar and with the sanction of the Executive Committee, be invested in the following manners, namely: - (a) in promissory notes, stock or other securities of the Federal Government or of any Provincial Government; (b) in stock or debentures or shares in Companies, the interest whereon shall have been guaranteed by the Federal Government or the State Bank of Pakistan.*[96]

Although required to compile monthly accounts and for its budget to be audited by an outside body, PMDC accounts including its total budget are not publicised.

9.3 Registration process and requirements

9.3.1 **Flow and Quantity of Applications**

The medical regulatory system in Pakistan does not distinguish between registration and licensing, and registration automatically entails the right to practise medicine. In order to remain on the PMDC register doctors have to pay an annual fee. The fee varies depending on the type of registration.

- Basic medical/dental qualification only, such as Bachelor of Surgery and Bachelor of Medicine (MBBS)/Bachelor of Dental Surgery (BDS): Rp 1,500 for five years at Rp 300 per annum (equivalent to £2.50).

- Basic medical/dental qualification MBBS/BDS with postgraduate qualifications: Rp 2,500 for five years at Rp 500 per annum.

- Name retention fee for overseas nationals: Rp 2,000 per annum.

- Late fee (this will be charged if a license is renewed after the expiry of the three months grace period after the expiry of a registration certificate): Rp 100.

- Any change in registration certificate: Rp 500.

- Extension of provisional registration: Rp 500.

Provisional registration refers to the one year internship doctors undertake after they complete their initial education.

---

[96] "Medical and Dental Council Regulations, 2007" (www.pmdc.org.pk/reg2007.pdf, last accessed October 2008).

In a single calendar year (2007) the PMDC registered 4,766 MBBS doctors. As of 30 October 2008, the total number of doctors registered by the PMDC was:[97]

Table 9-1: Total number of doctors registered with the PMDC

Province	MBBS*	LSMF**	Specialists	Total
Punjab	43517	565	10852	54934
Sindh	48253	306	6420	54979
NWFP	11715	54	2802	14571
Balochistan	3335	55	741	4131
AJK	1910	4	437	2351
Foreign Nationals	2784	106	77	2967
TOTAL	111514	1090	21329	133933

* MBBS refers to *Bachelor of Medicine, Bachelor of Surgery*, the degree awarded upon graduation from medical school in Pakistan. Other abbreviations of the degree include MB BChri., MB BCh, and others.

** LSMF refers to *Licentiate of State Medical Faculty*, a diploma no longer commonly awarded by medical schools in Pakistan.

It is worth considering that the PMDC register by definition fails to cover the medical black market – it is only a record of doctors that are registered with the PMDC. Given the size of quackery (see section 9.6.2 below), doubts exist over how accurate a reflection PMDC register is of the real number of individuals practising medicine in the country.

9.3.2 Registering Overseas Doctors

One of the PMDC's functions is to send delegations abroad to determine how compatible other countries' standards of medical education are to Pakistan's own.[98] Doctors who have gained their basic medical degree abroad and who want to practise in Pakistan have to sit an exam that is conducted twice a year. It consists of two parts (theory and clinical examination) and costs Rp 4,000.[99] The numbers of overseas trained doctors practising in Pakistan is reported in table 9-1.

9.4 Revalidation / Re-registration

To remain on the PMDC register requires a payment, and both annual and five-yearly rates are stated. However, re-registration is not linked in any way to the re-testing of medical skills or to further education. There is a programme of continuous education for nurses and paramedics in Pakistan, but not for doctors. The PMDC – and Pakistan in

---

[97] www.pmdc.org.pk/stat.htm - statistics are also split by gender here (last accessed October 2008).

[98] Its list of countries with comparable standards is here - www.pmdc.org.pk/what_it_does.htm (last accessed October 2008).

[99] Regulation Instructions for Registration Examination of Foreign Medical Graduates (www.pmdc.org.pk/mden.doc, last accessed October 2008).

general – is institutionally unequipped to provide a Continuous Professional Development (CPD) programme for doctors. According to one study this is because:

> *…there is currently no structured or systematic CPD program for doctors in Pakistan. A doctor's link with their teaching institution is lost as soon as he/she graduates or specialises.[100]*

A survey of 329 doctors observed that lack of time, funding, a non-permissive organisational culture, and poor awareness were the main barriers to the uptake of CPD. Overall, there appeared to be a lack of incentives for doctors to take part in continuous education.

9.5 Standards & ethics

The Council has prescribed the Code of Medical Ethics for the Registered Medical Practitioners to enforce ethical practice and prevent professional negligence.[101] The stated purpose of the Code of Medical Ethics is to:

> *…provide guiding principles for use in every day practice for the Registered Medical and Dental Practitioners (RMDP) in their roles in regard to patients, students, community, colleagues, researchers and citizens (people)…. It is intended for the welfare and protection of the individuals and societies with which the profession interacts. It states the responsibility of professionals to society and individuals; and the rights of an individual. It serves public interest… When a Registered Medical or Dental practitioner's conduct or practice and consequently registration, are questioned, these are the principles and standards against which s/he will be judged.[102]*

The Code of Medical Ethics includes specifications on:

- Applicability;
- Oath of Medical and Dental Practitioners;
- Duties of Medical and Dental Practitioners;
- Medical Ethics in Islam;
- The Teaching of Medical Ethics;
- Expectations;
- Fundamental Elements of Patient – Doctor Relationship;
- Ethical Standards of Professional Competence, Care and Conduct;
- Confidentiality;

---

[100] Zarrin Seema Siddiqui, "Continuous Professional Development of Medical Doctors in Pakistan: Practices, motivation and barriers." (www.aare.edu.au/07pap/sid07623.pdf, last accessed October 2008).

[101] "PMDC Code of Ethics for Medical and Dental Practitioners", 2001 (www.pmdc.org.pk/ethics.htm, last accessed October 2008).

[102] Ibid.

- Conflict of interest;

- Truth Telling;

- Advertising;

- Certificates, Reports and other documents ;

- Business and contractual obligations;

- Consent;

- Teaching Photography and Consent;

- Research Ethics and Consent;

- Organ Transplantation and Consent;

- Adoption;

- Resource Allocation;

- End-of-Life Care;

- Genetics in Medicine;

- Procedures for Review of the Code;

- Procedure for Enforcement of Code.

9.5.1 Process / Actors involved

The enforcement of the Code forms the basis of the disciplinary action. Doctors are expected to remain vigilant regarding the practise of their colleagues. While the PMDC has jurisdiction for setting these regulations and for hearing complaints, local and national health authorities also have a role in detecting negligence. The problem is that there are frequent tussles between the PMDC and the Ministry of Heath regarding disciplinary hearings. A lack of transparency over the enforcement of the Code is one of the key challenges for medical regulation in Pakistan.

9.6 Fitness to practise (FTP) and related disciplinary procedures and sanctions

9.6.1 Disciplinary Procedures

The interviewees consulted for this chapter concur that the PMDC could do more in combating negligence. The PMDC has regulations aplenty for investigating medical malpractice, but in practice it plays a rather small role in seeing through disciplinary action. The PMDC authorises the following list of officers to file a complaint against medical practitioners:

- Health Secretary of the province in question (Punjab, Sindh, Baluchistan, NWFP);

- All members of PMDC located in the province;

- Director General and all Directors of Health Services in the province;

- All District Health Officers;

- Superintendents of the Teaching/GHQ Hospitals.[103]

The process for addressing complaints consists of the following stages:[104]

Figure 9-1: Process to address complaints against doctors

PMDC's Disciplinary Committee: examines and investigate complaints. The Committee seeks relevant information from persons and records in order to reach a decision on whether the Medical Code has been violated. If disciplinary action is requested, the case will be referred to the Executive Committee.

PMDC's Executive Committee: reviews and endorses the Disciplinary Committee recommendations. It may agree, or may ask for a further review of the case by another or the same or expanded Disciplinary Committee, or may disagree and modify the recommendations on the basis of available information. It will then pronounce the disciplinary decision. The matter will be referred to Court if needed.

Disciplinary action: The disciplinary action may either be an admonition, a temporary suspension for a specified period or lifelong expulsion from membership of the PMDC. The PMDC will when making the latter decision consider whether it is in public interest to retain the name of the practitioner on the Register. The PMDC expects that every member will report infringement of the code by a fellow member in the interest of patient. In minor infractions, it is expected that members will advise the individual on a one on one basis. If this fails to bring about corrective behaviour the matter should be brought to the attention of the PMDC.

In practice, the PMDC can find itself marginalised in the process. The misconduct report might end up with the Ministry of Health who then recommends action, and there are a number of "gray areas" in this process regarding where the PMDC's role begins and ends. If the doctor is referred to a court of law the "PMDC becomes disinterested" because its role becomes subservient to the legal process. The whole process is compounded by "secrecy" and "opaqueness" in which personal favours can be invoked by the accused from influential political and judicial figures they know to lessen the accusations. The outcomes of individual cases are not published.

Some statistics about the FTP hearings were recently relayed in a press article and attributed to PMDC Secretary Dr Sohail Hashmi, speaking in December 2008 at 28th biennial medical conference of Pakistan Medical Association (PMA). PMDC received complaints against 2500 doctors during the last five years (2004-2008 inclusive), out of which 500 doctors have been "penalised". Out of 500 penalised doctors, four had appealed against the decision with the judiciary. Dr Hashmi said that the PMDC has also cancelled registration for a surgery professor in Lahore on account of an unsafe procedure.[105]

---

[103] www.pakistan.gov.pk/divisions/health-division/media/FAQ_PMDC.doc (last accessed October 2008).

[104] Ibid.

[105] Imtiaz Ali, "PMDC penalises 500 doctors", 21 December 2008, http://www.thenews.com.pk/daily_detail.asp?id=152953

Determining whether a doctor is fit to practise is not an exact science in Pakistan. Although there is, in theory, a system detailing who can raise a complaint and how the complaint is dealt with, in practice there is little transparency when a disciplinary proceeding begins. Critics of Pakistan's regulatory system say that bribery and corruption play some role in the raising and the resolution of complaints. Outcomes may appear in the press if the case is particularly controversial, but otherwise remain from public view.

9.6.2 Quackery

There are significant numbers of illegal practitioners of medicine in Pakistan (quacks):

> *The Federal Health Ministry submitted a report [that] stated that the ministry served notices on 132 quacks in the federal capital, 217 in Punjab, four in North West Frontier Province (NWFP) and two in Balochistan for running illegal clinics... The petitioner claimed that that 600,000 unqualified doctors, hakeems and homeopathic practitioners were operating across the country [with] one third operating in Sindh.*[106]

The problem is often that paramedics or GPs administering medical services are not qualified and licensed. The PMDC has established a *Committee to Suggest Measures to Combat Quackery*, but the operative word here is "suggest". In practice there is little the PMDC can do because of the realities of operating in a country in which regulatory frameworks in all areas of governance are weakly institutionalised and enforced. But the PMDC is often not an honest broker because some of its senior clinicians own private colleges that employ quacks – again reflecting the problem of vested interests obstructing regulation.

In a country with a literacy rate of under 50% and where poverty is often rife, it is unlikely that patients are fully aware of their rights. This is especially true in rural areas where quackery is heavily pronounced and patients are defrauded on a regular basis.

9.7 Medical education

9.7.1 Education, Examination and Qualification

The undergraduate degree is the Bachelor of Medicine and Bachelor of Surgery (MBBS). Its entry requirement has recently been changed to a minimum 60% score in the F.S.c. exam (*Fellow of Science* high school qualification in Pakistan). Candidates need to be between the age of 17 and 25 at time of admission. The stated objective of the MBBS is to:

> *…prepare a caring, general purpose, community oriented doctor who is competent to deal with the common health problems of the people in a scientifically sound and cost-effective manner using appropriate technology and a holistic approach. He/She should be able to assume leadership in a health care team, function and communicate effectively as a manager in accordance with the code of medical ethics prescribed by the PM&DC.*

---

[106] 'Report on quackery submitted in LHC', *Daily Times*, Islamabad, 25 July 2007 (italics added) www.dailytimes.com.pk/default.asp?page=2007%5C07%5C25%5Cstory_25-7-2007_pg7_38 (last accessed October 2008).

He/She should be a continuous self-learner who is able to pursue training in the specialty of his/her choice.[107]

The course is typically designed so that lectures account for less than one third of the time with greater emphasis on tutorials, seminars, workshops, practical work and clinical training. The course options comprehensively cover a wide array of areas of medical knowledge (with the addition of *Islamic Studies and Pakistan Studies*).

The trajectory for a student after admission to medical school is five years of academic and clinical training, and a one year internship as a provisionally qualified doctor (this is only necessary if they wish to practise in Pakistan). Once graduated, postgraduate qualifications (MD, MS)[108] are required for attaining full PMDC registration.

9.7.2 Quality Assurance

Medical colleges must attain recognition by the PMDC. A *Comprehensive Feasibility Report* is made of the college checking: infrastructure (availability of water, electricity, telephones, building materials, furniture); mandatory facilitates (laboratories, dissection hall, library); financial viability to be a self financing non-profit; proposed affiliation of the college to a recognised University of Pakistan; and availability of qualified teachers and staff.[109] colleges are then subject to inspection every five years to ascertain if they continue to meet PMDC standards.

One of the main challenges facing the PMDC is the growth of private medical colleges – currently, the split between public and private colleges is 50-50. One interviewee held that during the last decade, introducing the element of competition into Pakistani medical education has improved its overall standard. All inspectors are public sector employees, and according to the interviewee they are "very restrictive" when inspecting private colleges. However, critics argue that a large number of substandard private colleges exist.

---

[107] See: www.pmdc.org.pk/regulation_mbbs.htm (last accessed October 2008).

[108] See "Guideline for Postgraduate" www.pmdc.org.pk/post.doc (last accessed October 2008).

[109] See: www.pakistan.gov.pk/divisions/health-division/media/FAQ_PMDC.doc (last accessed October 2008).

Medical regulation in Poland

10.1   Overview

Three bodies with clearly defined remits share responsibility for the regulation of the medical profession in Poland, namely the Chamber of Doctors and Dentists, the Ministry of Health, and the Ministry of Science and Higher Education.

10.2   Structure and nature of medical regulation

10.2.1 Interaction between different regulatory bodies

The regulation of the medical profession in Poland is the responsibility of three bodies:

- the Chamber of Doctors and Dentists (*Naczelna Izba Lekarska* – NIL) and regional chambers (*Okregowa Izba Lekarska*), which are responsible for setting medical standards and ethics, medical registration and revalidation processes, and fitness to practise (FTP) and other related disciplinary procedures and sanctions;

- the Ministry of Health (*Ministerstwo Zdrowia*);

- the Ministry of Science and Higher Education (*Ministerstwo Nauki i Szkolnictwa Wyższego*), jointly responsible with the Ministry of Health for the regulation of medical education.

All of these have clearly defined responsibilities: the Ministry of Science and Higher Education is responsible for undergraduate medical education; the Ministry of Health has legislative responsibilities and oversees medical regulation; and the medical chambers set standards and ethical codes, oversee matters concerning professional conduct, regulatory procedures and the registration of medical professionals, and also provide opinions/consultations to the Ministry of Health.[110]

---

[110] The information for the Polish case study was obtained primarily from the websites of the Polish Chamber of Doctors and Dentists (NIL) and the Ministry of Health. Many policy documents and documents describing the organisation, structure and processes of medical regulation are publicly available on the relevant organisations' websites. Written data sources are comprehensive, mostly provided in Polish, but the main policy and regulatory documents are also translated into English and available on the NIL and Ministry of Health websites. When information was available only in Polish, it was translated by the case study author. Written data was complemented by two in-depth interviews with representatives of NIL and the Ministry of

Polish Chamber of Doctors and Dentists

The Polish Chamber of Doctors and Dentists (NIL) is a professional, self-governing organisation of doctors and dental practitioners. It was founded in 1922, dissolved in 1952 and reactivated in 1989. Its aims, objectives and activities are determined by Polish national law – the Chambers of Doctors Act (1989). Chambers deal with all matters relating to the practice of medicine and dentistry in Poland.

Regulation of the medical profession is closely connected with the history of the Polish medical chambers. The idea to form a self-governing medical organisation first developed when Poland gained independence after the First World War in 1918. The Polish Chamber of Doctors was established in 1922 with the aim of supporting other government and self-governing institutions in the task of providing public healthcare within the structures of the new Polish state.

The independence of the medical chambers was threatened during the Second World War and in the forty-year period of communist rule that followed. As the Polish Chamber of Doctors' website states: "Truly independent autonomy was contradictory to the assumptions of the totalitarian state. In spite of official declarations, self-governing bodies of doctors did not receive full approval or support from central state authorities or the majority of province authorities. The assumptions of self-government of doctors were contrary to the intention of subordination of all professional groups of healthcare workers to one ruling institution; the healthcare workers' trade union."[111]

Medical chambers were dissolved in Poland in 1952 and reactivated in 1989 when Poland again became a democratic country. In the same year, the Act on Chambers of Doctors was passed in national law, determining that one of the fundamental aims and objectives of medical chambers is "to take responsibility for the proper provision of professional services, consistent with medical ethics and the medical knowledge of doctors".

Since then NIL has been actively involved in various activities related to the medical regulatory system. Medical chambers are, for example, responsible for amendments to the Medical Code of Ethics, they grant licences to practise medicine and are involved in FTP procedures. In recent years, medical chambers – represented at a national level by the NIL – are also playing an active role in representing Poland on European fora of medical professions; for example since 2000 the NIL has been a member of the Standing Committee of European Doctors, the organisation representing all medical doctors in the EU; and since Poland became a member of the EU in 2004, its medical chambers have been classified as "competent authorities" as defined by the EU directives relating to the recognition of the professional qualifications of doctors.[112]

Health, and written communication with the Institute of Patients' Rights and Health Education as well as other organisations involved in the various aspects of medical regulation in Poland. All interviews and correspondence were conducted in Polish.

[111] http://www.nil.org.pl/xml/nil/wladze/nil_eng/history

[112] http://www.nil.org.pl/xml/nil/wladze/nil_eng/policy

There are currently 23 regional chambers and a separate chamber of military doctors and dentists that has the legal status of a regional chamber, although it is active in the entire country. The highest authority of the NIL is the General Medical Assembly, whereas the regional medical assemblies are the highest authorities of the regional chambers.

Chambers vary in size, with the largest ones located in Warsaw, Katowice and Poznan. The largest chambers employ approximately 50 members of staff each. Smaller chambers, such as those in Gorzow or Plock, employ a relatively small number of staff, on average five or six. Overall, we can estimate that there are about 500 employees of medical chambers in Poland.

By law every doctor and dental practitioner who holds the right to practise medicine in Poland must be registered with a chamber. In June 2007 the number of members of all the Polish chambers was: 127,290 doctors, 34,290 dental practitioners, and 571 persons with both professional titles.[113]

10.2.2 Purpose and values of medical regulation

The purpose and values of medical regulation in Poland can be assessed by examining the aims and objectives of the institutions involved in the medical regulatory system.

The main aim of medical chambers in Poland is to supervise the proper and conscientious exercise of the medical profession and to determine the principles of professional ethics binding all doctors and dentists, and ensure these principles are complied with. Medical chambers also represent and protect the medical profession and are active in delivering opinions on matters concerning public health, as well as cooperating with scientific and research institutions in Poland and abroad.[114]

Patients' safety and rights are important aspects of medical regulation in Poland (for instance these aspects are at the heart of the medical code of ethics). However, the direct responsibility to protect patients' safety does not rest with the NIL. Instead, the responsibility to represent and protect patients is shared by the Patients' Rights Ombudsman (*Rzecznik Praw Pacjentów*) at the National Health Fund (*Narodowy Fundusz Zdrowia*)[115] and the Patients' Rights Bureau *(Biuro Praw Pacjenta)* at the Ministry of Health. A number of NGOs are also involved in this area. These organisations have the authority to undertake some intervening actions when patients' rights are neglected (Patients' Rights Ombudsman)[116], and can advise patients about possible steps to report medical misconduct and negligence of patients' safety (Patients' Rights Bureau)[117].

There are numerous patients' interest groups organised in various NGO organisations. One of the biggest is the Institute of Patients' Rights and Health Education (*Instytut Praw*

---

[113] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_chamb (last accessed October 2008).

[114] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/aims (last accessed October 2008).

[115] Polish equivalent of the British NHS

[116] See: http://www.nfz.gov.pl/new/index.php?katnr=2&dzialnr=5&artnr=89 (last accessed October 2008).

[117] See: http://www.bpp.waw.pl/ (last accessed October 2008).

Pacjenta i Edukacji Zdrowotnej) and the Federation of Polish Patients (*Federacja Pacjentów Polskich*). The main aims and objectives of these two organisations are:

1. to integrate numerous not-for-profit non-governmental patients' organisations

2. to protect the rights and representation of patients and their interests – for example through the provision of legal services to patients (free legal advice)

3. to represent patients' interests.

These organisations are often involved in initiatives leading to changes in the regulations of the healthcare system in general, and in particular in all issues that have a direct influence on patients. An example of such involvement is participation in summits for all involved in the delivery of healthcare services in Poland, organised by the office of the prime minister. Their role mainly involves lobbying and participating in public consultations.

Information on patients' rights is widely available, for example in leaflets in hospitals or GP practices, on websites, via press campaigns, etc. In addition, all amendments to medical regulations are communicated through the standard media channels. Doctors are not legally obliged to inform patients about their rights - though nurses, on the other hand, are legally required to do so.

In practice, however, patients have very limited knowledge about their rights, medical standards and regulations. An indication of the extent of patients' knowledge is provided by the results of a study conducted by the Institute of Patients' Rights and Health Education (study conducted February–March 2008 on a representative sample of Polish citizens aged 15–75).[118] The study findings reveal that more than half the individuals interviewed had some knowledge about patients' rights, but 42% of interviewees had never come across that concept. Of those who had heard about patients' rights, only 40% were able to name at least one of the rights (less than one in five of the sampled population – 189 out of 1004). At the same time, 76% of respondents declared that they would like to obtain more information on patients' rights.

10.2.3 Funding arrangements

Aspects of medical regulation falling within the scope of the Ministry of Health and the Ministry of Science and Higher Education are publicly funded. Because medical regulatory activities constitute only a fraction of the overall activity areas of these ministries, it is difficult to estimate the combined annual budget of the bodies responsible for medical regulation. NIL funding arrangements are even more complex. It receives public money to cover the cost of the registration process of medical doctors (in Poland, doctors do not pay a registration fee), while the rest of its activities are financed from doctors' annual membership fees and some business activity, like the publication of the *Medical Journal*.

---

[118] http://www.prawapacjenta.eu/index.php?pId=1366

10.3 Registration process and requirements

10.3.1 Registration and licensing process

There is no clear distinction between the registration and licensing process in Polish medical regulation. In the Polish context, licensing is called "right to practise medicine" (*prawo do wykonywania zawodu lekarza*) and only in rare cases – for example when a doctor undergoing a FTP procedure is suspended from practising medicine – can a doctor remain on the medical register (i.e. be registered as a doctor) without a licence to practise. On the other hand, medical regulation in Poland distinguishes between a provisional and full licence to practise medicine.

The conditions under which a medical licence can be granted are specified in the Law on Medical Professions (*Ustawa o zawodzie lekarza*) from 1997, which was later amended.[119] As set out in these conditions, each candidate applying for a medical licence must:

- be of Polish nationality or a national of another EU country (requirements of international medical graduates are presented in section 10.3.3);

- have a higher university degree in medicine awarded by a Polish medical school or by a medical school (or equivalent) from another EU country;

- have full civil rights;

- present a medical certificate confirming good health allowing the candidate to practise medicine;

- be of a impeccable ethical attitude (*nienaganna postawa etyczna*).

Upon fulfilling these conditions, a provisional licence is granted for a period of five years. During these five years, the holder of the provisional licence must complete a 13-month internship programme and pass the National Medical Exam (discussed further in the Education section). Upon meeting these last two conditions, a full, permanent licence to practise medicine is granted.

All doctors registered with the regional medical chambers in Poland receive a doctor's membership card (physical document) and are listed on the publicly available medical register that is kept by the NIL (updated on a monthly basis). Information provided by this register includes[120]:

- the doctor's name and surname (also maiden name if applicable);

- the number of the doctor's licence to practise medicine;

- the number of the doctor's membership card;

- the name of the regional medical chamber the doctor is affiliated with;

- the doctor's status (provisional or full licence);

---

[119] See: http://www.portalmed.pl/xml/prawo/medycyna/medycyna/r2001/011801u (last accessed October 2008).

[120] See: http://www.nil.org.pl/xml/nil/rejlek/hurtd (last accessed October 2008).

- the area and level of the doctor's specialisation[121] (if any);

- any restrictions imposed on a doctor's licence to practise medicine.

A person is removed from the list of members of the given regional chamber of doctors and dentists in the event of:

- death;

- losing the right to practise the profession:

  o by virtue of a decision of the medical court or a criminal court

  o because of her/his physical inability to practise;

- renouncing the licence to practise;

- moving to the jurisdiction of another chamber.[122]

In general, police and civil and criminal courts inform the NIL of any convictions that a medical doctor (or a medical graduate intending to register) has been given. The NIL also proactively seeks additional information from the National Criminal Register (*Krajowy rejestr karny*)[123], in case of any doubts about a doctor's ethical attitude.

10.3.2 Flow and quantity of applications

The decentralised system of medical registration and licensing in Poland means that candidates register with one of the 23 regional chambers, depending on the region where they intend to practise medicine. There are about 2400 applications for a provisional licence annually, and about the same number for a full licence. Currently, there are about 127,000 doctors on the medical register and slightly fewer than 80,000 doctors working in Polish medical institutions.

10.3.3 Recognition of medical degrees granted abroad

The recognition of non-EEA professional medical qualifications is regulated by separate legal instruments. The Ministry of Health lists all the qualifications that are recognised in Poland as comparable to Polish qualifications and professional credentials. A Centre of Recognition of Qualifications was established within the NIL in order to assist in and coordinate the activities of the regional chambers. The chambers and the Centre are actively cooperating with the competent authorities for doctors and dental practitioners in other countries.

In general, regional medical chambers issue licences to practise medicine to EU doctors on the condition that these doctors present a certificate issued by the relevant authorities of a given EU member state showing that he or she has been given permission to practise medicine in that country. Non-EEA qualified doctors need to legalise their medical diplomas at one of the Polish medical schools. Non-EEA qualified doctors also need to pass a specialised medical Polish language exam confirming that their command of written

---

[121] The old system of specialisation distinguished between level 1 and level 2.

[122] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/rights (last accessed October 2008).

[123] The equivalent of the British Criminal Record Bureau.

and spoken Polish is of the standard required to practise medicine. These international doctors also have to undertake postgraduate medical training (for one year), under the supervision of a Polish doctor (similar to the internship programme for newly qualified Polish medical school graduates). All doctors trained abroad also need to present a certificate of good standing, or as it is called in Polish, a "certificate on the impeccable ethical attitude" (*certyfikat o nienagannej postawie etycznej*). All non-Polish qualified doctors need to physically present themselves at the relevant regional medical chamber in order to receive their licence to practise medicine in Poland. In general, the number of foreign-trained doctors in Poland is very small, with about 1,000 doctors in total on the Polish Medical Register (less than 1% of the total doctors' population in Poland).

10.4 Revalidation / Recertification

Doctors registered with the medical chambers are obliged by law – Law on Doctor Professions (*Ustawa o zawodzie lekarza*) and Ministry of Health Decree from 2004 – to revalidate their licence (in the Polish context it is called the recertification process – *process recertyfikacji*).[124] However, as stated by interviewees, there are no direct sanctions if doctors do not observe this law. There are some control procedures and medical chambers may advise a doctor to retrain (e.g. in cases where a doctor has not practised medicine for a period longer than five years), but in practice, once a medical licence has been granted it cannot be revoked (except under those specific circumstances specified in the section on Registration and Licensing processes).

The certification/accreditation of organisations providing continuous professional training/postgraduate training in medicine is the responsibility of the NIL. The NIL (through its Committee for Medical Education – *Komisja Kształcenia Medycznego*) also keeps a register of all accredited training providers.[125]

Currently, several forms of continuous professional training/postgraduate training count towards recertification, such as postgraduate diplomas, training courses, PhDs, participation in conferences/symposia, publishing activities, etc. The general rule is that doctors need to collect 200 points every 48 months, with one point awarded for each hour of study.[126] Although, as previously stated, there are no direct sanctions imposed on doctors who do not participate in further training, the NIL is often consulted during the recruitment process relating to appointments of senior medical practitioners. On these occasions, lack of evidence of a doctor's recertification acts to his or her disadvantage and the NIL may advise hospitals/other medical providers not to appoint particular candidates who may otherwise meet other recruitment criteria.

---

[124] See: http://www.portalmed.pl/xml/prawo/medycyna/medycyna/r2001/011801u (last accessed October 2008).

[125] See: http://www.nil.org.pl/xml/nil/tematy/komisje/0609/ksztalc (last accessed October 2008).

[126] See: http://www.abc.com.pl/serwis/du/2004/2326.htm (last accessed October 2008).

Interviewees also pointed out that there are some initiatives currently taking place to strengthen the requirement for recertification and further developments in this area are in progress.

10.5 Standards & ethics

10.5.1 Content

The content of medical standards and ethics in Poland is determined by Polish national law – the Law on the Profession of Doctors (*Ustawa o zawodzie lekarza*) and the Medical Code of Ethics[127]. In general, members of the medical chambers are obliged to observe:

- the ethical principles and other regulations on practising as a doctor, and;

- resolutions of the authorities and bodies of self-government of doctors and dentists.[128]

In more detail, the main sections of the Medical Code of Ethics in Poland focus on the following aspects[129]:

- Duties of a doctor

  o The doctor's duties are: the protection of human life and health; the prevention of diseases; the treatment of patients, and; the relief of suffering. The doctor shall not use his/her medical knowledge and skills for any purpose that is in contradiction with that vocation.

  o The greatest ethical imperative for the doctor is the welfare of the patient.

- Quality of medical care

  o The doctor should perform all diagnostic, therapeutic and preventive procedures with due exactitude and devoting the necessary time.

- Respect for patients' rights

  o The doctor should approach patients with consideration, respecting their personal dignity, right to intimacy and privacy.

- Medical confidentiality

  o The doctor has the duty to maintain confidentiality. Information obtained in the course of a doctor's professional duties concerning the patient and his/her background is to be kept confidential. The death of the patient does not release the doctor from the duty of maintaining confidentiality.

- Professional conduct

---

[127] See: http://www.nil.org.pl/xml/nil/wladze/str_zl/zjazd7/kel (last accessed October 2008).

[128] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/rights (last accessed October 2008).

[129] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_code (last accessed October 2008).

      o   It is the duty of every doctor to continually update and develop professional knowledge and skills as well as to share them with co-workers.

- Relationship with the medical industry

      o   The doctor should not accept benefits from representatives of the medical industry, if it could influence the objectivity of his/her professional judgment or undermine trust in the medical profession.

10.5.2 Process and actors involved

The General Medical Assembly, the highest authority within the NIL, has the power to make amendments to the Medical Code of Ethics. The first version of the document was passed at the second General Medical Assembly in 1991. It was significantly amended at the third General Medical Assembly in 1993 and at the seventh General Medical Assembly in 2003 in order to update the code in line with current developments, for example new provisions on the relations between the doctor and the medical industry were introduced. All activities relating to the Medical Code of Ethics are overseen by the Medical Ethics Committee, which is one of the constituting bodies of the Supreme Medical Council.[130]

Amendments to the Medical Code of Ethics are communicated to doctors through the *Medical Journal* (every doctor receives a copy), and to the wider audience through the media (announcements in the press, radio and TV, also some brochures). Formally, patients are not involved in the process of updating and amending of the Medical Code of Ethics.

10.6   Fitness to practise (FTP) and related disciplinary procedures and sanctions

10.6.1 Content/substantive characteristics

The concept of FTP in the Polish medical regulatory context is called professional liability (*odpowiedzialno ć zawodowa*) and is an additional responsibility procedure, not being a part of the common law.[131] Professional liability proceedings (professional disciplinary proceedings) are based on the law on Medical Chambers from 17 May 1989, and Enactment of the Minister of Health and Social care pertaining to the medical professional liability proceedings from 26 September 1990.

The scope of medical professional liability is clearly defined and encompasses all doctors listed in the registers maintained by the regional medical chambers. Persons being in possession of a medical diploma but without a licence to practise are not subject to the above proceedings. Initiation of proceedings is decided by the factual status on the day of receiving the complaint.

---

[130] See: http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_code (last accessed October 2008).

[131] This section (10.2) is based on the information from the following websites:
http://www.nil.org.pl/xml/nil/wladze/str_sad/odpzawod and
http://www.nil.org.pl/xml/nil/wladze/str_sad/odpzawoden (last accessed October 2008).

The objective scope of professional liability is defined rather generally, and the prohibited conduct is not specifically defined. The Medical Chamber law states that doctors are liable to professional disciplinary proceedings for "conduct not befitting and being in breach of the code of ethics and regulations pertaining to the doctor's profession". The ethical principles are established in the Medical Code of Ethics (*Kodeks Etyki Lekarskiej*). The regulations pertaining to the exercise of the doctor's profession are contained in the Doctors' Profession Law of 5 December 1996, listed in the Journal of Laws of 1997, No. 28 pt. 152 as well as numerous other normative acts. The objective scope is therefore quite extensive, all the more so that both the Medical Code of Ethics as well as the law on the doctor's profession do not so much define what is prohibited as what is indicated as proper conduct.

10.6.2 Flow/quantity of FTP procedures

Table 10-1 below summarises the FTP procedures from 2000 to 2007 in Poland. The table relates to *first instance medical courts*, a term explained in detail in the next section. The NIL website states that due to changing definitions of individual items, the comparison is only an approximation and should be used as a reference only. The data for the last two to three years is more accurate than figures for previous years.[132]

Table 10-1: Selected data for first instance medical courts 2000–2007, Poland

	2000	2001	2002	2003	2004	2005[133]	2006	2007
Cases brought to the court	251	243	318	341	368	368	464	461
Number of doctors involved in cases brought to court	292	268	381	419	437	437	448	428
Cases remaining from the previous year	112	100	86	130	126	126	197	196
Court sessions	154	167	239	270	242	242	431	553
Cases heard	257	236	322	365	327	327	421	354
Closed sittings	181	158	205	249	235	235	299	298
Decisions terminating proceedings in the first instance	187	143	259	305	268	268	384	289
Number of doctors involved in court decisions	230	172	274	324	306	306	419	336

---

[132] See: http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat_porownan_00_04_en ,
http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2005_1inst,
http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2006_1inst, and
http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2007_1inst (last accessed October 2008).

[133] Data for 2005 is exactly the same as data for 2004.

	2000	2001	2002	2003	2004	2005	2006	2007
Total number of penalties	151	118	214	211	208	208	285	224
Cases dismissed (*umorzone postepowanie*)	47	34	14	32	25	25	25	22
Acquittals (*uniewinnienie*)	65	63	61	109	97	97	99	105
Admonitions (*upomnienie*)	104	89	149	155	152	152	193	154
Reprimands (*nagana*)	37	25	54	46	45	45	75	57
Suspensions (from 6 months to 3 years) (*zawieszenie prawa wykonywania zawodu*)	10	4	10	8	11	11	16	13
Bans from practising the profession (indefinitely, without the right to register with NIL in the future) (*pozbawienie prawa wykonywania zawodu*)	0	0	1	2	0	0	1	0
Appeals to Supreme Medical Court								
By defendant	43	44	55	54	58	58	49	50
By Screener for Professional Liability	7	6	6	3	5	5	8	4
By plaintiff	27	29	20	30	30	30	38	35
Number of doctors in cases concerning incidents during:								
Employment in public healthcare institutions	231	185	230	214	236	236	n/a	n/a
Employment in private healthcare institutions	26	45	45	49	81	81	n/a	n/a
Private practice	37	43	53	52	47	47	n/a	n/a
Emergency service	30	39	42	46	43	43	n/a	n/a
Relations among doctors	15	12	8	15	18	18	n/a	n/a
Time in months (average) from:								
Incident to filing complaint	6	4	5	4	5	5	3	7
Filing complaint to bringing case to court	7	7	10	10	11	11	n/a	n/a
Bringing case to court to decision terminating proceedings in first instance	7	5	6	5	5	5	5	7

10.6.3 **FTP procedures**

There are two professional disciplinary proceedings bodies: the Screener for Professional Liability (SPL) and medical courts. The SPL considers the filed complaints against a doctor and conducts explanatory proceedings (fulfilling a role similar to that of a prosecutor in criminal proceedings); the courts adjudicate on the motion for the imposition of a penalty submitted by the SPL. The first instance proceedings are usually conducted by the Regional Screener and the Regional Medical Court (RMC) of the chamber of which the defendant had been a member on the day of the complaint. The Supreme Screener for Professional Liability and the Supreme Medical Court (SMC) hear all appeals from verdicts and decisions passed in the first instance proceedings. The members of the professional liability bodies are elected by the regional and national medical conventions for a four-year term and carry out their function as a form of voluntary social service.

Similarly to other liability proceedings, the medical liability proceedings are adversarial, in other words based on the participation of at least two equal opposing parties. The SPL represents the injured party as well the interests of the professional corporation and fulfils the role of a prosecutor. The injured person is not a party in the proceedings and, in contrast to criminal proceedings, there is no position of a subsidiary prosecutor. The party opposing the SPL is the defendant who may have up to three defence counsellors chosen from among the members of the medical chamber or defence lawyers. The bodies in charge of professional disciplinary proceedings are obliged to maintain the proper course of the proceedings (adhering to procedural principles) as well as to inform the participants of the proceedings of their rights (such as submitting evidentiary motions, access to the records of the proceedings in case, refusal to testify, the right to lodge a complaint and an appeal).

10.6.4 **Involvement and role of external actors**

The SPL initiates explanatory proceedings after *obtaining credible information pertaining to the offence in performing medical duties*. Most frequently it is an action of the injured person but the SPL is obliged to start the proceedings based on any other information, which he/she will find to be credible. If the initial evaluation of the complaint or information shall unequivocally indicate that it is not credible, the SPL may refuse to start the proceedings. Cases in which explanatory proceedings have been started can be either discontinued or brought to the court with motion for a penalty. The motion for a penalty (being the equivalent of an indictment act) is then heard by a court of the first instance during a court session, which is open only to members of the medical self-governing body. The SMC hears all appeals to first instance verdicts and decisions. The jury in the first instance is composed of three doctors, members of the RMC. The RMC sets the date for the proceedings and informs all persons whose presence at the proceedings is necessary. The SPL and the defendant constitute the Parties, the injured person (usually a patient or his family member) as a rule is a witness in the case. The verdict of the medical court may be:

- The case is sent back to the SPL with the objective of correcting the motion for penalty and/or supplementing the explanatory proceedings;

- The procedure is discontinued;

- An acquittal is granted;

- The court finds the defendant guilty and passes one of the following sentences:
  - an admonition
  - a reprimand
  - suspension of the licence to practise for a period of six months to three years
  - irrevocable withdrawal of the right to practise without the possibility of application for a repeated registration as a practising doctor.

The SPL and the defendant have the right to file an appeal against the verdict of the first instance court to the SMC. The jury in the SMC is composed of five members – doctors appointed from the SMC members. The SMC hears all cases within the limits of the appeal. The result of the SMC's hearing may be upholding the verdict/decision passed by the first instance court or reversing it and sending the case back to the first instance court for a re-examination. Only in exceptional cases will the SMC change the verdict of the RMC, supplement the evidence or consider the case beyond the limits of the appeal. Doctors sentenced by the SMC to have their licence to practise suspended or withdrawn may appeal the verdict in the Appeal Court (common court). The other verdicts are final.

These rules had been in place since 1989. In 2002 the Law on Supreme Court changed the regulations concerning the participation of Supreme Court judges in SMC hearings and since 2003 the SMC has been composed of doctors only (till 2002 the chairman of the five person-jury was a Supreme Court judge). Several amendments to regulations governing medical professional disciplinary proceedings have been suggested since 1994 by the NIL. The main outcome of these amendments would be making hearings more open and increasing the choice of penalties which – at present – are either relatively light or very severe. The suggestions have been submitted to legislators and are being discussed.

10.6.5 Position/attitude of doctors

Doctors undergoing professional disciplinary proceedings hold their licence and right to practise medicine until the final verdict of the medical court. The medical chamber holds a register of doctors found guilty in professional disciplinary proceedings (NIL resolution no. 23/141/01/III from 27th March 1992).[134] Information about the right to practise medicine and the revocation of licences, and any limitations on a doctor's licence is also available in the medical register, publicly available on NIL website.

10.7   Medical education

10.7.1 Education trajectory

There are 11 public medical schools in Poland that offer around 2,400 places for medical students per year.[135] The undergraduate education lasts six years and is followed by a one-year compulsory internship. Each medical school can individually organise medical

---

[134] See: http://www.nil.org.pl/xml/nil/rejlek/informacje (last accessed October 2008).

[135] There were around 4,000 places in medical schools before 1989.

training for its students but has to follow National Standards for Medical Education (*Standardy kształcenia dla kierunku studiów: Kierunek Lekarski*) issued by the Ministry of Science and Higher Education.[136] National Standards divide subjects taught at medical universities into two main groups: general medical knowledge (such as anatomy, genetics, pharmacology, microbiology, public health, etc.) and specialised medical education (such as internal medicine, paediatrics, surgery, psychiatry, radiology, oncology, gynaecology and obstetrics, etc.), and describe the minimum number of hours each subject needs to be taught at the university level. There are some subjects in the general medical knowledge group that can be broadly defined as having a more practical approach. These subjects include: medical psychology, medical sociology and medical ethics. In general, however, medical students often complain that there is no adequate number of hours dedicated to practise "soft" skills, such as communication skills.

An integral (compulsory) part of medical education is practical training in a medical setting. More details on this are presented in table 10-2.[137]

Table 10-2: Practical training in a medical setting, Poland

Type of practical training	Number of weeks	Number of hours
Nursing	4	140
General practice	4	140
Internal medicine	4	140
A&E	2	70
General surgery	2	70
Paediatrics	2	70
Obstetrics & gynaecology	2	70

Upon completion of the study programme and practical training, junior doctors can register with the regional chamber of doctors, and they receive a provisional licence to practise medicine.

The next step in medical education in Poland is the compulsory 13-month internship. Internships can start twice a year (11 October or 1 March) and are carried out on the basis of the employment status equal to a doctor. In order to receive a permanent licence to practise medicine in Poland, a doctor trainee has to obtain the approval of an internship coordinator and has to pass the state examination – the National Medical Exam (*Lekarski Egzamin Państwowy*). Passing this exam ends the first stage in medical education in Poland.

At this stage, doctors can start their specialist training. The old form of two-level specialisation lasted five to ten years. The single-level specialisation that was introduced in 2001 follows the European standard for doctors' training. The number of places in certain

---

[136] See: http://www.rgsw.edu.pl/files/active/0/lekarski20070210.pdf (last accessed October 2008).

[137] See: http://www.rgsw.edu.pl/files/active/0/lekarski20070210.pdf (last accessed October 2008).

specialisation areas is reviewed and approved by the Ministry of Health allocating specific number of specialisation contracts. Postgraduate education and training is administered by the Medical Centre for Postgraduate Education and the Centre for Medical Examinations (the body responsible for the organisation of the state examinations). After passing the state exam, a doctor acquires the diploma of specialist in a given discipline. Doctors who have completed a specialisation in one of the basic disciplines may apply for admission to a specialisation course in any other discipline. Doctors are also required to advance their knowledge through self-education and participation in further training.[138]

10.7.2 Examination and Qualification

There is strong competition to get a place at a medical university on the medical programme. Normally, medical schools are required to accept candidates with the best exam results; however, it is common practice for medical schools to organise an additional test to further check the skills of the candidates. There are no statistics on the pass/fail rate at the first stage of medical education. However, some statistical data exists on the results from the National Medical Exam published by the Centre for Medical Examinations (*Centrum Egzaminów Medycznych*).[139] In general, the pass rate is set at the 56 percent level, and the average number of points in the autumn 2008 session was 144 (out of 200 possible points). The National Medical Exam is a written test that consists of 200 multiple choice questions with only one correct answer in each question. It contains a mixture of medical knowledge testing questions, some practical questions about specific medical processes and analysis of medical records, and some more descriptive questions (e.g. establishing a medical diagnosis, etc). The content of the state examination does not exceed the scope of the internship programme, and thus renders it possible to evaluate the quality of the training programme carried out by the assigned hospitals.[140]

Because it is a written test, oral skills are not tested. The language of medical tuition as well as medical internship in Poland is Polish, therefore all tests are also in Polish. It is possible to study medicine in English at Polish medical universities, but students are required to have completed at least two years of the medical programme before enrolling on the English taught course.

10.7.3 Funding

Medical education is funded from public money in Poland, and medical students do not have to pay any fees for their study. Medical education in English, however, is offered on fee-based programmes, and the fees range from US $8,000 to US $12,000 per year of study. These programmes are, therefore, mainly aimed at foreign nationals. In addition,

---

[138] Ministerstwo Zdrowia (Ministry of Health), 2007. "Monitorowanie migracji polskich lekarzy, pielęgniarek i położnych po przystąpieniu polski do Unii Europejskiej" (Monitoring of the migration of Polish doctors, nurses and midwifes after the EU accession). www.mz.gov.pl See also http://www.mz.gov.pl/wwwmzold/index?mr=m0&ms=&ml=en&mi=535&mx=0&mt=&my=464&ma=5168, last accessed October 2008).

[139] It is also possible to download the last version of the National Medical Exam test and the list of correct answers (translated into English) from the following website: http://www.cem.edu.pl/ (last accessed October 2008).

[140] See: http://www.cem.edu.pl/ (last accessed October 2008).

Polish nationals cannot apply for medical courses taught in English at some medical schools.

10.7.4 Quality assurance

Quality assurance of Polish medical universities is the responsibility of the Commission for Accreditation of Medical Universities (*Komisja Akredytacyjna Akademickich Uczelni Medycznych*, KAUM), appointed through the resolution of the Conference of Rectors of Polish Medical Universities in 1997. KAUM is a body representing the academic community of Polish Medical Universities, independent of state authorities, with decision-making and advisory capacities whose activities are regulated by their statutes.[141]

The fundamental aims of KAUM are as follows:

- To define conditions necessary to establish and conduct undergraduate studies in medical universities.

- To define the educational standards relating to undergraduate studies in medical sciences: medicine, dentistry, pharmacy, laboratory medicine, public health.

- To provide a continuous assessment of the educational standards in the above disciplines.

KAUM focuses its activities on undergraduate education taking into account its curriculum, organisation, staff qualifications, teaching facilities, and internal quality control.

KAUM consists of the following members: academic teachers (at least one from each university) and one student nominated by the Commission for Medical Education of the Students' Parliament in Poland. In addition, the following members participate in activities of KAUM as observers without a right to vote: one representative of the Ministry of Health appointed by the minister and one representative of the Centre for Postgraduate Medical Education.

The accreditation procedure starts with the Self-Evaluation Questionnaire, distributed to all medical universities. Accreditation by KAUM is voluntary. The formal procedure of accreditation starts when the university returns the completed Self-Evaluation Questionnaire. Upon return of a completed questionnaire, a site visit is organised to the medical university. On the basis of the Self-Evaluation Questionnaire as well as observations of the visiting team, the Final Report is prepared including recommendations for improvement. After discussion on the plenary meeting of KAUM the report is sent to the rector of the university seeking accreditation, for acceptance. Accreditation decisions are taken by a majority vote with a minimum of two-thirds of KAUM members present. KAUM decides whether to award the accreditation for five years or three years or deny accreditation. In the middle of the period for which accreditation was granted KAUM is obliged to perform a follow-up evaluation of the school and to check to what extent recommendations given in the Final Report have been implemented. If information provided by correspondence on the occasion of follow-up is not satisfactory, KAUM

---

[141] See: http://www.medaccred.edu.pl/statut.php?w=a (last accessed October 2008).

organises a control survey visit.[142] Results of the accreditation process are published on KAUM's website and are publicly available.

---

[142] See: http://www.medaccred.edu.pl/proces.php?w=a (last accessed October 2008).

Medical regulation in South Africa

11.1 Overview

The Health Professionals Council of South Africa (HPCSA) is the key medical regulation body in the country, which contains 12 Professional Boards responsible for developing specific standards and policies for particular medical fields.

11.2 Structure and nature of medical regulation

The Health Professionals Council of South Africa (HPCSA) is the key medical regulation body in the country, with the mandate to "protect the public, all consumers of health care services, and to provide guidance on educational, professional and ethical issues to practitioners". [143]

The vision of the HPCSA is to ensure "quality healthcare standards for all, by enhancing the quality and developing strategic policy frameworks for the effective co-ordination and guidance of twelve professional boards in: i) setting healthcare standards for training and discipline in the professions registered with Council; ii) ensuring ongoing professional competence; and iii) fostering compliance with those standards". "All individuals who practise any of the health care professions incorporated in the scope of the HPCSA are obliged by the Health Professions Act, 1974 to register with the Council. Failure to do so constitutes a criminal offence."

---

[143] The majority of information on the South African medical regulatory system was obtained through a combination of desk research and interviews with senior members of the key regulatory body, the Health Professionals Council of South Africa (HPCSA), and academics with knowledge and experience of the medical regulation environment. Desk research included analysing information on the website of the HPCSA, and archival documents. The latter were requested and obtained through contact with the HPCSA Chief Executive Officer and Registrar, and were particularly useful for accessing quantitative evidence and information on the structure, organisation and scope of activities of medical regulatory bodies. Other information from grey-literature was also investigated and was particularly informative in understanding aspects of medical education in South Africa and the history of the medical regulation system. More in-depth qualitative insights were obtained through interviews with three key informants, all of them national experts in various aspects of the medical regulatory system, and two of which had positions with both the HPCSA and medical schools in the country.

The HPCSA was established in 1974. Its origins date to 1928, when the South African Medical and Dental Council (SAMDC) was given the mandate to govern the practice of medicine and allied professions. During 1928, two statutory councils were established: the South African Medical Council (SMAC) and the South African Pharmacists' Commission (SAPC) to oversee the registration and conduct of practitioners and protect the public. In 1971, various professional and occupational councils were also established and registered with the SAMDC. In 1974, the SAMDC was renamed the HPCSA.

The HPCSA is guided by a regulatory framework, including their founding act (Health Professions Act No 56 of 1974) which outlines the HPCSA's activities, scope and operational procedures. In South Africa the following observation was made to us: "Nowadays much better medical regulation exists than in the past. There are many new good policies and regulations that did not exist before (e.g. CPD)". One interviewee noted: "Politics in the council is bad, but the functioning of the council is good". Also, strong concerns were voiced about the representation of people of different race, ethnicity, gender on councils, although it is difficult to get representation from people with severe disabilities.

There are three sections of the HPCSA:

- The Council which plays a coordinating function for the formulation of policy and regulation of professions registered with the HPCSA. It determines the "strategic policy of the Professional Boards with respect to finance, education, registration, ethics and professional conduct, disciplinary procedures, scope of the professions, inter-professional matters and maintenance of professional competence"; and acts as an arbitrator and mediator in disputes between professional boards, and between professional boards and the public.

- 12 Professional Boards responsible for developing specific standards and policies for a profession. "All matters affecting education and training, as well as the professional conduct and practice of the relevant professions, remain the responsibility of the Professional Boards." These Boards are: Dental Therapy and Oral Hygiene; Dietetics; Emergency care; Environmental Health; Medical and Dental; Medical Technology; Occupational Therapy/Medical Orthotics/Prosthetics and Arts Therapy; Physiotherapy, Podiatry and Biokinetics; Psychology; Radiography and Clinical Technology; Optometry and Dispensing Opticians; Speech, Language and Hearing Professions.

- An administration office responsible for administrative support and the execution of council policies by the professions. There are eight administrative departments. One of these is concerned with the interests of the various Professional Boards, while the remaining departments are responsible for the day-to-day operations. These departments include Financial Services and Information Technology, Legal Services, Registration, CPD and Records, Support Services, Human Resources and Public Relations, and Service Delivery.

In addition to the formal, internal structure of the regulator, other stakeholders are involved in matters of regulation and standards. According to our interviewees, the representation and involvement of social groups is integral to medical regulation.

Consultation occurs with patient groups, and there is representation of laymen as members of the Council Committees (members of the public, non-professions, lawyers etc, activists, people of different ethnicities/gender/age, etc). These people bring a different and very important perspective on regulatory issues, and are highly valued by the HPCSA. Each of the 12 Professional Boards also has a member of the public appointed by Minister of Health to sit on the Boards and give a lay perspective. This stakeholder inclusive approach to setting standards has been helpful in identifying important regulatory issues concerning the quality of patient care, equality/equity, race).

Finally, there are other regulatory bodies such as the Pharmacy Council, SA Nursing Council, Allied Health Professions Council, and Higher Education Regulatory Councils that the HPCSA interacts with. For example, the HPCSA has a representative on the Nursing Council. With the Pharmacy Council, there have been negotiations regarding the changes in regulation which now require doctors to get special permission to dispense medicines. There are also challenges with the Education Council, in terms of which body is responsible for setting training standards and accreditations; there is some overlap of functions between the HPCSA and the Education bodies. According to our interviewees, this issue is currently being addressed.

11.2.1 Stated purpose

The core purpose of medical regulation in South Africa is to ensure that practitioners on the register are competent and safe to practise, i.e. making sure that only those who are fit to practise are practising. As one interviewee put it: "We do not want ambulance drivers practising medicine". This relates to the underlying goal of *protecting the public by guiding the professions*. As such, there is a strong focus on the quality of professional education and professional services.

11.2.2 Drivers and influential events

The most important events influencing how medical regulation has evolved include (a) the political change in the post-apartheid era and its influence on making sure that the regulatory bodies ensure the same standards for all (because previously, disadvantaged communities did not have the protection that was needed during apartheid); and (b) the independence of the HPCSA from government (i.e., to make sure the regulatory body is independent from the political establishment and that members are democratically elected by practitioners). With respect to the latter, one interviewee expressed his concerns that this will change, because the Council will now be appointed by the Department of Health, and not elected democratically by professionals. However, another interviewee was confident the HPCSA will remain independent.

During apartheid there was a lot of complicity with the State in violating ethical standards. In terms of dealing with practitioners who violated ethical standards, regulation was subjective (depending on who was appearing in front of the council).

Other drivers included (c) the stark inequities in access to health care between the rich and poor, which played a role in making equitable access to quality healthcare for all a key agenda for regulators (ensuring equitable access is still a process and an aspiration, rather than something that has been achieved), and (d) the HIV epidemic forced regulatory bodies had to make sure that - despite unclear political stances on the epidemic – doctors

knew that their roles and responsibilities lay in providing quality care to AIDS patients, with respect for their dignity and rights for privacy.

11.2.3 Values within medical regulation

Key values in the South African medical regulatory system are ethics, equality, accountability, the desire to safeguard and protect the public, and the desire to guide the practitioners. In addition, South African medical regulation is very much concerned with issues of race, ethnicity, religion, disability, gender and patient involvement in regulation. These issues underpin everything the HPCSA does (e.g. the human rights and ethical practice guidelines address all these areas).

Some of our interviewees, however, suggested that regulatory bodies such as the HPCSA are primarily perceived as a policing system, in the eyes of the professions. This is because the HPCSA is there to ensure adherence to standards.

The following are Professional Boards under the HPCSA's jurisdiction:

- Professional Board for Dietetics
- Professional Board for Dental Therapy & Oral Hygiene
- Professional Board for Emergency Care Practitioners
- Professional Board for Environmental Health Practitioners
- Professional Board for Medical Technology
- Medical & Dental Professions Board
- Professional Board for Occupational Therapy, Medical Orthotics & Prosthetics
- Professional Board for Optometry & Dispensing Opticians
- Professional Board for Physiotherapy, Podiatry & Biokinetics
- Professional Board for Psychology
- Professional Board for Radiography & Clinical Technology
- Professional Board for Speech, Language & Hearing Professions

11.3 Registration process and requirements

There are currently a total of 344,482 medical doctors and 3,732 interns on the South African register. Since 2006, approximately 34,000 doctors registered each year. For the last few years there have been no applications requiring above average investigation or scrutiny, and no rejected applications.

In addition to doctors trained in South Africa, there are a number of doctors registered who have trained abroad. The percentage of medical practitioners trained in other countries registered since 2006 is as follow:

- 2006: 15.58%
- 2007: 16.02%

- 2008: 16.30%

Registration is a mandatory requirement for medical professionals in South Africa, a pre-requisite for being able to engage in professional practice. Registration guidelines vary between the 12 different professional boards, but the same principles apply:

> " In order to safeguard the public and indirectly the professions, registration in terms of the Act is a prerequisite for practising any of the health professions with which Council is concerned. Registration confers professional status upon a practitioner and therefore the right to practise his or her chosen profession. Practitioners thus enjoy the security of being registered in terms of an Act in the knowledge that no unqualified person may practise their profession. The register is furthermore to the advantage of health care practitioners whose names appear in it, since this confers public recognition on the competent practitioner who will thus be able to command a reward for his or her services." [144]

All individuals who practise any of the health care professions incorporated in the scope of the HPCSA are obliged by the Health Professions Act, 1974 to register with the Council. Failure to do so constitutes a criminal offence. As a legal requirement, all personal details have to be kept updated, once in practice. This is the onus of the practitioner.

Registration involves an annual fee. Voluntary erasure from the register is possible if the practitioner does not intend to practise his/her profession in South Africa for a given period of time. Doctors can then apply to re-register if they return to practise

There are six main registration categories (not all of which apply to all professions). These are: student, intern, public service (including people undertaking community service), supervised practice, education (i.e. for lecturers) and independent practice (including Registrar's who are training in a specific speciality) registration.

When an individual completes one category that is a pre-requisite for movement to the next (e.g. from student to intern, from intern to public service), they need to re-register for the new category. A person needs to be registered in a previous required category for a relevant time period.

Registration does not have to be done in person, with the following documents:

- Certified copy of ID document and passport with a clear photo;
- Certified copy of qualifications by a notary public;
- Registration forms (downloaded online but returned by post).

There are additional registration requirements for practitioners who have qualified in institutions outside of South Africa that serve to validate their employability and their credentials:

> " Foreign nationals with qualifications that enable them to practise medicine or dentistry in their country of origin may obtain registration with the Health Professions

---

[144] From http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

Council of South Africa, (provided the stipulations mentioned in this document are complied with), in the category Public Service. Applicants meeting the minimum requirements of the Board may be exempted from the examination of the Board. The National Department of Health does not encourage the recruitment of doctors from developing countries. Registration with the HPCSA does not imply that employment is guaranteed. The onus for finding employment rests with the individual. Registration is conditional on the applicant submitting the required information, meeting the Board's criteria for registration and passing the Board Examination for foreign qualified practitioners, as specified in the attached memorandum".[145]

According to HPCSA regulations, the following procedure should be followed by practitioners that have qualified outside South Africa:

- Apply to the Board for registration by submitting all relevant documentation and a letter confirming employability issued by the National Department of Health. Medical graduates trained abroad have to have their credentials verified by the Educational Commission for Foreign Medical Graduates (ECFMG) international credentials service;

- If required sit the Board examination and pay the examination fee. Results are made available after two weeks;

- If the examination is passed and on receipt of confirmation from the Board, obtain a formal offer of employment from the Department of Health and register with the HPCSA in the category Public Service (General Practitioner)/Intern.

The fees received from registered healthcare professionals cover the costs of the Council and the Professional Boards for administrating the professions registered with the HPCSA and maintaining the standards of education, training and professional practice required.

Practitioners can be removed from the register if they are found to be unfit to practise (for more information see section 11.4).

11.4   Revalidation / Performance assessment

In South Africa there is no regulation for the revalidation of practising doctors but there are requirements for medical practitioners to accrue Continuing Education Units (CEUs) (CPD activities, for more information see sections 11.6 and 11.7.3). Although there are criteria for re-registration following a leave of absence or a verdict of misconduct, there is no regulation for the revalidation of competencies of those who remain in professional practice over time.

Our interviewees stated that the HPCSA is just beginning the discussion on revalidation, but "*at the moment it is still a very quiet discussion*". However, the Department of Health and the Educational Training and Quality Assurance Committee of the HPCSA have

---

[145] From http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

made clear that developing revalidation regulations is an important aspect of the development strategy for the HPCSA.

The system that the HPCSA is considering would see the gradual introduction of performance assessments. The first phase will focus on high-risk individuals (e.g. older practitioners over the age of 70; those doctors that consistently receive a high number of complaints). The second phase will extend performance assessment to all doctors.

11.5 Standards & ethics

The ethical standards set by the HPCSA for the medical profession are on the HPCSA website - through which the public may access them.[146] They are also circulated to training institutions and other relevant organisations. "The Patients' Rights Charter" and "Batho Pele Principles" are posted in most public hospitals, although it is unclear whether they are also made available in private hospitals. Nevertheless, it was clear from our research that some members of the HPCSA think there could be improvements in the way healthcare practitioners inform patients of their rights.

There are various booklets produced by the HPCSA which explain the standards and criteria for professional conduct and ethical practice. They include:

- Booklet 2: Generic Ethical rules

- Booklet 3: National Patients' Rights Charter

- Booklet 6: Guidelines on over-servicing, perverse incentive and related matters

- Booklet 8: General Ethical guidelines for biotechnology research

- Booklet 9: Research, development and use of chemical and biological weapons

- Booklet 10: Seeking Patients' informed consent: the ethical considerations

- Booklet 11: Confidentiality: protecting and providing information

- Booklet 12: Ethical guidelines for good practice with regard to HIV

- Booklet 13: Guidelines for the withholding and withdrawing of treatment

- Booklet 14: General Ethical guidelines for reproductive health

- Booklet 15: Guidelines on the keeping of patient records

The Hippocratic Oath is the oath to the medical profession that all practitioners swear to.[147] There are also booklets describing undesirable business practice. For example, there is a requirement for doctors/health practitioners to inform patients about fees, especially if they are above the medical aid (health insurance) rates.

---

[146] See http://www.hpcsa.co.za/hpcsa/default.aspx?id=152 (last accessed April 2009).

[147] See: http://www.hpcsa.co.za/hpcsa/default.aspx?id=275 (last accessed April 2009).

Doctors very often approach the HPCSA for advice on issues regarding ethical and professional conduct (e.g. to ask for advice when there are concerns about a colleague; how to deal with an undesirable business practice etc). Queries are often referred to relevant committees of the Council (e.g. Committee on Undesirable Business Practice). The HPCSA is very much seen as an advice service.

In addition to the guidelines and codes of ethics and standards of the HPCSA, human rights and medical law courses are now compulsory in medical education/health professions education. The HPCSA Human Rights and Ethics Committee devised the curriculum for this. The course will be part of the accreditation review of medical schools.

Standards for professional conduct and ethical practice have been going through a process of review and improvement over the past 5 years. This was driven by the need to better align medical regulation with the needs of society. The process of devising the new regulations for ethical practice and concern for human rights has been an iterative and stakeholder inclusive process.

11.6 Fitness to practise (FTP) and related disciplinary procedures and sanctions

The HPCSA is responsible for ensuring that practitioners are fit to practise (i.e. not guilty of any misconduct in the exercise of their profession), that is that they are not impaired due to any physical or mental ill health. The HPCSA is committed to offering effective management for impaired practitioners. There is also a national strategy for managing impairment in students and practitioners registered with the council.

Practitioners can be removed from the register if they are found not to be fit to practise medicine. Most complaints come from members of the public, primarily patients. There are three ways a doctor can be taken to justice: if the doctor has done something criminal, if professional conduct has been violated, and if a patient wants compensation for some mistake.[148] In these cases, there is an assessment, investigation and decision process by the Health Committee of the HPCSA.

The HPCSA have now classified complaints (minor to serious) to improve management of decisions, e.g. immediate consultation and warning, or a lengthier and more formal investigation. Complaints go to the Council first and then to the relevant Professional Boards. Initial complaints are processed by HPCSA's legal department. They are then sent to the Preliminary Committee of Inquiry of the appropriate Professional Board (there are 12 Professional Boards of the HPCSA) which includes both members of the profession and lay members of the Board. The Committee will assess and deliberate on a way forward. Once a determination has been made to proceed with a hearing, a committee of professional and lay members of the Board not previously involved in the process will conduct a disciplinary hearing with a judge (legally trained) as advisor to the committee, with the complainant and the defendant present. Amendments to the Health Professions Act require a lay person to chair this committee.

---

[148] The medical regulation system interacts with the civil law system. If a practitioner is in violation of civil law, this will influence his right to practise.

In line with a decision taken by the council the names of practitioners who have been found guilty of misconduct are published in the HPCSA publication (Bulletin). However, the names of those who are being investigated are currently not made public. Whether the doctor is allowed to practise during a fitness to practise (FTP) case against him/her is determined on a case-by-case basis.

Equally, there are processes to restore practitioners to the register. If a practitioner has been removed from the register for more than a year but less than two years, and has been attending CPD activities then he/she can be restored to the register. If the practitioner has not been collecting CPD points then he must submit a special application for restoration which the HPCSA CPD Committee considers. The candidate may need to fulfil one or more of the following requirements: pass a professional board examination, work under supervised practice, collect at least one year worth of CPD points. If a practitioner has been erased from the register for more than 3 years and wants to re-register, he/she then needs to submit a new application to the CPD Committee which is passed on to the Professional Board for resolution.

Table 11-1 provides information on the numbers of FTP cases the HPCSA processed in 2006/7 and 2007/8.

Table 11-1: FTP cases

	2006/07	2007/08	TOTAL
Complaints received	2 342	2 628	4 970
Complaints Dismissed	873	592	1 465
Complaints Followed Up	1 469	2 036	3 505
Complaints Leading to Panel Hearings (Committees of Preliminary Inquiry)	1 078	1 274	2 352
Complaints Leading to Disciplinary Action (Professional Conduct Inquiry)	261	210	471
Doctors Struck Off the Register	10	09	19

The average duration of an inquiry varies depending on the merits and circumstances of each case. The HPCSA target for finalising a matter from the date of receipt is eighteen months (Preliminary and Conduct Inquiry processes included), although inquiries can be as short as 12 months or longer than 18. It is sometimes necessary for the HPCSA to wait for a criminal matter to be finalised (where a criminal matter runs concurrently with the HPCSA case) before proceeding with the case against a registered practitioner. This would inevitably lead to a delay in the finalisation of the inquiry.

11.7 Medical education

The medical curriculum has largely been inherited from the British system (in the early 20th century).[149] There are eight medical schools in the country. Medical students are registered as "students" with the HPCSA. There are also accredited training posts for interns and specialists.

South African Medical education has been strongly influenced by the transition to a post-apartheid era. During apartheid, medical schools were divided into those for white students, and those for black students. When all medical schools opened up to black students, they found themselves in severe competition for the best black students.

Some of the key changes affecting medical education in South Africa include:

- the transition to democracy in 1994 and "the transformation from a white staff and student profile;

- the redistribution of state funding away from tertiary academic facilities towards primary health, leading to diminished teaching and research capacity and academic-private medicine partnerships; and

- a paradigm shift towards integrated, student centred, community based learning".

In spite of changes, medical education in South Africa is still subject to controversy. For example, it has been argued that medical schools produce "elitist doctors" best suited to practise in urban or wealthy areas rather than in the less privileged communities of South Africa, most notably in rural areas.[150]

11.7.1 Education trajectory

Undergraduate medical education lasts 5 years, then there is a 2 year intern period, followed by 1 year of compulsory community service. Teaching is predominantly performed by specialists through formal lectures, and practical clinical attachments to departments in large teaching hospitals. The hospital departments have autonomy in setting the content of teaching and time spent with medical students.

Specialisation in medical education consists of a range of postgraduate diplomas in some of the specialist disciplines through the Colleges of Medicine, formal specialisation through a registrar programme attached to a university, and vocational training as a family doctor. Medical registration allows medical practitioners unrestricted and independent practice (general practice) after completion of their intern and community service years, without the need for vocational training.

---

[149] Sources for this section included: HPCSA website; Medical Education and Training in South Africa: Extract from international overview of medical education and training prepared as part of national Preparation for Practice project led by Universidade Nova de Lisboa, Faculdade de Ciências Médicas, Portugal, by Judy McKimm and Carol Jollie, May 2004 (http://www.fcm.unl.pt/investigacao/pedagogia/FCM-UNL%20Lit%20review%20South%20Africa%2027%20May%2004.pdf); "The Changing Profile of Medical Education in South Africa" by Dan J Ncayiyana *deputy vice-chancellor*; University of Cape Town (http://student.bmj.com/back_issues/0900/editorials/306.html).

[150] "The Changing Profile of Medical Education in South Africa" by Dan J Ncayiyana *deputy vice-chancellor*; University of Cape Town (http://student.bmj.com/back_issues/0900/editorials/306.html).

11.7.2 Funding

Medical education is funded by the state but there is debate about whether private providers should be involved in funding and delivering undergraduate medical education. Many students pay from their own sources (i.e. do not have scholarship support) and have to take out large loans to cover the costs of training, which they then have to repay. These loans often act as a barrier to specialisation.

11.7.3 Quality assurance in medical education

The quality of undergraduate education and curricula is regulated by the HPCSA. The HPCSA sets out guidelines for curricula but different medical schools can establish their unique curricula as long as they fit within the criteria set out in the guidelines. Each medical school is reviewed for accreditation every 4 years.

According to our interviewees, the penalties and implications of violating quality levels is something that the regulatory body is still working on. Previously, each of the Boards would conduct accreditation visits. The HPCSA and then the Ministry of Health would make the accreditation decision based on information provided by the professional board. If a programme does not meet accreditation criteria, then the Board can now de-accredit immediately. In the past de-accreditation would take a significant amount of time. De-accreditation depends on how severe the limitations of a school are. In many instances, the regulatory body adopts a more developmental approach, to help schools and programmes to improve and meet accreditation criteria (e.g. with the help of education committees of professional boards) rather than de-accrediting them.

There are also processes in place to accredit CPD activities. The Professional Boards appoint "accreditors" (organisations who will review and accredit CPD activities). "Accreditors" may be: Accredited Higher Education Institutions (Universities), Professional Associations, Professional Boards (a few Boards opted to maintain control over this aspect). Service Providers (who require CPD activities to be approved prior to offering them) - Universities, Professional Associations, Interest groups, Individuals with expertise.

11.7.4 Examinations and qualifications

There is not an entry exam for undergraduate education. South African Students are examined in the subjects they take at final year of high-school, and these marks are used together with the application in making decisions. High-school examination results influence take up in to medical school, but there are also considerations of other factors. There is a need for students with knowledge of an African language and English as a second language. There is also a need to address the imbalances of the past (i.e. the fact that black students were disadvantaged in their opportunities to receive the best quality education).

Regarding exit exams, at undergraduate level there is no national level Board examination. The accredited schools are in charge of ensuring quality standards. Undergraduate students are examined with a final exam at university level, after their training. The exit exam includes theory, practice, and ethics components. Communication skills, and interaction and behaviour with the public and patients is also very strongly encouraged and monitored - for example by video-taping students as they work with colleagues and through mock

interviews with patients (they are assessed from another room – this is at least the case at Pretoria Medical School).

Medical students then have two years of an internship where their performance is monitored by supervisors. There is a strict regulation of supervision to ensure that interns receive the necessary supervisions. Intern committees of the council perform site visits to make sure the supervision of interns is up to standard. They then have one year of community service. They can then register for independent practice.

To register as a specialist, doctors have to spend time in an accredited training institution where they study and work in a hospital at the same time. Students then need to pass a national formal exit examination set by the Colleges of Medicine - an umbrella organisation for all the health professions allowing for external assessments. However, in the past not everyone practising as a specialist did the independent exams and marks were sometimes rejigged. In the future to register as a specialist (regulation currently in process of establishment) a candidate will have to present:

- A certificate of continuous assessment from a training institution;

- Evidence of successfully completed research projects;

- Proof of passing the single exit examination.

Specialist supervisors conduct continuous assessments of their interns/trainees. There are also professional examinations for various specialties. Examinations need to be passed for registration. These are Board Exams with a medical part and an ethics part which include a written exam and a practical exam. The pass mark for both parts is 50% or above.

11.7.5 Continuous professional development

The HPCSA introduced a system of compulsory CPD in 1999. The systems is designed to improve overall patient care, by requiring all professionals registered with HPCSA to earn a prescribed number of Continuing Education Units (CEUs) annually by attending HPCSA-approved education initiatives. CPD requirements are 50 hours (50 points) annually gained through publishing and reviewing articles, attending conferences, courses, and meetings. Some points must be in ethics. The goal is to develop a system for diagnosing skills a practitioner needs and which interventions he/she needs, to feed into the CPD activities. 10% of people are randomly audited every year to ensure compliance with CPD requirements.

One of the initiatives in the systems is a newly-developed user-friendly programme which allows a forum for healthcare professions to get together and to share new knowledge on a regular basis. All practitioners have to ensure that ethics and human rights CPD activities form an integral part of their CPD portfolio.

The HPCSA states that:

> "The professionalism, level of education and training of our country's health care practitioners is of the highest importance. Health care practitioners are continually learning and adding to their knowledge and skills, allowing them to help the public, keeping them as healthy as possible. They also need to ensure that guidelines, set out by the Council, on the best medical practices are adhered to at all times…..As a health

care practitioner, the process of learning never ends – it may begin with a passion to help others while in school or in university, but there is always so much to learn and minds are continually fuelled, as long as a health care practitioner is in practice, or even long after that".[151]

[151] From http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

Medical regulation in Spain

12.1 Overview

The official medical regulatory body in Spain is the General Council of Official Colleges of Doctors, although its remit is limited and responsibilities shared with other bodies, most notably the ministries of health and education, but also medical schools and the justice system.

12.2 Structure and nature of medical regulation

The regulation of the medical profession in Spain is not in practice a function of one single organisation or body. While there is a statutory body that officially regulates the medical profession in Spain, our research indicates that in practice a number of organisations play an important role. Most notably, the Ministries of Education and Health, the medical schools, and the courts have key roles in different aspects of medical regulation, as discussed below[152].

Nevertheless, the role of the official regulator, the General Council of Official Colleges of Doctors (CGCOM its Spanish acronym) and its provincial colleges of doctors, are of particular interest to this research and the centre of the discussion in this country study.

In Spain at the moment there are approximately 209,000 registered doctors, of whom about 190,000 are still practising (the others are retired doctors, etc). More than 90% of doctors in Spain are employed rather than self-employed/independent practitioners.

---

[152] Most of the information on the Spanish medical regulatory system was obtained from the website of the General Council of Official Colleges of Doctors (CGCOM) and those of a number of the individual Provincial Colleges of Doctors. These contain a significant amount of information on various aspects of the regulatory system, including its structure and key processes, standards, quality assurance and so forth. Additional information was obtained from the websites of the Ministry of Health and the Ministry of Education. Quantitative information is particularly difficult to obtain, in part because of the decentralised structure of the medical regulatory system and the fact that little quantitative information is collated and stored centrally. Most documents were available only in Spanish and were translated into English by the case study author. Two key informant interviews were conducted; one with a representative of one of the provincial colleges, and the other with a member of the largest union of medical professionals in Spain. Both interviews were conducted in Spanish.

12.2.1 Purpose of medical regulation

There are 52 provincial official colleges of doctors which group all qualified doctors, either in public or private medicine. These regulate, represent, defend and promote the medical profession, and protect the standards of practice in the interest of patients and wider society. The central General Council of Official Colleges of Doctors (*Consejo General de Colegios Oficiales de Medicos de España* - CGCOM) groups, coordinates and represents the 52 provincial colleges, and aims to safeguard the fundamental values of the medical profession: the ethical code.

The decentralisation of medical regulation in Spain was a process that lasted many years, starting with the return to democratic rule in the mid- to late-1970s. During the following years, a process of transfer of power from central authorities to the authorities of Spain's autonomous regions took place which included the transfer of some powers in the area of health. It was during this time that the role of the provincial colleges of doctors was defined and strengthened in Spain.

In order to fulfil its purpose and remit the CGCOM has a number of specific roles and functions, listed below[153]:

- Exclusive representation, regulation and defence of the medical profession

- Centralise and address requests or claims from the provincial official colleges to the government

- Promote the improvement/development of legislation on professional colleges

- Study the problems of the profession, propose appropriate reforms and intervene in conflicts that affect medicine

- Know and resolve the claims that registered medical professionals may make against the official colleges

- Represent the provincial official colleges in defence of their professional interests

- Hold disciplinary powers

- Establish the ethical principles underpinning medical practice

- Cooperate so that information and publicity related to the medical profession responds/is appropriate to professional norms/criteria

- Adopt the necessary measures to avoid disloyal competition, safeguard the dignity and decorum in the medical profession, and denounce irregular exercise of the medical profession

- Update the professional competence of doctors, promoting continuing professional development, and exercising the functions of accreditation and official registry

- Establish the criteria for registration

---

[153] See: http://www.cgcom.org/cgcom/funciones (last accessed November 2008); translated from the CGCOM's website by the authors of this report.

- Cooperate with the public authorities of the state in the formulation of public health policy and social insurance programmes, and their execution

- Provide registered doctors with certifications that may be required in EU countries

- Promote and participate in the social protection of retired and disabled doctors, widows and orphans of doctors, homes/residential facilities of doctors, scholarships, assistance and other similar initiatives

- Formalise cooperation frameworks that are necessary to fulfil the purposes and aims of the organisation

- Promote the search for new professional avenues for doctors

- Promote equity in the exercise of the medical profession

- Promote the improvement of the conditions of the exercise of the medical profession

- Ensure that the exercise of the medical profession responds to the interest of citizens

- Promote the scientific, cultural, economic and social level of the medical profession.

These are relatively broad functions, some of them with relatively clear scope and meaning, others much less so. However, our research suggests that in spite of the stated aims of the CGCOM, also laid down in its statutory specifications, the key area of recognised competence of the organisation centres primarily around debates on the ethics of the profession, and to a lesser degree around issues of qualifications for the exercise of medicine. Unlike in the UK, where the medical regulatory system is centralised, the decentralised Spanish system means that the registration (*colegiación*) of doctors is the responsibility of each regional College of Doctors rather than of the CGCOM. The regional colleges (see section 12.3.1) are also able to set their own requirements for registration, and are even able to determine whether the registration of doctors wishing to practise in their regions is even mandatory.

Additionally, in practice the CGCOM exercises little influence in areas included in some of its stated purposes. For example, even though one of its stated objectives is to act at the "exclusive representative of the medical profession", the CGCOM plays no role in negotiations and decision-making regarding the working conditions of doctors; according to Spanish law, only trade unions can participate in these processes. So the CGCOM has no role in the representation of doctors in this respect. Nevertheless, in summer 2008 a *Forum of the Medical Profession* was established where the trade unions and CGCOM discuss their common interests with respect to the profession; the Forum is co-led by both organisations. The discussion below provides more details of other areas of competence of the CGCOM vis-à-vis other institutions including the regional colleges.

12.2.2 Drivers and influential events

The regulation of the medical profession in Spain begins in the mid-19th century; a law from 1855 already established provincial bodies which aimed to prevent and sanction the

faults of doctors in the exercise of their professional duties, as well as to regulate their pay, prevent abuses against medical professionals and establish a strict medical code of conduct.[154] This system of regulation had been essentially abandoned by the middle of the 20th century, as other laws on the regulation of health professions came into being which did not require this arrangement for the medical profession. For example law 14/1986 of 25 April on General Health refers to the free exercise of the health professions making no reference to their regulation except to specify that the State should have competence in the areas of postgraduate education and specialisation of Health professionals, and the standardisation of health occupations.

While the first general Statutes for the CGCOM were recognised by law in 1980, a 2003 law recognised a "normative vacuum" for the health professions, which had broad social impacts given the "intimate connection between the exercise of the health professions and the right to health protection, with the right to life and physical integrity, with the right to personal and familiar privacy, with the right to human dignity and with the right to free development of the person".[155] This, and the need for greater convergence with other European Union member state practices, led to the conclusion that it was necessary to enshrine into law a more direct, specific and differentiated regulation of the health professions, including the medical profession.

In terms of the CGCOM, its general statutes were updated in 2006 in response to various legislative changes in the intervening period, which affected the role and remit of the CGCOM, as well as to changes in the "transformations in the reality of the exercise of the medical profession".[156] These statutes specify the functions, structure and governance of the CGCOM.

12.2.3 Extent of patient involvement

Patients are involved to some extent in medical regulation in Spain. Patient associations in civil society often participate in debates, workshops and seminars organised or attended by the Colleges of Doctors. These events provide an informal forum for the exchange of ideas and views, and for the colleges to be informed of the interests and needs of patients as represented by the associations. Some regional colleges, for example the one in Madrid, also participate in, or organise, education campaigns targeted to the general population, for example to educate the public on the range of medical services they can use.

In addition, patient associations often channel claims and complaints against medical practitioners, which are made to the Courts or directly to the Colleges of Doctors. Finally, patients are represented, through patient associations, in the Health Council (*Consejería de Sanidad*) of each autonomous region. These Councils group and regulate all health

---

[154] Law 44/2003 of 21 November of regulation of the health professions (available at: http://noticias.juridicas.com/base_datos/Admin/l44-2003.html, last accessed November 2008).

[155] Law 44/2003 of 21 November of regulation of the health professions (available at: http://noticias.juridicas.com/base_datos/Admin/l44-2003.html, last accessed November 2008). Translated from Spanish by the authors.

[156] Ministry of Health (2006) Royal Decree 757/2006 (available at: http://www.cgcom.org/sites/default/files/06_06_31_estatutos_boe_0.pdf last accessed November 2008).

organisations operating in a given region, which includes the Colleges of Doctors. The Council provides an additional, more formal forum for exchange and dialogue between patients and the colleges. While according to our research there is increasing openness towards the inclusion of patients in medical regulation, there are no formal structures for the involvement of patients within the medical regulatory bodies yet.

12.2.4 Funding arrangements

All regional colleges of Doctors charge fees to their registered doctors. These fees constitute the primary source of funding for the regional colleges. The larger colleges (such as the ones in Madrid and Barcelona) have a larger number of registered doctors, and therefore a greater income than smaller colleges. Each college sets it own fees for doctors, which often vary depending on the doctor's age, years in practice, employment status and so forth. Some colleges also own property from which they derive a small rent, for example from hire of rooms and auditoriums for events.

The regional colleges in turn pay fees to the CGCOM, which are the central body's main source of funding. In addition to these fees, the CGCOM received a small proportion of its funding from central government.

12.2.5 Interaction between different regulatory bodies

As mentioned in section 12.2.1, the CGCOM works in cooperation with other public bodies in the regulation of the medical profession. In addition to the CGCOM and its provincial colleges, the most important organisations in this respect include the Ministry of Health, the Ministry of Education, the medical schools, and the courts. These organisations are each responsible for one or more of the various aspects of medical regulation.

The Ministry of Health (Ministerio de Sanidad y Consumo)

As set out in a 2003 law, the Ministry of Health regulates and provides accreditation to Spanish medical schools.[157] This law establishes that the Ministry of Health has responsibility for setting the standards of accreditation of centres for teaching of medicine, and can also withdraw accreditations following the same due diligence as to accredit an institution in the first place. The law also mandates that the Ministry of Health has ultimate responsibility for the various committees that oversee and provide advice on health specialisms, provide technical support to this Ministry and to the Ministry of Education, and so forth. The Ministry of Health also has regulatory authority over continued professional development.

The Ministry also regulates, with the health administration of each autonomous community and the scientific colleges (see below), specialist medical education, although the issuing of the actual degree is the responsibility of the Ministry of Education (see below). The Ministry also administers the MIR exam (see section 2.2).

The Ministry of Education

---

[157] Law 44/2003 of 21 November of regulation of the health professions (available at: http://noticias.juridicas.com/base_datos/Admin/l44-2003.html, last accessed November 2008).

The Ministry of Education has competence for various areas of medical regulation. For example, the Ministry holds sole responsibility for the accreditation/recognition (*homologación*) of medical degrees obtained outside Spain, a process that must take place before doctors who trained abroad can practise medicine in the country.[158] The presence of professional organisations in this process is very limited (the CGCOM has no role, but scientific organisations play a small role when the *homologación* is for specialist degrees).

The Ministry of Education is also ultimately responsible for issuing medical degrees (both first degrees and specialisation) through the universities.

The Medical Schools

The Medical schools are the only providers of medical education and degrees in Spain. As mentioned above, the degrees are ultimately issued by the Ministry of Education, but are delivered to graduates by the schools themselves. Professionals within medical schools are also often members of committees within the regional colleges and the CGCOM.

The Courts

The courts have an important role in settling claims regarding the fitness for practise of individual doctors. Claims and complaints often go directly to the judicial system and are settled by the Courts. These complaints come from the public, from other doctors and from the Colleges of Doctors, who can derive cases initially sent to them. The courts occasionally use members of the Colleges of Doctors as expert witnesses in trials.

Scientific colleges/societies[159] (equivalent to UK Medical Royal Colleges)

These organisations are independent from the CGCOM, and are to a significant extent involved in determining the professional competences of the different types of medical professionals (by specialism). The CGCOM therefore has a limited role with regards to medical competencies. These organisations are also involved in debates about, and setting of, ethical and professional standards for medical professional, promoting continuing medical education, the representation of its members, and other activities which often (at least on paper) overlap with those of the CGCOM.

12.3 Registration process and requirements

12.3.1 Registration and licensing process

Medical professionals have to register in the College of Doctors in the province in which they intend to practise. Those trained abroad, either in the EU or in third countries, must also register in the college of the province where they intend to practise. Because of the

---

[158] It is interesting to note that according to one of our interviewees, many stakeholders within the medical profession (including the largest medical trade union) argue that responsibility for the process of *homologación* should be transferred to the CGCOM from the Ministry of Education, in order to promote increased centralization of the regulation of the medical profession within the CGCOM.

[159] For a full directory of Spanish medical scientific societies, see: http://www.fisterra.com/recursos_Web/no_explor/sociedades.asp#Medicina%20Intensiva (last accessed November 2008).

decentralised nature of medical regulation in Spain, there are some exceptions to this rule: a small number of autonomous regions (which includes Andalucía and Asturias) do not require medical graduates to register before starting to practise.

This process of registration primarily involves the submission of documentation on their medical degree and the payment of a fee. Each provincial college has the right to determine any other registration requirements that apply to their province exclusively. The colleges are also responsible for ensuring the legitimacy of the degree documentation presented by the candidates.

In those autonomous regions where registration is compulsory (which is in fact the majority of regions in Spain) doctors are obliged to register only after finalising their first degree; there is no specific requirement to register following specialisation (although this is increasingly being called for from some quarters within the medical field).

Provincial colleges have publicly accessible registers of registered doctors.

12.4 Revalidation

There is no process of revalidation (*re-acreditación*) within the medical profession in Spain. Once doctors in Spain obtain their medical degrees (for general practice, specialist practice, or obtained abroad and accredited by the Spanish authorities), they are not subject to any additional regulatory processes until they retire. In addition, doctors do not have to report to the CGCOM (or the provincial colleges) of any changes in their practice of medicine (for example, if they change specialism within the profession); once a doctors has registered with the CGCOM, there is no obligation to notify the organisation of any subsequent changes in specialisation).[160]

Interviewees, however, stated that this is a contentious issue at the moment within the profession. A number of quarters have called for the establishment of qualifying examinations and other quality control mechanisms before medical school graduates can begin practising, and during doctors' careers. The issue of re-validation is linked to the lack of a qualifying exam, as they both represent instances of a failure to ensure and monitor quality among medical professionals once they obtain their degrees. In a very small number of autonomous communities doctors must pass a qualifying exam before they can practise medicine, but this is not compulsory at a national level. According to them, the CGCOM should have an important role in the process of accreditation and re-validation of medical professionals.

12.5 Standards & ethics

The CGCOM, as a representative of all registered doctors in Spain, assumes as one of its main objectives the promotion and development of its *Code of Ethics*. Failure to abide by

---

[160] As a result, there is no central registry holding details about the different types of doctors in Spain. Some stakeholders, including trade unions, are advocating the creation of such a registry, which would be based on a requirement that doctors notify the CGCOM of changes in their specialisation.

the principles in the code constitutes an offence under the general statutes of the CGCOM.

The *Code of Ethics* includes principles regarding a doctor's relationship to his/her patients, doctor-patient confidentiality, the quality of medical care (*atención medica*), a doctor's duty regarding organ donation, abortion and the prolongation of life, and other issues.

Each provincial college also has its own Ethics Commission, dealing with fitness to practise (FTP) cases, as well as a wider range of issues related to standards of ethics in the medical profession. For example, they provide advice and counsel on issues of ethics and law to the other Commissions and bodies both within and outside each college.[161] They are also often tasked by the boards of the colleges with preparing reports on ethical issues around the relationship between doctors and patients, doctors among themselves, and between doctors and other health professionals. The Commissions can also decide to prepare these reports themselves.

12.5.1 Standards and education

There are increasing calls from some stakeholders in the medical field for a more systematic and structured approach to the transmission of standards of ethics to medical students during their education. At present, the provision of much of this education depends on individual universities' approaches, but increasingly there is pressure to consolidate ethical education within medical degrees.

12.6 Fitness to practise (FTP) and related disciplinary procedures and sanctions

While, from a statutory point of view, the CGCOM has a mandate to act in response to FTP concerns, and are able for example to sanction medical practitioners through their removal from the registry, in practice the CGCOM has a limited role in the area of FTP.

According to our interviewees, most complaints regarding the competence of individual doctors are processed through the judicial system rather than the CGCOM and its provincial colleges.[162] One interviewee indicated there is little confidence in Spain in the ability of the CGCOM to address issues of FTP, which is why most complaints are taken directly to the courts, where they are settled (including the judicial decision that doctors can no longer practise medicine). When this happens, the CGCOM has little or no role, and the final decision on sanctions is taken by the courts themselves.

Nevertheless, given the decentralisation of the medical regulation system in Spain (with each provincial college having its own Ethical Commission dealing with FTP cases as well as with other aspects of standards and ethics), it is expected that different provincial colleges have varying experiences in relation to FTP. When dealt with by the colleges, sanctions and resolutions in FTP cases can include agreements between parties (with the

---

[161] See for example: http://www.cgcom.org/noticias/2007/10/07_10_24_deontologica (last accessed November 2008)

[162] It is worth noting, however, that this information was relayed to us by interviewees, and we have not been able to obtained confirmation of its accuracy elsewhere.

colleges acting as mediators), temporary or permanent removal of registration to practise, and the transfer of a case to a court of law.

With reference to the extent of public confidence in the system, one interviewee explained that "different colleges are at different of development of their role as "disciplinarian" and as an institution that protects society from medical malpractice". In any case, our research suggests that in most provincial colleges FTP complaints that are presented to the college come from a variety of sources, including the courts themselves (when they hear of a case directly), individual patients, other doctors and so forth.

12.7 Medical education

12.7.1 Education trajectory

There are a set number of places (*números clausos*) for students applying to medical schools across the country. Every year only about one in four applicants enters medical school. The numbers of students for medical schools were set twenty years ago following a period of increasing numbers of doctors entering and graduating from medical schools, which exceeded the demand for medical professionals in the country. This in turn led to the emigration of many doctors.

The number is now set at about 5,900 students per year, but varies depending on estimates of the future demand for doctors in the country (until a few years ago, the number of new places in medical schools was around 4,200 a year).

It is estimated that between 5% and 12% of each cohort of medical students drops out of medical school before completing the degree; interviewees reported that this low dropout rate (compared to a high of about 25% before the qualifying entry exams were set two decades ago) is due to the strict admissions procedures in place.

12.7.2 Examination and qualification

In order to gain a place in medical school, applicants take a qualifying exam; students are admitted to the schools on the basis of their exam results. As mentioned above, the medical degree is determined and regulated by the Ministry of Education, but within this each medical faculty has some discretion in the setting of examination and courses.

The degree takes on average six years. After the third year students begin their clinical education, which takes place primarily in hospitals. Over the last years the weight of clinical education increased over academic-based learning, so that by the final year most of the learning takes place in clinical settings.

For access to places for specialist medical education, which is between 4 and 5 years, candidates must take a national exam (a test of 250 multiple choice questions called the MIR exam). Places are allocated on the basis of the MIR exam and a process of "valuation" of the candidate's academic records. By 2010 this exam will include a practical element which will include clinical competence. Candidates can take the exam as many times as they want.

12.7.3 Funding

There are private and public medical schools in Spain. Medical education in public schools in not free, but small fees are paid for registration and for courses. While most students fund their studies privately, a relatively small proportion receives scholarships awarded on the basis of need rather than merit.

Financially, medical faculties depend directly on the governments of their autonomous community.

CHAPTER 13 **A comparative analysis of medical regulation**

The preceding ten chapters provided detailed descriptions of the medical regulation systems in the countries selected for this study. This Chapter synthesises and summarises the key findings from all ten country case studies, and briefly discusses their implications for understanding medical regulation in different jurisdictions.

13.1 Structure and nature of medical regulation

13.1.1 Interaction between different regulatory bodies
Findings

The countries surveyed have developed a number of different medical regulatory systems and, while all have departments of health, the development of standards and codes of ethics together with responsibility for the regulation of individual doctors has been devolved to other organisations. These range from a unitary state authorised body such as the Egyptian Medical Syndicate (EMS), the Medical and Dental Council of Nigeria (MDCN), the Pakistan Medical and Dental Council (PMDC) and the Health Professions Council of South Africa (HPCSA), through to the decentralised polycentric Spanish and Italian systems where regulation is the prerogative of, respectively, the provincial Official Colleges of Doctors, and the regional medical associations *(Ordini dei Medici Chirurghi e degli Odontoiatri).* Unsurprisingly, the extent to which medical regulation is devolved from national to regional and even local regulatory bodies reflects the structure of the state itself and the form of devolution that has developed. Thus responsibility for medical regulation in Germany is shared between the federal state and the *Länder*, and in India between the Medical Council of India (MCI) and the states' own medical councils.

Furthermore, countries also differ in the extent of self-regulation. The enforcement of medical regulation in Germany is not only devolved to the *Länder* level, but also delegated to doctors' self administration.

The extent to which regulation is combined with representation again varies. The EMS also represents Egypt's doctors and has considerable dominance while the MDCN and the Health Professions Council of South Africa (and its constituent professional boards) are solely statutory regulators, representation being the function of, respectively, the Nigerian and South African Medical Associations.

Discussion

While the systems may appear broadly similar, the devil is in the detail. Egyptian doctors working in the public sector must register with the EMS while those working for private clinics do not have to register with the private sector licensor, the Ministry of Health and Population (MoHP). In Spain, the individual provincial colleges have their own registration requirements. There is however a good deal of awareness regarding these issues and inconsistencies do receive attention, particularly where they arise as a result of regional autonomy. For example, the Spanish are considering centralising registration rather than leaving it to each of the provincial colleges and in Germany medical exam questions are harmonised by the German *Länder*'s Institute for Medical Exam Questions (*Institut für medizinische und pharmazeutische Prüfungsfragen, IMPP)*. There are a number of such coordinative organisations, such as the National Federation of Medico-Surgical and Dental Orders in Italy (*Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri (FNOMCeo))*, and the central General Council of Official Colleges of Doctors in Spain *(Consejo General de Colegios Oficiales de Medicos de España - CGCOM)*. Of more concern perhaps are countries such as India where coordination between the states is poor.

It should be noted that the influence of doctors on the regulatory process, and the concept of professional self-regulation, seems to be less of an issue than might be expected. This is consistent with the relatively low level of public engagement with medical regulation in some countries. Involvement of doctors in the regulation of their own behaviour and the development of ethics and codes of practice varies but was only described as a major public issue in Egypt, where the EMS dominates the whole regulatory system, and Germany where the regional chambers of doctors are responsible for developing as well as enforcing the physicians' codes of pratice. However, to devolve regulatory functions to representative bodies must always risk the suspicion of conflict of interest. For instance, the vast majority of the documentary output (and one might speculate, resources and thus effort) of Spanish provincial colleges appears to be heavily geared towards supporting doctors rather than the protection of patients.

13.1.2 Purpose of medical regulation
Findings

The medical regulatory organisations in the countries surveyed set as their primary objectives a combination of registering/licensing medical practitioners, setting standards for the profession, promoting best practice and patient safety, promoting fair access to healthcare and regulating medical education. There are some local variations. The MDCN has responsibility for homeopathy and alternative medicine, reflecting the practice of native medicine in the country. In devolved systems the bodies that represent groupings of provincial medical associations, such as the central General Council of Official Colleges of Doctors in Spain *(Consejo General de Colegios Oficiales de Medicos de España - CGCOM),* may have some additional regulatory responsibilities in respect of their organisational memberships.

Purpose may also be driven by circumstances. In Greece, the relatively low rate of pay accorded to public sector doctors has led some to charge or solicit bonus payments directly from patients. This is considered a major disciplinary offence - however, it remains

common. In South Africa the experience of apartheid has influenced regulatory objectives with a focus on equal medical treatment irrespective of race.

Discussion

There is a core set of regulatory functions to which all medical regulators subscribe with few exceptions. The issue is really one of the effectiveness of the regime and its capacity and resolve to attain its stated objectives. The influence of the medical profession itself on the regulatory process is a real concern in Egypt and the failure of the Greek state to enforce its own law on doctors demanding commissions is worrying. While some of the informants interviewed for this research did indeed comment on this issue further research is needed to investigate the implementation of medical regulations in the countries surveyed.

13.1.3 Values within medical regulation
Findings

Values can be stated or implied. If explicit they may be expounded in legislation or set out within codes of ethics. As with regulatory purpose, there are a set of core values to which most regulators subscribe. They are expressed however in a multitude of different ways. Most can be grouped, however, into those relating to respect for patients, for scientific knowledge and for colleagues. For instance, the German doctors' code, the *Berufsordnung* requires doctors: to preserve and enhance the trust between doctors and patients; to ensure, in the interest of the whole population, the quality of doctors work; to preserve the freedom and the reputation of the medical profession; to encourage worthy behaviour and to prevent unworthy behaviour of doctors. There are a few additional values arising out of culture or tradition. In Egypt the first part of the code of ethics is an oath to God and there are references to Islam and pan-Arabic aspirations contained within the detail of the code, while in South Africa there is a strong emphasis on education as means of protecting the public.

Discussion

Most of the values set out in the preamble to legislation or in codes of ethics are stated in aspirational terms rather than possessing any instrumental orientation, which is to say that, for example with respect to patients none referred explicitly to reducing the risk of harm. In fact there seemed very little emphasis on the concept of regulation or the measurement and reduction of risk amongst the European countries studied or elsewhere in the world. There was therefore no evidence of any real use or understanding of some of the regulatory strategies familiar to UK regulators such as better regulation, smart regulation or risk-based regulation. Of course, rather than being indicative of a substantive difference to UK understandings of regulation in respect of aims and objectives, this may reflect cultural and linguistic differences and indeed different political imperatives.

13.1.4 Funding arrangements
Findings

Funding for medical regulation comes from the state, from medical associations, medical schools, and individual doctors and complainants. The typical model is for the state not to

recover expenditures on medical regulation incurred directly by government departments, but for medical associations to cover their costs for all their services including regulation from their members, individual doctors. This may consist of a flat fee or a flat fee plus a %age of earnings. The problem is that medical regulation is rarely the prerogative of a single dedicated regulatory body. (Possibly the Health Professions Council of South Africa is the nearest thing to a dedicated unitary regulatory body in the countries surveyed here – see the country study on South Africa for details.) Medical associations such as those in Egypt and Italy do not distinguish the amounts to be allocated to different purposes and in the case of the latter the purposes include the provision of pensions for doctors in retirement.

Discussion

The actual cost of medical regulation proved very difficult to capture as much of medical regulation is carried out by multi-function agencies, departments and associations. So, as an alternative, numbers of employees were requested. However, as it is difficult to separate out regulatory functions, in many cases even these were not provided or of little value as they referred to both regulatory and non-regulatory staff.

13.2 Registration process and requirements

13.2.1 Registration and licensing process

Findings

In all studied countries, registration with a medical regulatory body is a formal requirement before medical doctors start practising. The only exceptions are a small number of autonomous Spanish regions (which include Andalucía and Asturias) where medical graduates are not required to register before starting practising medicine.

In most of the countries in this study, medical regulatory authorities do not formally distinguish between registration and licensing processes, and registration alone may be sufficient to entitle doctors to practise. In Germany, Egypt and Italy, however, registration and licensing are separate. In Egypt, registration is controlled solely by the Egyptian Medical Syndicate, whereas licensing for public sector doctors is the preserve of the Ministry of Health and Population, and doctors cannot apply for a licence with the MoHP until they have been registered with the EMS. Similarly, a two stage process is to be found in Germany; doctors first need to obtain the licence to practise issued by *Länder* authorities and later register with the local chamber of doctors. Application to the Ministry of Health is also a prerequisite to register with the medical associations in Italy. The distribution of responsibility between two regulators in Egypt, Germany and Italy, although a formal requirement, does not in practice have significant implications for the process of registering doctors in those countries.

From the perspective of medical regulation, the more interesting aspect is the centralisation versus decentralisation of the regulatory process; the countries in this study represent either one or the other model. In Germany, Spain, Poland, Italy and Greece doctors need to register with the regional office, in the province/geographical area where they intend to practise, although their licence may be valid for the whole country. In other countries,

such as India, Pakistan, South Africa and Egypt, one centralised registration office exists serving all doctors wishing to practise medicine in these countries.

Another variation between analysed countries is in relation to the types of registration granted by registration bodies. In some countries, such as Italy or Egypt, doctors are granted a full licence for life. In other countries, registration is either renewable or various types of licences are granted depending on the seniority, knowledge and skills of the applicant. More details about variations in the type of registrations are presented in table 13-1.

Table 13-1: Type of registration/licences

	Type of registration / licences
Egypt	Full for life.
Germany	Two main types: 1. full, indefinite licence to practise (Approbation); 2. limited, temporary permission to work as a doctor.
Greece	Full for life. Must be renewed each year.
India	Depending on qualifications: provisional registration (valid for one year only) and a full registration.
Italy	Indefinite licence.
Nigeria	Provisional and full registration, limited or temporary registration, registration as specialist.
Pakistan	Depending on qualifications: provisional, basic medical, basic medical with postgraduate qualifications.
Poland	Two main types: 1. provisional licence valid for 5 years; 2. full permanent licence.
SA	Six main registration categories: student, intern, public service, supervised practice, education and independent practice.
Spain	Full for life – compulsory in most – but not all - autonomous regions

There are also differences between the compulsory fee imposed on doctors for the registration process and for remaining on the register of medical doctors. In Poland, doctors do not have to pay an initial registration fee, but are required to pay an annual membership fee. In Germany, doctors are obliged to pay annual membership fees based on their earnings. In South Africa, doctors have the possibility to voluntarily erase from the medical register and do not pay an annual fee if a practitioner does not intend to practise their profession for a given period of time. In Pakistan, Nigeria and India, doctors pay for registration and to retain a medical practitioner name on the register.

Discussion

As the preceding section shows, there is some variation in the registration and licensing processes and requirements across the ten countries examined here. The differences include type of registration and length of validity, bodies responsible for managing registration and overseeing the registration process, and their level of authority.

The study raises a number of issues around licensing and registration. First, management of the registration process is more consistent and possibly easier to control in countries with centralised regulatory structures, such as Nigeria, India, Pakistan, Egypt and South Africa. Integrity is also maintained in systems where regional authorities are responsible solely for the administration and implementation of national strategies (for example in Poland or Germany). However, in countries where regional regulatory authorities have greater autonomy, such as Spain and to a certain degree Greece, it is more difficult to have internal (national) consistency between regions. The more independent role of regional associations in establishing and applying their own regulations means that regulatory requirements can vary significantly within a single country.

Assessing medical qualifications can be also more complex in the case of countries with large numbers of individuals unlawfully practising medicine, most notably India and Pakistan. In these countries, it is estimated that the number of individuals practising medicine without a formal qualification is nearly equal to the number of officially qualified and recognised doctors suggesting regulations may not be applied with the same vigour as they are in the UK.

An important aspect that differentiates medical regulatory models analysed in this study also relates to the requirement (or lack of a requirement) to re-register or renew a registration or licence. In many countries, once a registration or licence is granted the doctor remains on the register as long as the appropriate fees are paid – which may mean they can remain on the register for life. It means that the medical regulatory authorities have only limited oversight of doctors on the register and may have little knowledge of the extent to which qualifications and skills are updated.

Finally, an important factor when analysing medical registration and licensing is the issue of the real purpose of registration. In countries such as Germany, Poland and Spain, registration entitles registrants to additional benefits (for example pensions, legal advice regarding complaints and Continuous Professional Development (CPD) activities). For that reason, the benefits of registration with a medical authority may be expressed to a great extent in terms of benefit to the doctor in contrast to the UK, where the primary objective of medical registration is to protect patients and ensure compliance with standards.

13.2.2 Flow and quantity of applications

Findings

Most countries do not report the exact number of annual applications for a medical registration/licence. In most cases this is because this process is decentralised, or because there are differences between the numbers of applicants who registered and those who are licenced. However, even where numbers are not recorded in any systematic way estimates are possible, which we set out in Table 13.2:

Table 13-2: Registration numbers of doctors in the 10 countries analysed

	Egypt	Germany	Greece	India	Italy	Nigeria	Pakistan	Poland	South Africa	Spain
Annual number of applications	~12,000 (2008)	~9,000 (2008)	~800 (2008)	~28,000 (2007)	5,915 (2007), 3,516 (2008)		4,766 (2007)	~2,400 (2008)	250-320 (2006-2008)	n/a
Total number of registered /licenced doctors	~200,000 (2008)	413,696 (2007)	~46,000 (1999, practising doctors)	675,334 (2007)	333,212 (2009)	Over 35,000 (registered with the Nigerian Medical Association) (2008)	133,933 (2008)	~127,000 (2007)	34,448 (2008)	~209,000 (2008)
Percentage of doctors trained abroad	insignificant	~20,400 (~5%) (2008)			12,525 (2004) 3.5%		2,967 (2008)	~1,000 <1% (2008)	15-16% (2008)	n/a

Similarly, obtaining the total number of doctors registered in the studied countries also proved challenging, and information on some countries can be only estimated. Furthermore, in many countries number of registered doctors does not always equal with the number of practising doctors. For that reason, countries such as Germany, Poland, Greece or Italy keep two types of registers; first one being a general register listing all doctors allowed to practise medicine, and a second register of practising medical individuals (either in public or private medical practice). In Spain, for example, the single register includes both practising and non-practising doctors.

Finally, some countries also collect data on the number and country of training of overseas doctors registered within their national medical regulatory system. However, these data are not always collected in a systematic way in the countries analysed here.

Discussion

Most countries have some type of medical register, thus it is possible to provide or estimate the total number of medical doctors registered, even when data is not collected in a systematic way. On the other hand, there is less information on the number of annual applications and in most countries these numbers can only be estimated. A possible implication of this finding is that medical authorities have limited knowledge about the flows and stock of medical doctors, and as a consequence have restricted abilities to effectively plan for their national healthcare services provision.

13.2.3 Interactions between regulator and medical professionals
Findings

Conditions to be granted a licence to practise medicine are relatively similar across all analysed countries. In general, applicants have to meet the following conditions:

- Be a citizen of the country where they apply for a licence (or EEA national in the case of European countries);

- Have full entitlements to public rights;

- Have a medical university (or equivalent) degree;

- Be of professional good standing, and;

- Pay a registration fee.

Some countries impose additional requirements. For example, doctors registering in Italy, Spain and Greece need to produce a document certifying their residence in the area of the relevant regional registration authority, whereas in Poland in order to be granted permanent registration doctors need to pass a national medical exam.

Within the EU, community law formally prohibits imposing any additional requirements on EU candidates moving to another member state, including language testing. However, in some of the countries examined here doctors are required to sign a declaration stating that they possess a level of language that would allow them to practise medicine in that country, or pass a language test during the recruitment process. Within the EU, this can only be a requirement for medical graduates from non-EEA countries.

In all of the analysed countries, there are additional medical and linguistics requirements imposed on non-EU applicants at the point of registration, unless special bilateral agreements to accept each other's education standards are in place. Normally, candidates are examined on their medical knowledge and skills, and often they are also tested on their fluency in the language spoken in the country where they are registering.

Discussion

As mentioned above, the conditions for award of a medical licence are broadly similar across the countries in this study, including for doctors trained overseas. It is interesting to note that in contrast to the UK, some of the countries analysed in this study (such as Pakistan and Nigeria) can be called "emigration" countries as they report higher numbers of doctors emigrating from them than immigrating to them. Other countries, such as Germany, Spain and Italy and indeed the UK are unable to meet the demand for doctors so rely on recruiting from overseas. The management of the recruitment and assessment processes for doctors that have qualified abroad in the countries studied present a number of challenges and medical authorities could potentially benefit from sharing their experiences.

13.3 **Revalidation / competence assurance / recertification**

Findings

None of the countries we examined have a formal system for revalidation similar to the one being developed in the UK although some have a form of re-registration. These include Egypt, Germany, Greece, Italy, Pakistan and Spain. Only in Poland is some form of revalidation (recertification) required, although there are no direct sanctions if a doctor does not get recertified.

In India, re-registration requirements vary by state, with some states (e.g. Delhi, Maharashtra) issuing registrations for only a stipulated period of time (generally 5 years)

with the requirement to renew thereafter. Although renewal is purely an administrative procedure.

Some countries, such as Egypt, South Africa and Spain, are currently developing proposals for a revalidation system. In Egypt, the proposed system would use a points system, and be tied explicitly to CPD.

Discussion

Revalidation is not widespread across the ten countries, although interestingly in some the issue is increasing in importance on the policy agenda as countries consider introducing similar systems in the future. For most countries it is difficult to assess how advanced the development of such systems is, or how long full implementation would take.

It is not clear why revalidation is not widely established. The costs associated with the implementation of revalidation may be high, but it could be argued that revalidation could prevent certain (costly) fitness to practise (FTP) procedures and ensure patient safety.

13.4 Standards & ethics

13.4.1 Content

Findings

All the surveyed countries have a code of medical ethics. These may be established by act of parliament or ministerial decree after consultation with the medical profession (Egypt, Greece, Poland) or developed and instated by a national medical association - sometimes as a template for regional associations (Germany, India, Italy, Nigeria, Pakistan, South Africa, Spain). In Germany the regional chambers of doctors set their own individual codes based on the nationally developed *Muster-Berufsordnung*.

The standards contained therein are detailed in the country reports but include sections on the imperative to preserve life and health and other duties to patients, dealings with colleagues and the public or society at large. Many also contain standards in respect of special interventions relating to HIV, abortion, organ donation, genetics, CPD, and even adoption and "truth-telling" (Pakistan). Most include definitions of malpractice and set out the potential disciplinary procedures to be faced. Of especial interest is the Egyptian Code, which is in three parts. The first is a religious oath, the second focuses on the duties of doctors, the third on special treatments such as gender reassignment and drug testing.

Discussion

The content of the codes follows a relatively uniform pattern with the exception of religion and special treatments. If research being carried out elsewhere suggests that the details of regulation such as the content of the doctor's home country code of ethics affects their perceptions of their duties when employed in other domains then a detailed line by line comparison may be useful.

13.4.2 Legal basis for standards

Findings

Standards may be fully codified in a dedicated act of parliament or decree (Egypt, Greece) but more frequently are developed by national or regional medical associations. These associations are usually brought into being by statute and thus have quasi-judicial status in terms of monitoring and disciplining their members (Pakistan, South Africa). Some go further. The MDCN disciplinary panel has the formal status and powers of a high court of the federal republic. All standards have some sort of statutory framework.

Although this was not an attitudinal survey the informants were asked in interview for their opinion of the extent to which the medical profession seeks advice on standards and other matters from their regulator as opposed to merely viewing regulation as a policing operation. There were few responses but of those who did answer both the EMS, and the Health Professions Council of South Africa were seen as supportive and organisations from which doctors would actively seek advice. The former is of course effectively an Egyptian trade union while the latter, although a statutory regulator, puts a good deal of effort into its educative function. In the case of Spain, doctors were felt to be sympathetic to their colleges but wary of their regulatory function.

Discussion

In Egypt the EMS produces the standards and also assesses them leading our informant to comment, "while the sentiments expressed in this document are worthy, this is so far removed from the reality of medical practice in Egypt today. ...The regulation of commercial activities by doctors is particularly poorly implemented." In fact only four disciplinary cases are cited on the EMS website. These resulted in suspensions of practice of between one and nine months.

So while all the codes are either statutory or instated by a statutorily authorised body perhaps the real question is the extent to which codes of practice – and indeed regulations as a whole – are applied, a question a follow on research project may want to address.

In terms of developing the code there was no evidence of any requirement for periodic review except in Nigeria, and no formal consultation processes were evident although it should be noted that surveying each individual regional and local medical association was beyond the scope of this project.

13.4.3 Actors involved

Findings

Most standards and codes of practice originate with the national medical association, whether or not they are subsequently incorporated into statute and these associations tend to drive forward standards. The exceptions of course are those devolved states where the regions are responsible entirely for their own codes (India, Spain).

Credible information on dissemination of the codes is hard to obtain. Most are set out in full or summary form on websites although not all are easy to locate (e.g. Egypt). By law, every hospital in Greece must have an office for citizens' rights to deal with patients' complaints which would suggest that the doctor's code of practice ought to be available. This is also the case in South Africa where the code, the Patient's Rights Charter and the

Batho Pele Principles (an initiative to enhance the quality and accessibility of government services) are readily available on the internet and are posted in every hospital. Poland also makes a virtue of disseminating information on ethics, using medical journals, print media, TV and radio. In Nigeria distribution of copies of the Code is seen as a way of disseminating best practice and information on what patients ought to expect of their medical practitioners. Poland is probably typical in that there is, in theory, a good deal of information available to patients on their rights but in practice they remain fairly ignorant on such matters.

Discussion

Only South Africa describes its process of code development as "iterative and stakeholder inclusive." Certainly the public in most countries are rarely consulted on such matters, if at all, and there is doubt as to the extent to which patients really know the content of the relevant code of ethics even as it relates to their own rights in respect of dealings with medical practitioners. This suggests that standards and codes of practice matters may not be foremost in the minds of medical practitioners in their dealings with their patients.

13.5 Fitness to practise (FTP) and related disciplinary procedures and sanctions

13.5.1 Content / substantive characteristics

Findings

While the term fitness to practise (FTP) is common in the UK medical regulatory system, similar (but not necessarily identical) regulation appears under different names in other countries. For example, in Poland, this type of regulation is referred to as "Professional liability", while in Germany at least two procedures would fall under the FTP label, the "Berufsrechtliches Verfahren" (Procedures under the professional code) used to enforce the professional code, and a procedure by the *Länder* authorities to revoke the licence.

Although all countries have disciplinary procedures, there is substantial variation with respect to the structure of the bodies responsible. In some countries, there is only one organisation handling FTP. For example, in Egypt all procedures are handled by the Egyptian Medical Syndicate, in India by the MCI and in Pakistan by the PMDC.

In other countries, parallel tracks exist. In Germany, there are procedures under the professional code as well as under federal licensing law.

Perhaps a more common distinction is at geographic level. In Egypt, FTP procedures can be at national or local level. In Spain, FTP is at regional level, while in Greece, a hierarchy exists, where procedures start at the hospital level, and may be escalated to regional association level with the possibility of appealing at the national level to the Supreme Medical Disciplinary Board

Finally, in some countries (such as in Pakistan) even though the medical council is the formal body responsible for FTP, its role appears to be marginalised in practice, because the ministry of health might play an important role as well, or the judicial system (Spain).

In Poland the definition of proscribed behaviour is rather broad. This is because in principle doctors could be subject to a disciplinary hearing for any behaviour in breach of

the code of ethics or other regulatory requirement or for breaching their own chamber's rules.

Table 13-3 compares the different types of sanctions (shown as "X") that can be imposed in each of the 9 countries for which we have data.

Table 13-3: Types of sanctions in FTP cases

	Warning	Admonition	Suspension	Removal	Public statement of blame	Fine
Egypt	X	X	X	X	X	X
Germany	X	X	X	X	X	X
Greece		X	X	X		
India			X	X		
Italy	X	X	X	X		
Nigeria			X	X		X
Pakistan		X	X	X		
Poland	X	X	X	X		
South Africa	X			X		
Spain				X		

* In the cases of Spain, South Africa and India, no evidence could be found on whether other types of sanctions than those marked in the table are used in FTP cases. For those countries, reliable evidence could only be found on the use of the sanctions marked with an X.

The table shows that all countries have the option of suspending or removing the doctor from the register. Warnings and admonitions occur in most countries as well, but only a few countries can issue a public statement of blame or issue a fine.

Discussion

FTP, or disciplinary procedures, exist across all 10 countries, and makes these countries to that extent comparable to the UK. However, local definitions of what is covered by FTP can vary greatly.

13.5.2 Flow / quantity of FTP procedures

Findings

Table 13-4 shows, for those countries where data were available: how many complaints were issued, how many were dismissed, and how many eventually led to disciplinary action.

Table 13-4: Quantity of FTP procedures

	Period	Received	Dismissed	Formal judgement
Egypt	2007	705	542	20
Pakistan	Annual average 2004-2008	500	n/a	100
Poland	2007	461	289	224
South Africa	2007-8	2628	592	210

The table shows a wide variation of the number of cases resulting in a formal judgement. In particular, the ratio of judgement to cases received is much smaller in South Africa (210/2628) and Egypt (20/705) compared to Pakistan (100/500) and Poland (224/461).

Discussion

Unfortunately, we were only able to retrieve data on the flow and quantity of FTP procedures for a limited set of countries. This in itself is interesting, as one would expect regulators would maintain and publish records on matters such as disciplinary procedures. The figures available reveal an important point – the chance of a formal judgment after a complaint has been received can vary greatly.

13.6 Medical education

13.6.1 Regulation and quality assurance

Findings

All countries examined here have some structures in place to regulate and/or quality assure medical education. However, the bodies responsible for these functions vary from country to country. While in some (India, South Africa, Pakistan) the formal regulation of medical education is primarily the remit of the medical regulatory body, in others responsibilities are shared between medical councils, local authorities, and ministries or health and/or education (Spain, Poland, Germany, Egypt, Greece). Regulatory and quality assurance activities in these countries included: setting of curricula, administering entry exams, issuing degrees, conducting inspections of and issuing accreditations to medical schools, and other duties.

The evolution of medical education regulation and quality assurance is at different stages in some of the countries, and faces different challenges. In Pakistan, for example, one of the key concerns regarding the regulation of medical education is that many new private medical schools were started by professionals who are members of the regulatory body, thus compromising the transparency and reliability of regulatory and quality assurance processes. In Egypt, there are growing calls – including from international bodies such as the WHO – to centralise some of the functions of medical education regulation, such as the setting of curricula which is still the preserve of individual medical schools.

Discussion

The regulation and quality assurance of medical education appeared to be a relatively uncontroversial issue in most of the countries. With the notable exceptions of Pakistan and Egypt, which face distinct challenges in this area, in other countries the regulation and quality assurance of medical education did not seem to raise particular concerns. It is apparent from our research that the countries examined here have different approaches towards the regulation and quality assurance of medical education but, unlike other areas of medical regulation, there is little sense of growing international convergence in this area, or of a need for such convergence.

13.6.2 Funding

Findings

In most of the countries in this study, medical education is financed primarily by the state, although in some, students are required to pay for some form of tuition (students in some *Länder* in Germany; students at schools providing medical education taught in English in Poland; some students in South Africa).

In a small number of countries, most notably Pakistan and to a lesser extent Egypt, private medical schools pose somewhat of a challenge for regulation and quality assurance. While private medical schools do not typically receive any public funds (and are primarily funded through tuition fees), the regulation of their standards and quality is a matter of public interest and concerns about the ability of statutory bodies to do this effectively are prevalent.

Discussion

The data on funding for medical education in the ten countries examined here is at best patchy. There is limited information on issues that could be of interest to the GMC, such as the cost per student of medical education, or the cost of the regulation of medical education and how this is met. In light of this, it is difficult to assess the impact of medical education *funding* on medical education *regulation*. Nevertheless, the research shed light on one particular challenge facing some of the countries studied, namely the issue of the regulation and quality assurance of private medical schools.

13.6.3 Education trajectory

Findings

While there is some variation across the countries examined here, the general characteristics of the trajectory of medical students are broadly similar. In all countries, *undergraduate* medical education consists of both academic and practical training, with the amount and time of initiation of clinical practice training during the undergraduate years being the element that varies the most. For example, in some countries, such as Germany and Spain, students embark on clinical practice training, based in hospital, between the 3rd and 5th years of education. In most others, clinical practice training takes place only towards the 6th year. In all countries students have to complete work placements/internships/rotations in hospitals, which are often one year in length (plus two years of community service in South Africa), as one of the final requirements of their

degrees. The length of *specialisation* also varies across the different countries (and disciplines), ranging from between 2-6 years.

The above indicates that in all the countries we examined, medical students are exposed to clinical practice and the healthcare system (primarily through internships and rotations in hospitals) at some stage during their training. The extent of this, of course, varies from country to country. Germany is a notable example of a medical education system that exposes its students to the healthcare system at various stages and in different ways: in addition to the compulsory work placements at the end of the undergraduate training, medical students have to complete a four-month internship between the 3rd and 5th years, and a three-month nursing internship either prior to or in the first two years of their medical training. In Egypt, on the other hand, there is a drive towards a reform of the medical education curriculum that would give a much stronger community focus, and experience in providing clinical care from an earlier stage in medical education, although questions remain about the medical schools' ability to implement and deliver these reforms.

In terms of CPD, in most countries this is part of the medical code of practice, but the organisations that promote CPD vary from country to country. In Spain and Germany, for example, CPD is one of the main areas of activity of the provincial medical colleges, or the regional chamber of doctors, which often provide training courses and related services. In others, such as South Africa, standards and the promotion of CPD is done primarily by the central medical council/organisation, which randomly audits about 10% of all doctors every year to check on their compliance with the South African CPD requirements. However, other bodies such as ministries and scientific societies are also involved. In Egypt, the regulation or promotion of CPD is rudimentary although talks of a system of CPD are quite advanced. The proposed system, administered by the MoHP, would be based on credits, to be accumulated year-on-year, to ensure that training is kept up to date. There are concerns, however, regarding the country's capacity to implement such a system in practice.

Discussion

In spite of some variation, the formal structure of undergraduate and specialist medical education in these countries is relatively similar overall. The main differences are likely to reside in the resources (material, financial and human) available for medical education in each of these countries, but this was beyond the scope of the present study. An interesting question to emerge is the extent to which the differences in the education trajectories, and in particular the ways in which medical students are exposed to clinical practice and to the healthcare system, shapes their understanding of and relationship with the regulation of the medical profession. As with many other aspects of doctors' experiences of medical regulation throughout their careers in the different countries examined here, this question would need to be explored through research looking at doctors' perceptions directly.

However, it is worth noting that in a number of the countries examined here (most notably South Africa and India, but also Spain), there is ongoing debate about the way in which medical education should be reformed in order to better prepare doctors to practise, or to adjust to the current situation in that particular country (for example in South Africa where there is a growing focus on community-based medicine and changing clinical

exposure due to the increasing prevalence of HIV). To the extent that the medical regulator in these different countries has a remit in setting the curriculum or assessing the quality of medical education, they will be involved in this debate.

The divergence in the CPD systems in the ten countries in this report is also of great interest. This issue appears to be increasing in importance on the policy agenda in many countries. Our research suggests that the extent to which CPD is rooted within the regulatory structures of the medical field varies significantly between the countries examined. South Africa is a notable case in which the debate on CPD is highly advanced and systems to ensure CPD among professionals have been developed and implemented. While the implications of this are uncertain, it is possible that the prominence of CPD in the different countries to some extent shapes doctors' perceptions of and attitudes towards it.

13.6.4 Examinations and qualifications

Findings
There is variability in the examination requirements of medical degrees in the other countries examined in this report. Entry to medical school is broadly divided into two main categories: it is either determined by school leaving averages (Egypt, Pakistan, South Africa), or by specific university entry exams (Spain, Italy, India). In Poland some schools apply a mixture of both systems. In South Africa, other requirements also influence admissions to medical schools, for example knowledge of an African language and English as a second language.

There is slightly more variability in terms of exit exams from undergraduate training, and admissions/exit exams for specialist education. For example in Spain, South Africa, Poland, Italy and Germany, students take exams marking the end of their undergraduate training, in addition to exams at the end of their specialist education. These exams include theory and practice components in some countries (Italy and South Africa), or only theory – mostly multiple choice questions - with no practical element (MIR, the exam to enter specialist medical education in Spain). The undergraduate exit exam in South Africa also explicitly includes an ethics component. In Egypt, even though exams marking the end of undergraduate medical education should include a theory *and* a practice element, limited resources means that currently the practice element in assessments is minimal.

Discussion
The issue of how different regulatory jurisdictions examine medical students and graduates is interesting in that it sheds light on other approaches in assessing the skills students gain. Of particular interest to the GMC could be the nature of examinations in EU countries. This is because according to EU regulations, medical graduates from within the region can practise in any other EU country without having to undergo admission examinations or tests. Evidence on the way in which their skills are assessed during their education in their country of origin can help the GMC understand more about their training and readiness to practise medicine once out of medical school.

A number of the countries in this study appear to be moving towards more concerted efforts to effectively test the clinical practice skills of medical students during

undergraduate and specialist medical education. This is true not only in non-EU countries such as Egypt and South Africa, but also in EU member states, most notably Spain.

CHAPTER 14 **Conclusions and recommendations**

In the previous chapters we discussed a broad range of aspects of medical regulation for each of the ten countries, and analysed similarities and differences. Due to limitations of the data it was not always possible to compare all countries across all aspects. Nonetheless, for most of the issues examined in this study we were able to make comparisons across at least the majority of countries. This chapter summarises some of the key messages to emerge from the cross-country comparative analysis.

It is important to note that our analysis only relates to the ten countries included in this study. Therefore it would not be appropriate to generalise the conclusions that follow to medical regulation across the world.

1. In many countries medical regulation is a shared responsibility between a number of bodies, most notably regulators, ministries of health and education and professional bodies. Scientific colleges, medical schools, the judicial system and others also play a role in medical regulation in the countries included in this study.

2. The extent to which regulation is decentralised tends to reflect the extent to which state authority as a whole has been devolved.

3. There are a core set of regulatory processes which are part of the remit of all medical regulators (with few exceptions). These functions include: registering/licensing medical practitioners; setting standards for the profession; promoting best practice and patient safety; promoting Continuous Professional Development (CPD); contributing to the regulation of medical education.

4. The values of medical regulation found across the ten countries can be grouped into three clusters: those which are patient-focused, those which focus on scientific knowledge, and those which focus on the welfare/interests of medical professionals. These values are typically worded in aspirational rather than procedural terms.

5. Very little information is available on the costs of medical regulation. Funding typically comes from the state, from medical associations, medical schools, and individual doctors and complainants. Similarly, little is known about the implications of different types and quantity of funding and resources available to medical regulation processes and structures.

6. All the surveyed countries have a code of medical ethics. The code of medical ethics typically originates with the national medical association. For all but one

(Nigeria) we could not find evidence that periodic review was required. It appears the involvement of the public in the development of the code is very low;

7. It is unclear for most countries the extent to which medical professionals are aware of and familiar with their respective codes of ethics. Only for South Africa could we find evidence that the regulator places great emphasis in fully embedding ethics and standards in doctors' everyday practice.

8. All countries have formal processes to deal with doctors about whom there are fitness to practise (FTP) concerns, although the terminology used to describe these situations, and the exact processes in place, can differ substantially. The outcomes of such processes typically include admonitions, temporary suspension, or removal from the register. For about half of the countries, evidence on the number of FTP complaints, procedures and judgments was not easily obtainable. Where this information was available, it showed large variations. In particular, the chance of receiving a judgment after a complaint has been filed can differ greatly.

9. Registration is mandatory in all countries before doctors can start to practise. Only in a few autonomous regions in Spain was registration not mandatory. In most countries there is no separation between registration and licensing, except for Germany, Egypt and Italy. There appears to be substantial variation in the degree of centralisation of the registration process, and the duration of the registration (in some countries registration is automatically for life, in others it is not). Little is known about the (annual or total) number of registered / licensed doctors.

10. There appears to be a core set of requirements for registration/licensing across all countries, including being a citizen of that country, having completed a medical degree, being in good health and good professional standing, and payment of a registration fee.

11. Revalidation is mostly non-existent across the ten countries, with Poland and India as exceptions. In some countries there is substantial interest in the development of the revalidation process.

12. Responsibility for quality assuring medical education differs across countries, sometimes it is the sole responsibility of the medical council, sometimes it is shared with other bodies. In some countries the regulation of private medical schools is a concern.

14.1 Implications for the GMC

This report provides a wealth of information on medical regulation in ten different jurisdictions. As highlighted in the introduction to the report, this information aims to contribute to an evidence base to inform GMC policy and practice. It may help frame and inform approaches to dealing with some of the more salient challenges facing the GMC when dealing with non-UK qualified doctors.

For example, improvements in communication with other regulators could be beneficial. At present the GMC may not know if a doctor who applies to practise in the UK has

previously been removed from a register overseas. However, improved communication with other regulators is a necessary but probably not sufficient condition for effective information flows. The fact is that a number of jurisdictions simply do not have central or comprehensive data about registered doctors. Awareness of such facts may assist the GMC to tailor its communication with specific regulators.

More challenging for the GMC is the issue of how medical practitioners make the transition from their own jurisdictions into the UK regulatory system, and the processes of adjustment they undergo. How can the GMC facilitate this? One way could be to engage non-UK qualified doctors more actively in understanding, and adopting, the GMC's standards and codes of ethics and practice. According to our research, in many of the countries examined the primary focus of the regulator is not the patient and the quality of care but the interests/welfare of the professional; patient interests are often referred to in a rather general fashion which in turn may only provide doctors with the most general form of guidance. It would seem important, therefore, that newly-arrived doctors are made aware of the *detail* of what a patient-centred approach means and what it therefore implies for everyday medical practice.

Similarly, differences were found in the emphasis placed on "soft" skills, such as communication with patients during and after a doctor's training. Our research indicates that countries, with perhaps the notable exception of South Africa, have an uneven record of focusing on the soft skills of medical practitioners. This raises the issue of how best to ensure incoming doctors understand UK standards relating to good communication and behaviour, and how such lessons are reinforced.

Some issues and debates that have occupied the GMC may be only just emerging in some countries, if at all. For example, our research indicates revalidation processes are in place in only a few countries. The new regulations around licensing and revalidation that will come into place shortly in the UK will be new to many incoming doctors.

These examples provide an indication of the way in which the information presented in this report may be used to assist with policy and practice development.

14.2 Recommendations for further research

1. Extending the coverage. Our analysis and findings raise a number of questions that could be explored in future research. First, the typology developed for this study can be used as a starting point for characterising medical regulatory systems in a larger set of countries. Expanding the set of countries could enable the GMC to develop a better and broader understanding of international approaches to medical regulation.

2. Focussing on an area of regulation. As this study was to some extent of an exploratory nature, this report used a very wide definition of medical regulation, including several areas of regulation, such as:

    - Licensing regulation;

    - FTP regulation;

- Regulation of professional ethics and standards;

- Implementation of medical regulation;

- Elements of patient safety regulation.

These regulations are often implemented through different institutional arrangements. To achieve a deeper understanding, further research could focus on one of these areas only.

3. Perceptions of regulation. Important work remains to be done to better capture the attitudes and perceptions of medical professionals trained abroad towards medical regulation both in the ten countries we examined (and any others of interest to the GMC) and within the UK itself. This would provide insights into the values and role of medical regulation overseas and the way that experience of overseas regimes informs attitudes towards the UK regulatory system. This study provides an overview of the stated values of ten medical regulatory systems. Attitudes and perceptions of doctors were outside the scope of the research.

4. Medical regulation systems – confidence levels. The current study, as specified, is primarily descriptive. Follow-on research might usefully examine the relationship of process to outcomes. For example, it may be feasible to construct a set of explicit indicators or a "medical regulation index" (similar to the World Bank's Worldwide Governance Indicators Project[163]), which could be used to estimate "confidence" levels in the different medical regulatory systems. These indicators could be developed from both desk based research on, for example data on medical errors, and from field research, such as the attitudes of doctors to regulation, public trust in both doctors and the regulatory system, and so on.

5. Regulatory learning. An important area for further research would be to identify best practice in medical regulation in the UK and abroad, and whether and how best practice lessons can be transferred from one system to another. The question of the transferability of lessons is a particularly interesting one; while our own analysis suggests that there is some degree of convergence in the direction in which medical regulation is evolving in the ten countries examined, it also indicates that the challenges facing medical regulation in these countries can be quite distinct.

6. Velocity and trajectory of medical regulatory system development. We found that rates of development of medical regulation vary. Going forward it may be useful to capture the rates of change and the trajectory to feed into the development of the GMC knowledge base on the regulation of IMG and UK trained doctors.

7. Relating FTP issues to medical regulatory systems. Finally, our research could be complemented by a detailed study of FTP cases from a sample of both UK and non-UK qualified medical graduates, examining the extent to which characteristics of these cases can be mapped onto, or associated with, characteristics of medical regulation in a doctor's country of origin.

---

[163] See: http://info.worldbank.org/governance/wgi/index.asp

REFERENCES

Reference List

Ali, I. (2008) "PMDC penalises 500 doctors", *The News*, 21 December 2008. http://www.thenews.com.pk/daily_detail.asp?id=152953

Bourassa Forcier, M., Simoens, S. and A. Giuffrida (2004) "Impact, regulations and health policy implications of physician migration in OECD countries", *Human Resources for Health*, 2004, 2:12.

Buchan, J. (2006) 'Migration of health workers in Europe: policy problem or policy solution?' [in:] Dubois, C. A., McKee, M., Nolte, E. (eds.): 'Human resources for health in Europe' [in:] *European Observatory on Health Systems and Policies Series*, Maidenhead, New York: Open University Press.

Carpenter, M. (2003) "On the Edge: The Fate of Progressive Modernization in Greek Health Policy", *International Political Science Review* Vol. 24, No. 2, 257–272.

Chaloff, J. (2008) Mismatch in the formal sector, expansion of the informal sector: immigration of health professionals to Italy, OECD Health Working Paper No. 34.

Department of Health (2004) *Code of practice for NHS employers involved in international recruitment of healthcare professionals*, London, p. 7.

El-Feky, A (2006), 'Advancing accreditation through strengthening the educational infrastructure', *ASJOG 3*, 26-8.

El-Nahhas, M. (2002) "The doctors' dilemma", *Al Ahram Weekly*, 20th-26th June 2002. Online at: http://weekly.ahram.org.eg/2002/591/feat2.htm (last accessed January 2009).

France, G. and F. Taroni (2005) "The Evolution of Health-Policy Making in Italy", *Journal of Health Politics, Policy and Law*, Vol. 30, Nos. 1–2, p. 169-187.

Garcia-Perez, M. A., Amaya, C. and A. Otero (2007) "Physicians' migration in Europe: an overview of the current situation", *BMC Health Services Research* 2007, 7: 201.

Johnson, J. (2004) Speech of the chairman of Council of the BMA, 28 June 2004, London: British Medical Association. Available from http://www.bma.org.uk/ap.nsf/Content/ARM04chCouncil>. Last assessed 3rd, April 2008.

Kofman, "The state, skilled labour markets, and immigration: the case of doctors in England", *Environment and Planning A*, 2002, v. 34, pp. 2071-2089.

Medical and Dental Council of Nigeria (2004) *Rules of Professional Conduct for Medical and Dental Practitioners*. Lagos: Medical and Dental Council of Nigeria, 2004.

Medical and Dental Council of Nigeria (2006) *The Red Book: Guidelines on the Minimum Standards of Medical and Dental Education in Nigeria*. Revised edition. Abuja: Medical and Dental Council of Nigeria, 2006.

Merakou K. and E. Tragakes (1999) "Development of Patients' Rights Legislation", European Journal of Health Law, Volume 6, Number 1, 1999 , pp. 71-81(11).

Ministerstwo Zdrowia (Ministry of Health) (2007) „Monitorowanie migracji polskich lekarzy, pielęgniarek i położnych po przystąpieniu polski do Unii Europejskiej" (Monitoring of the migration of Polish doctors, nurses and midwifes after the EU accession). Available from www.mz.gov.pl

MWSAC (1997) "Planning the medical workforce'', third report, Medical Workforce Standing Advisory Committee, <www.doh.gov.uk/medical/mwsca3.htm>, in: Raghuram, P. and E.

Ncayiyana, D.J. (2000) "The Changing Profile of Medical Education in South Africa", student BMJ, September 2000. (http://student.bmj.com/back_issues/0900/editorials/306.html).

Nikolentzos, A. and N. Mays (2008) "Can existing theories of health care reform explain the Greek case (1983-2001)?", *Journal of European Social Policy* 2008; 18(2); 163-176.

"Quackdown. India's face doctors" (2008) *The Economist*, 21st February 2008.

http://www.economist.com/world/asia/displaystory.cfm?story_id=10727817 (last accessed December 2008).

Piccolo, S. (2008) "La difficile integrazione dei medici stranieri", *M.D. Medicinae Doctor -* Year XV Number 8, p. 14 (available at: http://www.passonieditore.it/md/08/Riflettori.pdf, last accessed November 2008).

Raghuram, P. and E. Kofman, "The state, skilled labour markets, and immigration: the case of doctors in England", *Environment and Planning A*, 2002, v. 34, pp. 2071-2089.

"Report on quackery submitted in LHC" (2007) *Daily Times*, Islamabad, 25 July 2007 www.dailytimes.com.pk/default.asp?page=2007%5C07%5C25%5Cstory_25-7-2007_pg7_38 (last accessed October 2008).

Rowe, A. and M. García-Barbero (2005) *Regulation and licensing of physicians in the WHO European Region*, Division of Country Support of the WHO Regional Office for Europe (available at: http://www.euro.who.int/document/e87789.pdf , last accessed December 2008).

Sharma, D.K. (2003) "9,465 quacks in Punjab, shows survey", The times of India, 14th May 2003.

http://timesofindia.indiatimes.com/articleshow/46302273.cms (last accessed December 2008).

Sood, R. and Adkoli, BV (2000) "Medical education in India – problems and prospects", *Journal Indian Academy of Clinical Medicine* 1:3.

Wiskow, C. (2006) *Health worker migration flows in Europe: Overview and case studies in selected CEE countries – Romania, Czech Republic, Serbia and Croatia*, International Labour Office, Geneva.

World Health Organization (1996) *Health Care System in transition: Greece*, WHO, Regional Office for Europe, Copenhagen. www.euro.who.int/document/e72454.pdf (last accessed January 2009).

World Health Organisation (2006) *Health Worker Migration in the European Region: Country Case Studies and Policy Implications*, WHO, Regional Office for Europe, Copenhagen.

World Health Organization (2006) *Health System Observatory: Egypt*. WHO EMRO report Online at: http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Health%20system%20 reform.pdf (accessed October 2008).

World Health Organization (2006) *Health Systems profiles: Egypt*, WHO: Regional Health Systems Observatory – EMRO.

http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Human%20resources.pdf (accessed October 2008).

Websites

Berlin chamber of doctors: http://www.aekb.de/35_Recht/08_Berufsrechtliches/05_BODurchs.html

McKimm J. and C. Jollie (2004) Faculdade de Ciências Médicas, Portugal, May 2004 (http://www.fcm.unl.pt/investigacao/pedagogia/FCMUNL%

20Lit%20review%20South%20Africa%2027%20May%2004.pdf);

Greek Orthodontic Society www.grortho.gr

"Guideline for Postgraduate" www.pmdc.org.pk/post.doc (last accessed October 2008).

Hellenic Dental Association www.eoo.gr

HPCSA website; Medical Education and Training in South Africa:

Extract from international overview of medical education and training prepared as part of national Preparation for Practice project led by Universidade Nova de Lisboa.

Institute for Medical Exam Questions www.impp.de

Law 44/2003 of 21 November of regulation of the health professions (available at:

http://noticias.juridicas.com/base_datos/Admin/l44-2003.html, last accessed November 2008).

Medical and Dental Council of Nigeria (MDCN): www.mdcnigeria.org (accessed January 2009).

"Medical and Dental Council Regulations, 2007" (www.pmdc.org.pk/reg2007.pdf, last accessed October 2008).

Medical and Dental Practitioners Act CAP M8 2004 under the Laws of the Federation of Nigeria. Available at www.mdcnigeria.org; West African College of Surgeons (WACS): www.wacs-coac.org (accessed January 2009).

Medical Code of Ethics (in Greek): http://www.mohaw.gr/ministry/nomothesia/kdikas-iatriksdeontologias/

files/K-MEDCODE-PAP-1.pdf (last accessed January 2009).

http://www.mz.gov.pl/wwwmzold/index?mr=m0&ms=&ml=en&mi=535&mx=0&mt=&my=464&ma=5168, last accessed October 2008).

Ministry of Education at http://www.ypepth.gr/docs/90__epityxontes_080828.xls (last accessed January 2009).

Ministry of Health (2006) Royal Decree 757/2006 (available at:

http://www.cgcom.org/sites/default/files/06_06_31_estatutos_boe_0.pdf last accessed November 2008).

Nigerian Medical Association (NMA): www.nigeriannma.org/index.htm (accessed January 2009).

"Pakistan's health sector: does corruption lurk?" (Section 3.5)

http://www.u4.no/training/incountry-open/pakistan-materials/health-sector-corruption-pakistan.pdf

"Pakistan Registration of Medical & Dental Practitioners Regulation 2008", pp. 5-7.

(www.pmdc.org.pk/registration.pdf, last accessed October 2008).

"PMDC Code of Ethics for Medical and Dental Practitioners", 2001 (www.pmdc.org.pk/ethics.htm, last accessed October 2008).

"PMDC Ordinance Act 1962", p. 672 (www.pmdc.org.pk/pmdcord.pdf, last accessed October 2008).

Regulation Instructions for Registration Examination of Foreign Medical Graduates

www.pmdc.org.pk/mden.doc (last accessed October 2008)

Siddiqui, Z.S. "Continuous Professional Development of Medical Doctors in

Pakistan: Practices, motivation and barriers." (www.aare.edu.au/07pap/sid07623.pdf, last accessed October 2008).

http://student.bmj.com/back_issues/1001/life/384.html (accessed October 2008).

http://www.qaap.net/about_us.htm (accessed October 2008)

http://www.qaap.net/about_us.htm (accessed October 2008).

http://www.norddeutsche-schlichtungsstelle.de

http://www.norddeutsche-schlichtungsstelle.de

www.zvs.de

http://www.pis.gr/medassociations/index.html (last accessed January 2009).

www.enet.gr/online/online_print?id=96109740 (last accessed January 2009).

http://www.isth.gr/?page=2628 (last accessed January 2009).

http://mciindia.org/know/mci/mci_activities.htm (last accessed November 2008).

http://mciindia.org/helpdesk/how_to_start/inspection_fees.htm (last accessed January 2009).

http://mciindia.org/tools/ann_reports/index.htm (last accessed December 2008).

http://mciindia.org/know/rules/rules_mbbs.htm (last accessed December 2008).

http://timesofindia.com/articleshow/2279230.cms (accessed November 2008).

http://www.ministerosalute.it/dettaglio/pdPrimoPianoNew.jsp?id=3&sub=1&lang=it (last accessed November 2008).

http://www.assomedici.it/assopazienti.htm (last accessed November 2008).

http://www.mdcnigeria.org/Downloads/Cap%20M8.pdf (accessed January 2009).

http://www.mdcnigeria.org/Downloads/Copy%20of%20Guideline%20on%20minimum %20standard-Red%20book.pdf (accessed January 2009).

www.mdcnigeria.org (accessed January 2009).

www.nigeriannma.org/index.htm; www.mdcnigeria.org (accessed January 2009).

http://www.mdcnigeria.org/mandateframe.htm (accessed January 2009).

www.pmdc.org.pk/what_it_does.htm (last accessed October 2008).

www.pmdc.org.pk/how_it_works.htm (last accessed October 2008).

www.pakistan.gov.pk/divisions/health-division/media/FAQ_PMDC.doc (last accessed October 2008).

www.pmdc.org.pk/stat.htm (last accessed October 2008).

www.pmdc.org.pk/what_it_does.htm (last accessed October 2008).

www.pmdc.org.pk/regulation_mbbs.htm (last accessed October 2008).

www.pakistan.gov.pk/divisions/health-division/media/FAQ_PMDC.doc (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/history

http://www.nil.org.pl/xml/nil/wladze/nil_eng/policy

http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_chamb (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/aims (last accessed October 2008).

http://www.nfz.gov.pl/new/index.php?katnr=2&dzialnr=5&artnr=89 (last accessed October 2008).

http://www.bpp.waw.pl/ (last accessed October 2008).

http://www.prawapacjenta.eu/index.php?pId=1366

http://www.nil.org.pl/xml/nil/wladze/str_sad/odpzawod and
http://www.nil.org.pl/xml/nil/wladze/str_sad/odpzawoden (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat_porownan_00_04_en

http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2005_1inst,

http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2006_1inst, and

http://www.nil.org.pl/xml/nil/wladze/str_sad/statystyki/stat2007_1inst (last accessed
October 2008).

http://www.nil.org.pl/xml/nil/rejlek/informacje (last accessed October 2008).

http://www.portalmed.pl/xml/prawo/medycyna/medycyna/r2001/011801u (last accessed
October 2008).

http://www.nil.org.pl/xml/nil/rejlek/hurtd (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/rights (last accessed October 2008).

http://www.portalmed.pl/xml/prawo/medycyna/medycyna/r2001/011801u (last accessed
October 2008).

http://www.nil.org.pl/xml/nil/tematy/komisje/0609/ksztalc (last accessed October 2008).

http://www.abc.com.pl/serwis/du/2004/2326.htm (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/str_zl/zjazd7/kel (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/rights (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_code (last accessed October 2008).

http://www.nil.org.pl/xml/nil/wladze/nil_eng/med_code (last accessed October 2008).

http://www.rgsw.edu.pl/files/active/0/lekarski20070210.pdf (last accessed October 2008).

http://www.rgsw.edu.pl/files/active/0/lekarski20070210.pdf (last accessed October 2008).

http://www.cem.edu.pl/ (last accessed October 2008).

http://www.cem.edu.pl/ (last accessed October 2008).

http://www.medaccred.edu.pl/statut.php?w=a (last accessed October 2008).

http://www.medaccred.edu.pl/proces.php?w=a (last accessed October 2008).

http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

http://www.hpcsa.co.za/hpcsa/default.aspx (last accessed November 2008).

http://www.cgcom.org/cgcom/funciones (last accessed November 2008).

http://noticias.juridicas.com/base_datos/Admin/l44-2003.html (last accessed November
2008).

http://www.fisterra.com/recursos_Web/no_explor/sociedades.asp#Medicina%20Intensiva (last accessed November 2008).

http://www.cgcom.org/noticias/2007/10/07_10_24_deontologica (last accessed November 2008)

APPENDICES

Appendix A: Typology

Structure and nature of regulation and regulatory body(ies)

- o *Purpose of medical regulation*
    - ▪ Stated purpose
    - ▪ Drivers and influential events
- o *Values within medical regulation*
    - ▪ Perceived definition of excellence in medical regulation
    - ▪ Extent to which medical regulation is risk-based
    - ▪ Extent to which regulations aims at pro-actively educating doctors or re-actively imposing disciplinary action
    - ▪ Extent of concern with race, ethnicity, religion, disability, age and gender
    - ▪ Extent of patient involvement
- o *Funding arrangements*
    - ▪ Combined annual budget of medical regulatory bodies (absolute)
    - ▪ Payers
- o *Interaction between different regulatory bodies*
    - ▪ Organizations involved in medical regulation, their tasks and status (i.e. government / semi-government / private)
    - ▪ Nature of relation between different regulatory bodies
    - ▪ Extent to which regional regulators are conditioned by national regulator
    - ▪ Extent of overlap in functions/objectives between different regulatory bodies
    - ▪ Extent to which medical council represents doctors professionally

Medical education

- o *Regulation*

- - Governance/regulation of medical education through medically oriented regulators
    - Governance/regulation of medical education through educationally oriented regulators
  - *Quality assurance*
    - Inspection (type of inspection, which regulator, how often)
    - Extent to which quality standards for medical education are explicit and public
    - Penalties and implications of violations of minimum quality levels
  - *Funding*
    - Payers
    - Annual total cost of medical education
    - Annual total cost of regulation of medical education
  - *Education trajectory*
    - Different stages in education (e.g. under- and postgraduate)
    - Average length (years) to complete each stage
    - Point at which doctors specialise
    - Extent to which education is embedded in healthcare system
    - Extent to which medical students are allowed to train overseas (if allowed: % of medical students training overseas)
  - *Examination and qualification*
    - Entry requirements for each of the stages
    - Pass/fail %ages at the end of each stage
    - Extent to which communication skills and behaviour are tested
    - Extent of language testing (in particular, English language)
    - Nature of examination (knowledge reproduction, problem solving, practical skills)

Standards & ethics

- - *Content*
    - Main pillars of standards
    - Values underlying the standards
  - *Legal basis for standards and process*
    - Ways in which standards are assessed

- Extent to which doctors actively seek guidance on their expected performance
- Ways in which guidance is kept up-to-date (i.e. through public consultation or as a "closed" process)

o *Actors involved*

- Extent of involvement of regulator(s)
- Extent of involvement of patients
- Extent of involvement of general public
- Existence of (internal) committee to oversee standards
- Ways of communication of standard to doctors (e.g. implied, taught, send out by mail)

o *Linkages*

- Extent to which standards receive attention in medical education curriculum
- How standards connect to FTP process
- Extent to which standards are in the public domain
- Extent to which standards are used outside directly medical regulation

Fitness to practise (FTP) and related disciplinary procedures and sanctions

o *Content / substantive characteristics*

- Objective of FTP (e.g. deterrence or education/persuasion)
- Naming / definition of FTP
- FTP minimum standards / requirements
- Relation of FTP standards to civil/criminal law
- Procedures to verify FTP
- Nature/type of possible sanctions if minimum requirements are not met

o *Flow / quantity of FTP procedures*

- Type of complaints
- Characteristics of procedure for investigating complaints
- Annual number of complaints
- Annual number of complaints that are dismissed vs. followed up
- Annual number of complaints leading to panel hearings
- Annual number of complaints leading to disciplinary action

- Annual number of doctors struck off the register

- Average length (duration) of hearings

  o *Characteristics of staff (within the regulator) dealing with FTP procedures*

    - Constitution of panels

    - Extent of representation of lay members (i.e. non-doctors) on panels

    - Extent of involvement of lawyers

  o *Involvement and role of external actors*

    - Source of complaints (e.g. other doctors, patients, hospitals, police, breakdown in %)

    - Extent of involvement of external experts

    - Extent of monitoring doctor behaviour / performance by hospitals

    - Interaction between regulator and hospital

  o *Position / attitude of doctors*

    - Extent to which doctors can practise during period of investigation

    - Extent to which attitude of doctor (e.g. defensive / cooperative) during investigation determines panel decisions

    - Extent of trust from doctors towards regulator and acceptance of outcomes of investigation

    - Degree to which outcomes of investigation are public

Registration process and requirements

  o *Registration and licensing process*

    - Extent of differentiation between licensing and registration

    - Extent of differentiation between types/classes of registration

    - Initiation of registration (e.g. automatic during/after education)

    - Constraints imposed by supranational bodies

    - Constraints imposed by legislation outside medical regulation (e.g. privacy laws)

    - Process of re-registration

    - Possibility and process of appeal against rejection of registration

  o *Flow and quantity of applications*

    - Total annual number of applications

- - Annual number of applications that require above-average investigation/scrutiny

    - Annual number of rejected applications and most common reasons for rejection

    - Annual number of fraudulent applications

    - Total number of medical professionals currently on the register

    - %age of applications from doctors trained in other countries

  - *Interaction between regulator and medical professionals*

    - Extent to which applicants from different countries/origin are treated differently from national applicants

    - Procedures/materials to verify applicant identity and credentials

    - Mode of registration (on-line, written, physical appearance)

Revalidation / competence assurance / recertification

- *Purpose*

  - Extent of involvement with quality improvement

- *Assessment process*

  - Characteristics of process

  - Tools used to assess performance

  - Evidence required for revalidation

  - Extent to which revalidation applies to all doctors or is limited to certain groups

  - Procedures to assess integrity of evidence

  - Consequences for doctors not meeting revalidation requirements (e.g. impact on registration)

- *Actors*

  - Extent of involvement of professions own representative bodies

  - Extent of involvement of employers (e.g. hospitals)

  - Extent of reliance on self-reporting