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TECHNICAL REPORT

International Comparison of Ten Medical Regulatory Systems

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

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Prepared for the UK General Medical Council

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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 below¹:

- 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 an 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 of 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.