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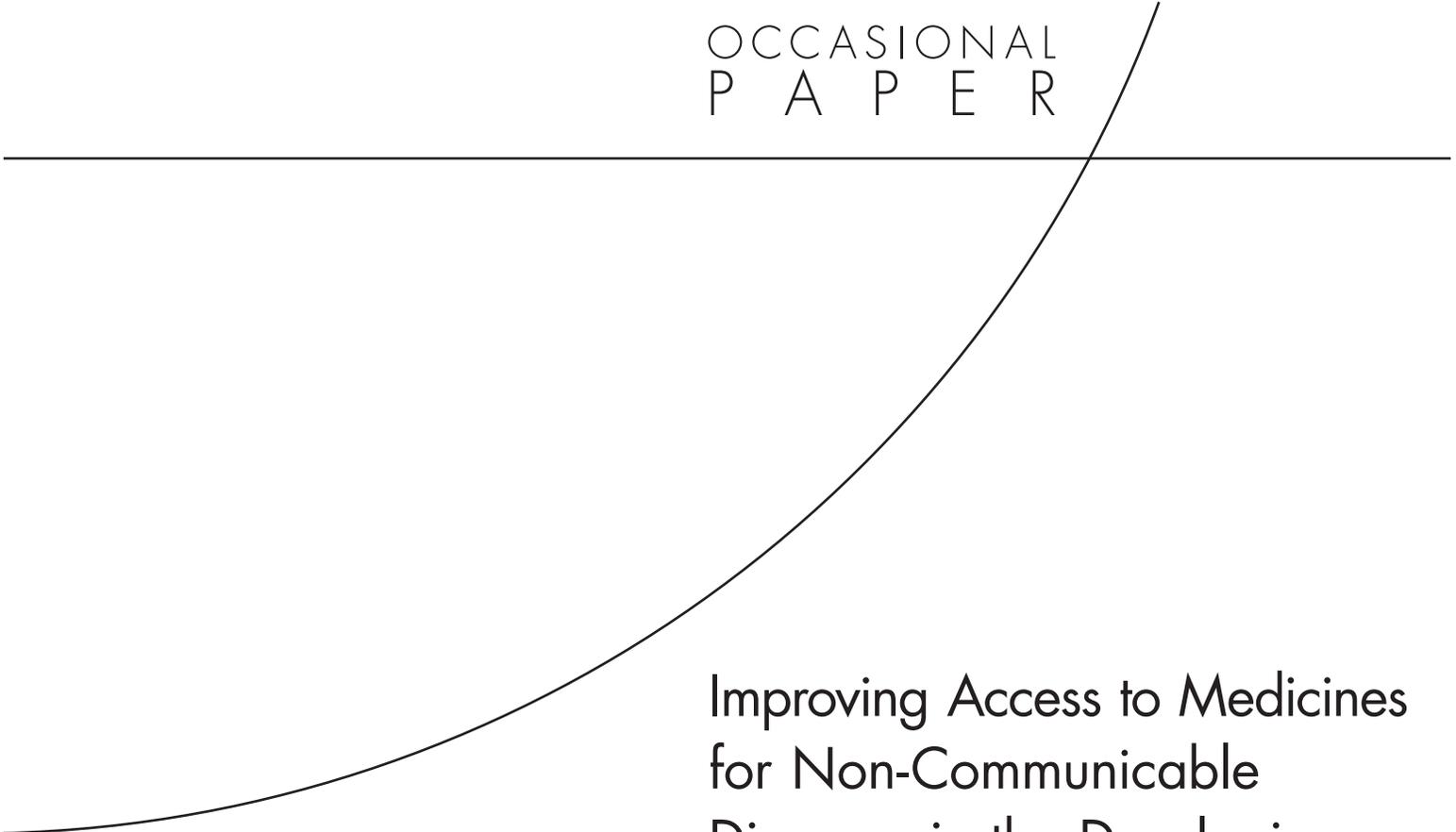
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OCCASIONAL
P A P E R



Improving Access to Medicines for Non-Communicable Diseases in the Developing World

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Summary

Non-communicable diseases (NCDs) now account for the lion's share of global morbidity and mortality. Much of the burden is falling on developing countries, whose relatively recent adoption of Western-style health behaviors and lifestyle choices has led to increased prevalence of risk factors for NCDs. At the same time, developing countries also hold the greatest burden of infectious disease, and the rapid increase of NCDs has left countries with under-resourced health care systems to deal with a double burden.

Spurred by growing attention to the global devastation caused by NCDs, the United Nations (UN) General Assembly will hold a high-level meeting on non-communicable diseases on September 19 and 20, 2011, to “set a new global agenda” on NCDs.

Scope and Purpose of This Paper

In connection with the upcoming meeting, this paper is a first step toward developing a policy research agenda, on behalf of the research-based pharmaceutical industry, on how to improve access to NCD medicines in developing countries. This paper is to serve as the basis for further stakeholder consultation, the objective of which is to finalize a policy research program that will be executed by the research-based pharmaceutical industry in close collaboration with other stakeholders.

Given this purpose, the paper focuses narrowly on improving access to medicines, even though health promotion and disease prevention must play a key role in reducing the NCD burden. Because NCDs are not entirely preventable and reversing lifestyle trends and their impact on population health will take time, adequate access to NCD medicines remains essential for mitigating the negative impact of NCDs. This paper also focuses on ideas and innovations that leverage core industry capabilities that, when developed and implemented in partnership with other stakeholders, will improve access to medicines within the constraints that developing countries face today, as opposed to those that would require fundamental systems change and/or economic development.

A Framework for Understanding Obstacles to NCD Medicine Access

Obstacles to access to NCD medicines can arise at and need to be addressed at multiple levels, and understanding the continuum of obstacles is important to developing a coherent policy research agenda. For this purpose, we are proposing a conceptual framework that lays out five

categories of obstacles to NCD medicine access (see Figure S.1). We use this framework to organize evidence for the relative importance of the five categories and to identify promising ideas to overcome them.

Our analysis was based on a literature review combined with Internet-based research on relevant organizations and their activities, as well as on expert and key stakeholder interviews with academic and non-academic researchers and policy experts, officials from national and multilateral organizations, and industry representatives. Based on our review, we propose four priority areas for further research that can produce actionable recommendations for improving access to NCD medicines in the short run.

Toward a Policy Research Agenda for Identifying and Promulgating Best Practices to Improve Access to NCD Medicines

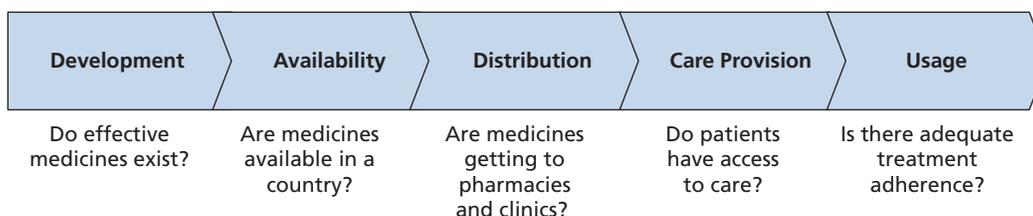
Like many other reviews, ours shows that NCDs present a growing challenge for developing countries and create the real possibility that gains in health that have been made possible by better control of infectious disease and economic development are being eroded. Since NCD medicines offer substantial public health gains, access to medicines is a critical component of NCD care.

Our framework approach identifies structural obstacles across health care systems and ways to systematically overcome them, but it also illustrates that overcoming those obstacles will not be a trivial task. NCDs are the result of multiple causative factors over the course of a life time and require a horizontal, integrated approach to care with the patient, family, and the entire community as active participants. This particular nature of NCDs implies that existing paradigms for improving access to medicines do not provide sufficient answers, because they address obstacles that we find to be less relevant for access to NCD medicines—i.e., drug development and manufacturer prices.

Regarding drug development, many potent NCD medicines have already been developed and will continue to be developed. This is contrasted by the experience with medicines for communicable diseases that predominately affect developing countries, making it more difficult for individual pharmaceutical companies to rationalize and recoup the necessary investment in innovative medicines.

Regarding manufacturer prices, the role they play in impeding access to NCD medicines is minor, since generic alternatives are available for most first-line treatment requirements.

Figure S.1
A Conceptual Framework of Obstacles to NCD Medicine Access



Schemes to provide medicines to developing countries at differential prices, which are critical to maintaining access to anti-retroviral medicines, are therefore less relevant for many first-line NCD medicines and exist for many NCD medicines that are still under patent protection, such as insulin and inhalers for chronic obstructive pulmonary disease and asthma.

The complexity of the challenge of improving access to NCD medicines means that a multi-stakeholder effort will be necessary to make a fundamental difference. Our goal, however, was more modest in that we were trying to set priorities for the policy research agenda of the research-based pharmaceutical industry. To this end, we focused on promising ideas that build on the industry's core capabilities and that can realistically be implemented. Our analysis points to four areas for further study that emerged from the research we undertook:

1. *Realizing product improvement beyond the chemical compound.* While our analysis revealed that the gains from development of additional compounds will be comparatively small, innovative ways to improve NCD medicine adherence are still dearly needed. We suggest that industry best practices be compiled in the areas of packaging, pricing, and patient education to achieve better drug treatment adherence. A particular focus should be research into the viability of fixed-dose combination products (polypills) for NCD treatment. While conceptually intuitive, the development and manufacturing of polypills are less than straightforward, because a limited range of population-adequate formulations has to be defined and produced at consistent quality. Similarly, regulatory approval may be difficult to obtain, as manufacturers would have to prove safety and efficacy of the co-administration of different compounds.
2. *Enhancing supply chain efficiency and integrity.* We observed that in contrast to what occurs with many consumer products, secure and efficient distribution of NCD medicines is far from guaranteed in developing countries. Availability in poor and remote areas remains limited, hefty markups along the supply chain are common, and the share of counterfeited product is substantial. At the same time, our review points to several creative ideas that should be studied further. A specific area of research could be an assessment of policy options for improving supply chain integrity—for example, a comparison of the potential impact of a public-sector solution to improve supply chain integrity for all medical products with a private-sector approach to marketing medicines, whose value proposition is the security of the supply chain and ability to verify product authenticity.
3. *Achieving gains from regulatory harmonization.* Although potent NCD medicines exist, their availability in developing countries can be hampered by regulatory obstacles. Uncertain timelines and variable requirements for product registration, Good Manufacturing Practice (GMP) inspections, labeling, and product identification codes can increase cost, sometimes to a level that makes product registration prohibitively difficult in a country. Many regional initiatives aim at achieving greater harmonization of regulatory requirements that would allow for increased availability. A logical next step would be to quantify the benefits from regulatory harmonization to promote a data-driven dialog with national authorities, and to promote the optimal use of such available schemes as the World Health Organization (WHO) Certificate of Pharmaceutical Product (CPP) scheme, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), and the International Conference on Harmonisation Global Cooperation Group (ICH GCG) scheme.

4. *Improving access to primary care.* We found consistent evidence that limited access to quality primary care is the key obstacle to improving NCD drug treatment. In the absence of a robust primary care system, NCDs go unnoticed until complications arise, adequate treatment is not initiated, treatment effect is not consistently monitored and terminally ill patients do not receive palliative care. At the same time, improving access to primary care is a complex challenge requiring that such fundamental issues as resourcing, governance, and capacity building be addressed. As an initial step, we propose a survey of innovative approaches for delivering effective and efficient primary care in developing countries and an assessment of which of those approaches can be scaled up in which contexts. Our initial review points to several promising ideas to which an in-depth review could add.

We are confident that further research into these priority areas can yield actionable guidance on how to improve access to NCD medicines in the developing world and that the research-based pharmaceutical industry is committed to executing this program. While far from resolving the fundamental issues of preventing and treating NCDs, the evidence generated by this program will allow the industry, in partnership with other stakeholders, to contribute meaningfully to the global efforts to reduce the NCD burden. The UN high-level meeting on NCDs will generate awareness and can galvanize decisionmakers to address the issue. From this can come an opportunity to make sustainable progress, if the attention around the meeting is leveraged to engage all stakeholders in a constructive dialog. Providing evidence-based concrete steps that can be taken in the short run is critical to generating momentum and moving the agenda forward.