Access to Medicines and Corporate Social Responsibilities of the Pharmaceutical Industry

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Research-based pharmaceutical companies have the role of developing, producing and distributing innovative medicines that can save lives, cure diseases and improve quality of life and must do so in a profitable way. This societal mandate is currently not shared with any other actors. The long-term viability of a pharmaceutical company depends on its wise use of resources and its behaviour as a corporate citizen in a globalized society. In recent years, 'corporate social responsibility' of pharmaceutical companies is increasingly understood to also include efforts to make medicines more accessible, particularly to poor people in low and middle-income countries (LMIC).

The World Health Organization (WHO) reports that a third of the world's population lacks access to essential medicines (WHO 2004). Availability of generic medicines is low (at 38%) in the public sector in LMIC (Cameron *et al.* 2009). While availability is somewhat better in the private sector (at 64% on average), private sector medicines purchases tend to be more expensive and are often not affordable for the lower income strata. Medicines constitute a sizable economic burden on health systems and households, consuming up to 67% of total public and private spending on health (Lu *et al.* 2011) and 60-90% of household expenditure on health in developing countries (Quick 2003). Spending on medicines is often not cost-effective. Almost half of all medicines are inappropriately prescribed, dispensed, or sold (WHO *et al.* 2009) and patients do not adhere to about 50% of the medicines they receive (Bowry *et al.* 2011). The pharmaceutical industry has often been criticized as aggravating the problem in its drive to maximize profits through the exertion of ownership rights in patents over medicines, for instance.

Controversies around Profits and Patents

Patents provide incentives and are a means of cost recovery for research and development of innovative drugs and vaccines (WHO, WIPO, WTO 2013). However, patents should not be the focus of the debate on access to medicines, as weakening intellectual property rights would not necessarily improve access. Patents are not the reason

for lack of access to essential medicines. In 65 LMIC (where four billion people live), very few of the medicines on WHO's Model List of Essential Medicines have been patented: only 17 of the 319 products were patentable, and only in 1.4% of instances (300 out of 20,735 essential medicine-country combinations) were essential medicines patented, predominantly in larger markets (Attaran 2004). Lack of patents does not guarantee that generic medicines will become available or acceptable in LMIC (Cameron *et al.* 2009; Patel *et al.* 2010).

Access to pharmaceutical innovations for poor patients requires a rational and ethically defensible mix of public and private research and incentives. The challenge is to find innovative strategies for the responsible use of patents under conditions of market failure. Creative ideas are emerging for the development of new antibiotics and medicines for neglected diseases (Health Impact Fund 2012). These developments should in turn be considered in the broader context of the corporate social responsibility of the industry.

Responsibilities of the Pharmaceutical Industry – A Framework

Corporate social responsibility may be conceptualized within the framework of the United Nations Global Compact, which provides internationally accepted norms for business on human rights, labour standards, environmental care and anti-corruption (Leisinger 2005). More specifically, the responsibilities of a pharmaceutical company could be considered to apply at three levels: the 'must', the 'ought to', and the 'can' (Leisinger 2009; see Figure 1). Pharmaceutical firms 'must' develop new medicines, make a profit, and comply with applicable laws and regulations. Voluntary corporate activities to improve access to medicines can be classified as either corporate responsibility ('ought to') or philanthropy ('can'). Exactly which activities fall into each category may be debated, and given evolving paradigms, pharmaceutical companies increasingly consider access to medicines considerations to be intrinsic to their business strategies.

Several research-based pharmaceutical companies have committed to improving access to medicines in LMIC through a number of corporate strategies and promising partnerships with other stakeholders (IFPMA 2012). A recent report found that 40% of research-based pharmaceutical firms expect to increase their commitment to global health partnerships focused on chronic conditions and 90% expect to engage increasingly with governments (Little *et al.* 2012). While these corporate activities could be viewed as philanthropic ('can') endeavours, many should – in the light of public expectations and stakeholder requests – also be considered as a part of a firms' corporate responsibility ('ought to') and business model.

However, there is no consensus among pharmaceutical companies on which activities they 'ought to' pursue or prioritize. There is also a lack of evidence about which activities are the most effective. Differential pricing seems to be a promising strategy since it meets the goals of corporate responsibility by improving access to medicines for the poor and could in theory help increase profits through price discrimination (World Health Organization and World Trade Organization 2001; Yadav 2010). However, the success of differential pricing depends on the ability to regulate arbitrage, accurately forecast the market, and distribute medicines through a functioning health system. While differential pricing is applied by several companies, it will be important to share successes and set-backs so that the industry can improve upon this strategy. Other strategies include donations (following WHO Guidelines) for disease eradication programs or emergencies, research and development investments for 'neglected' diseases (especially those affecting poor people), support for broader health and development goals, providing opportunities for developing production skills in developing countries and innovative collaborations with different stakeholders (Leisinger 2005). These initiatives are consistent with Millennium Development Goal 8, which calls upon the international community to cooperate with

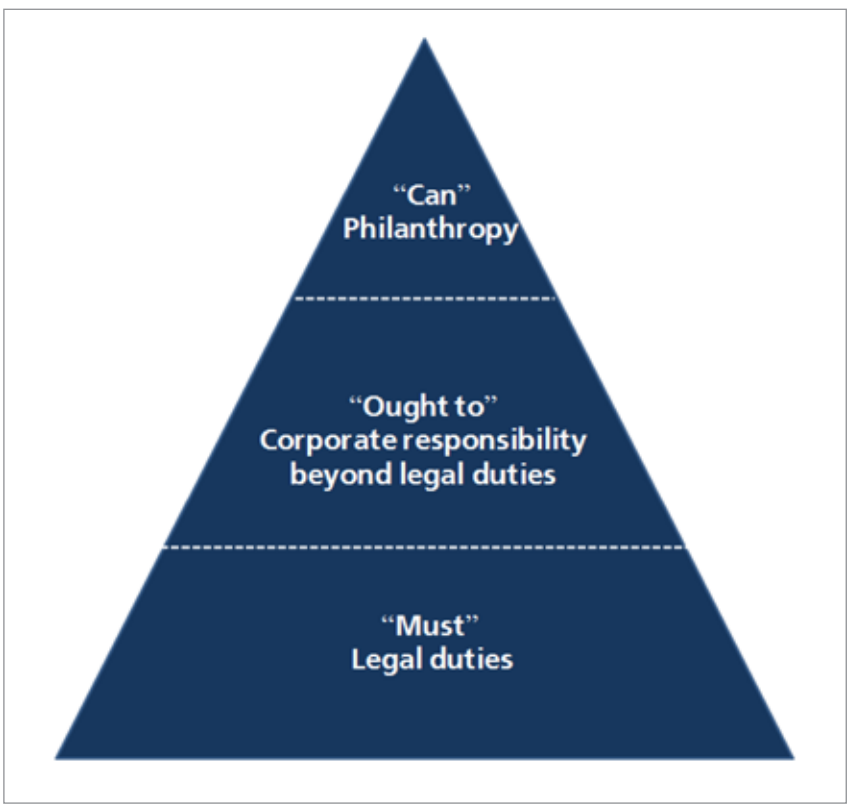


Figure 1. The Hierarchy of Corporate Responsibility

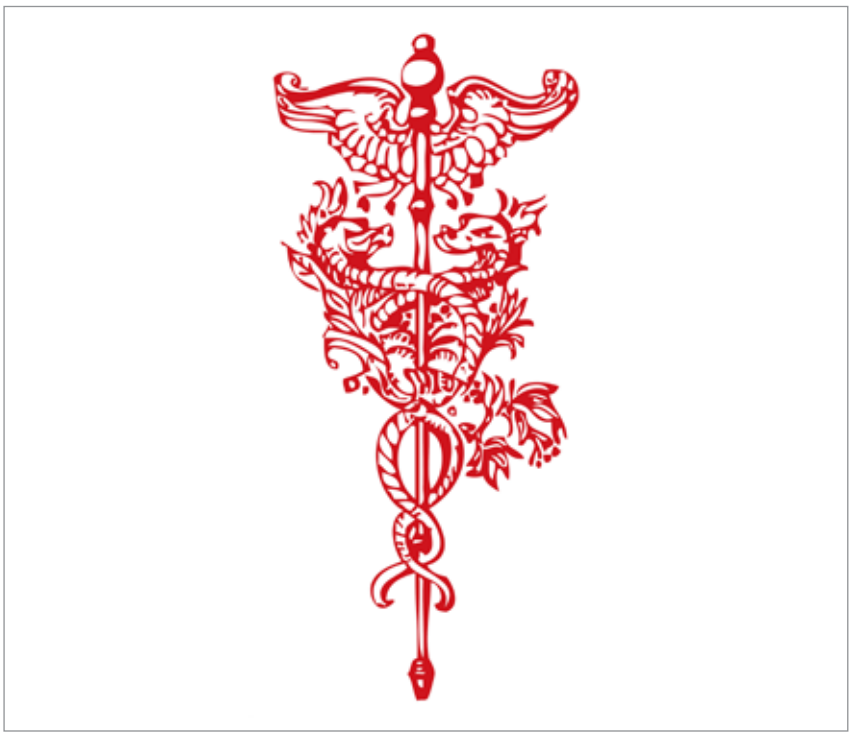
pharmaceutical companies to provide access to affordable, essential drugs in developing countries.

In addition to the 'must', 'ought to', and 'can' activities, the industry 'must not' engage in certain activities, such as inappropriate marketing. Industry must not use misleading, dishonest, or illegal promotional practices, promote uses of medicines that will not benefit patients, and misrepresent results from the medical literature and clinical trials.

Joint Action Needed

Despite a lack of consensus over what causes inadequate access to essential medicines, pharmaceutical companies are assuming a more prominent role in working with other stakeholders in initiatives to improve access to medicines for the poor (IFPMA 2012). The bi-annual Access to Medicines Index reported in 2012 that pharmaceutical companies are becoming more organized in addressing access concerns, and that an increasing number of companies consider this to be a strategic issue (Access to Medicines Index 2012).

In the light of immense suffering due to inadequate access to medicines, strategies to improve access should be a corporate responsibility priority for the entire pharmaceutical industry. The legitimacy of pharmaceutical companies will increasingly depend on them being recognized as fulfilling a socially constructive and ethically responsible role in addressing challenges arising from poverty-related illnesses and premature mortality. However, corporate initiatives can only have optimal impact if other stakeholders are also doing their parts. For instance, the most sophisticated breakthroughs in research and the most generous offers of low-priced medicines will make little difference for the poorest people if there is no basic health infrastructure to reach them (Novartis Foundation for Sustainable Development 2012). Extensive system investments continue to be pressingly needed given the lack of health care infrastructure, insufficient workforce, logistical challenges, particularly in remote rural areas, and patient factors, such as misperceptions and stigma about disease and medicines, lack of health education, and poor adherence. Along with constructive dialogue to build trusting relationships, the pooling of resources, skills, experiences, and goodwill across multiple stakeholders is necessary for sustainable solutions (ICIUM 2011). In addition, more comprehensive measures to track outcomes and impacts (UN Global Compact LEAD Team 2012, p. 19) are a critical success factor for innovative partnerships.



Authors' Note

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Klaus Leisinger, PhD, is Chairman of the Board of Trustees of the Novartis Foundation for Sustainable Development, and Professor of Sociology at the University of Basel, where he pursues research and teaches a wide range of topics related to international development and health policy as well as business ethics, corporate responsibility, and business and human rights. Dr Leisinger is a member of the European Academy of Sciences and Arts, and serves as an advisor to national and international organizations, such as the UN Global Compact, the World Bank and the World Economic Forum (Global Agenda Council on Human Rights). He was Special Advisor for the UN Global Compact to the then UN Secretary General, Kofi Annan, during his mandate. He was also a member of the high-level Commission on Information and Accountability for Women's and Children's Health. He continues to serve as the Co-Chairman of the Digital Health Initiative – a unique multi-stakeholder collaboration between the ICT and healthcare sectors to implement the Millennium Development Goals. In addition, he is also a member of the Broadband Commission and the steering committee of the UN Global Compact's LEAD Initiative. He is the chairman of the Board of Trustees of the German Network Business Ethics, and a member of the Executive Committee of the German Society for the United Nations. In November 2012, Dr Leisinger was appointed by the Global Compact as "Special Advisor on the Post 2015 Development and Business Ethics" and also as member of the Leadership Council of the newly created Sustainable Development Solutions network (Chaired by Professor Jeff Sachs). He is a believer in multi-stakeholder-solutions and tries to build bridges between civil society organizations and the business sector. Dr Leisinger was awarded an honorary doctorate in Theology by the University of Fribourg (Switzerland) in November 2004, and the "South-South Award" by a consortium of several institutions linked to the United Nations (UN) in 2011. For his "outstanding contributions" in the fight against Leprosy, Dr Leisinger was awarded the "2012 Republic of Korea Hansen Grand Award" on December 4th, 2012.

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