

The regulation of the South African pharmaceutical market

Pharmaceutical policy and regulation have been a central, if contested, element of the wide-ranging health reform programmes discussed since the inauguration of the new South African government in 1994. Unlike many other low- and middle-income countries, South Africa's regulatory framework is in line with most industrialized countries. Legislation of the market authorization process is governed by the Medicines and Related Substances Control Act of 1965. The Act contains the classical regulations concerning safety, quality and efficacy conditions for approvals. The purpose of this study is to map out the major regulations in the South African pharmaceutical market. The study draws on data from official statistics, documentation of regulations and interviews with key informants.

Recently, conduct of the market authorization process shows impairment in terms of an increase in the registration time of most types of drugs. There are small differences in approval times between generics and original products, implying that the former could be handled more efficiently. Drugs aimed at severe disease problems such as the HIV/AIDS epidemic show a similar time for registration. There are also indications that some multi-national pharmaceutical companies first launch their new drugs in the developed markets and then later apply for registration in countries like South Africa.

The system of employing part-time evaluators in the approval process often leads to blockages. Evaluators are not offered enough incentives to encourage them to prioritize their involvement in the process. The regulator is also limited with regard to the use of policing mechanisms, since evaluators can easily opt out. The option of establishing in-house evaluation capacity also entails problems of resources in terms of costs and available competence. The perceived inefficiencies in the approval process have created tension with the industry. To some extent this tension has been reduced through improved processes of communication between the regulator and the regulatees. Inadequate human resources also contribute significantly to the capacity problem.

Comparatively, the regulations of the South African pharmaceutical market do not appear to be controversial. After the court case in 2001 between the pharmaceutical industry and the government, the subsequent revision of the Act in question seems to be accepted by the industry and the feared violation of intellectual property rights turned out to be exaggerated. Still, a closer examination of some of the management and implementation aspects of these regulations show that there are unintended effects of these regulations. Other areas where potential improvement could be made are the encouragement of generic competition in the private market.

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Consumer protection in the health sector in Thailand

In Thailand, the Consumer Protection Act does not extend to cover products and services for which specific regulations are enacted. Regulations on consumer protection in the health sector are fragmented and varied, and have been established under the responsibility of health related organizations namely the Ministry of Public Health and professional bodies. Evidence shows that medical complaints have increased and there is a growing public interest in medical errors. This raises concerns about the appropriateness of having the regulatory function under providers' responsibility as in the case of professional councils. A study to investigate the management mechanism of medical liability, regulatory framework, and involvement of stakeholders, using the cases of organ transplantation and medical complaints as tracers, is providing an insight for further policy recommendations.

Extensive document review, key informant interviews, and focus group discussions were employed. Results show that the regulatory system relating to medical error has been well established and developed over time. However, the regulation cannot be adjusted to cope with recent changes in the health sector, such as growing private involvement and greater consumer expectations. Although the existing regulations are well accepted by providers, they have a low level of enforcement. The evidence of organ trafficking, increasing number of cases pending at the Medical Council, and key stakeholders' responses reflect the system's ineffectiveness. Factors influencing the ineffectiveness are a lack of transparency and time limits in the regulatory process, and poor performance of regulators due to low motivation. Patient interviews also show that consumers have a low level of awareness and accessibility to the regulatory process, and in the case of medical complaints, the compensation system is not well developed. Due to high financial and time costs involved in the process, informal negotiation between the provider and patients is widely in use in which some amount of compensation is agreed and provided in exchange for not pursuing a lawsuit.

In conclusion, results from two case studies share common findings that there is a lack of interest among key players in enforcing the regulations. To avoid a conflict of interest, an independent organization representing patients and a hospital complaints centre should be established in the community in the future to facilitate fair compensation. Alternatively, the short-term recommendation is that the Medical Council should be made more accountable to the public by involving external stakeholders in its governance functions. The Medical Council's ethical sub-committee should function on a full-time basis and with a time limited process to reduce the complainant's financial and time costs.

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