



Good Governance for Medicines

Promoting Transparency in Medicines Regulation and Procurement

More than US\$ 3 trillion is spent on health services each year. Such substantial funds are an obvious target for abuse. Transparency International estimates that, on average, 10 to 25% of public procurement spending in the health sector is lost to corruption. Resources that could otherwise be used to buy medicines or recruit much needed health professionals are wasted as a result of corruption, which reduces the availability of essential medicines and can cause prolonged illness and even deaths.

In response to this serious problem and guided by WHO's Medicines Strategy 2004-2007¹, WHO initiated the *Good Governance for Medicines* programme in late 2004. The programme's overall goal is to curb corruption in the pharmaceutical public sector through the application of transparent administrative procedures and the promotion of ethical practices by health professionals.

WHO recognizes that corruption is an immense, complex problem, and one that is difficult to tackle. The World Bank identifies it as the single greatest obstacle to economic and social development. However, the programme is helping to increase momentum, as more and more public health colleagues in ministries of health and national medicines regulatory authorities become interested in working on this challenging topic.

Why is good governance relevant to the pharmaceutical public sector?

The value of the global pharmaceutical market is estimated at over US\$ 500 billion, making the pharmaceutical sector highly vulnerable to corruption and unethical practices. Determining the level of this corruption is not an easy task, but Transparency International estimates that in some countries up to two thirds of medicines supplies at hospitals are lost through corruption and fraud. The impact on the pharmaceutical sector is three-fold:

- **health impact** — wastage of public resources reduces government capacity to provide access to good-quality essential medicines, while at the same time the risk of unsafe medical products on the market increases due to counterfeiting and/or to bribery of officials;
- **economic impact** — pharmaceutical expenditure in low-income countries may represent up to 50% of total health care costs, which means that corrupt pharmaceutical practices are extremely detrimental to national health budgets;
- **government image and trust impact** — inefficiency and lack of transparency reduce the credibility of public institutions, and erode public and donor confidence in government capacity to deliver on promises.

In addition, the donor community is providing sizeable grants or contributions of in-kind medicines for global public health problems such as high child mortality, the spread of infectious diseases and neglected diseases (e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Bill & Melinda Gates Foundation, the PEPFAR). However, corruption within the public sector risks undermining these efforts by misappropriating some of this vital aid. Ultimately, successful implementation of such funds will depend on good governance at national level.

Implementing the Good Governance for Medicines programme at the country level

Tackling corruption in the pharmaceutical sector requires a long-term strategy and the implementation of good governance. WHO has identified a three-step approach.

1

Phase I: National assessment of transparency and potential vulnerability to corruption

In order to address the problem of corruption in the pharmaceutical sector, it is necessary to assess the level of transparency and potential vulnerability to corruption of a few key functions in medicines regulation and procurement. The national assessment will be carried out after government clearance, by independent national investigators and using the standardized WHO assessment instrument². The national investigators will collect information through a combination of desk research and semi-structured interviews of key informants, and assessment will focus on the following key functions of the pharmaceutical sector:

- *registration* of medicines,
- *control of medicine promotion*,
- *inspection* of establishments,
- *selection* of essential medicines,
- *procurement* of medicines.

2

Phase II: Development of national ethical infrastructure

Assessing the level of transparency and the potential vulnerability to corruption is not an end in itself. It is rather the beginning of a process aimed at bringing long-lasting changes to promote good governance practices among health professionals in the public pharmaceutical sector. Once a national assessment has been carried out and problems identified, WHO suggests, as a next step, developing through a consultation process, a national ethical infrastructure responding to the needs of individual countries. The WHO Ethical Infrastructure for Good Governance in the Public Pharmaceutical Sector³ can serve as reference in developing the national ethical infrastructure.

3

Phase III: Socializing the national ethical infrastructure

It is very important to avoid a national ethical infrastructure remaining just another policy document developed by a few key actors at central level and not widely used. Socialization is the process by which an ethical framework and code of conduct can be learnt, internalized, applied and promoted by a group of key actors within the pharmaceutical sector of ministries of health, until they become fully integrated into the institutional culture⁴.

Progress in the implementation of the programme

The programme operates in eight Asia-Pacific countries and one Latin American one. The focus is now, on the one hand, on consolidating on-going efforts in the countries which are already part of the programme, and, on the other hand, on adding new ones, including those from other regions of the world. Selection of new countries and activities is based upon requests from governments, in collaboration with WHO Regional Offices.

Additional information:

<http://www.who.int/medicines/areas/policy/goodgovernance/home/en/index.html>

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¹ WHO Medicines Strategy 2004-2007: countries at the core.

² Measuring transparency to improve good governance in the public pharmaceutical sector. Working document, January 2007.

³ WHO ethical infrastructure for good governance in the public pharmaceutical sector. Working document, November 2006.

⁴ WHO guidelines for socializing the ethical infrastructure. In preparation.