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Approaches to corruption in drug management

Query:
What approaches have been taken to combating corruption in drugs management (drugs procurement and their subsequent distribution, storage and use), particularly in sub-Saharan Africa? Are there any innovative approaches being taken to combat both large scale corruption in this sector and the lower level endemic corruption? What assessments have been undertaken of the impact on health outcomes and on development in the wider sense, of corruption in drugs management?

Purpose:

We are currently leading on the development of a development partner Joint Response to Corruption in Uganda. One element of this approach is the development of a graduated response to specific 'test cases', including corruption in drug management.

Content:

Summary:

There is a broad consensus and much anecdotal evidence that corruption in drug management affects the price, availability and quality of drugs, undermining safe and affordable access to essential medicine in many developing countries. The complexity, heavy regulation and opacity of health systems combined with the large flows of money involved provide opportunities for fraud and corruption at all points of the pharmaceutical chain, from the registration, selection, procurement, distribution to the promotion of medicines. This is likely to have a long term impact on health and economic outcomes, especially in developing countries affected by the AIDS pandemic.

A number of initiatives are currently being implemented at both national and international levels to address corruption risks in drug management. Approaches to address corruption risks in drug management include the enforcement of strong and harmonised drug regulations, the promotion of open, transparent and competitive procurement processes, the establishment of effective and participatory monitoring mechanisms, and vigorous prosecution of health related corruption. Cutting across most promising anti-corruption

Author(s): Marie Chêne, U4 Helpdesk, Transparency International, mchene@transparency.org
Reviewed by: Robin Hodess Ph.D., Transparency International, rhodess@transparency.org

Date: 17 December 2009 **Number:** 225

interventions is the need to promote transparency at all stages of the drug supply chain system, especially with regard to the quality, availability and prices of medicines.

1 Corruption risks in drug management

Drugs, pharmaceuticals and medicines are the second health sector expenditure after salary costs in most developing countries and constitute the greatest share (50-90%) of out-of-pocket spending on health for the poor. In these countries, pharmaceutical expenditures and drug procurement account for 20 to 50% of public health budgets. (For more information, see U4 Thematic Page on Health and Corruption). Yet, according to the World Health Organisation, 30% of the world population still lack access to essential medicines.

Fraud and corruption are key factors that seriously compromise access to safe and affordable medicine in most developing countries. This is particularly preoccupying as developing countries[1] that are most affected by AIDS and other pandemics are also especially vulnerable to corruption. Weak governance systems and lack of transparency expose these countries to higher corruption risks in the regulation, selection, procurement, promotion, distribution and sales of essential medicine.

Corruption risks at the various stages of the drug management process

Medicine entering a health system may already be ineffective, of reduced quality or unsafe due to corruption taking place at the production, distribution and storing stage, resulting in the administration of diluted, substituted, recycled or counterfeited or expired medicine. The Global Corruption Report (GCR) 2006 on Corruption and Health (TI 2006) and the U4 Theme on Health and Corruption identified key areas of vulnerability in the management of medical supplies.

Drug registration and selection

Drug licensing, accreditation and registration require a series of regulatory decisions and approvals that can be very costly for pharmaceutical companies seeking to market their product in a given country. There is a high risk of regulation capture by the pharmaceutical lobby or bribery to influence or speed up the registration process. Regulatory officials can also be offered lucrative consulting assignments by the pharmaceutical industry to influence decisions towards the industry's interests. This is especially true in developing countries where regulatory agencies often lack resources and capacity. Similarly, the process of licensing pharmacies and drug stores can be vulnerable to corruption and bribery.

Most public health systems limit procurement or reimbursement of medicines to drugs selected on a national list of essential medicines that is established based on efficacy, safety, quality and value for money criteria. Interests groups can interfere with the selection process through bribery and other forms of undue influence, resulting in national drug lists that don't reflect the most appropriate and cost-effective drugs.

Different pricing

Research indicates that there are wide variations of price in similar markets and significant difference in price for similar products across countries. Manufacturers are encouraged to practice different pricing in developing countries and sell drugs at prices close to the manufacture costs. This provides incentives and opportunities to re-import or smuggle cheap generic drugs.

Procurement of drugs

Medical procurement is a very complex, highly specified and technical process. It involves a large variety of actors from both the private and the public sectors. As public officials in developing countries often lack the skills and capacity to write technical specifications and supervise competitive bidding, medical supplies procurements are often poorly documented and processed. Corruption can occur at any stage of the process and distort decisions on the nature of procurement (direct rather than competitive), type and volume of supplies needed, purchase prices as well as selection criteria. In addition, the lack of transparency that characterises methods used to determine the volume of drugs needed combined with the difficulty to monitor price and quality of drug products make procurement of medical supplies

[1] UNAIDS estimates that 70% of all people infected by HIV live in Sub-Saharan Africa, and only 11% of those needing treatment were receiving Anti-retroviral drugs.

especially vulnerable to corruption. Different pricing practices also create opportunities for fraud and corruption, with suppliers artificially inflating prices for the same product.

It is difficult to monitor price and quality of medical supplies. According to WHO 2008, an estimated 20-25 % of public procurement costs are lost to corruption. (Nordberg and Vian 2008). In Kenya for example, the Kenyatta National Hospital alone reportedly lost over US $12 million to procurement between 1999 and 2002 (TI 2006).

As in other procurement processes, forms of corruption in drug procurement include collusion among bidders leading to higher prices for purchased medicines, kickbacks from suppliers and bribes to public officials overseeing the bidding and contract implementation processes. There are many other opportunities for fraud in procurement processes. Due to lack of management and monitoring capacity, substandard, expired, counterfeit or harmful drugs can be delivered, partially delivered or not delivered at all.

Distribution

The supply systems through which medicines are taken from manufacturers to suppliers are often unreliable, due to poor infrastructure, siphoning and inefficiencies all along the supply chain. As a result, stock loss is a common problem in public sector medical stores, often exceeding 15% (Vian 2006).

The process of ensuring that drugs are allocated, transported and stored appropriately where they need to be dispensed involves high risks of theft. Weak management and underfinanced health systems combined with poor accountability mechanisms and poor record keeping lead to leakages of resource and misuse of medical supplies for private gain. Drugs can be stolen from central stores and individual facilities, and diverted for resale for personal gain in private practices or on the black market. For example, in 2008, the Uganda Minister of Health told the media that half of the medicines bought by the government for the public health system were being siphoned off (MeTA 2009a).

Promotion and Service Delivery

Aggressive marketing strategies from the pharmaceutical industry may lead to collusion between the various stakeholders at different levels of the supply chain, e.g. between physicians and prescribing physicians/health providers. Pharmaceutical industries commonly provide incentives to encourage the use of their products, such as free sample, gifts, sponsored trips and seminars, etc, generating conflicts of interest. This distorts market efficiency with decisions that are no longer made in the best interest of the patient. WHO and Health Action International report that doctors who rely more on promotion tend to prescribe less appropriately, more often and adopt new drugs more quickly.

What makes the health sector especially prone to corruption?

There are also a series of specific sectoral challenges that contribute to make the health sector especially prone to corruption and affect corruption risks in the drug management process.

Large flows of funds

The large flows of funds spent worldwide on health services are attractive target for abuse[2]. With the scaling up of aid recommended by the Paris Declaration on aid effectiveness, increased aid flows are channelled through health procurement and supply systems in developing countries.

Complexity of health systems

There are a large numbers of parties involved in the drug management system, both at the national and international levels with differing and sometimes conflicting interests, asymmetric information flows and opaque relationships.

Nature of the pharmaceutical industry

The pharmaceutical industry worldwide is one of the most aggressive and less competitive industry sectors worldwide.

Heavy government regulations

Regulations governing drug licensing, registration and market approvals provide necessary safeguards against sub-standard drugs and unfair pricing but also make this sector vulnerable to corruption.

Imbalance of information

Insufficient information on price and quality (especially for generic products) hampers the consumers' ability to

[2] According to the WHO 2008 report, total expenditures on health worldwide represent 8% of the world GDP and it is estimated that US$ 3,1 trillion are spent each year.

make informed choices, make pressure for change and contribute to market regulations. For example, drug users often have little knowledge of the various treatment options, their costs, quality and relevance to their condition, leading to overpricing, over treatment or selling unnecessary product of substandard quality. This is especially true in developing countries, where, because of shortage of drugs and high treatment costs, patients often buy their drugs from informal sources.

2 Impact of corruption on health outcomes

Impact of corruption in the health sector

The impact of corruption in health in general is relatively well documented. There is a growing body of evidence that demonstrates that corruption undermines the cost, volume and quality of public service delivery, undermining the access and quality of patient care. Diverted resources reduce the level of resources and investments available for the public health system on which most vulnerable populations are more reliant on.

A 2006 qualitative study conducted in Ethiopia (Serneels 2008) suggests that resources drained from health budget through embezzlement, fraud and corruption reduce the funding available for salaries, health services and maintenance, contributing to lower staff motivation, quality of care and declining service availability and use. A 2005 study conducted in the Philippines (Azfar and Gurgur 2005) found that corruption delays and reduces the vaccination of newborns, discourage the use of public health clinics, reduces satisfaction of households with public health services and increases waiting times at health clinics. A 10% increase in corruption reduces immunisation rates by 10 to 20 %. It confirms the findings of a 2000 IMF working paper (Gupta et al 2000) that provides evidence that reducing corruption can result in significant social gains as measured by decreases in child and infant mortality rates, as well as percent of low-birth weight babies.

Specific impact of corruption in drug management

The specific impact of corruption in drug management on health outcome has been less systematically documented. However, there is a broad consensus and much anecdotal evidence that corruption in drug management affects the availability and quality of medicines, with a direct effect on patient care and long term impact on health outcomes, especially in developing countries affected by the AIDS pandemic. The 2006 GCR (TI *op cit*) and U4 Issue Paper on Corruption in the Health Sector (Nordberg and Vian *op cit*) have highlighted some of the linkages between corruption in the supply chain of medicine and health outcomes.

Availability and access to essential medicines

Corruption in procurement and distribution of pharmaceutical and medical supplies leads to cost overruns, drug shortages and low quality of drug supplies, ultimately reducing access to essential medicines at affordable prices, especially for the most vulnerable groups who rely more on the public services for care. In many cases, medical supplies are diverted from the public health system for resale by medical staff running their own private practices. Findings from a UN report of the MDG Gap Task Force, for example show that the availability of medicines in 30 countries is far from optimal, reaching only 34.9% availability in the public sector and 63.2% in the private sector (UN 2008).

As a result of fraud and corruption, essential medicines and services become more costly and unaffordable, with millions of people – especially the poor who can't afford paying or bribing for medicine - lacking access to treatment. Current estimates from **WHO** (Nordberg and Vian *op cit*) indicate that not less than 2 billion people and about 30% of the world population lack regular access to medicine. A study conducted by Health Action International in Kenya in 2007 (HAI 2009) mentions that only about 30 % of Kenyans have access to essential medicines and that high prices and poor availability were the major factors limiting access.

Quality of drugs and treatments

Corruption also affects the quality of available drugs when bribes are offered to avoid or influence government regulations and quality controls, contributing to the circulation of substandard or counterfeit products that can be useless or even harmful to the patients. For example, a survey found that 40% of artesunate drugs (based on the wormwood plant) bought in Southeast Asian Markets to treat malaria contained no active ingredients. In Nigeria, drug regulators were bribed by drug counterfeiters to access the market and some study estimated that overall, up to a third of medicines on the market in

developing countries are counterfeits. In 2005, 60.000 Nigerian were vaccinated with what was later discovered to be counterfeit. (MeTA 2009b)

The situation is aggravated by the fact that in many developing countries, there is no regulatory authority (or if there is, it lacks resources and capacity) to exert effective controls on the quality of available medicine.

Similarly, unethical drug promotion creates conflict of interest for physicians who can be tempted to act for profit maximisation rather than in the best interest of the patient. Several studies indicate that these activities result in unethical practices, non-rational prescribing and increased costs with little of no health benefits. Patients' life can also be at risk when some doctors enroll unqualified patients in trials or prescribe unnecessary treatments. (Nordberg and Vyan *op cit*)

Longer term impact of corruption in drug management on health and economic outcomes

The circulation of sub-standard or counterfeited drugs has direct implications on health outcomes, with patients putting their health at risk with useless, harmful and at worst lethal drugs. According to WHO (nd a), unregulated and low quality drugs can contribute to the development of drug resistant organisms, jeopardise patients' health and increase the threat of pandemic disease spread. In addition, sub-standard products can contribute to undermine the public confidence in life saving medicines. This has also an impact on the economic situation of poor patients who spend a greater proportion of their meagre resources on worthless and potentially dangerous medicines.

The impact of corruption on health outcomes through the availability and quality of drugs is particularly visible in connection with the AIDS pandemic. The effect of the pandemics is estimated 30 times higher in low income countries than in developed countries, as lack of access to anti-viral retroviral (ARV) drugs due to inadequate registration, procurement and supply management systems result in drug stock outs and treatments that are not consistent with WHO's recommendations. Data from Botswana suggests that in the year after ARV treatments were made available in the country, adult deaths fell by eight percent (MeTA 2009a).

In the long term, drug shortages, poor quality treatments and lack of access to medicine has particularly damaging effects in terms of economic loss, seriously undermining social and political stability as well as sustainable development.

3 Approaches to addressing corruption risks in drug management

Approaches to address corruption risks in drug management include the enforcement of strengthened and harmonised drug regulations, the promotion of transparent, efficient and accountable procurement processes, the establishment of effective and participatory monitoring mechanisms, the promotion of ethical standards and vigorous prosecution of health related corruption. The WHO has developed ethical guidelines (Anello 2006) that cover the functions of registration, promotion, inspection, selection and procurement and provide a good example of an ethical infrastructure for the pharmaceutical sector.

Transparency and participation cut across all preventative measures developed to address corruption risks in the management of drugs and medical supplies for example through multi-stakeholder initiatives such as the Medicine Transparency Alliance (MeTA).

Regulation, registration and selection of drugs

The first prerequisite to prevent corruption in the drug supply chain is to develop harmonised regulation of pharmaceutical products on the national and international markets. In addition, national governments must promote transparency in drug regulation processes, regulate the aggressive promotion of medicines, impose tougher restrictions on doctors overprescribing drugs and ensure closer monitoring of the relationships between health departments and the drugs industry (TI *op cit*).

Strengthening drug regulation

The registration of drugs and selection of essential medicines needs to use transparent criteria and consultative processes to avoid conflicts of interest, abuse and influence peddling. Regulatory policies, procedures and criteria for decision-making need to be published and made easily accessible.

Despite international efforts to improve drug regulation at national and international levels, drug regulation remains weak or non-existent in many developing countries. According to WHO (Wondemagegnehu

1999), less than one in six WHO member states had well-developed drug regulation and two in six had either no drug regulatory authority in place or an authority with very limited capacity. WHO has highlighted some of the issues that countries should consider when designing drug regulation policy and formulated a set of recommendations (Wondemagegnehu *op cit*). To reduce corruption at this stage of the process, WHO stresses the importance of limiting the discretionary power of regulators in order to prevent abuse and risks of regulatory capture.

Effective regulatory authorities

At country level, efficient regulatory authorities need to be established to ensure the implementation of regulation and manufacturing practices, combat fake and substandard products, inspect distribution channels and monitor new information on serious adverse effects of pharmaceutical products.

Registration and selection committee

A formal committee responsible for the registration and selection of medicines needs to be established, with clear terms of reference, members selected based on clear and technical criteria and decisions based on the latest scientific evidence. All countries should have publicly available written procedures and documents describing the composition and the terms of reference of the registration committee. Regulatory authorities should have written rule to avoid conflicts of interest and provide training on how to manage them when they arise.

Monitoring and inspection mechanisms

Regulatory authorities should also ensure transparency with regard to criteria for the recruitment of inspectors and on procedures for conducting inspections to prevent personal relations between an inspector and manufacturers or distributors that might provoke unethical behaviour.

Regulatory authorities should be allocated sufficient human, technical and financial resources to ensure that inspection staff is adequately qualified and rewarded. In Tanzania for example, drug inspectors were given hand-held computers with a data base of all legally registered drugs. In Nigeria, as part of the anti-counterfeit campaigns, local media were used to raise people's awareness and encourage them to report suspicious dugs to the regulatory authorities (MeTA 2009b).

Drug procurement

Preventing corruption in the drug procurement process involves defining clear and transparent procurement rules to increase the probability for corrupt practices to be detected and sanctioned and implementing guidelines that reduce discretionary powers where they are likely to be abused. The WHO has developed Operational Principles for Good Pharmaceutical Procurement (WHO 1999) that can inspire the development of country level procurement procedures.

Monitoring and publicising price information

Establishing lists of reliable and well performing suppliers as well as making price information widely available can also help reduce prices and opportunities for corruption. The WHO's Drug Price Information Service, or the MSH/WHO International Price Guide are examples of international initiatives in this area.

Price reporting systems have been used successfully to reduce opportunities for fraud and corruption and decrease input prices by allowing comparisons for basic medical goods and services.

In Argentina (Savedoff 2008) for example, transparency and accountability measures were used to hold hospital administrators accountable. The publication of hospital procurement prices revealed very wide dispersion of prices, in some facilities up to 10 times higher than in others. Purchase prices for the monitored items immediately fell by an average of 12 percent. Prices eventually began to rise again, but stayed below the baseline purchase price for the entire time the policy was in place. However, unless there are consequences for fraud and malpractices, monitoring and publishing price information is unlikely to guarantee sustained gains over time.

Companies found to have engaged in corrupt practices should be debarred from participating in further tender processes for a specified period of time.

The use of information technology

Advances in information technology offer promising opportunities to increase the transparency and accountability of drug procurement.

Electronic bidding systems

In **Chile** for example, an electronic bidding system has been introduced for drug procurement that uses

internet for publishing the lists of supplies offered in tenders with the view to providing public access to prices, products and quantities as well as bidding results. It was estimated that hospitals have saved from 5 to 7% by using this electronic bidding system. Such approach also allows civil society involvement and oversight at all stages of the procurement process (Cohen and Montoya 2001).

Publication and dissemination of price information

International partners and other national procurement agencies also increasingly use information technology to improve transparency in drug price information, as demonstrated by the procurement of HIV/AIDS medicines. The **Global Fund to Fight AIDS, TB and Malaria** has introduced unprecedented standards of transparency for the procurement of medicines. All medicines and commodity procurement are mandated to be reported by the principal recipients and posted on the Global Fund's publicly available website. Some procurement data is also made available through other public databases such as the WHO Global Price Reporting Mechanism.

However, according to WHO, data on HIV/AIDS medicines procurements made available through these public data bases remain largely under-used. More effective transparency would involve increasing the coverage of public disclosure of information, improving the reliability and accuracy of data and assuring consistent and reliable access to disclosed information in a practical format (Waning and Vian 2008).

Civil society participation and oversight

The involvement of civil society at all stages of the procurement processes is a key dimension of promoting transparency and accountability in procurement processes.

The Guatemalan chapter of Transparency International for example was invited by the Government to monitor drugs procurement in mid-2005. TI Guatemala uncovered significant bias and high levels of discretion on the part of the governmental body responsible for checking compliance with quality controls. (Information can be obtained by contacting directly the Guatemalan national chapter).

In **Bolivia**, following the devolution of health care facilities to municipalities, a study found that hospitals that were supervised by active "Local Health Directorates" involving citizen representatives paid up to 40% less on average for 5% dextrose solution (Savedoff *op cit*).

Integrity pacts

Corruption risks in the procurement of pharmaceutical products can be mitigated by the implementation of an integrity pact, which is a binding agreement by both bidders and contracting agencies not to offer or accept bribes in public contracting. For example, integrity pacts have been promoted by Transparency International Peru (Proética) for the purchase of medication for the National Police, or by Transparency Colombia and the National Social Security Institute for the purchase of medicines and dialyses services. (Information can be obtained by contacting TI 's national chapters).

Distribution

At the distribution stage of medical supplies, there are many measures that can be taken to reduce opportunities for fraud and corruption. These include strengthening inventory control systems, improving record keeping and control procedures, as well as introducing effective monitoring mechanisms, etc.

Commercial best practices

Some commercial best practices can be applied to public sector's supply chain management to mitigate drug diversion risks along the supply chain, as illustrated by the President's Emergency Plan for AIDS Relief (US PEPFAR initiative) and the related Supply Chain Management System. In South Africa, Pharmaceutical Healthcare Distributors managed to reduce stock loss to less than 0,1% by using such an approach (Vian 2006). Such practices include:

- Open, transparent and competitive procurement system that includes measures taken to promote price transparency;
- Reinforced physical protection and security of warehouses including gated facilities, security guards, controlled access, etc;
- Segregation of workforce and duties to prevent internal risks of collusion and limit discretion;
- Risks analysis of routes and shipments with higher levels of control and security on high risks routes (such as satellite tracking and monitoring);
- Information management, batch monitoring or specific packaging to avoid drug diversion of

products intended for the public sector to private markets.

Community participation

Local communities and beneficiaries can also play a crucial role in preventing drug diversion along the supply chain by monitoring and overseeing drug delivery and stock-outs at facility level.

In Zambia (MeTA 2009c), for example, theft was cut by providing information on the delivery of medicines in rural health centres to local health committees made up of members of the local community.

In Kenya, Malawi, Uganda and Zambia (PlusNews 2009), Stop the Stock-Outs campaign[3] activists used text messaging to report stock-outs of essential medicines at public health facilities and put pressure on governments to address the issue.

The establishment of effective complaints mechanisms can also empower beneficiaries to report wrongdoings and malpractice. In **Uganda** for example, HEPS-Uganda - a health consumer organisation- collects complaints through stakeholders' meetings, complaints boxes installed at health facilities, and questionnaires filled out by health consumers and observations. These complaints are analysed and reports are written which are then discussed with health facility management to agree on the needed improvements and/or redress.

Other tools and examples

There are many other approaches that have been developed to improve drug distribution systems. The **USAID funded DELIVER Project** for example has developed many tools, including guidelines for forecasting, supply chain management, process mapping for improved health logistics system performance and warehousing of health commodities. In partnership with the US Pharmacopeial Convention (USP), USAID 's **Promoting the Quality of Medicines Programme** also established a large scale continuous monitoring programme for medicine quality in Africa, Asia and Latin America through 107 sentinel sites set up to perform quality testing.

Promotion

Approaches to address unethical drug promotion techniques can include limiting practices of gift and sponsorship, based on **WHO ethical guidelines on medicines promotion** (WHO nd b), raising professional and ethical standards and promoting codes of ethics in marketing through trade and professional organisations. Raising physicians' awareness on conflict of interest through training can also be envisaged. Information dissemination on the benefits, risks, and cost-effectiveness of specific drugs is also critical to influencing how drugs are used and protecting patient interests. Further approaches to unethical drug promotion can include passing laws, establishing marketing regulators, creating independent sources of information on pharmaceutical products, providing advertising guidelines and limits on gifts, perks and inducements (MeTA 2009d)

Call for transparency: The Medicine Transparency Alliance (MeTA)

From the above mentioned examples, the need for transparency cuts across the most promising approaches developed to address fraud and corruption risks in the drug management process. Public accountability in the medical supply chain is only possible when sufficient and accurate information about the quality, availability and prices of medicine is publicly available and accessible. In many developing countries, there is little information available on these critical areas of transparency.

The Medicine Transparency Alliance (META)

MeTA is an effort to collaborate with the pharmaceutical sector at national and international levels to address these challenges. Its aims at improving access and affordability of medicines by improving information flows and promoting transparency and accountability in the selection, regulation, procurement, sale, distribution, and in developing countries. Launched in 2008, it is a multi-stakeholder initiative that brings together representatives of all parties involved in the medicine supply chain including governments, the pharmaceutical industry and civil society and advocates for disclosure of information about the quality, registration, availability and price of medicines as well as about drug promotion policies and practices.

[3] This campaign is a call to action for African governments to meet their obligations to provide essential medicines.

Countries signing up to MeTA are expected to make formal commitments to disclose and analyse data around the medicines supply chain and form a national stakeholder group to collect and disseminate the required data and information. Seven pilot countries to date have signed up to MeTA, including Ghana, Jordan, Kyrgyzstan, Peru, the Philippines, Uganda and Zambia.

MeTA is applying a range of tools[4] to support the process of collecting and disclosing data about medicines (MeTA 2009 e).

MeTA Uganda

Scheduled to be launched in 2009, core work of the MeTA Uganda country programme involves: 1) mobilisation and capacity building of civil society to advocate for increased access to essential medicines; 2) production and dissemination of research and information on policies and practices on access to essential medicines; 3) advocacy to influence policy formulation and implementation; and 4) monitoring and evaluation with increased CSO representation in decision making structures.

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[4] Tools include a pharmaceutical sector baseline scan; a disclosure tool; a household and health facility survey; communication and media scan; private sector, civil society and supply chain mapping; drug price monitoring, rational use assessment tool, etc.

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