
A review of WHO's work on the issue of access to quality, safe, efficacious and affordable medical products

Report by the Secretariat

1. WHO's work on access to essential medicines supports countries in their efforts towards universal health coverage, and is a key element for the achievement of the Millennium Development Goals, and of the Sustainable Development Goals in the years to come. It is based on the principles of **rational selection** and **use** of a limited range of quality medicines, **efficient procurement** and **effective distribution systems** and **affordable prices**. These activities promote better management of medicines, a more cost-effective use of resources and higher-quality health care; their effective implementation will increase access to medicines, avoid high out-of-pocket expenses, and support national policies for universal health coverage. However, low- and low-to-middle-income countries continue to face problems with essential medicines that are in short supply and/or prohibitively expensive. This paper reviews the progress made in a number of targeted initiatives and examines the linkages between gaps in the implementation of these initiatives and the emergence of substandard/spurious/falsefully-labelled/falsified/counterfeit (SSFFC) medical products.

Rational selection and use of medicines

2. The WHO Model List of Essential Medicines has been a flagship area of activity for the Secretariat for well over thirty years. The work on the Model List is supported by the Expert Committee on the Selection and Use of Essential Medicines. At its recent meeting in April 2015, the Expert Committee adopted the 19th WHO Model List of Essential medicines, comprising over 400 medicines for adults and 289 for children. The Secretariat supports country-based activities to promote the principle of evidence-based selection for national model lists of essential medicines, and to further the rational use of the medicines included on the national lists and the WHO Model Lists. Many Member States use the WHO Model Lists to draw up their national lists and to adapt them to their national circumstances. Although this assists in targeting the most essential medicines for national health systems, financing their procurement remains a significant challenge for all governments, and stock-outs of medicines are frequent in the public sector supply. As a result, patients have to seek medicines in the private sector. Stock-outs contribute to the irrational use of medicines, which continues to be a major issue that leads not only to the loss of valuable financial resources but also causes significant harm to consumers, such as, antibiotic resistance. WHO has received reports of SSFFC medical products in all of the main therapeutic categories.

Efficient procurement and effective distribution systems

3. Good governance in the area of procurement and distribution is key to ensuring supply chain integrity. In order to support Member States in managing aspects of transparency and institutionalizing good governance, WHO has been promoting the Good Governance for Medicines programme, by providing guidance on improving efficiency in procurement and supply, and tools to assess the transparency and vulnerability of selected areas of the public pharmaceutical sector. The Good Governance for Medicines programme is implemented in 37 countries. The Secretariat supports countries in collecting data on transparency and accountability and monitoring progress; and in supporting multistakeholder dialogue, capacity building and awareness raising. If structures and processes are not transparent and the institutional checks and balances are insufficient, systems are vulnerable to dysfunction. Dysfunctional practices lead to the waste of limited resources, compromise health outcomes, and tarnish public trust and confidence in medicine supply systems. Incidents that have resulted in the entry of SSFFC medical products into regulated supply chains have been traced back to poor and less-than-transparent procurement practices in some countries.

4. Over the past few years, **international shortages** of medicines have become a growing concern, in both high- and low- income countries. These sometimes occur when a single plant is responsible for the manufacture of both active pharmaceutical ingredients and finished products. In such cases, finite production capacity or the observance of good manufacturing practice may impose constraints that can rapidly translate into supply problems. Shortages can also be caused by market changes; older generic medicines in particular can be affected, as their prices may become so low that companies have little incentive to produce them. Although large countries can be affected by shortages, it is small markets that face the worst problems, as they are commercially less interesting. Several countries maintain websites and information systems on shortages, and have arrangements with the pharmaceutical industry for the notification of problems with availability. The evidence suggests that SSFFC medical products enter the market when shortages occur. Improved supply and demand information is therefore required in order to improve the efficiency of supply chains. Better anticipation of shortages could help to protect against the problem of SSFFC medical products.

Affordable prices

5. Managing medicine costs and prices is central to achieving equitable and affordable access. Member States may use several WHO medicines price information sources and the *WHO guideline on country pharmaceutical pricing policies*¹ as references for pricing medicines and as tools for increasing efficiency in medicine supply systems. The Secretariat also provides support to Member States in developing cost-effective methods for collecting reliable data, providing training in data analysis and presenting data in formats that are useful for national decision-making. Adequate financing for essential medicines remains a major challenge for countries as they move towards universal health coverage. Using generic medicines can enhance the supply and affordability of medicines in general. Policies that promote use of generic medicines are important, as is ensuring the quality of generic medicines in circulation. Quality assurance systems and education campaigns promoting the use of generic medicines are needed in order to reassure prescribers and the public that low prices do not equal low quality. The Secretariat supports countries in monitoring information on pricing and in learning from the experiences of other countries. Both high-priced specialist medicines and low-cost common medicines have been subject to falsification. Early indications suggest that the scale of demand is the driver of falsification, rather than the price of medicines. Variation in pricing

¹ WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 (<http://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf>, accessed 29 October 2015).

from country to country and between public and private sectors has led to the movement of medicines to countries where greater profits can be made, which has, in turn, resulted in shortages in the original country and leakages from one sector to another.

Collaboration across the Organization to promote access to essential medicines

6. **Managing the quality of medicines.** Ensuring the availability of quality, safe and efficacious medicines is a major concern of WHO Member States. In order to support the improved quality of pharmaceuticals globally, WHO sets norms and standards, develops guidelines, and advises Member States on issues related to the quality assurance of medicines on national and international markets. WHO supports countries in building national regulatory capacity through networking, training and information sharing. These activities have been endorsed and supported by Member States through numerous Health Assembly resolutions. Prequalification was originally intended to give the United Nations and other international procurement agencies, such as UNICEF, the Global Fund, and the GAVI Alliance, a larger range of affordable essential medicines of assured quality for a set of priority diseases and conditions. With time, the growing list of products that meet the quality requirements has also become a useful tool for countries that are making bulk purchases of medicines. Prequalification draws on the expertise of some of the best national regulatory authorities to provide a list of prequalified products that comply with unified international standards. The scope of the prequalification programme is currently limited to medicinal products used for HIV/AIDS, tuberculosis, malaria and other selected diseases, and for reproductive health. A significant number of products are not subject to stringent controls for ensuring good manufacturing and good distribution practices; substandard products may enter supply chains as a result. However, through the Member State mechanism on SSFFC medical products, the Organization has adopted a workplan to prevent, detect and respond to the risks posed by SSFFC medical products that compromise access to quality-assured medical products and undermine the trust people place in their health systems.

7. **Access to medicines for noncommunicable diseases.** The WHO global action plan for the prevention and control of noncommunicable diseases offers cost-effective methods for the early detection and subsequent management of major noncommunicable diseases. The Secretariat has designed a package of essential technologies, medicines and risk prevention tools for the primary care of noncommunicable diseases in resource-constrained settings, and will support countries in improving financing for medicines for noncommunicable diseases, in monitoring the quality, availability and prices of important medicines for noncommunicable diseases, and in assessing their rational use. In addition, the Secretariat supports countries in improving the quantification of and access to medicines for pain. Owing to the wide range of medicines for the treatment of noncommunicable diseases, large budget outlays are required. These budgets are often not met in many national health systems, and the result is that many patients are forced to seek their medicines in the private sector at considerably high prices.

8. **Access to medicines for HIV/AIDS, tuberculosis and malaria, reproductive and maternal and child health.** In addition to its work on the rational selection of medicines for these areas, the Secretariat works with partners on the efficient procurement and distribution of such medicines and on monitoring their safe clinical use. Patients treated with antiretroviral medicines may require access to quality, affordable medicines to treat co-morbidities, such as tuberculosis and noncommunicable diseases. Access to these medicines requires the integration of vertical disease-oriented programmes into the wider health system and the national procurement systems for medicines for noncommunicable diseases and other acute diseases. The Secretariat, through the AIDS Medicines and Diagnostic Service, is developing strategic information on medicines and diagnostics for HIV, publishing an annual forecast on global demand for antiretrovirals, and supporting capacity-building activities for health supply chains. Many of the medicines in this category of products benefit from significant funding interest on the part of donors. This, together with the coverage of the prequalification programme for their quality assurance,

means that these medicines are, on the one hand, generally less susceptible to quality failures, while, on the other, being more vulnerable to falsification. It should be noted that owing to their very wide distribution and usage, antimalarials remain susceptible to falsification.

9. **Antimicrobial resistance.** The Sixty-eighth World Health Assembly adopted the global action plan on antimicrobial resistance.¹ Antimicrobial resistance is a complex matter to tackle, with few new antibiotics entering the market, widespread inappropriate use in humans and animals, and the rapid transmission of resistant strains of microbes across countries. Its presence has an adverse impact on both health care and health care budgets. The Secretariat plays an important role in supporting countries to implement existing recommendations, as highlighted in the global action plan, in order to limit the emergence and spread of antimicrobial resistance and to develop innovative approaches for tackling this threat. The Secretariat contributes to efforts: (i) to strengthen guidelines and regulations in countries regarding the responsible use of and access to quality-assured antimicrobial agents; and (ii) to monitor the use of such agents. Moreover, it participates in the elaboration of new business models for the research and development of new antibiotics – which will encourage investment into the discovery of novel molecules and ensure their future preservation through responsible use. The Secretariat supports countries in: carrying out antimicrobial consumption studies; establishing and managing stewardship programmes; enforcing regulations for the sound dispensing of antimicrobial medicines and the prevention of over-the-counter sales; enforcing regulations to ban advertising on the use of antimicrobials; and providing training for health professionals. As a consequence of their widespread and often irrational use, anti-infective medicines (especially antibiotics and antimalarials) are the category of SSFFC medical products most often reported.

10. **Innovation and the local production of medicines.** The intersections between intellectual property rights, innovation and public health need to be dealt with, if market failure in respect of medicine development for unmet needs in developing countries is to be resolved. The Secretariat plays an important role in working with WIPO and WTO on these research and development issues, in the context of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.² The Secretariat also works with Member States at their request to enhance local production, where it may assist in improving access to quality-assured essential medicines. The Secretariat's current work streams in the area of public health and innovation include: facilitation of sustainable alternative ways to finance and coordinate the research and development of priority health technologies for developing countries in response to market failures; policy guidance and provision of technical assistance to countries in support of the management and application of intellectual property, with a view to promoting needs-based innovation and access to patent-protected essential medicines and health products; facilitation of technology transfer to and build capacity in developing countries for the manufacture of strategically-selected health products, in order to improve access; provision of WHO global leadership on innovation in essential health technologies, including point-of-care diagnostics; monitoring and evaluation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in order to provide evidence for its impact and direction; and management of the Global Cooperation on Assistive Technology initiative. It is anticipated that the cumulative effects of these efforts will lead to increased local production and availability of certain medical products. However, unless significant economies of scale are achieved, the product prices will generally remain high and undermine affordability.

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¹ See resolution WHA68.7 (2015).

² See resolution WHA61.21 (2008).