

## **Access to essential medicines**

### **Report by the Secretariat**

1. The Executive Board at its 134th session noted the attached document EB134/31;<sup>1</sup> the Board also adopted resolution EB134.R16.<sup>2</sup>

#### **ACTION BY THE HEALTH ASSEMBLY**

2. The Health Assembly is invited to note the report and adopt the draft resolution recommended by the Executive Board in resolution EB134.R16.

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<sup>1</sup> See the summary records of the Executive Board at its 134th session, ninth meeting, section 1 and thirteenth meeting, section 1.

<sup>2</sup> See document EB134/2014/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.





**World Health  
Organization**

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1. WHO's strategy to improve access to essential medicines is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement, affordable prices, effective distribution systems, and the rational use of medicines. Together these elements promote better management of medicines, more cost-effective use of resources and higher-quality health care, and their effective implementation will increase access to medicines, avoid high out-of-pocket expenses, facilitate progress towards universal health coverage and achievement of the health-related Millennium Development Goals, and ensure the effective treatment and care of noncommunicable diseases.
2. Despite the continued provision of support by the Secretariat and other international organizations to Member States over several decades, problems with the low availability and affordability of essential medicines in low- and low-middle-income countries remain. The poor availability of essential medicines for the treatment of noncommunicable diseases has been well documented,<sup>1</sup> and WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 sets a target of 80% availability of affordable essential medicines required to treat major noncommunicable diseases in both public and private facilities.<sup>2</sup> Effective prevention, treatment and care require access not only to affordable, high-quality medicines but also to vaccines, blood products, diagnostic tests and quality-assured devices.
3. Every two years the Organization updates the WHO Model List of Essential Medicines, with guidance from the Expert Committee on the Selection and Use of Essential Medicines. In 2013, the Committee considered 52 applications and 15 reviews for the 18th Model List, evaluating the scientific evidence on comparative effectiveness, safety and cost-effectiveness. The Expert Committee's methods are an example of the rigorous health technology assessment approaches that are being more broadly applied in health care.<sup>3</sup> The Secretariat supports country-based activities to promote the principles of evidence-based selection for national model lists of essential medicines and to further the rational use of medicines included in the national lists and the WHO Model List.

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<sup>1</sup> Millennium Development Goal 8 The Global Partnership for Development: the challenge we face. New York: United Nations MDG Gap Task Force Report; 2013.

<sup>2</sup> See document WHA66/2013/REC/1, Annex 4.

<sup>3</sup> See also document EB134/30.

4. Many Member States use the WHO Model List to draw up their national list and to adapt it in line with local considerations. Many countries are now using similar evidence-based methods to those used by the Expert Committee, including specific provisions to address potential conflicts of interest of members of the decision-making committee and a focus on the transparency of the decision-making process.

5. Although the decision-making processes for national model lists of essential medicines continue to improve, important barriers remain to their acceptance and use. In some cases, clinicians believe that these medicines are only appropriate for primary health care in the public sector and their inclusion reflects choices based mainly on cost considerations. The choice of cheaper but equivalent medicines may also be difficult to accept for dispensing doctors or health care institutions that derive profits from the sale of medicines – a perverse incentive to prescribe more expensive medicines.

6. The supply chains for medicines are long and complex. Unless the structures and processes within each link work optimally, access to good-quality medicines will be compromised. If the structures and processes are not transparent and there are insufficient institutional checks and balances in place, the system is vulnerable to corruption. Corrupt practices lead to the waste of limited resources and the failure to realize good health outcomes; they tarnish public trust and confidence in medicine supply systems.

7. WHO's Good Governance for Medicines (GGM) programme provides guidance on improving efficiency in procurement and supply, and includes tools to assess the transparency and vulnerability of selected areas of the public pharmaceutical sector. The programme comprises three stages: a national transparency assessment; the development of a national good governance framework, and implementation of a national GGM programme.

8. The Good Governance for Medicines programme is currently being implemented by 37 Member States and territories. The programme's performance in a country critically depends on the priority and support accorded by that country to tackling corruption in general and also on having high-level political support. A dedicated and motivated national team is needed to deal effectively with the many interrelated issues, particularly as engagement across other government ministries is often required.

9. With support from international agencies and donor programmes, substantial progress has been made in improving access to medicines for HIV/AIDS, malaria and tuberculosis. High-priority medicines for maternal and child health, however, are not always included in national model lists of essential medicines, and access to medicines for other infectious, acute and noncommunicable diseases remains unacceptably low, with large disparities between high-, middle- and low-income countries and within countries. Yet, paradoxically, many medicines for noncommunicable diseases are off-patent and cheap to produce.

10. Affordable access to medicines for the long-term prevention and treatment of noncommunicable diseases needs government commitment to the adequate financing of health care, and medicines in particular; the careful selection of cost-effective, prioritized medicines; and efficient procurement and distribution systems. Pharmaceutical systems must be strengthened; the Secretariat has a pivotal role in supporting countries to formulate and implement policies and systems to improve and sustain access to essential medicines for noncommunicable diseases.

11. In many settings, access to medicines in the public sector is poor, and, even though medicines are more available in the private sector, they are often much more expensive, leading to high out-of-pocket expenses that are a burden for patients and their families, thereby limiting access to care. Better and more efficient procurement and distribution may help in the public sector, but pricing policies may be

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necessary in order to manage the costs of medicines in the private sector. This may include consideration of freight costs, government tariffs, taxes and mark-ups that affect medicine prices.

12. Managing medicine costs is central to achieving equitable and affordable access. Member States use the WHO Guideline on Country Pharmaceutical Pricing Policies<sup>1</sup> as a reference for pricing medicines and ensuring sustainable medicine supply systems. Issues of health financing, and, in particular, adequate financing for essential medicines, are major challenges for countries; the Secretariat's support is crucial for countries to develop and implement financing and pricing strategies to support universal health coverage. Access to, and the affordability of, medicines can be enhanced by the use of generic medicines; policies that promote their use 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 price does not equal low quality.<sup>2</sup>

13. One important activity is the regular monitoring of the availability and prices of medicines and routine use of those data for assessing progress and identifying areas in need of policy development and implementation. The Secretariat can provide support to Member States in developing cost-effective methods for collecting reliable data, training in data analysis and presenting data in formats that are useful for national decision-making.

14. Over the past few years, international shortages of medicines have become a growing concern, in both high- and low-income countries. These shortages are sometimes due to the concentration of production of active pharmaceutical ingredients and finished products in one production plant. As a consequence, good manufacturing practice or capacity constraints can rapidly translate into supply problems. Shortages can also be caused by market changes: these especially affect older generic medicines whose prices have become so low as to provide companies with little incentive to produce them. Although large countries can be affected, it is small markets that experience shortages more as they are perceived by pharmaceutical companies as being commercially less interesting markets. Several countries maintain websites and information systems on shortages and have arrangements with the pharmaceutical industry for notification of problems with availability. Currently, there is no complete overview and analysis of the problem, nor is there a comprehensive approach on how health care professionals can manage it and maintain adequate patient care.

15. Although attention is often focused on procurement, supply, availability and pricing measures for essential medicines, their rational use is crucial to maintain a sustainable pharmaceutical supply. Setting-specific studies should explore the reasons why prescribers and consumers choose particular medicines and assess the concordance of prescribing practices with national and international best practice guidelines for clinical treatment. Because of its own rigorous methodologies, the Secretariat plays a central role in supporting countries in the conduct of such studies. The evolving threat of antimicrobial resistance has given renewed impetus to these initiatives to promote the rational use of medicines.

16. Accurate information on medicines and its dissemination to health care professionals and consumers is essential for the appropriate use of medicines. The searchable WHO Essential Medicines and Health Products Information Portal<sup>3</sup> is updated monthly and aims to improve access to information

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<sup>1</sup> WHO Guideline on Country Pharmaceutical Pricing Policies. Geneva: World Health Organization; 2013.

<sup>2</sup> Cameron A, Laing R. Cost savings of switching private sector consumption from originator brand medicines to generic equivalents. World Health Report (2010), background paper 35. Geneva: World Health Organization; 2010.

<sup>3</sup> <http://apps.who.int/medicinedocs/en/> (accessed 13 December 2013).

on essential medicines and health products, bringing together related publications from Member States, WHO, United Nations partners, global nongovernmental organizations, development partners and academics. The regulation of promotional practices is a national and regional issue. Building on WHO's criteria for ethical promotion,<sup>1</sup> Stichting Health Action International, in collaboration with the Medicines Transparency Alliance, has developed tools for the systematic examination of national regulatory frameworks and the assessment of major stakeholders' perceptions of the regulatory situation regarding medicines promotion.

## AREAS OF ACTIVITY TO PROMOTE ACCESS TO ESSENTIAL MEDICINES

17. **Supporting universal health coverage.** As countries move towards universal health coverage, underpinned in some cases by health insurance programmes, the Secretariat will need to provide support to Member States and tools to guide the development of medicines reimbursement lists that are aligned with national model lists of essential medicines, and clinical treatment guidelines. Member States will need to develop and review pricing strategies to ensure the sustainability of these schemes, and good governance must be implemented in order to reduce inefficiencies, shortages or waste in the medicines supply chain. New models need to be explored for organizing the supply chains from central medical stores, which may incorporate private sector contracting arrangements.

18. Countries are increasingly using health technology assessments to inform policy-making in health care, both in terms of priority-setting for health interventions and decision-making on the uptake and price-setting of new technologies. Supporting low- and middle-income countries to build capacity for such assessments and to incorporate the evidence from them into national decision-making is an important function for the Secretariat.

19. **Monitoring and the use of information.** In many settings, the increasing demand for health care and the limited human and financial resources necessitate judicious choices of interventions and effective management of adopted technologies. The Secretariat will provide support to countries in carrying out routine data collection for the regular monitoring of medicine availability, affordability and use to support countries in the continuous improvement of their pharmaceutical systems.

20. **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 the rational use of medicines for noncommunicable diseases.

21. **Rational use of medicines.** Countries will need support for the regular conduct of studies on the rational use of medicines in clinical practice and by consumers, and the development of interventions to rectify problems identified. In some cases, countries will need support in revising national therapeutic guidelines to bring them into line with WHO and other international best practice guidelines. New methods are needed to ensure practical, affordable studies to examine the rational use of medicines, particularly those for noncommunicable diseases.

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<sup>1</sup> See resolution WHA41.17.

22. **Antimicrobial resistance.** Antimicrobial resistance is the subject of a high-level WHO strategic and technical advisory group. The issue is complex, with few new antibiotics coming to market, widespread inappropriate human and animal use and the rapid transmission of resistant strains of microbes across jurisdictions and borders, with resulting adverse impacts on health care and health care budgets. The Secretariat has an important role in working with countries to implement existing recommendations to limit the emergence and spread of antimicrobial resistance and to develop innovative approaches for tackling this threat. It can contribute to efforts to strengthen guidelines and regulations in countries regarding the use and access to antimicrobial agents, and to monitor their use. Moreover, it can participate in the elaboration of new business models for the research and development of new antibiotics – models that at the same time will incentivize investment into the discovery of novel molecules and ensure their future preservation through rational use.

23. **Access to medicines for HIV/AIDS, tuberculosis and malaria, reproductive and maternal and child health.** In addition to work on the rational selection of medicines for these areas, the Secretariat will work with partners on efficient procurement and distribution. It will also participate in strategies to monitor their safe clinical use. Patients treated with antiretroviral medicines may require access to high-quality, affordable medicines to treat co-morbidities, such as tuberculosis, and noncommunicable diseases. Access to these medicines will require the integration of vertical disease-oriented programmes with the wider health system and the national procurement systems for medicines for noncommunicable diseases and other acute diseases.

24. **Innovation and the local production of medicines.** The intersections between intellectual property rights, innovation and public health are important if the issues of market failure in medicine development and manufacture, and unmet needs for research and development, are to be resolved. The Secretariat has an important role in working with WIPO and WTO on these research and development issues. At the same time, the Secretariat is working with Member States at their request to explore possibilities for local manufacture and production where that may assist in improving affordable access to essential medicines.

#### **ACTION BY THE EXECUTIVE BOARD**

25. The Board is invited to note the report.

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