



**World Health
Organization**

REGIONAL OFFICE FOR **Europe**

Regional Committee for Europe

67th session

Budapest, Hungary, 11–14 September 2017

Provisional agenda item 5(d)

EUR/RC67/11

+EUR/RC67/Conf.Doc./9

1 August 2017

170686

ORIGINAL: ENGLISH

Strengthening Member State collaboration on improving access to medicines in the WHO European Region

This document outlines the key issues and priority areas of work for improving access to medicines in the WHO European Region, led by the Health Technologies and Pharmaceuticals programme of the Division of Health Systems and Public Health of the WHO Regional Office for Europe. The purpose of this document is to propose strategic areas in which increased Member State collaboration could be undertaken with the support of the Regional Office.

Member States are invited to consider the strategic areas for collaboration presented and, in follow-up discussions with the Regional Office, to identify potential areas or initiatives for collaboration.

In addition to outlining opportunities for Member State collaboration, this document describes the supporting role that the Regional Office can play. Successful collaboration and progress will depend on the political will of Member States and on providing support that meets country-specific needs.

Contents

	page
Access to medicines as a global issue	3
Improving access to medicines: a long-standing WHO agenda.....	3
Ensuring a values-based approach	5
Strategic areas for Member State collaboration	6
Pricing and reimbursement	7
Strategic procurement	8
Information-sharing and mutual learning	9
Moving the agenda forward: next steps	10

Access to medicines as a global issue

1. It is estimated that almost a third of the world's population (approximately 2 billion people) lacks access to essential medicines. In some of the poorest countries in Africa and Asia this affects up to half of the population, and there is often a correlation between certain diseases (such as tuberculosis and malaria) and poverty. In many low- and middle-income countries, medicines are not affordable for those who need them, and many new medicines are too expensive even for the health systems of high-income countries.

2. The access to medicines agenda is a global topic. In November 2015, the Secretary-General of the United Nations, Ban Ki-moon, established the High-level Panel on Access to Medicines, which delivered its final report in September 2016. The High-level Panel drew particular attention to imbalances of power among institutions and inconsistencies between law, policy and practice with regard to the right to health, international trade and intellectual property law, and public health objectives and their effects on health technology innovation and access. The report delivers a series of recommendations to help improve research and development in health technologies and to ensure access to vital high-price therapies.

3. Health and well-being occupy a central position in the 2030 Agenda for Sustainable Development. Target 3.8 of Sustainable Development Goal 3 (ensure healthy lives and promote well-being for all at all ages) focuses on the pursuit of universal health coverage in all countries, including financial risk protection, access to quality essential health care services, and access to safe, effective, high quality and affordable essential medicines and vaccines for all. Target 3.b focuses on support for the research and development of vaccines and medicines. Improving access to medicines is also relevant to a number of the other Sustainable Development Goals (SDGs). These include target 5.6 on ensuring universal access to sexual and reproductive health under Goal 5 (achieve gender equality and empower all women and girls) and several targets under Goal 10 (reduce inequality within and among countries) and Goal 17 (strengthen the means of implementation and revitalize the global partnership for sustainable development). The SDGs provide the opportunity for a sustained global effort to ensure that everyone has access to the affordable, high-quality medicines they need to be healthy and productive throughout the life-course.

Improving access to medicines: a long-standing WHO agenda¹

4. WHO plays a fundamental role in promoting access to medicines around the world, specifically by addressing barriers to access at the global level, providing targeted interventions and support at the national level, and advocating evidence-informed policies and the application of international norms and standards for the quality, safety, efficacy and use of medicines. WHO is engaged in key global issues, including promoting affordable medicines, promoting needs-based research and development, ensuring the quality of and access to vaccines, conducting health technology assessments, regulating biotherapeutic products (biologicals), tackling antimicrobial resistance, regulating medical devices, and eliminating substandard and falsified medical products.

¹ While WHO works to promote affordable access to quality medicines and medical devices, both of which are crucial for a well-functioning health system and for the pursuit of universal health coverage, the focus in this document is on medicines (pharmaceutical products and vaccines), not medical devices.

5. WHO's Twelfth General Programme of Work 2014–2019 includes access to essential, quality-assured, affordable medical products as one of its six leadership priorities. A number of World Health Assembly resolutions, including resolutions WHA67.22 and WHA69.25, adopted in 2014 and 2016, respectively, have drawn the attention of Member States to the importance of improving access to medicines and addressing shortages of medicines and vaccines. It is recognized that shortages of medicines occur for various reasons, including production-related issues as well as marketing-related considerations of manufacturers. While improving access to and addressing shortages of medicines are crucial for the management of infectious diseases such as HIV and tuberculosis, changing epidemiological patterns mean that the availability and affordability of essential medicines is also central to the implementation of the Global Action Plan for the Prevention and Control of Noncommunicable diseases 2013–2020, which sets the target of ensuring "... an 80% availability of the affordable ... essential medicines ... required to treat major noncommunicable diseases ...". In 2016, WHO launched an initiative to develop a fair pricing model for pharmaceuticals, which involves a wide range of stakeholders (including the pharmaceutical industry). The initiative seeks to achieve an appropriate balance between guaranteeing access to affordable medicines and encouraging companies to develop new and improved medicines, while also ensuring that lower-cost generic medicines remain available.

6. The United Nations High-level Panel on Access to Medicines noted the misalignment among market-based models that incentivize innovation, the need to obtain treatments for patients, and the prices charged by rights holders that place severe burdens on health systems and individual patients. WHO put forward similar findings in 2012 in the report of its Consultative Expert Working Group on Research and Development: Financing and Coordination. Examining the appropriateness of different research and development financing and coordination approaches and the feasibility of implementing those mechanisms in the WHO regions, the Expert Working Group proposed a number of measures to allow for quicker and cheaper access to quality drugs. Its recommendations included a call for a global research and development agreement (treaty) to ensure sustainable financing in necessary areas (a point that was echoed by the High-level Panel) and prioritization and coordination to ensure that the medicines required come to market and are available to those who need them. Importantly, it also set out potential norms and principles on how research and development should be financed to ensure innovation and accessibility. The Expert Working Group suggested that research and development:

- must be needs-driven, evidence-based and delinked from prices;
- must ensure affordability, efficacy and equity; and
- must be a shared responsibility.

7. In the WHO European Region, ensuring access to high quality, affordable medicines and promoting their responsible use are key aspects of the people-centred health systems priority area under Health 2020. At its 65th session, the WHO Regional Committee for Europe, in resolution EUR/RC65/R5, unanimously endorsed Priorities for Health Systems Strengthening in the WHO European Region 2015–2020: walking the talk on people-centredness (document EUR/RC65/13), which set out two strategic priorities:

- transforming health services to meet the health challenges of the 21st century; and
- moving towards universal health coverage for a Europe free of impoverishing out-of-pocket payments.

8. Pharmaceuticals and medical technologies are a key consideration in pursuing these two strategic priorities. In Regional Committee discussions, Member States called for more focused, affordable and effective medicines, with cutting-edge research committed to the discovery, development and uptake of value-added treatments.

9. Along with improving access to medicines, another issue of growing concern for health policy-makers in Europe is the continuing rise in spending on pharmaceuticals. The most recent data for the WHO European Region shows a considerable variation among countries in terms of public expenditure on pharmaceuticals, which ranges from less than 10% of total health-care expenditure in countries such as Denmark, the Netherlands and Norway, to more than 30% in Georgia, Hungary, Serbia and Tajikistan. Pharmaceuticals are the main contributor to out-of-pocket health payments in the Region and, consequently, in some settings lead to catastrophic and impoverishing medical expenditure. With the continuing rise in noncommunicable diseases, many of which are chronic conditions that require long-term treatment, the financial burden will become even greater. For example, in several economies in transition in the European Region, a one-month course of simple hypertension treatment can cost up to 35 days' wages, most of which is paid out-of-pocket. For the most vulnerable segments of the population, life-saving essential medicines may be impossible to afford.

10. One of the greatest challenges for health decision-makers is to achieve fair pricing and access to the most effective and safe medicines, while ensuring the long-term financial sustainability of health systems. Responsible and appropriate prescriptions for and use of medicines are also crucial, particularly in view of the growing threat from antimicrobial resistance, as recognized by Member States in several policy documents adopted at the global and regional levels.

Ensuring a values-based approach

11. The pursuit of an agenda to improve access to medicines is not new and many obstacles to progress persist, some of which are regulatory, some legislative, and some related to human and financial capacity. The European Region is characterized by diversity in population, health system structures and organization, and financial resources. However, when it comes to health, Member States in the Region are united by shared values of solidarity and equity, as reflected in Health 2020.

12. Member States in the European Region share common views on the importance of universal health coverage and effective and efficient health care systems to serve all people. Joint support for health systems strengthening and a commitment to improve access to medicines are part of this value-based approach. Indeed, the Declaration of Alma Ata, which includes the provision of essential medicines as one of the key components of primary care (1978), the Ljubljana Charter on Reforming Health Care (1996), Health21: the health for all policy framework for the WHO European Region (1998), the Tallinn Charter on Health Systems for Health and Wealth (2008), Health 2020 (2012) and the Minsk Declaration: the Life-course Approach in the Context of Health 2020 (2015) all demonstrate a consistent expression of commitment to the shared values of solidarity and equity among Member States in the European Region.

13. In the context of Health 2020's focus on strengthening people-centred health systems and public health capacity, including emergency preparedness and response capacity, the WHO Regional Office for Europe promotes a value-based approach on access to medicines. Noting the varying availability of high-quality medicines across the Region, even for prevalent conditions such as hypertension and asthma, Health 2020 calls on Member States to consider mechanisms to improve access and contain costs. These include the rational selection and appropriate prescription and use of medicines, streamlining delivery systems, increasing the quality and use of generic medicines, and the use of health technology assessment to inform reimbursement decisions. In addition, Member States are dissuaded from using unproven therapies and interventions and are urged to be vigilant and to strongly regulate the promotion of medicines.

14. It is nevertheless clear that improving health care and increasing access to medicines are complex issues, and that stakeholders include not only ministries of health, but also ministries of education, finance, industry, labour and social affairs, as well as the pharmaceutical sector, medical associations, patient groups and consumers. It is recognized that patients' and health professionals' perception of medicines is influenced by promotion and marketing, including through the Internet. Furthermore, it is acknowledged that transparency on the part of all stakeholders is important and that governments have a role in ensuring transparency and the quality and safety of medicines and in fostering competition. While these issues often need to be addressed from a national perspective, Member States can harness opportunities to share knowledge and best practices, engage in formal or informal collaboration among groups of countries with shared interests and concerns and, where appropriate, undertake joint or shared activities to maximize the value of scarce human and financial resources. The importance of medicines has been highlighted by the uptake of health and medicine-related issues as key themes under a number of presidencies of the Council of the European Union, most recently that of the Netherlands Government (1 January to 30 June 2016).

Strategic areas for Member State collaboration

15. Through the work of the Health Technologies and Pharmaceuticals programme in the Division of Health Systems and Public Health, the Regional Office works with Member States to help ensure that people have equitable access to affordable medicines of assured quality and that those medicines are prescribed and used appropriately. This involves:

- (a) providing direct technical and policy support to countries (particularly countries in transition);
- (b) facilitating networks on policies related to drug regulation, quality, pricing, reimbursement and responsible use;
- (c) building capacity through training and setting up systems for the regulation, provision and use of medicines in countries;
- (d) providing evidence-based tools for implementing pharmaceutical policies; and
- (e) supporting monitoring of implementation of policies in countries and networking among countries and professionals.

16. Through the Health Technologies and Pharmaceuticals programme, the Regional Office has prioritized three areas of activity in the pharmaceutical sector during the 2016–2017 biennium. These areas of activity, which include measures at both regional and national levels, are:

- (a) **policies and regulation:** the development of pharmaceutical policies, legislation and regulation, good governance in the pharmaceutical sector, and efficient procurement and supply chain management to ensure the quality of medicines and health technologies in circulation;
- (b) **medicines selection:** evidence-based selection of medicines and technologies and the application of the principles of health technology assessment and prioritization of public pharmaceutical expenditure to support equitable access to cost-effective medicines and technologies; and
- (c) **data and information:** monitoring the use of and expenditure on medicines and technologies, which is critical to understanding and improving the responsible use of medicines and health technologies, including antimicrobials, and reducing the waste of limited health-care resources on inefficient practices.

17. In the context of those three areas of activity and building on previous actions – both those of the European Union, for example, the European Network for Health Technology Assessment and the European Integrated Price Information Database (EURIPID), and those supported by the Regional Office, such as the Pharmaceutical Pricing and Reimbursement Information (PPRI) network – several opportunities arise for Member State collaboration, specifically in relation to pricing, reimbursement and strategic procurement, and by information sharing and mutual learning through good-practice networks.

Pricing and reimbursement

18. In conjunction with academic and international partners, the Health Technologies and Pharmaceuticals programme conducted a technical review of policies and evidence from 27 European countries relating to the process of introducing new and expensive medicines. The report, “Access to new medicines in Europe: technical review of policy initiatives, opportunities for collaboration and research”, notes that the number of new medicines being introduced in Europe is rising, particularly for chronic diseases such as cancers, type 2 diabetes and hepatitis C, and that governments are finding it increasingly difficult to afford them. Not all Member States in the European Region have mechanisms in place to evaluate the cost-effectiveness of new drugs, which hampers value-assessment and decision-making processes at the national level to the detriment of patients.

19. During the 66th session of the Regional Committee for Europe in September 2016, the Division of Health Systems and Public Health conducted a technical briefing, “Access to new high-priced medicines: challenges and opportunities”, which resulted in recommendations calling on the Regional Office to promote collaboration among Member States and to support the development of regional and subregional networks to address topics such as horizon scanning, health technology assessment, the willingness to pay for innovation, and the delinking of medicine prices from research and development costs. While joint activities on health technology assessment are being conducted among member States of the European Union, the same opportunities do not exist for other countries in the WHO European Region. Although national and cross-national activities on horizon scanning are in place, such as the

International Information Network on New and Emerging Health Technologies (also called the EuroScan International Network), existing mechanisms do not meet the needs of all Member States in the European Region and efficiency could be improved by sharing expertise and resources.

20. The PPRI network is an initiative for networking and information-sharing on issues concerning pharmaceutical policy from a public health perspective. The network involves more than 90 institutions in 46 countries (mainly in Europe), along with European and international institutions including WHO, the Organisation for Economic Co-operation and Development, and European Commission services and agencies. The network secretariat, funded by the Austrian Federal Ministry of Health, is hosted by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. To date, there is no equivalent networking and information-sharing opportunity or forum for non-European Union countries in the Region. A similar network for the Commonwealth of Independent States countries could be an important mechanism for collating country information and sharing country experiences and for discussing issues such as medicines pricing and reimbursement.

21. The WHO global initiative on the fair pricing of medicines provides important support for health systems in the European Region, and will help to promote a social contract that balances access to needed medicines and health technologies, provides rewards for true innovation and supports the sustainability of health care systems. WHO and the Government of the Netherlands co-hosted the first Fair Pricing Forum consultation in May 2017, bringing together experts to discuss high drug prices and government purchasing of medicines. The meeting included key stakeholders involved in negotiating which medicines governments purchase. The outcomes of this global meeting can provide opportunities for developing initiatives that address gaps in the access to medicines in the European Region.

Strategic procurement

22. Member States of the European Region vary in capacity and negotiating power for procuring new medicines and health technologies. Not only do different countries frequently pay different prices for the same treatments, the prices any given country pays may be disproportionately high and incompatible with its purchasing power. It has been estimated, for example, that the cost of treating the entire hepatitis C-infected population with sofosbuvir and ledipasvir-sofosbuvir would account for only 10.5% of the total pharmaceutical expenditure in the Netherlands, but 190.5% in Poland. In Turkey, the price of a single course of sofosbuvir is equivalent to 5.28 years of the average annual salary.

23. Countries can collaborate on procurement at different levels – multilateral, subregional or regional – and in different areas. One example could be joint price negotiations; others include informed buying (where participating countries may share information on prices, suppliers and health technology assessment methodologies, but conduct their own procurement individually) and central contracting and procurement (where participating countries issue joint tenders through a central buying unit). The Nordic Forum and the BeneluxA group are important examples of joint procurement efforts, along with the European Union's Joint Procurement Agreement to Procure Medical Countermeasures. More recently, on 8 May 2017, the ministers of health of Cyprus, Greece, Italy, Malta, Portugal and Spain signed the Valletta Declaration for better access to medicines, agreeing to establish a technical committee to explore possible voluntary cooperation in several areas, including joint

price negotiation and joint procurement. Changes in funding models for the provision of medicines for the treatment of tuberculosis and other infectious diseases in some Member States provide additional impetus for informed and effective procurement of medicines.

24. Another priority on the European Union's agenda is to increase structured collaboration among health systems of EU member States; this reflects growing interest at the bilateral and multilateral levels. Voluntary intercountry collaboration on procurement of medicines can enhance transparency through better information-sharing; facilitate cross-country learning by sharing experiences; and strengthen bargaining power and mitigate overly high transaction costs by pooling skills and capacities and through joint negotiations. Collaboration can also ensure sustainable access to health technologies by sharing resources through cross-border exchanges of products in short supply. Thus far, cross-border collaboration in Europe remains limited and it will take time to assess the impact and effectiveness of such initiatives.

Information-sharing and mutual learning

25. Some Member States in the European Region face a lack of information with regard to several aspects of the pharmaceutical sector, which hampers efficient decision-making. Lack of transparency in pharmaceutical prices and the use of managed entry agreements and confidential rebates have undermined the value of external reference pricing mechanisms. This, coupled with the lack of negotiating power of Member States with small markets, has led to differential prices, meaning that small countries and those with limited resources are paying disproportionately higher prices for medicines, in particular new medicines. In some cases, this means that new products either do not reach the market at all or only arrive on the market some years after being made available in larger markets and economies, thus undermining the principles of solidarity and equitable access in the Region.

26. Early sharing of information about medicine shortages and mitigating strategies may reduce the incidence and duration of shortages and their impact on treatment decisions by doctors and patients. In 2016, the World Health Assembly, in resolution WHA69.25, urged Member States to address this issue, including the development of strategies that may be used to forecast, avert or reduce shortages or stockouts; implement effective notification systems that allow remedial measures to avoid medicines and vaccines shortages; and advance regional and international cooperation in support of national notification systems, including the sharing of best practices and training for human capacity-building through regional and subregional structures.

27. At present, monitoring the use of medicines is not conducted in a uniform manner by Member States in the Region. Data analyses can identify patterns of expenditure, medicines use and wasteful management practices that compromise the sustainability of health systems, in general, and health insurance schemes, in particular. Routine data analysis supports efficiency and helps to identify the optimal mix of policies to provide affordable access to medicines in the context of constrained health-care budgets. One example of this is the Health Technologies and Pharmaceuticals programme's ongoing work to measure antibiotic consumption in countries outside the European Union. With the inclusion of initial data collection and analysis from various countries in eastern Europe and central Asia, this work has revealed an almost fourfold difference between the highest and lowest antibiotic consumption rates among 42 countries in the Region, and enables the identification of areas

where improvements are needed to address antibiotic overuse and misuse. This is important for both local and international health policy-makers.

Moving the agenda forward: next steps

28. The three strategic areas noted above are examples of key issues on the international pharmaceutical agenda that afford opportunities for effective Member State collaboration. Although in some cases there can be political, legislative and cultural barriers to information-sharing and joint activities, the shared values of solidarity and equity provide a strong rationale for engagement. Member States must identify which activities best align with their own national interests and imperatives. Such collaboration may be based on similarly developed pharmaceutical sectors, shared disease profiles or geographic proximity.

29. Opportunities to extend or to adapt existing platforms for Member State collaboration should be explored. Although mainly benefiting European Union member States, the PPRI network, EURIPID, the EuroScan International Network and the European Network for Health Technology Assessment provide useful examples of networks addressing a broad range of issues in health technology assessment, horizon scanning, pricing and reimbursement decisions. The same challenges for providing access to new high-cost medicines exist in the WHO European Region, although the nature of the challenges may differ with regard to regulatory, legal and fiscal constraints, the limited opportunity for negotiation and low bargaining power of small (single country) markets, and industry-driven pricing strategies predicated on confidential pricing and managed entry agreements. Member States could consider the value of establishing new subregional networks or collaboration that focus on horizon scanning, health technology assessment and pricing and reimbursement policies for countries not actively participating in currently existing European networks.

30. The Regional Office could support the development of such networks (new or existing) as it did for the PPRI network, which has since become self-sustaining under the auspices of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Austrian Public Health Institute. Member States are also invited to consider Member State collaboration on joint horizon scanning, which could include activities such as identifying and filtering new/emerging medicines in clinical development for use, and reimbursement based on estimations of budget impact and clinical effectiveness.

31. Significant progress has already been made to advance access to medicines and to explore barriers and facilitators to joint procurement activities. Nascent activities need to be evaluated for their impact and effectiveness, and experiences and lessons learned should be shared among Member States. The Regional Office can facilitate country collaboration and support activities for information-sharing and dissemination with a view to exploring the feasibility of closer collaboration on strategic procurement issues. The Regional Office has already hosted several country consultations focused on reviewing national experiences in the area of regulation and procurement of medicines with a view to helping countries to take informed decisions.

32. It is clear that one of the key elements of access to medicines, particularly in Europe given the diverse needs and interests of Member States, is the sharing of information and data and the need for countries to learn from each other. This appreciation of common challenges and opportunities, coupled with well-trained and informed decision-makers, fosters

collaboration in areas such as joint procurement in the case of the BeneluxA initiative. Where necessary, the Regional Office can promote collaboration, provide training, support capacity-building and facilitate dialogue among countries with similar needs and interests. This would include continuously providing scientific evidence and analysis to Member States through collaborative actions, as well as promoting transparency, and identifying best-practice (and less good-practice) models of pharmaceutical reimbursement in order to ensure affordability of medicines, in particular for vulnerable population groups. Further areas for Member State collaboration could include the development of a subregional pharmaceutical pricing and reimbursement group for the countries of the Commonwealth of Independent States or establishing a procurement practitioners' network with other United Nations agencies and partners to facilitate knowledge sharing and capacity-building.

33. The Regional Office can provide guidance on Member State collaboration in these areas in an effective, integrated and evidence-informed manner and can promote debate and discussion on important topics relevant to access to medicines and broader pharmaceutical issues. Political will and mutual trust among Member States will be essential for successful collaboration.

34. To make the most of limited resources, the Regional Office engages independent experts, at both regional and country levels, and works closely with numerous partners including patient organizations, the European Centre for Disease Prevention and Control, the European Commission, the European Observatory on Health Systems and Policies, the United Nations Children's Fund, the Organisation for Economic Co-operation and Development, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank, leading academic centres, national authorities and WHO collaborating centres. Working in partnership enables the Regional Office to deliver in areas where it has a comparative advantage and can garner critical expertise, to keep abreast of the latest evidence and to ensure alignment between regional and global agendas. Ultimately, the success of any new network or collaboration will depend on its ability to meet the needs of Member States and to promote useful strategies that can be applied to improve access to medicines.

= = =