World Health Organization
REGIONAL OFFICE FOR Europe

SDG target 3.8: achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

SDG target 3.b: support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

Fact sheets on sustainable development goals: health targets

Access to essential medicines, vaccines and health technologies

Essential medicines policies are crucial to achieve universal health coverage and sustainable development *(1)*. Access to essential medicines is a global concern, irrespective of country income. Medicines are not affordable for those who need them in many low- or middle-income countries, and many new medicines are too expensive even for the health systems of high-income countries *(1,2)*. The Sustainable Development Goals (SDG) 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.

Overview

Essential medicines are a subset of the total range of pharmaceuticals that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and cost–effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, with assured quality and in appropriate dosage forms. They should also be provided with adequate information and at a price the individual and the community can afford and that is sustainable in the long term *(3)*. Beyond medicines, the principles described above also apply to health technologies in general (both medical equipment and a wide range of medical devices and care supplies) for health care in various settings, including the home *(4)*.

In November 2015, the Secretary-General of the United Nations, Ban Ki-moon, established the High-level Panel on Access to Medicines "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies" *(5)*.

The High-level Panel final report, delivered in September 2016, drew particular attention to inconsistencies between public health objectives and the law, policy and practice governing the right to health, international trade and intellectual property. It also noted that these imbalances of power among institutions had effects on health technology innovation and access. *(2)*. The High-level Panel also noted the misalignment among market-based models that create incentives for innovation, the need to obtain treatments for patients and the prices charged by rights holders, which 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 *(6)*.

A number of World Health Assembly resolutions, including resolutions WHA67.22 in 2014 and WHA69.25 in 2016 *(7,8)*, have drawn the attention of Member States to the importance of improving access to medicines and addressing shortages of medicines and vaccines. While the Member States of the WHO European Region are very diverse, they have, over the years, demonstrated a consistent expression of commitment to the shared values of solidarity and equity. 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 values-based approach on access to medicines *(4)*. Joint support for health systems strengthening and a commitment to improve access to medicines are part of this values-based approach.

Access to essential medical products and SDGs: facts and figures

Pharmaceuticals are the main contributor to out-of-pocket health payments in the WHO European Region and, consequently, in some settings lead to catastrophic and impoverishing medical expenditure *(9)*. Ensuring access to essential medicines without creating financial hardship will contribute to ending poverty.

In the WHO European Region, the pursuit of an agenda to improve access to medicines is not new and many obstacles to progress persist.

Responsible and appropriate use of pharmaceuticals: WHO estimates that more than half of all medicines worldwide are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take medicines correctly. Overuse, underuse and misuse result in wastage of scarce resources, continued health problems or adverse reactions to drugs *(10)*.

- Recent inclusion of initial data collection and analysis from various countries in eastern Europe and central Asia has revealed an almost fourfold difference between the highest and lowest antibiotic consumption rates among 42 countries in the WHO European Region *(9,11)*.In some areas of southern and eastern Europe, 20–30% of antibiotics are consumed without prescription *(9,12,13)*.
- Monitoring the use of medicines is not conducted in a uniform way among Member States in the European Region. Routine data analyses support efficiency and help to identify the optimal mix of policies to provide affordable access to medicines in the context of constrained health care budgets and also enable areas to be identified where improvements are needed to address inappropriate use.

Pricing and reimbursement: challenges in providing access to new high-priced medicines exist across the WHO European Region, although the nature of the challenges may differ with regard to regulatory, legal and fiscal constraints; limited opportunities for negotiation and low bargaining power of small markets; and industry-driven pricing strategies predicated on confidential pricing and managed entry agreements *(14)*.

- Not all Member States in the WHO European Region have mechanisms in place to evaluate the cost–effectiveness of new drugs, which hampers value-assessment and decision-making processes to the detriment of patients at the national level *(14)*. While joint activities on health technology assessment are being conducted among Member States of the European Union, the same opportunity does not exist for other countries in the WHO European Region. Efficiency could be improved by sharing expertise and resources.

Strategic procurement: Member States of the WHO European Region have varying capacity and negotiating power when procuring new medicines and health technologies.

- Different countries frequently pay different prices for the same treatments *(15,16)*.
- The lack of negotiating power of some Member States with small markets has led to differential prices, meaning that the prices any given country pays may be disproportionally high and incompatible with its purchasing power, particularly for new medicines *(16)*. 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 across Europe *(16)*.
- It has been estimated, for example, that the cost of treating the entire population infected with hepatitis C using sofosbuvir and ledipasvir–sofosbuvir would account for 10.5% of the total pharmaceutical expenditure in the Netherlands and 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 *(17)*.
- Countries can collaborate on procurement at different levels – multilateral, subregional or regional – and in different areas. One example would 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. All of these are in line with the dimensions of SDG 17 (finance; technology and innovation; capacity-building; fair trade; policy and institutional coherence; multistakeholder partnership; and data monitoring and accountability).

Information-sharing and mutual learning: some Member States in the WHO European Region lack 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 *(16)*.

End the epidemics of communicable diseases: improving access to and addressing shortages of medicines are crucial for the management of infectious diseases such as HIV, tuberculosis and viral hepatitis, among others. Research and development is required to ensure that pharmaceuticals are available to deal with communicable diseases.

- Since the mid 2000s, only two new classes of antibiotic have come to market, despite the looming crisis of antimicrobial resistance *(2)*.
- In high-income countries, 60% of research and development investment is from the private sector and 40% is from public and non-profit-making sources. However, for diseases that heavily affect the poor (HIV, tuberculosis and malaria) the public sector provides approximately two thirds of research and development investment and the private sector only finances about 10% of research into these diseases *(2)*.

Reduce premature mortality from noncommunicable diseases: the availability and affordability of essential medicines is also central to the implementation of the Global action plan for the prevention and control of NCDs 2013–2020, which set the target of ensuring "an 80% availability of the affordable … essential medicines … required to treat major noncommunicable diseases" *(18)*. However, for the most vulnerable segments of the population, life-saving essential medicines may be impossible to afford.

- In several economies in transition in the WHO European Region, a one-month course of simple hypertension treatment can cost up to 35 days of wages, most of which is paid out of pocket *(10,19)*.

Ensure access to sexual and reproductive health care services is central to people-centred care and achieving universal health coverage.

- In the WHO European Region, the contraceptive prevalence rate, using modern methods, increased slightly from 55.6% in 2000 to 61.2% in 2015, largely as a result of increased usage in eastern and southern Europe *(20)*. However, based on the most recent data available, unmet family planning needs continues to be an issue, ranging from 5% to nearly 23% in Member States *(21)*.

Achieve universal coverage: the continuing increase in health financing that is allocated to pharmaceutical costs is a growing concern for health policy-makers in the WHO European Region.

- The most recent data for the Region shows a considerable variation among countries in terms of 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 *(22)*.
- The number of new medicines being introduced in Europe is increasing, particularly for chronic diseases such as cancers, type 2 diabetes and hepatitis C. However, governments are finding it increasingly difficult to afford them *(14)*.
- 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 *(23)*.
- Using generic medicines rather than more expensive originators is one way to reduce the cost for pharmaceuticals (Box 1) *(24)*. However, the share of generic medicines varies widely across the Region. As an example, the proportion of prescriptions filled with generics ranges from 17% in Switzerland to 83% in the United Kingdom *(15)*.
- For health technologies in general, the market value of devices for medical and care purposes is estimated to be as large as that for medicines. Estimating needs and identifying high-priority technologies and devices (both medical equipment and a wide range of medical and care supplies) for health care in various settings, including the home, are significant challenges in the WHO European Region *(4)*.

Commitment to act

At its 65th session, the WHO Regional Committee for Europe unanimously endorsed "Priorities for health systems strengthening in the WHO European Region 2015–2020: walking the talk on people-centredness" *(26)*, 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.

Pharmaceuticals and medical technologies are a key consideration in pursuing these two strategic priorities. On this occasion, 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.

Ensuring that quality essential medicines and health technologies are available in sufficient quantities and affordable to the population requires functioning regulatory and procurement systems as well as legal provisions for universal health coverage, governance and efficient management of resources. Improving access to medical products will further require tackling common barriers to access, which can be financial (insufficient monetary resources), geographical (distance to providers), organizational (lack of available providers) and sociological (such as discrimination or language barriers) *(14)*. In addition, minimizing wasteful spending on pharmaceuticals will be key and there is a range of opportunities to do so through more efficient regulation and improved decision-making. Using generics rather than originators is one example to limit operational waste *(24)*.

Priority areas in the WHO European Region include:

- **efficient procurement systems** to increase access to medicines *(14)*;
- **national policy development** to formulating evidence-based policies and ensuring good practice and good governance throughout the health and pharmaceutical sector *(23)*;
- **effective regulations and quality control** for medicines and medical devices to promote and protect public health by ensuring that medicines and medical devices are of the required quality, safety and efficacy as well as appropriately manufactured, stored, distributed and dispensed; since quality systems are built by manufacturers and assessed by national authorities, the quality of medicines and health technologies and the capacities of both to safeguard patient safety should be developed equally *(23,27)*;

- **responsible use** of medicines and medical devices *(23)*; and
- **research and development** to ensure innovation and access that must be needs driven, evidence based and unlinked from prices; ensure affordability, efficacy and equity; and a shared responsibility of all stakeholders, including governments, the biomedical industry, institutional funders of health care and civil society *(2,23)*.

Box 1. Leaving no one behind...

"The imbalance between human rights, intellectual property rights and public health objectives is leaving people behind": this conclusion was drawn by the Secretary General's High-Level Panel *(25)*. Mechanisms to improve access and contain costs that Member States could implement include increasing the use of quality generic medicines, which would support the efficient use of resources and reduce the health divide between countries of higher and lower incomes.

Intellectual property rights granted to promote scientific innovation are one cause of the high prices of medicines. Countries should also promote research and development work on those diseases for which no effective treatment is currently available. Although discussions on this topic have been ongoing for many years, further support is needed for innovations against the diseases that disproportionately affect people on low incomes *(4)*.

A conducive policy environment is needed at regional and multinational levels, ideally also at a global level, that takes into account the need to provide equitable access to medicines.

It is clear that one of the key elements of access to medicines is the sharing of information and data and the need for countries to learn from each other. Therefore, strengthening collaboration between Member States on improving access to medicines in the WHO European Region is an opportunity, particularly in Europe given the diverse needs and interests of Member States. Pricing and reimbursement, strategic procurement and information sharing and mutual learning are examples of key strategic areas on the international pharmaceutical agenda where effective Member State collaboration is key (Box 2). Member States must identify which activities best align with their own national interests and imperatives *(16)*.

In addition, actions around pricing and reimbursement policies, such as the network of the Commonwealth of Independent States, and knowledge-sharing networks on horizon scanning and strategic procurement, facilitate knowledge sharing and capacity development among Member States. Political will and mutual trust among Member States will be essential for successful country collaboration supported by the WHO Regional Office for Europe.

Box 2. Intersectoral action

Improving health care and increasing access to medicines are complex issues: stakeholders in this area include ministries of health, education, finance, industry, labour and social affairs, as well as the pharmaceutical sector, medical associations, patient groups and consumers.

It is recognized that the perception of medicines by both patients and health professionals is influenced by promotion and marketing, including through the Internet *(28)*. 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.

Action across all stakeholders *(23)* is necessary to ensure that:

- health professionals and patients have the necessary information to enable them to use medicines and other medical products responsibly;
- promotion and advertising are fair, balanced and aimed at responsible use; and
- unjustified regulatory work does not hinder access to essential medicines and health technologies.

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.

Monitoring progress

The WHO Regional Office for Europe is developing a joint monitoring framework for the SDG, Health 2020 and noncommunicable diseases indicators[1] to facilitate reporting in Member States and to provide a consistent and timely way to measure progress. Lack of access to essential medical products compromises all Health 2020 targets *(29)*. The following, as proposed in the global indicators framework of the United Nations Economic and Social Council (ECOSOC) *(30)*, will support monitoring progress in the access to essential medical products.

ECOSOC indicators

3.b.1. Proportion of the population with access to affordable medicines and vaccines on a sustainable basis

3.b.2. Total net official development assistance to medical research and basic health sectors

3.8.1. Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health; infectious diseases; noncommunicable diseases; and service capacity and access, among the general and the most disadvantaged population)

Health 2020 core indicators (indicator-level alignment)

(1) 1.1.a. Age-standardized overall premature mortality rate (from 30 to under 70 years) for four major noncommunicable diseases (cardiovascular diseases (ICD-10a codes I00–I99), cancer (ICD-10 codes C00–C97), diabetes mellitus (ICD-10 codes E10–E14) and chronic respiratory diseases (ICD-10 codes J40–J47) *(31)*) disaggregated by sex

(5) 1.2.a and (5) 5.1.b. Percentage of children vaccinated against measles (one dose by second birthday), polio (three doses by first birthday) and rubella (one dose by second birthday)

(7) 2.1 and (7) 3.1.b. Life expectancy at birth, disaggregated by sex

(16) 5.1.a. Private household out-of-pocket expenditure as a proportion of total health expenditure

(17) 5.1.c. Total expenditure on health (as a percentage of gross domestic product)

WHO support to Member States

WHO envisions a world where every child, man and woman can afford and has access to the quality essential medicines and health products they need to lead a healthy and productive life *(32)*. Increasing access to medical products is one of six WHO global leadership priorities *(33)*.

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.

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

- providing direct technical and policy support to countries (particularly countries in transition);
- facilitating networks on policies related to medical product regulation, quality, pricing, reimbursement and responsible use;
- building capacity through training and setting up systems for the regulation, provision and use of medicines and medical devices in countries;
- providing evidence-based tools for implementing pharmaceutical policies; and

[1] EUR/RC67/Inf.Doc./1: joint monitoring framework: proposal for reducing the reporting burden on Member States.

- supporting monitoring of implementation of policies in countries and networking among countries and professionals.

The Health Technologies and Pharmaceuticals programme 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 policies and regulation, medicines selection, and data and information.

Partners

The WHO Regional Office for Europe collaborates with the following partners to make the most of limited resources to improve access to medicines:

- European Centre for Disease Prevention and Control
- European Commission
- European Observatory on Health Systems and Policies
- Global Fund to Fight AIDS, Tuberculosis and Malaria
- Organisation for Economic Co-operation and Development
- United Nations Children's Fund
- World Bank
- WHO collaborating centres and patient organizations, leading academic centres and national authorities.

Resources

- Health Technologies and Pharmaceuticals (HTP) programme annual report 2015 http://www.euro.who.int/__data/assets/pdf_file/0004/299623/HTP-Programme-Annual-Report-2015.pdf.pdf?ua=1
- Access to new medicines in Europe http://www.euro.who.int/__data/assets/pdf_file/0008/306179/Access-new-medicines-TR-PIO-collaboration-research.pdf?ua=1
- Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region http://www.euro.who.int/__data/assets/pdf_file/0003/323598/Challenges-opportunities-improving-access-medicines-efficient-public-procurement.pdf?ua=1

Key definitions

- **Antimicrobial resistance.** The resistance of bacterial, viral, parasitic and fungal microorganisms to antimicrobial medicines that were previously effective for treatment of infections *(34)*.
- **People-centred care.** The management and delivery of health services such that people receive a continuum of health promotion, health protection and disease prevention services, as well as diagnosis, treatment, long-term care, rehabilitation and palliative care services through the different levels and sites of care within the health system and according to their needs *(35)*.

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