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13:00–14:30, Press Room

Access to new high-priced medicines: challenges and opportunities

Background

The United Nations General Assembly resolution A/RES/70/1 adopting *Transforming our world: the 2030 Agenda for Sustainable Development* with its commitment to "leave no one behind" must by definition include affordability of treatment. One of the main barriers to accessing many new medicines, including cancer medicines, orphan drugs and new treatments for hepatitis C, is high prices, even in cases where evidence shows that manufacturing is relatively inexpensive. In today's economy, this issue is relevant to all countries, whether in the low-, middle- or high-income category.

Increasing access to medical products is one of six global leadership priorities for WHO and, while Member States of the European Region provide better access to medicines and medical devices for their citizens than some countries of other WHO regions, inequities continue to exist across and within countries, and access to new high-priced medicines, in particular, is an issue of concern for many countries.[1]

In 2015, the Regional Office for Europe published a report, *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research*, which focuses on sustainable access to new medicines. The report reviews policies that affect medicines throughout their life-cycle – from research and development to disinvestment. While traditionally some European countries have not required active priority-setting for access to medicines, the high prices of many new medicines has changed the decision-making landscape. Appraising new medicines using

[1] Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. Copenhagen: WHO Regional Office for Europe; 2015 (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015).

pharmacoeconomics and budget impact analysis is increasingly seen as critical in order to improve efficiency in spending while maintaining an appropriate balance between access, cost–effectiveness and affordability.

While the rapid pace of innovation, particularly with regard to treatments for noncommunicable diseases, is very positive from a patient's perspective, the introduction of new medicines frequently increases both their therapeutic complexity and their cost. As a result, decision-makers, including payers, must make choices about which new high-priced medicines to fund, and for which populations, while at the same time fostering innovation. Key steps in the decision-making process should include methods that distinguish and reward meaningful clinical innovation, as well as evaluation mechanisms to assess the benefits of introducing new medicines and their impact on health system budgets.

Member States in the European Region use a variety of different methods for setting the price of medicines; many rely on external reference pricing (ERP). Consensus is increasing among payers that medicines should be priced according to the added therapeutic and/or societal value they deliver. Nevertheless, implementing such a value-based pricing system is complicated by methodological challenges and limited by data availability.

Increasingly, countries are using health technology assessment (HTA) to guide their reimbursement decisions. This may be done in conjunction with budget impact analysis. Managed-entry agreements (MEAs), rebates, clawbacks and paybacks are widely used tools to generate savings for governments and third-party payers without affecting official list prices.

Achieving fair pricing and ensuring long-term sustainability of health care systems and access for patients are big challenges for health and pharmaceutical systems in Europe and worldwide, as evidenced by a request to include medicine prices on the agenda of the G7 Summit in Japan in May 2016.[2]

[2] France wants medicine prices to be on agenda at G7 summit [e-news]. New York: Reuters; 21 March 2016 (http://www.reuters.com/article/us-health-france-g-idUSKCN0WN1PS).

Scope and purpose

In September 2015, the 65th session of the Regional Committee for Europe endorsed resolution EUR/RC65/R5 on Priorities for health systems strengthening in the WHO European Region 2015–2020: walking the talk on people-centredness (document EUR/RC65/13), which calls for access to affordable quality medicines and technologies as a fundamental principle of health systems strengthening.

The aim of this technical briefing is to consider ways to improve access to new medical products in the European Region from a Health 2020 perspective; that is, by espousing the principles of solidarity, equity and participation. The session will present priorities for action at the national level and the potential for intercountry collaboration based on the findings of the WHO report. The briefing will also provide a platform for generating ideas for future activities that can contribute to the "access to new medicines" agenda.

The objectives of the technical briefing are:

- to report on the results of the WHO report, *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research*, and on follow-up work taking place in 2016;
- to receive feedback from participating stakeholders on the overall findings of the report and on suggestions for the way forward from a national, a regional and a global perspective; and
- to outline the next steps towards the development of strategies for intercountry collaboration and national actions that increase access to new medicines in the European Region in an equitable manner consistent with Health 2020 and the 2030 Agenda for Sustainable Development.

Provisional programme

Time	Topic/speaker
5 min	Welcome and introduction by the Chair • Hans Kluge Director, Division of Health Systems and Public Health WHO Regional Office for Europe
10 min	Challenges and opportunities in accessing new high-priced medicines • Panos Kanavos Programme Director, Medical Technology Research Group London School of Economics
30 min	Panel member presentations on specific challenges and their solutions (6 x 5-minute interventions) Member States • **Belgium**: Jo De Cock, CEO, National Institute of Health and Disability Insurance • **Greece**: Ioannis Baskozos, Secretary General for Public Health • **Netherlands**: A.A. Golja, Senior Policy Advisor, International Affairs regarding Drug Financing, Pricing and Reimbursement, Ministry of Health, Welfare and Sport • **Norway**: Bjørn Guldvog, Director, Directorate of Health • **Republic of Moldova**: Ruxana Glavan, Minister of Health Non-State Actors • **The European Federation of the Pharmaceutical Industries and Associations**: Richard Bergström, Director
40 min	Discussion moderated by • Panos Kanavos Programme Director, Medical Technology Research Group London School of Economics
5 min	Summary • Hanne Bak Pedersen Programme Manager, Health Technologies and Pharmaceuticals WHO Regional Office for Europe

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