Oslo Medicines Initiative

Statement by WHO/Europe
CONTEXT AND BACKGROUND

1. Member States of the WHO European Region have voiced concern over the escalating prices and budgetary impact of novel medicines that have restricted patient access. The market for these specialized medicines is anticipated to expand significantly in the next decade; this will offer new opportunities for patients but will also challenge health systems, therefore, urgent action is required to ensure equitable access for all patients in need now and in the future and to ensure the sustainability of health care systems. The economic context forces us to quickly find fair solutions to safeguard the interest of patients and the financial and fiscal sustainability of our health systems. Such solutions will need to build on the leadership of national authorities and maintain the optimal functioning of the pharmaceutical market through a combination of regulation and cooperation.

2. Major steps in biopharmaceutical research and advances in prevention, screening, diagnosis and treatment have been made in recent decades due to investment from both the public and private sectors. Medical innovation is happening at a good pace, including for rare diseases, encouraged by policy changes that include incentives and conditional regulatory pathways. Further incentives are required to ensure remaining areas of unmet need are addressed, including noncommunicable diseases with high prevalence in populations.

3. National health authorities and the pharmaceutical industry agree that patients' equitable access to safe, effective and novel medicines must be improved, and barriers to access reduced, including language and product registration. A new approach that balances the incentives needed for innovation with financial and fiscal sustainability for health care systems, while respecting the right to health for all and ensuring the affordability of medicines for patients is required. The approach should consider the clinical need, proven therapeutic value and cost-effectiveness, volumes of medicines produced and budget impact while requiring robust evidence generation to reduce uncertainties about benefits. Public and private initiatives developed in response to the ongoing COVID-19 pandemic demonstrate that greater collaboration is possible and are a shared responsibility between the national health authorities and the pharmaceutical industry, with inherent price transparency.

4. To look into these issues, in line with the Sustainable Development Goals and in accordance with the European Programme of Work, 2020–2025, the WHO Regional Office for Europe (WHO/Europe), in collaboration with the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency, launched the Oslo Medicines Initiative (OMI) based on the principles of solidarity, transparency and sustainability. The OMI identified that there is an urgent need to define more clearly the roles and social and ethical responsibilities of the public and the private sectors with respect to research, development and affordable access to effective, novel, high-cost medicines. OMI proposes this should happen through dialogue, as part of a shared responsibility and commitment to realize a “social contract”.

TOWARDS A NEW AGENDA TO PROMOTE STAKEHOLDER COLLABORATION IN THE WHO EUROPEAN REGION

5. Building on the successful work undertaken through the OMI, WHO/Europe is proposing the development of a multi-stakeholder platform to improve affordable and equitable access to effective, novel, high-priced medicines in the Region. The platform will promote constructive dialogue and collaboration to agree on concrete actions and deliverables. In addition to the public and private sectors (with regional and individual company involvement), stakeholders would include patient and relevant civil society representation, and professional bodies, as appropriate. As the collaborations developed in response to the COVID-19 pandemic have shown, the key to progress is working together to identify and agree on potential solutions, for enhanced solidarity and equity.

6. WHO/Europe believes that the platform will enable direct and open discussions between the different stakeholders to explore the feasibility of collaboration in the following areas to elaborate concrete
actions that could contribute towards a new joint way of working that respects the principles of solidarity, transparency and sustainability to achieve equitable access and competitive prices:

(a) continuing the implementation of the relevant provisions laid out in resolution WHA 72.8 (Improving the transparency of markets for medicines, vaccines, and other health products). Increasing transparency, including on costs, prices and public and private spending on research and development can increase trust, accountability, affordability and sustainability, improve the effectiveness of pharmaceutical policies, and help better understand the market across the Region;

(b) horizon-scanning and early sharing of information on pipelines and product launch plans, organizational impact and supply issues, numbers of patients, degree of unmet clinical need, and alignment of pricing expectations with budgetary realities;

(c) developing mechanisms to generate reliable evidence on safety and clinical effectiveness across the product life cycle, including before and after the market launch, to inform transparency in the understanding of clinical, social and economic value;

(d) exploring affordable pricing, reimbursement and funding approaches (for example, external reference pricing, price regulation, equity-based tiered pricing, value-informed pricing, and staggered, performance-based or subscription payment models);

(e) exploring the feasibility of voluntary and collaborative cross-country mechanisms such as best practices and information exchanges, demand pooling and other purchasing models, when applicable, in order to strengthen the purchasing capacity of the Member States; and

(f) determining the key elements needed for governance of the market in the Region, especially with regard to access for patients that is sustainable for health systems and the private sector, including the elaboration of a framework that uses relevant metrics for measuring patients’ access to safe and cost-effective novel medicines while allowing for the diversity of national systems.

7. WHO/Europe is seeking support from Member States to establish a joint stakeholder platform, hosted and facilitated by WHO/Europe, that brings representatives of the Member States together with non-State actors (private-sector entities, nongovernmental organizations, philanthropic foundations and academic institutions). The platform will elaborate concrete proposals on the topics identified in paragraph 6 and create joint working groups to propose pilot projects. Member States can participate on a voluntary basis and help shape the Terms of Reference for this platform, including a clear timeline, membership, organizational approach and expected deliverables.

8. WHO/Europe pledges to work collaboratively with Member States, non-State actors and regional partners, including the Organization for Economic Co-operation and Development and the European Commission, to support the discussions and deliver the aforementioned agenda in accordance with the agreements laid out in the Framework of Engagement with Non-State Actors. Carrying forward the legacy of the OMI, WHO/Europe pledges to do so in a spirit of sustainability, transparency and solidarity towards improving affordable and equitable access to novel, effective, high-priced medicines in the Region. Progress reports will be presented on a regular basis to the WHO Regional Committee for Europe, as well as the Standing Committee of the Regional Committee for Europe.