



The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors

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Consultation for Member States and areas

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Scope and purpose

1. Background and context

Equitable and sustainable access to safe, effective, affordable and quality-assured medicines and health products is critical to universal health coverage and achieving the Sustainable Development Goals (SDGs) by the target date of 2030.¹

Member States and areas in the WHO European Region have expressed increasing concern about high prices restricting access to potentially effective and novel medicines, including advanced therapy medicinal products. In response, several voluntary country- and area-led collaborations have developed, with examples of successful collaboration on horizon scanning, assessments, price negotiations and pooled procurement.

For pharmaceuticals, there is no explicit agreement or “social contract”² in place that details the rights and duties of each stakeholder. Patients, health systems and governments expect to have the right to reasonably priced pharmaceuticals that meet their needs, while investors and the pharmaceutical industry expect to earn sufficient profit to compensate for the risk inherent in developing or manufacturing those medicines. Striking this balance requires coherence between the public and private sectors on aspects such as: public funding for research; legislation; regulation; tax incentives; grants; patent protection; participation in clinical trials; pricing; health technology assessment; and health system payment policies.

The COVID-19 pandemic has seen unprecedented collaboration between stakeholders to speed up research and development and ensure critical products are available to health systems and patients. There is no doubt that the public health and economic impacts of the pandemic are severe and affect everyone. Moreover, the pandemic will increase pressure on health care budgets and direct spending choices. Yet, the pandemic has revealed not just the

¹ The SDGs (see <https://sustainabledevelopment.un.org/sdgs>) include a specific goal for improved health and well-being (SDG 3) with a dedicated 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).

² A social contract is a voluntary agreement between groups of stakeholders for their mutual benefit, which details the rights and duties of each stakeholder.

need for, but the reality of, increased transparency and trust between parties for the benefit of all stakeholders.

At its 70th session, the WHO Regional Committee for Europe approved the European Programme of Work, 2020–2025 – “United Action for Better Health in Europe”.³ One of the five areas of focus for WHO/Europe’s core priority of moving towards universal health coverage is to support Member States’ and areas’ efforts to ensure universal access to medicines, vaccines and health products, by:

- convening stakeholders, including patients, non-State actors and the pharmaceutical industry, to work towards a new social contract through which patients, health systems and governments can attain affordable pharmaceuticals that meet their needs, while investors and the pharmaceutical industry are sufficiently incentivized to develop or manufacture those medicines;
- identifying and supporting the correction of vulnerabilities in regulation, production, procurement and supply chains, with a focus on substandard and falsified medicines and health products; and
- accelerating implementation of World Health Assembly resolution WHA72.8 on Improving the transparency of markets for medicines, vaccines, and other health products,⁴ to improve access to effective, novel, high-priced medicines and vaccines by strengthening information systems, expanding voluntary intercountry collaborative platforms and supranational procurement groups and developing technical options for fair pricing.

To meet these objectives, WHO/Europe and the Government of Norway, through close collaboration with the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency, has launched the Oslo Medicines Initiative. An 18-month programme of work will be undertaken, which will culminate in a high-level meeting in Oslo in March 2022 to propose a new vision for collaboration between the public and private sectors for better access to effective, novel, high-priced medicines. The Oslo Medicines Initiative will build on access-related activities that are being undertaken at the global level by WHO and other United Nations agencies.

2. Objectives of the Oslo Medicines Initiative

This high-level Initiative launched by WHO/Europe jointly with the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency, aims to continue the collaborative spirit seen during the COVID-19 pandemic to advance the public health agenda and outline a new vision for collaboration between the public and private sectors. Joint actions to improve access to medicines in the WHO European Region, in line with SDG 3 (good health and well-being), SDG 9 (sustainable industrialization, innovation and infrastructure) and SDG 17 (partnerships for the goals) and the European Programme of Work, 2020–2025 will be considered.

The high-level Oslo Medicines Initiative will benefit from the participation of senior decision-makers from the Member States and areas, delegates from intergovernmental organizations, and representatives of non-State actors (non-governmental organizations, philanthropic foundations, academic institutions and private sector entities) and will give them the opportunity

³ See <https://www.euro.who.int/en/health-topics/health-policy/european-programme-of-work/about-the-european-programme-of-work> (accessed 9 December 2020).

⁴ See https://apps.who.int/gb/ebwha/pdf_files/WHA72-REC1/A72_2019_REC1-en.pdf - page=25 (accessed 9 December 2020).

to share viewpoints and discuss roles and responsibilities for achieving sustainable access to effective, novel, high-priced medicines.

The objectives of the Initiative are to:

1. reflect on the state of the market for effective, novel, high-priced medicines in Europe from diverse stakeholder perspectives;
2. discuss key issues that are impacting access to effective, novel, high-priced medicines and potential steps to address these in the context of the European Programme of Work, 2020–2025;
3. exchange experiences on voluntary multi-country/area collaborations as a mechanism to enable collaboration;
4. continue the dialogue and allow the exchange of experiences to advance the implementation of World Health Assembly resolution WHA72.8 on transparency;
5. share successful initiatives undertaken during the COVID-19 pandemic;
6. discuss and agree on the main components for action to enable a new vision for collaboration and agree on the principles and process; and
7. identify and define potential future actions to address collaboration challenges.

3. Format of the Oslo Medicines Initiative

Due to the ongoing pandemic and resulting travel restrictions, the Initiative will be a hybrid (virtual/physical) format, as outlined below.

- Informal online consultations will be held, first with representatives of the Member States and areas and subsequently with non-State actors.
- Background documents will be commissioned to reflect on key issues under the themes of the Oslo Medicines Initiative, namely solidarity, transparency and sustainability.
- A series of webinars and technical sessions will be held during 2021 with invited keynote speakers and panellists from stakeholder groups across the WHO European Region.
- A physical meeting will be held in spring 2022 to agree on commitments for collaborative action to ensure solidarity, transparency and sustainability in the innovation process for medicines and health care systems, to improve access to effective, novel, high-priced medicines throughout the European Region.

4. Themes

In line with the SDGs and the European Programme of Work 2020–2025, the meeting will ensure a strong focus on equity and leaving no one behind. Access to effective, novel, high-priced medicines will be looked at through the lens of the three themes listed below, reflecting on the innovative responses to the COVID-19 pandemic.

- **SOLIDARITY** – achieving greater solidarity between stakeholders to meet the SDGs and improve access for patients in the WHO European Region.
- **TRANSPARENCY** – understanding how transparency can be used to build trust and support access.
- **SUSTAINABILITY** – considering how to ensure a sustainable industry and health care systems.

5. Consultation process

Two sets of informal, online consultations will be held, in line with WHO procedures. Member States and areas will also be given the option to submit written statements and interventions. With the agreement of Member States and areas, the invitation to participate in an online consultation, and the option to submit written statements and responses, will be extended to agreed non-State actors. A summary report will be produced, and the statements and interventions submitted will be posted on the dedicated Oslo Medicines Initiative website.

For the initial consultation, a background document will be prepared. Member States and non-State actors will be asked to comment on the conference objectives and themes in order to:

- give their perspectives on access to effective, novel, high-priced medicines, particularly with regard to the current roles and responsibilities of the public and private sectors in the context of SDGs 3, 9 and 17;
- provide feedback on the proposals for the Oslo Medicines Initiative set out in the draft scope and purpose; and
- inform the development of a draft outcome statement that will seek commitments for collaborative actions to enhance solidarity, transparency and sustainability between the public and private sectors in order to increase access.

A second consultation process on a draft outcome statement will be undertaken in winter 2021.

6. Expected outcome

In support of WHO's goal of ensuring healthy lives and promoting well-being for all, the Oslo Medicines Initiative will aim to set out a new vision for collaboration between the public and private sectors to improve access to effective, novel, high-priced medicines in the WHO European Region.

Building on the input from the consultation process, technical webinars, and the conference themes, an outcome statement will be prepared to pledge commitment to collaborative actions to ensure solidarity, transparency, and sustainability in the innovation process for medicines and in health care systems.