



**Access to Novel Medicines Platform
consensus-building meeting
UN City, Copenhagen, Denmark
2–3 July 2024**

**29 April 2024
Original: English**

Scope and purpose

Background

WHO's European Programme of Work 2020–2025 – “United Action for Better Health”¹ highlights the importance of equitable and sustainable access to high-quality medicines in order to achieve universal health coverage and to meet the Sustainable Development Goals. The Oslo Medicines Initiative (OMI)² was established in 2020 by the WHO Regional Office for Europe in collaboration with the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency to address the key challenges around access to novel, high-priced medicines in the WHO European Region. The OMI published a series of technical reports,³ and identified the urgent need to define more clearly the roles and social and ethical responsibilities of the public and private sectors with respect to research and development and affordable access to effective, novel, high-cost medicines. It proposed that this should happen through multistakeholder dialogue, as part of a shared responsibility and commitment to realize a social contract.

At the 72nd session of the WHO Regional Committee for Europe in September 2022, WHO/Europe, in agreement with the Member States in the Region, issued a statement of intent⁴ to continue the work of the OMI by creating a formal WHO/Europe-hosted stakeholder collaboration platform to improve patient access to novel medicines in the Region. On 14 March 2023 in Almaty, Kazakhstan, the Subgroup on Governance of the Standing Committee of the Regional Committee approved the establishment of this unique multistakeholder platform, comprising representatives of Member States, patients' organizations, payer/funder bodies and industry: the WHO/Europe Access to Novel Medicines Platform (NMP).⁵ The Regional Office appointed a secretariat for the NMP and acted as the neutral convenor, host and facilitator of the platform.

¹ European Programme of Work 2020–2025: United Action for Better Health. Copenhagen: WHO Regional Office for Europe; 2021 (<https://apps.who.int/iris/handle/10665/339209>, accessed 29 April 2024).

² The Oslo Medicines Initiative. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2024 (<https://www.who.int/europe/initiatives/the-oslo-medicines-initiative>, accessed 29 April 2024).

³ Technical reports. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2024 (<https://www.who.int/europe/initiatives/the-oslo-medicines-initiative/technical-reports>, accessed 29 April 2024).

⁴ Oslo Medicines Initiative: statement by WHO/Europe. Copenhagen: WHO Regional Office for Europe; 2022 (EUR/RC72/INF./8; <https://iris.who.int/handle/10665/362320>, accessed 29 April 2024).

⁵ Establishment of WHO/Europe's Access to Novel Medicines Platform receives support from Standing Committee of the Regional Committee. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2023 (<https://www.who.int/europe/news/item/21-03-2023-establishment-of-who-europe-s-access-to-novel-medicines-platform-receives-support-from-standing-committee-of-the-regional-committee>, accessed 29 April 2024).

The NMP

Major steps in biopharmaceutical research and advances in prevention, screening, diagnosis and treatment have been made in recent decades, thanks to investment from the public and private sectors. However, all countries in the WHO European Region have voiced concern over the escalating prices and budgetary impact of novel medicines – such as advanced therapeutic medicinal products – which, despite uncertainties over longer-term risks and benefits, have restricted patient access, increased inequities and led to financial hardship. Provisions for early access for patients with otherwise incurable diseases – such as conditional marketing authorizations – also mean that there are often major uncertainties about the effectiveness of such medicines due to an immature evidence base. The need for urgent collective action to ensure equitable access for all patients in need, and to safeguard the resilience and sustainability of health-care systems and the innovation process, is widely acknowledged.

By ensuring a safe space for dialogue and collaboration between different stakeholder groups, the NMP has sought to identify concrete actions, including through the use of demonstration projects, to improve affordable and equitable patient access to novel medicines in the Region. To date, and in accordance with WHO's Framework of Engagement with Non-State Actors,⁶ 50 Member States and 49 non-State actors and other partners have joined the NMP. These stakeholders have provided nominations to participate in four time-limited working groups, which started work in June 2023 and are expected to run until December 2025.

Objectives of the working groups

The NMP working groups (WGs) focus on the three themes that underpin the NMP – transparency, solidarity and sustainability – with a fourth WG focusing on novel antimicrobials. The aims and objectives of the four groups are set out below.

Transparency

The aim of WG 1 is to agree on actions to improve transparency in order to build trust, promote collaboration, enable horizon scanning and develop indicators to facilitate accountability and corrective actions by focusing on:

- agreement on what information can be made more transparent, in accordance with the framework set out in World Health Assembly resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products;
- identification of indicators to assess patient access to effective, novel, high-cost medicines, and exploring approaches to improve and standardize their collection, analysis and use.

Solidarity

The aim of WG 2 is to strengthen voluntary collaborations that focus on solidarity to achieve patient access, including evidence generation, demand aggregation, procurement and management of the lifecycle of medicines by focusing on:

- collaboration for the accrual, evaluation and use of evidence of clinical and economic value across the lifecycle of effective, novel, high-cost medicines;
- a feasibility exercise to explore scaling up existing voluntary efforts to pool demand and support joint negotiation on effective, novel, high-cost medicines.

Sustainability

The aim of WG 3 is to develop principles – including for payment, pricing, health technology assessment and reimbursement – that recognize the need for the sustainability of health systems and industry, and

⁶ Framework of engagement with non-State actors. Geneva: World Health Organization; 2015 (WHA68.9; <https://iris.who.int/handle/10665/253238>, accessed 29 April 2024).

enable risk-sharing and good governance of markets, including ways of addressing market failures and unmet needs, by focusing on:

- potential deliverables focused on reviewing affordable pricing principles;
- determining the key elements needed for governance of the market, including social contracts and the role of corporate social governance.

Novel antimicrobials

The aim of WG 4 is to identify policy options for sustainable innovation and access to novel antimicrobials, including:

- development of principles and policy options (including for payment, pricing, health technology assessment and reimbursement) to strengthen access to new and existing antibiotics;
- a review of incentive coordination mechanisms for research and development of new antibiotics, and securing equitable access to new and existing antibiotics.

Aims and objectives of the consensus-building meeting

WHO/Europe is convening the first NMP consensus-building meeting on 2–3 July 2024 at UN City, Copenhagen, Denmark, to enable the members of the four WGs to meet in person, together with the wider NMP membership. This will be a technical meeting, with the full engagement of all participants.

To ensure that the meeting goes beyond statements and delivers concrete actions, it will give an opportunity for each WG to outline its proposals, including demonstration projects, and to discuss and agree the next steps for implementation. The meeting will also provide a forum to discuss resource mobilization efforts for implementation of proposals through to 2026.

The consensus-building meeting will be the first opportunity for cross-fertilization of ideas between the four WGs, which have been working independently thus far. This bringing together of the groups will underscore the importance of approaching the issues around improving access to novel medicines in the WHO European Region from multiple perspectives, understanding that no single approach or area of focus is sufficient. The meeting will also allow the WGs to update the wider NMP membership, invited Member State representatives and other partners on their progress and proposals going forwards.

Each WG will present its work to date. It is envisaged that the meeting will lead to broad consensus around which proposals from each of the WGs are to be developed further over the second half of 2024. The proposals will be shared in background briefs made available before the meeting.

Participants

All nominated NMP focal points and active WG members have received personal invitations to the meeting as experts. Member States are also invited to nominate up to two high-level technical participants. In addition, invitations have been sent to academic experts and speakers, along with key stakeholder partner organizations.

Meeting format

The meeting will take place over 1.5 days, commencing on the morning of 2 July and closing on the afternoon of 3 July. The meeting will feature a high-level opening session with the WHO Regional Director for Europe and invited stakeholders and partners, followed by individual sessions organized around the four WGs. Each WG session will be divided into two parts. During the first segment, the Chair(s) or Vice-chair(s) will present the work the group has undertaken, and outline the proposal(s) or demonstration project(s) proposed for further development. This will be followed by discussion and deliberation by meeting participants.

The meeting will take place at UN City in Copenhagen, Denmark, and will require in-person attendance. It will be recorded and may be made available on the WHO/Europe website in due course.

Expected outcomes

As a technical meeting, no statement or document is planned as a formal outcome. However, by demonstrating the work already undertaken by the WGs and by seeking approval from the wider NMP membership – especially around employment of the demonstration projects in each WG – it is envisaged that participants will jointly agree on a number of key issues or topics to be continued in the NMP's future activities. A summary of NMP activities and outputs – including the consensus-building meeting report – will be made available for the 74th session of the WHO Regional Committee for Europe on 29–31 October 2024 in Copenhagen, Denmark. To this end, the meeting will inform the future priorities of the NMP.