Report of consultations with Member States, partner organizations and non-State actors on Access to Novel Medicines Platform

January–February 2023
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ABSTRACT

At the 72nd session of the WHO Regional Committee for Europe in Tel Aviv, Israel, in September 2022, the WHO Regional Office for Europe, in agreement with Member States, issued a statement of intent to act as a neutral convener for the establishment of a platform for collaboration, to agree on solutions and improve patient access to novel high-cost medicines. The Access to Novel Medicines Platform (NMP) will enable Member States, non-State actors and other partners to coordinate, collaborate, prioritize and align efforts to deliver solutions to improve access for patients. The strategic aims, terms of reference and areas of work for the NMP were drafted and refined in three virtual consultations in January and February 2023. The diversity of the markets was noted, as were specific issues for low- and middle-income countries and small markets, as well as challenges with markets for antimicrobials. This report summarizes the key points raised and suggestions for action proposed during the consultations.

KEYWORDS

ACCESS TO MEDICINES, PHARMACEUTICAL POLICY, HEALTH SYSTEMS, INTERSECTORAL COOPERATION, PUBLIC HEALTH

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This publication contains the Report of consultations with Member States, partner organizations and non-State actors on Access to Novel Medicines Platform, January–February 2023, and does not necessarily represent the decisions or policies of WHO.
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Executive summary

Significant progress was made through the Oslo Medicines Initiative (OMI) in 2020–2022 to establish multistakeholder dialogue to define more clearly the roles and social and ethical responsibilities of the public and private sectors with respect to research, development and affordable access to effective, novel, high-cost medicines. The work of the OMI culminated at the 72nd session of the WHO Regional Committee for Europe in Tel Aviv, Israel, in September 2022, where the WHO Regional Office for Europe, with the agreement of Member States, issued a statement of intent to act as a neutral convenor to establish a platform for collaboration, to agree on solutions and improve patient access to novel high-cost medicines. The Access to Novel Medicines Platform (NMP) will enable Member States, non-State actors and other partners to coordinate, collaborate, prioritize and align efforts to deliver solutions to improve access for patients. This requires sustained collaboration to agree, co-develop and implement a comprehensive set of actions in accordance with WHO’s Framework of Engagement (FENSA) with non-State Actors.

In January and February 2023, three preliminary online consultations were held with Member States, non-State actors and other partners to discuss the concept note, strategic aims, work packages and operating principles of the NMP. The participation rate was very high: 39 Member States, 10 partners and 25 non-State actors joined the consultations and offered universal support for the Platform to be established. Feedback from the consultation process will form the basis of the draft terms of reference for the NMP; these will be shared with eligible entities for further written feedback.

Key areas for action highlighted by the participants were as follows.

- It is now time to act: the NMP should aim to deliver concrete results, including proposals for pilot projects.
- A funding source for the Platform should be identified urgently, including for the initial phase, to ensure that the NMP’s priorities are implemented. The capacity of many Member States and nongovernmental organizations to participate and support is limited, although interest was expressed in doing so. To ensure equal representation, financial support for participation needs to be considered.
- It is important to have strict and transparent conflict-of-interest policies, and to ensure that all voices are heard, with fair representation across genders, geographical locations, income levels, types and sizes and types of eligible entities, in line with FENSA and other relevant WHO policies.
- The technical work of the NMP, operationalized through working groups, needs to be aligned with existing initiatives to ensure synergies and avoid duplication of efforts. The working groups need to have ownership of the work streams and further develop the activities and outputs through joint discussion. Progress should be measured to ensure delivery of agreed actions.
- Participants noted the diversity of the markets and highlighted specific issues for low- and middle-income countries and small markets.
- Member States proposed that oversight of the NMP should be governed by the Standing Committee of the Regional Committee.

Several key technical topics were emphasized during the consultations.
• Participants supported activity in all six of the technical areas highlighted in the statement. Transparency, affordable pricing and evidence generation were emphasized as potential initial priorities, with pooled demand and joint purchasing closely behind. It was also noted that all technical topics were important and should not be neglected, and that a staggered approach may be needed to ensure that work is done to cover all areas.

• The importance of transparency was highlighted – not only of markets but also of evidence generation, clinical trials, prices, publication of results, decision-making policies and horizon scanning.

• In terms of affordable pricing options, all mechanisms should be considered that include (but are not limited to) pricing based on ability to pay, and a focus on principles rather than methodology would be appropriate, given the remit of the NMP.

• Participants also felt that all purchasing models (not just demand pooling) should be considered in the scope of the Platform, including joint procurement.

• Additional topics were put forward, including the commercial determinants of health, responsible research and development, unmet needs, repurposing of medicines and real-world data.

• Participants highlighted that the scope of the Platform should consider different types of novel high-cost medicines and their associated diagnostics, as the issues vary for different subgroups of medicines (such as advanced technology medicinal products, biologicals and small molecules).

• Member States and non-State actors highlighted that other medicines and health products – such as essential medicines and vaccines – should not be excluded from NMP activities, as many countries face challenges in ensuring that patients have equitable access to them, including shortages and supply and registration issues. Markets for antimicrobials were highlighted as having particular challenges, which would benefit from better collaboration between the public and private sectors.

• Member States suggested expanding the strategic aims to ensure that demand-driven systems are considered and included.
Background and context

WHO’s European Programme of Work 2020–2025 – “United Action for Better Health” (2) highlights the importance of equitable and sustainable access to quality medicines in order to achieve universal health coverage and the Sustainable Development Goals (SDGs). Access to medicines and health products works at the interface of three SDGs: SDG 3 – good health and well-being; SDG 9 – industry, innovation and infrastructure; and SDG 17 – partnerships for the Goals.

The challenge for governments of ensuring equitable access to effective medicines that are affordable, appropriate and of high quality is greatly increasing in urgency as the demand for adequate health care expands, and as new therapies emerge. The market for pharmaceutical products has changed considerably in recent years, from a blockbuster model targeting high volumes of patients to therapies that are targeted to be more effective but for smaller patient groups affected by serious, often rare, low-prevalence diseases requiring complex treatments. Such medicines – including advanced therapy medicinal products and cell and gene therapies – are welcomed by patients, but are disruptive to health-care systems, and they are associated with significantly higher prices per product. There are also often major uncertainties about their effectiveness because of the immature evidence base, as a consequence of expedited regulatory approvals.

The Oslo Medicines Initiative (OMI) of 2020–2022 was a collaboration between the WHO Regional Office for Europe, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency (3). It provided a space for the public and private sectors to outline a joint vision of equitable and sustainable access to, and affordability of, effective novel high-cost medicines. The OMI placed strong emphasis on equity and leaving no one behind, and was underpinned by three pillars of solidarity, transparency and sustainability. It supported implementation of relevant World Health Assembly resolutions – in particular, resolution WHA72.8 of 2019 on improving the transparency of markets for medicines, vaccines and other health products.

In the spirit of the SDG 17 – which calls for partnerships between governments, companies, civil society and other eligible entities to achieve the SDGs – the OMI organized a number of consultations and webinars, which helped to frame areas of priority in this field. A series of technical reports were commissioned to summarize the relevant evidence and provide policy recommendations to be taken forward in the WHO European Region (4), (5), (6). All these elements informed discussions at a ministerial lunch held by the OMI at the 72nd session of the WHO Regional Committee for Europe in Tel Aviv, Israel, in September 2022; this culminated in a statement of intent by the WHO Regional Office for Europe (7), approved by Member States, to act as a neutral convenor to establish, host and facilitate a multistakeholder platform for collaboration, to agree on solutions and improve patient access to novel high-priced medicines. The Access to Novel Medicines Platform (NMP) will enable Member States, non-State actors and other partners to coordinate, collaborate, prioritize and align efforts to deliver solutions to improve access for patients. This requires sustained collaboration to agree, co-develop and implement a comprehensive set of actions in accordance with WHO’s Framework of Engagement with non-State Actors (FENSA).

Box 1 summarizes the technical areas of work to be considered through the NMP.
Box 1. Technical areas for the NMP to consider

- Agreement on what information can be made more **transparent** in accordance with the framework set out in resolution WHA72.8 of 2019, including to inform horizon-scanning activities.
- Identification of **key indicators** to improve and standardize collection, analysis and use of metrics on patient access to effective, novel, high-cost medicines.
- A feasibility exercise to explore scaling up of existing voluntary efforts to **pool demand** and support **joint purchasing** of effective, novel, high-cost medicines.
- Collaboration for the accrual, evaluation and use of **evidence** of clinical and economic value across the life cycle of effective, novel, high-cost medicines.
- Development of principles (including for payment, pricing, health technology assessment and reimbursement) that recognize the need for **sustainability** of health systems and industry, and enable risk sharing and good governance of markets, including how to address market failures and unmet needs.
- Determination of the key elements needed for **governance** of the market, including social contracts and the role of corporate social governance.

The activity of the NMP will also contribute to the Regional digital health action plan for the WHO European Region 2023–2030 and to development of the regional roadmap on antimicrobial resistance, which were also adopted by Member States at the 72nd session of the Regional Committee.

**Summaries of the consultations**

The consultations with Member States, partner organizations and non-State actors took place in January and February 2023. Participants were also offered the opportunity to submit written statements.

**Member States consultation**

The virtual consultation with Member States took place on 12 January 2022. It was very well attended, with 39 countries joining the session (see Annex 1 for the list of participants). The meeting was opened by Dr Natasha Azzopardi-Muscat, Director of the Division of Country Health Policies and Systems at the WHO Regional Office for Europe, who highlighted the commitment of the WHO Regional Director for Europe, Dr Hans Henri P. Kluge, to support countries in establishing, developing and improving structures and policies within the Region to improve access to novel high-cost medicines for patients. She emphasized the importance of WHO working with Member States to achieve this aim. She noted that the OMI started prior to the pandemic and the new geopolitical situation in Europe and stressed that it is even more important in the current climate – with the cost-of-living crisis and out-of-control inflation – to work together to get such policies right.

Dr Sarah Garner, Senior Policy Adviser at the WHO Regional Office for Europe, presented a summary of the work undertaken and the findings of the OMI, and outlined the agreed tasks and vision from WHO’s statement of intent for the NMP at the 72nd session of the WHO Regional
Committee for Europe. She presented the aim and objectives of the Platform and explained that this initial phase of establishing the NMP will focus on a series of consultations with Member States, non-State actors and other regional partners to prioritize the technical agenda. The goal was to identify areas for collaboration by means of establishing technical work packages for working groups, to align the strategic aims of the Platform with parallel work of partner organizations.

The operating principles of the NMP were discussed, paying particular attention to governance, participation and FENSA requirements for transparency and to avoid conflicts of interest. Based on the key strategic objectives, potential work packages were discussed, and a poll was taken to determine the areas of greatest need for prioritization.

Member States engaged in the discussion with questions and comments, and highlighted areas to be addressed. There was wide support for this work to be taken forward as a mechanism to turn the OMI discussions from previous years into tangible actions and pilot projects to see this work move forward as the NMP. Participants supported the creation of the Platform, its strategic aims and proposed work packages. They highlighted that collaboration is crucial to continue the dialogue and build trust between different entities, to identify suitable proposals and pave the way to sustainable access to medicines for patients.

It was agreed that WHO would act as the neutral facilitator, understanding the needs for all entities and ensuring a voice for all. Some comments were made about the voluntary nature of Member State participation, and how the level would depend on available resources in different countries. Participants agreed that it would be appropriate for the chair of the NMP to be a Member State, and for two vice chairs to be drawn from the other eligible entities (partners and non-State actors).

Further, it was recommended that the Standing Committee of the Regional Committee (SCRC) should undertake the governance function for the Platform, rather than duplicating it with an additional steering group. An additional aim was proposed of considering how governance of the market could facilitate creation of a demand-driven system based on unmet needs.

The main message of the consultation was that the NMP needs to ensure a common language and terminology, with work packages that outline clear goals for collaboration and have concrete deliverables whose progress can be measured. The prioritization poll of the work packages highlighted the importance of transparency initiatives, including horizon scanning and affordable pricing principles as key areas of work. Transparency of pricing and metrics to measure real access to medicines was proposed, as was transparency of research and development, and the importance was noted of getting the right balance between financial incentives and reliable frameworks for innovation. Other key elements highlighted were publication of clinical trials, measuring the performance of medicines with outcome-based data, and the role of regulation in improving structures and systems. Aligning with and complementing existing work are key to avoid duplication of efforts, so the work of the Organisation for Economic Co-operation and Development (OECD), International Horizon Scanning Initiative and the new European Union pharmaceutical strategy should be considered, among others. Participants recognized that many challenges are shared, so it is important to ensure that common ground is found – not only between Member States but with all relevant stakeholders. The NMP should become an avenue for knowledge exchange and sharing of best practices, facilitating discussion to gain greater insight into the current market, the needs of participants, and their interests, risks and incentives. The diversity of the markets in the WHO European Region was noted, and specific issues for low- and middle-income countries and small markets were highlighted.
Dr Garner summarized the key points raised and outlined the next steps: the consultations with partner organizations and non-State actors would also help to shape the draft terms of reference, which would be sent to the SCRC for review and input in March/April 2023. The updated terms of reference would then be sent to all entities again for a written consultation in April/May 2023. This would facilitate establishment of the technical working groups, with full proposals and complete documentation to be presented at the 73rd session of the WHO Regional Committee for Europe in Astana, Kazakhstan, in October 2023. Dr Azzopardi-Muscat thanked everyone for their active participation and closed the consultation.

Consultation with partner organizations

The virtual consultation with partner organizations took place on 2 February 2023, attended by 11 participants representing 10 partner organizations (see Annex 1 for the list of participants). The meeting was opened by Mr Cornelis De Joncheere, Regional Adviser a.i., on behalf of Dr Azzopardi-Muscat and Dr Kluge. He noted that supply chains have been disrupted in the WHO European Region; simultaneously, increased costs of living have exacerbated the issues considered by the OMI. Establishment of the NMP will enable those discussions to continue and move towards policy action.

As in the Member States consultation, Dr Garner summarized the background work done by the OMI and presented the strategic aims and the concept note of the NMP before opening the discussion for questions and feedback. Participants gave unanimous support for continuing the work begun by the OMI as a mechanism to turn those discussions into tangible actions and pilot projects for the NMP. The breadth and depth of the work ahead was noted, and the opportunities for and benefits of collaboration on topics such as horizon scanning were highlighted.

Participants emphasized that all partners needed to align their priorities and build on existing work, to avoid duplication and ensure the best use of resources. All consultees highlighted relevant work being undertaken, including initiatives by the European Commission and the OECD. This includes projects on horizon scanning, pharmaceutical regulation to cover innovation and affordability, examination of transparency, evidence generation, biosimilars competition, capacity-building in health technology assessments, cross-country information sharing from competent authorities, pooled public procurement and pooled demand and indicator development. It was therefore recommended that a mapping exercise of such initiatives should be undertaken as a starting point. Participants also agreed that it was important for the NMP to complement existing work and identify gaps to address. It was therefore suggested that the Platform could host a repository website to include the findings of the mapping exercise so that all existing initiatives were listed in one place.

The extent of transparency needs was discussed, with a recognition that this should go beyond the terminology of “markets” used in resolution WHA72.8 of 2019 to include, for example, clinical trial results and publications. There should also be clear agreement about what information can be made transparent and what needs to remain confidential. Participants requested clarification of whether the solidarity discussed was intended to relate to solidarity between countries or with the private sector: Dr Garner confirmed that the terminology was intended to be all-inclusive.

Experience of the use of pooled demand during the COVID-19 pandemic was highlighted, and it was noted that examples exist in other WHO regions and organizations – such as within the WHO Region of the Americas. There was clear support for the use of indicators in monitoring and evaluation, and the issue of not having agreed indicators was noted. The OECD has been working
with the European Commission DG Santé on the feasibility of key indicators in the area of access to medicines. Alignment will be crucial to moving this work under the auspices of the NMP.

Clarification was requested about membership of the WHO collaborating centres in the working groups, and whether the NMP work would fall within their existing workplans. Participants discussed whether the remit should be broadened from novel high-cost medicines to include access to other high-cost medicines and essential medicines: this remains a challenge across the WHO European Region and is an issue of human rights. It was highlighted that, given the voluntary basis of participation in the working groups, it was important that the different types of stakeholders were equally represented, and that clear criteria were established for membership and oversight. The prioritization poll of the work packages showed the importance of transparency initiatives including horizon scanning, affordable pricing options and evidence generation, followed by pooled demand and joint purchasing.

Dr Garner summarized the key points raised and outlined the next steps, as listed in the Member States consultation. Mr de Joncheere thanked the participants and closed the consultation.

**Consultation with non-State actors**

The virtual consultation with non-State actors took place on 8 February 2023, attended by 27 participants representing 25 organizations (see Annex 1 for the list of participants). In addition, nine non-State actors sent written statements to clarify their views, and five others that were unable to attend sent their input in writing (8). The meeting was opened by Dr Azzopardi-Muscat, who thanked the participants for their frank conversations and first of its kind participation of non-State actors at the ministerial lunch at the 72nd session of the WHO Regional Committee for Europe in September 2022. She highlighted the importance of identifying the solutions together, and thanked Norway for its support of the OMI work. She also noted that the next step needed, as agreed in Tel Aviv, Israel, was establishment of the NMP: it was important not to lose momentum but to work on common goals to support WHO’s 75th anniversary.

As in the previous consultations, Dr Garner summarized the OMI background work, presented the strategic aims and the concept note of the NMP, and opened the discussion for reflections and feedback. Participants noted that the previous wording of the aims and objectives from the WHO Statement of intent, included identifying and agreeing on solutions: agreement is a critical element as the strategic aims are non-binding, so having agreement and commitment among stakeholders on the way forward is vital. It was noted that the OMI statement includes the stated intention for pilot projects to be created, and the NMP would be uniquely placed to undertake this role, so the potential for pilots should be included in the NMP’s terms of reference.

Once again, the need for joint efforts that include pooled procurement and demand pooling was suggested as an important course of action for the Region. The importance of the NMP remaining neutral – and of WHO’s role in ensuring that neutrality – was highlighted, especially as membership of the technical working groups will be voluntary. Participants noted that many of the organizations involved are small and, as nongovernmental organizations (NGOs), they often have limited funding and resources. It was felt that their participation could be hampered if costs of attending meetings and contributing to the working groups had to be resourced by the NGOs alone. The need for very strict and transparent conflict-of-interest management was also emphasized, along with the importance of ensuring balanced and equally represented working groups. Participants agreed that the perspectives of the different stakeholders are all valid, although they may differ, and that all need to be considered if improvements in the system are planned.
From the perspective of patients, gaining access to novel medicines and therapeutics is of the utmost importance. The recent work done by WHO and others on the commercial determinants of health (9) was highlighted, and its impact on the health of populations noted and some relevant publications were also shared as part of the discussions (10). Participants clarified that the NMP has already established a very thorough risk management strategy and plan, in accordance with organizational procedures including FENSA. Further discussion is needed to safeguard co-financing of these activities, and to ensure that balanced perspectives are achieved within the working groups in terms of gender, geographical location, income level, size and type of eligible entity and so on. In accordance with FENSA, pre-defined criteria for selection of members for the working groups would help to ensure transparency and appropriateness.

The specific problem with new oncology drugs was also noted: these can often have a very immature evidence base at launch, as conditional regulatory decisions are being made earlier in the life cycle of the drugs to enable patients to access them. This transfers administrative burden and financial risk to the public sector, and it was felt that the responsibilities could be better shared. Reimbursement for such cases has been dealt with by creation of separate funds in many countries, but this often leads to variations in access across the WHO European Region, and a more thorough mechanism needs to be considered. In certain cases, the use of limited evidence and real-world data is sufficient and warranted to permit early access; however, when this is appropriate and how this issue can be managed in resource-constrained settings need careful consideration. Access to these medicines and health products is also closely linked to availability of better diagnostic processes and equipment, so considerations need to go beyond access to the medicine alone. Participants felt that the extent of transparency needs should go beyond the text of resolution WHA72.8 of 2019, and that publication of results such as negative trial results and quality-of-life outcomes should be considered. Repurposing of drugs and the importance of horizon scanning were also mentioned. The need for pilot testing of all these elements through the NMP was raised.

Clarity was requested about the term “pricing mechanisms”, and participants highlighted the opportunity to develop principles to ensure sustainability of health systems and industry, noting the importance of good governance, strong indicators, and monitoring and evaluation strategies. Lessons learned by the European Commission with pooled procurement of COVID-19 vaccines were highlighted, and it was suggested that use of the infrastructure for novel medicines could also be considered. Some national bodies, including in Italy and France, have taken strides in establishing good legislation where concrete steps in public funding and socially responsible licensing and procurement have been seen. Successful examples of joint evidence generation and assessment are also available. Therefore, the NMP could facilitate sharing of practices for all countries in the Region. This proposal for knowledge exchange was very much welcomed. Participants highlighted the example of the public investment in clinical trials during the COVID-19 pandemic, and recommended harnessing more this potential of public investment in trials.

Some practical queries arose, including on the duration of the proposed working groups and the importance of running pilot projects through the NMP. Clarification was also sought on whether all the six areas of work would be launched simultaneously, or whether a stepwise approach and prioritization would be applied. It was noted that the activity of the working groups would be fixed initially at 2–3 years, and that the number of groups would be determined by the success of resource mobilization. That said, at present, the plan was to prioritize and start implementation with three working groups in 2023, and then continue with a staggered approach, depending on resources and participation. The prioritization poll of the work packages once again highlighted the importance of transparency initiatives including horizon scanning and affordable pricing principles, with evidence generation a close third option.
Dr Azzopardi-Muscat reiterated that it was the hope of the WHO Regional Office for Europe that real change can be made through the NMP, moving towards facilitating equity in patient access across the Region. She thanked all the consultees for their active participation, for continuing to support open and frank conversations, and for creating a safe virtual space for discussions. She then closed the consultation.

**Conclusions and next steps**

The proposed plan for establishment of the NMP was widely supported by participants in all three consultations, and there was particular interest in action through developing pilot projects within the working groups. The areas of technical work identified as priorities to be taken forward by the working groups were similar across the consultations; thus, the draft terms of reference and the proposed work for the Platform could be drafted and would be sent for consultation and review by the governance subgroup of the SCRC. This would be followed by a written consultation with all the eligible entities, and – following finalization of the terms of reference – a briefing for the entities to enable clarification of membership in the technical working groups, after which the working groups can be established. Through the SCRC the progress and status will then be presented at the 73rd session of the WHO Regional Committee for Europe in Astana, Kazakhstan, in October 2023.
Annex 1

LIST OF PARTICIPANTS IN THE VIRTUAL CONSULTATIONS

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REGIONAL OFFICE FOR EUROPE

ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPÄ

ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Novel Medicines Platform
Consultations Q1 2023

20 April 2023
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1 All references accessed 30-31 March 2023.
The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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