FINAL REPORT OF THE OSLO MEDICINES INITIATIVE
Improving access to novel, high-priced medicines in the WHO European Region
Oslo Medicines Initiative

Established in 2020, the Oslo Medicines Initiative (OMI) is a collaboration between the WHO Regional Office for Europe, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency. The OMI aims to provide a neutral platform for the public and private sectors to jointly outline a vision for equitable and sustainable access to and affordability of effective, novel and high-priced medicines.

In line with the Regional Office’s European Programme of Work 2020–2025 – “United Action for Better Health”, equitable and sustainable access to quality medicines is critical for universal health coverage and for achieving the Sustainable Development Goals. The OMI provides a strong focus on equity and on leaving no one behind, and is underpinned by three pillars; solidarity, transparency and sustainability.

The OMI has commissioned a series of technical reports to summarize relevant evidence and provide policy considerations as a basis for discussion to inform its work. These reports are also in line with the implementation of World Health Assembly resolutions, in particular, resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products.
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Acknowledgements

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Strategic guidance on the OMI has been provided by Hans Kluge and Natasha Azzopardi Muscat (WHO Regional Office for Europe) and Bjørn-Inge Larsen (Norwegian Ministry of Health and Care Services).

The Regional Office gratefully acknowledges the funding and technical expertise provided by the Norwegian Government in delivering the work of the OMI.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ATMP</td>
<td>advanced therapy medicinal product</td>
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<tr>
<td>CGT</td>
<td>cell and gene therapy</td>
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<td>EHFG</td>
<td>European Health Forum Gastein</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>OMI</td>
<td>Oslo Medicines Initiative</td>
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<td>SDG</td>
<td>Sustainable Development Goal</td>
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<td>SPC</td>
<td>Scientific Programme Committee</td>
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Executive summary

Background

The market for pharmaceutical products has changed considerably in recent years, from a blockbuster model that targeted 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 that require complex treatments. Such medicines – advanced therapy medicinal products (ATMPs) and cell and gene therapies (CGTs) – are welcomed by patients, but they often come with challenges. They are disruptive to health-care systems and are associated with significantly higher prices per product – often over US$ 1 million per patient – despite uncertainties over longer-term risks and benefits. Provisions for early access for patients with otherwise incurable diseases, such as conditional marketing authorizations, also means that there are often major uncertainties about their effectiveness due to the immature evidence base.

In view of these challenges, the WHO Regional Office for Europe, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency launched the Oslo Medicines Initiative (OMI) in 2020. Its aim was to provide a neutral platform for the public and private sectors to jointly outline a vision for equitable and sustainable access to effective, novel, high-priced medicines. In line with the 2030 Agenda for Sustainable Development and its Sustainable Development Goals (SDGs) and the European Programme of Work 2020–2025 (the strategic framework for the WHO Regional Office for Europe), the OMI ensures a strong focus on equity and leaving no one behind. Reflecting also on the innovative responses to the COVID-19 pandemic, the OMI has three pillars: transparency, solidarity and sustainability.

SDG 17 to strengthen the means of implementation and revitalize the global partnership for sustainable development calls for partnerships between governments, companies, civil society and other stakeholders to achieve the SDGs. Bolstering these partnerships requires transparency to ensure that they become effective tools for building trust and finding sustainable solutions. To be effective in implementation and build the necessary trust, solidarity is required: governments, industry and other stakeholders need to engage positively with the dialogue around the need for change and the options available. Together, transparency and solidarity can lead to an outcome of sustainability in pharmaceutical and health-care systems.

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1 The SDGs include a specific goal for improved health and well-being (SDG 3), with a dedicated target (3.8) to 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 (Sustainable Development Goals [website]. New York: United Nations; 2022 (https://sdgs.un.org/goals, accessed 18 August 2022)).

It is important to mention that lower-income countries in the WHO European Region have specific constraints related to their health systems and budgets. Access to effective novel high-cost medicines is difficult and, for ATMPs and CGTs at current prices, virtually impossible. In this regard, policy interventions that may be applicable in a middle- or high-income country setting may require tailoring to local needs. Examples include a rigorous focus on careful applications of price control mechanisms, management of conflicts of interest and increasing the bargaining power of buyers and strengthening health systems – including prescribing practices. Exploring policy mechanisms to reduce inequalities in access to effective novel high-cost medicines across the Region is critical to meeting population health objectives.

Building on many years of work on increasing access to medicines in the Region by WHO, the European Commission, the Organisation for Economic Cooperation and Development (OECD) and other partners, the OMI focuses on reviving the social contract and nurturing a positive symbiosis between health systems and pharmaceutical companies. This is done by promoting dialogue on the opportunities for careful implementation, enhancing transparency, strengthening solidarity and increasing sustainability of health systems and the industry for the benefit of society.
Unprecedented collaboration between stakeholders took place during the COVID-19 pandemic to speed up research and development and ensure that 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, it has increased pressure on health-care budgets and direct spending choices. At the same time, the pandemic has revealed not just the need for, but the reality of, increased transparency and trust between parties for the benefit of all stakeholders.

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

For pharmaceuticals, no explicit agreement or social contract³ is 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 European Programme of Work, 2020–2025

At the 70th session of the WHO Regional Committee for Europe, Member States approved the European Programme of Work, 2020–2025 – “United Action for Better Health” (EPW). One of the five areas of focus for the Regional Office’s core priority of moving towards universal health coverage is to support Member State 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

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³ A social contract is a voluntary agreement between groups of stakeholders for their mutual benefit.
• 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.

In line with this, the OMI was launched as a neutral forum through which to build a new vision for collaboration between the public and private sectors to ensure better access to effective, novel, high-priced medicines. Recalling its three pillars of solidarity and transparency, the objectives of the OMI were to:

• reflect on the state of the market for effective, novel, high-priced medicines in Europe from diverse stakeholder perspectives;

• discuss key issues that affect access to effective, novel, high-priced medicines and potential steps to address these in the context of the EPW;

• exchange experiences on voluntary multicountry collaborations as a mechanism to enable collaboration;

• continue the dialogue and facilitate exchange of experiences to promote implementation of resolution WHA72.8 on transparency;

• share successful initiatives undertaken during the COVID-19 pandemic;

• discuss the main components for action, as well as principles and process to enable a new vision for collaboration;

• discuss potential future actions to address collaboration challenges; and

• issue a joint statement of commitment from Member States and non-State actors.

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The process

Funded by the Norwegian Ministry of Health, the OMI Secretariat – consisting of the WHO Regional Office for Europe and the Norwegian Government – developed a comprehensive process. It worked with key stakeholders from Member States, the pharmaceutical industry, civil society and intergovernmental organizations, as well as with leading experts from academia, to identify key policy solutions. The OMI process was guided by a Steering Committee comprising representatives from the Norwegian Government (Bjørn-Inge Larsen, Arne-Petter Sanne, Synnøve Ravnestad Eikefet, Audun Hågå), the WHO Regional Office for Europe (Hans Kluge, Natasha Azzopardi Muscat, Sarah Garner, Rebekka Aarsand, Louise Delaney, Govin Permanand), the European Commission (Sylvain Giraud), the OECD (Francesca Colombo), the French Presidency of the European Union (Emelie Sam) and expert advisers from Member States (Jo de Cock, Richard Bergstrom, Elias Mossialos). As shown in Fig. 1, this process consisted of various phases, including a landscape and needs assessment; building the evidence base; drafting results; and dissemination. This is also in line with the WHO principles of promoting evidence-informed decision-making highlighted in the EPW.

An overview of the initiative’s milestones is shown in Fig. 2. The work was due to culminate in a high-level ministerial meeting in June 2022 in Oslo, Norway, with the aim of producing a meeting statement, but for unforeseen reasons the meeting could not take place (see below).

Fig. 1. Overview of the OMI process

Fig. 2. OMI milestones
Landscape and needs assessment

To identify and understand the existing evidence gaps and the needs and expectations of stakeholders, the OMI Secretariat instigated two processes.

- A research study was commissioned, with the aim of developing a landscape assessment of existing initiatives to understand the position of OMI in relation to other existing United Nations and European initiatives focused on medicines, vaccines and other drugs; and to identify gaps and opportunities for the OMI. This report will be published in autumn 2022.

- A virtual initial consultation process with 33 Member States, five trade associations and 20 non-State actors was held in spring 2021, with the aim of assessing the issues affecting access to effective, novel, high-priced medicines and health products, and identifying potential solutions to improve the current state of the market. A key conclusion from the consultations was that all stakeholders welcomed the OMI proposal of a new vision for collaboration between the public and private sectors, and validated the three themes of sustainability, solidarity and transparency.

Building the evidence base

To build the evidence base, a Scientific Programme Committee (SPC) was established alongside the Steering Committee, and a series of technical reports and a comprehensive stakeholder engagement process – including webinars, consultations and bilateral meetings – were developed.

The SPC

The aim of the SPC’s work was to provide expert advice on the evidence generated in the technical reports, and to identify key policy considerations based on the findings as proposals for OMI to take forward. The SPC consisted of 12 experts from academia and other organizations (see Annex 1 for the full list). Five meetings were held between January and June 2022, in which SPC members discussed concrete policy considerations to take forward, the programme of the planned high-level meeting and the policy brief.

Technical reports

To inform the work of the OMI, eight technical reports were commissioned from independent renowned authors with the aim of analysing the current state of the market and policy implementation, and to identify policy considerations that may help Member States and the industry move towards ensuring equitable, sustainable access to effective, novel, high-priced medicines. These reports covered a range of topics, discussing the main issues at hand. As background documents for the OMI, the papers went through rigorous quality checks, including a peer review process. They will be published in autumn 2022, following a technical webinar on 1 September to launch them officially (for details, see below). Annex 2 gives a detailed list of all the technical reports.
Webinars

Five webinars were held in January to February 2022 to further engage OMI key stakeholder groups, and to enable open discussion and knowledge exchange of emerging findings from the technical reports from diverse perspectives. The webinars were open to the public; they attracted a substantial number of attendees from the public and private sectors, and particularly from the pharmaceutical industry. Of 2389 participants registered, around 1373 took part from around the world.

Authors of the background papers were invited to present an overview of their papers, and an expert was invited to discuss their findings. In the second half of each of these sessions, a panel of representatives from each stakeholder group debated the feasibility of the paper’s proposed solutions. The recordings are available on the WHO website.5

Stakeholder engagement

To ensure active participation and a regular exchange with key stakeholders, the OMI Secretariat decided to complement the consultation process with the following meetings.

- On 6 September 2021 the OMI Steering Committee and Secretariat met with representatives from the International Federation of Pharmaceutical Manufacturers and Associations and the European Federation of Pharmaceutical Industries and Associations to discuss challenges related to access to high-cost novel therapies in the WHO European Region. The meeting set the scene for deepened collaboration with the pharmaceutical industry, and identified joint areas of interest and potential projects to take forward.

- Preparatory meetings were held between February and April 2022 with the aim of undertaking informal interviews with key decision-makers representing the OMI stakeholder groups, including Member States, the pharmaceutical industry, intergovernmental organizations and civil society. A total of 21 individual one-hour online meetings were held, based on a semi-structured interview guide, in which technical experts shared their views (not reflecting official statements from organizations). Annex 3 gives a list of participating Member States and organizations.

The policy brief

The OMI policy brief aims to provide an overview of policy considerations for policymakers, industry representatives and other stakeholders. It also highlights potential opportunities for future work, including design and implementation of policies, as well as supporting tools that promote sustainable access to affordable, effective novel medicines. The policy brief is based on the outputs of the technical and stakeholder engagement process undertaken as part of the OMI between 2020 and 2022.

The policy brief will be available on the WHO website in autumn 2022.

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Dissemination

European Health Forum Gastein

• Since 2020, the OMI has been on the agenda of the European Health Forum Gastein (EHFG), with presentations on various topics.

• At EHFG 2020: Dancing with elephants: new partnerships for health, democracy, business, the Norwegian Government and WHO Regional Office for Europe launched the OMI, as part of the EPW. The launch took place in a webinar focused on lessons learned from the COVID-19 pandemic, and called for increased collaboration between Member States and stakeholders.6

• At EHFG 2021: Rise like a phoenix, a webinar focused on continuing dialogue with key stakeholders to find common ground and agreement to transparent, sustainable solutions of mutual benefit to Member States and non-State actors, including health systems, payers, patients and industry. The main topic of discussion was emerging proposals from the consultation process and key enablers for implementing system change, including metrics, transparency, social responsibility, establishing a collaboration platform, novel pricing models and pooled procurement.7

• At EHFG 2022: A moonshot for a true European health union, a webinar will focus on celebrating the achievements of OMI and establishing an innovative multistakeholder platform to develop potential joint solutions for improving access to effective, high-cost medicines in the European Region. It will invite representatives from Member States, industry, civil society and intergovernmental organizations to discuss and define concrete projects, building on the consultation process, bilateral meetings, policy proposals and the outcome of the 72nd session of the Regional Committee for Europe on 12–14 September 2022 in Tel Aviv, Israel.8

WHO Regional Committee for Europe

At the 71st session of the Regional Committee for Europe, held virtually on 13–15 September 2021, the WHO Regional Office for Europe co-hosted a virtual technical briefing with the Government of Norway.9 This provided an update on progress made so far with the OMI, and invited perspectives from Member States, the European Commission and non-State actors, including the views of patients, other consumers, health-care professionals and manufacturers.


To mark the end of the OMI, a high-level meeting in Oslo was planned on 13–14 June 2022. Due to unforeseen events, which meant that high-level participation would be limited, the decision was taken not to hold the meeting. Instead, presenting the OMI work during the 72nd session of the Regional Committee for Europe on 12–14 September 2022 in Tel Aviv, Israel, was seen as the best course of action. The WHO Regional Office for Europe will seek a formal mandate from its Member States to continue the agenda developed under the OMI. More specifically, the OMI process has led to a proposal to establish a joint stakeholder platform (comprising Member States and non-State actors, including representatives of private sector companies), managed by the Regional Office with Member State support and input, to create a neutral space in which joint solutions can be sought. Of potential interest are policy proposals around “buyers’ clubs” for high-priced products, equity-based tiered pricing and improved metrics for measuring genuine patient access to novel medicines.

Publication and launch of the technical reports

On 1 September 2022, the technical reports originally planned for publication during the high-level meeting in Oslo were launched at a webinar hosted by the OMI Secretariat. The two-hour webinar summarized the findings of the reports to enable discussion between participants comprising experts, industry and civil society representatives, and national and WHO officials. Complementing the webinar and the launch of the technical papers, a series of five articles and one editorial merging the key topics and proposals will be published in the British Medical Journal.
Conclusion

In summary, over the past two years the OMI has fostered in-depth dialogue with all relevant stakeholders on the pressing issues of solidarity, transparency and sustainability in the pharmaceutical sector. The work undertaken through the OMI has informed a WHO Regional Office for Europe statement, to be discussed during a special ministerial lunch at the 72nd session of the Regional Committee for Europe on 12–14 September 2022 in Tel Aviv, Israel. The statement, which was shared with Member States and non-State actors for their feedback with invitations to the Regional Committee, proposes that the Regional Office should work in close collaboration with Member States to develop a joint stakeholder platform to improve access to effective, novel, high-priced medicines in the Region. The aim of the platform is to promote constructive dialogue and collaboration between stakeholders, including Member States, industry, intergovernmental organizations, civil society and professional bodies. It is envisaged that the platform could also be used for collaborations on workable solutions to improve access to novel medicines. These could build on concrete proposals from the consultation process – such as those on pooled procurement/buyers’ clubs and improved metrics to measure access – and on wider policy considerations identified in the technical reports. Following finalization of the statement and, anticipating a mandate from Member States to take the work forward, the WHO Regional Office for Europe aims to develop the platform as a direct outcome of the OMI.
ANNEXES
Annex 1.
Scientific Programme Committee – list of nominated experts

Christine Årdal, Norway, Scientific Programme Committee Co-Chair

Reinhard Busse, Germany, Scientific Programme Committee Co-Chair

Hans Georg Eichler, Austria

Sylvain Giraud, Belgium

Aldo Golja, the Netherlands

Claudio Jommi, Italy

Ninell Kadyrova, Kyrgyzstan

Ruth Lopert, Australia

Dimitra Panteli, Greece

Momir Radulović, Slovenia

Richard Torbett, United Kingdom

Sabine Vogler, Austria
Annex 2.
List of OMI technical reports


Vogler S. Payer policies to support innovation and access to new medicines in the WHO European Region. Oslo Medicines Initiative technical report. Copenhagen: WHO Regional Office for Europe; 2022 (https://apps.who.int/iris/handle/10665/361753).


Annex 3.
2022 Stakeholder engagement process – list of participating Member States and organizations

<table>
<thead>
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<th>Member States</th>
<th>Industry</th>
<th>Other stakeholders</th>
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<td>Austria</td>
<td>Association of British Pharmaceutical Industry</td>
<td>European Cancer League</td>
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<td>Belgium</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
<td>European Network for Health Technology Assessment/International Horizon Scanning Initiative</td>
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<td>Denmark</td>
<td>International Federation of Pharmaceutical Manufacturers and Associations</td>
<td>TLV Sweden, Dental and Pharmaceutical Benefits Agency</td>
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<tr>
<td>France</td>
<td>Medicines for Europe</td>
<td>European Social Insurance Platform</td>
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<td>Spain</td>
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<td>United Kingdom</td>
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Annex 4.
List of OMI steering committee members

Arne-Petter Sanne, Project Leader, Norwegian Medicines Agency
Audun Hågå, Director General, Norwegian Medicines Agency
Bjørn-Inge Larsen, Special Representative for International Health, Norwegian Ministry of Health and Care Services
Elias Mossialos, Brian Abel Smith Professor, Department of Health Policy, London School of Economics and Political Science
Emelie Sam, Pharmacist, the French Presidency of the European Union
Francesca Colombo, Head of Health Division, Organisation for Economic Co-operation and Development (OECD)
Govin Permanand, Senior Policy Analyst, WHO Regional Office for Europe
Hans Kluge, Regional Director, WHO Regional Office for Europe
Jo de Cock, Senior Adviser, Administrator-General Emeritus, RIZIV, Belgium
Louise Delaney, Consultant, WHO Regional Office for Europe
Natasha Azzopardi Muscat, Director Country Health Policies and Systems, WHO/Europe
Rebekka Aarsand, Consultant, WHO Regional Office for Europe
Richard Bergstrom, Senior Adviser, Ministry of Health and Care Services, Norway
Sarah Garner, Senior Policy Advisor, WHO Regional Office for Europe
Sylvain Giraud, Head of Unit, Medical products: quality, safety, innovation, the European Commission
Synnøve Ravnestad Eikefet, Adviser, Norwegian Ministry of Health and Care Services
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.

Member States

Albania  Greece  Portugal
Andorra  Hungary  Republic of Moldova
Armenia  Iceland  Romania
Austria  Ireland  Russian Federation
Azerbaijan  Israel  San Marino
Belarus  Italy  Serbia
Belgium  Kazakhstan  Slovakia
Bosnia and Herzegovina  Kyrgyzstan  Slovenia
Bulgaria  Latvia  Spain
Croatia  Lithuania  Sweden
Cyprus  Luxembourg  Switzerland
Czechia  Malta  Tajikistan
Denmark  Monaco  Türkiye
Estonia  Montenegro  Turkmenistan
Finland  Netherlands  Ukraine
France  North Macedonia  United Kingdom
Georgia  Norway  Uzbekistan
Germany  Poland

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