

THE OSLO MEDICINES INITIATIVE: IMPROVING ACCESS TO HIGH-COST MEDICINES IN EUROPE

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Summary: The pharmaceutical market is changing. Today we are seeing an increasing number of highly-effective novel therapies for rare diseases and other relatively low-volume patient groups coming to market. However, many of these novel therapies come with a high price-tag, proving too expensive for national governments to provide them to all who would benefit. What can be done? How can we balance industrial, health care, and public health interests while ensuring increased access for patients? Bringing the key stakeholders together to consider these questions and to identify potentially sustainable 'win-wins' is the role of the Oslo Medicines Initiative.

> #EHFG2021 – SESSION 2:

Oslo Medicines Initiative: A new vision for collaboration between the public and private sectors

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Introduction

As the European health community continues to grapple with the ongoing COVID-19 pandemic, an oft-cited bright spot has been the speed at which highly efficacious vaccines have been brought to market. While some commentators and experts were hopeful of an early break-through, many others questioned not just the scientific feasibility of having vaccines before the end of 2020, but so too the practical.¹ But with the first COVID-19 vaccines being publicly available in early 2021, just one year into the pandemic, it was the optimistic view that prevailed. The mRNA and viral vector vaccines, in particular, released by some of the biggest names in the pharmaceutical industry, continue to save hundreds of thousands of lives

across the world, including some 750,000 by mid-December 2021 in Europe and the United States alone.² Moreover, manufacturers continue to adapt their products to be effective against mutations in the SARS-CoV-2 genome (the virus that causes COVID-19 disease) to counter new variants such as Omicron (BA.1 and more recently BA.2), and Delta before it.

At the same time as we can point to the success of COVID-19 vaccines, we are aware of their inequitable global roll-out. According to current data, more 'booster' doses have been administered in high-income countries than all vaccine doses combined in the world's lowest-income countries.³ Unfortunately, however, differential access to life-saving medicines and vaccines is not new; it is not even exclusive to differences between regions

of the globe. Within the European Region there is considerable inequality in terms of access to medicines, and this is especially the case with novel, efficacious but high-priced medicines. These include gene- and cell-therapies, orphan drugs for rare diseases, and certain oncology drugs.

“there is considerable inequality in terms of access to medicines

Novel, efficacious, high-cost medicines and the challenge to access

The reasons for this inequity are debated. Public authorities often point to private companies' commercial priorities and their duties to shareholders as the driver of high prices and subsequent unaffordability and inequitable access. Meanwhile, manufacturers argue that prices are appropriate given the value new technologies bring, alongside the high research and development costs, level of investment risk and attrition, and the comparative effectiveness of new treatments which may be fully curative. They cite lack of appropriate value assessment frameworks, difficulties paying high up-front costs, national registration systems, narrow national health budget space and inappropriate coverage procedures as the main hindrances to access. While there may be debate around the causes, what is clear, however, is that these new treatments are driving bigger gaps between the 'haves' and the 'have-nots'.

According to data from the Organisation for Economic Cooperation and Development (OECD), governments and compulsory insurance schemes cover around 56% of total spending on retail pharmaceuticals (i.e. medicines not used during hospital treatment), with some countries covering up to 80%.⁴ And we know that less well-off countries across the European Region have narrower

coverage lists in their benefits packages. The concern regarding novel medicines, therefore, is that countries cannot afford to provide the products to all those who need them, with even the wealthiest countries having to restrict coverage of some new products by narrowing indications or refusing reimbursement altogether. Negative decisions are sometimes also rendered on account of authorities not having sufficient clinical data to make an informed assessment. While there may be valid commercial reasons from the originator's side, some of the newest and most efficacious breakthrough medicines that offer clear therapeutic benefit with the promise of real population health gains will not even be marketed in some countries. A minority of wealthy patients may be able to access these products by 'shopping around' on the private market around the world and paying out-of-pocket. However, in general, only those with substantial resources will have access due to the unaffordable pricing levels that restrict selection and purchasing choices by governments. These widening inequalities are affecting progress towards Universal Health Coverage and our ability to deliver on the Sustainable Development Goals (SDGs).

Bringing stakeholders together to search for joint solutions – the Oslo Medicines Initiative

In view of these challenges to access, particularly to novel, effective high-priced therapies, the Government of Norway – through the Ministry of Health and Care Services and the Norwegian Medicines Agency – and the World Health Organization Regional Office for Europe (WHO/Europe), jointly established the 'Oslo Medicines Initiative' (OMI). The OMI facilitates a dialogue and learning platform between countries, the pharmaceutical industry, patient organisations, professional organisations and other stakeholders. It aims to help all parties work together to find common ground. It was formally launched during the 2020 European Health Forum Gastein (EHFG)⁵ and marked its one-year anniversary during this year's installment with a session entitled 'The Oslo Medicines Initiative: A new vision for collaboration between the public and private sectors'.⁶

Based on the premise that no matter how good a medicine is, it has no value if it remains on a shelf unused, the OMI takes as its starting-point that national authorities and the pharmaceutical industry share the same overarching goal. Namely, to improve public health outcomes by providing high-quality medical products to patients, with the consequent broader economic benefits brought by healthier populations. What both sides are looking for is the diffusion and uptake of new medical products within an environment that supports and rewards innovation. This means that governments need to avoid uncontrolled growth in pharmaceutical spending while maximising population health within current budget constraints. Industry needs to manage potential trade-offs between volume and price, and between profits, risks and research and development investments, while at the same time advancing innovation. The relationship between pricing, access and innovation is not linear and both sides need to work together to address a complex issue in which competing priorities need to be finely balanced.

Governments and industry are not the only stakeholders in this area. Patients and civil society, as the ultimate consumers and beneficiaries of these products, are a crucial set of actors. It is for this reason that the OMI aims to bring together all three groups to identify and implement pragmatic solutions to improve patients' access to safe, novel, high-cost medicines across Europe by focusing on affordability.

In this spirit, the OMI has two streams being pursued in tandem. The first is political in involving Member States in dialogue with the other stakeholders to better understand the issues at play from all sides. In this regard, a series of consultations with the stakeholders to gauge opinions, especially around access, and to try to tease out potential areas of commonality have been undertaken. The second is to ensure informed discussion and debate around key issues, with the aim of identifying potential policy directions to be taken forward jointly. This involves expert discussion and analysis and is being pursued through the publication of technical documents and hosting of topic-specific webinars



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(see: <https://www.omi-euro.org/>). The two streams are necessarily complementary, with one informing the other.

The OMI is underpinned by three pillars: transparency, solidarity, and sustainability, and is primarily focused on affordability (prices) – first, as a major barrier to patient access, and second, noting that unaffordable prices can also lead to lost sales income for manufacturers. In this regard, *transparency* is about understanding how transparency could be used to build trust between stakeholders, thereby enhancing negotiations and supporting access; *solidarity* in terms of achieving greater solidarity between stakeholders to address some of the challenging decisions that will be needed to meet the SDGs and improve access; and *sustainability* of access and a pipeline of innovations which does not bankrupt health systems is essential.

Important discussion points under the Oslo Medicines Initiative

Amongst the areas so far explored within the OMI, three approaches have attracted particular discussion.

The first concerns models of joint or pooled procurement involving several countries, where agreement on lower prices is achieved by joint negotiation for higher volume sales. Extant examples include the Beneluxa, whose initial focus was on orphan drugs; the Valletta Declaration group, which has

a particular focus on oncology drugs, treatments for autoimmune diseases and other high-cost treatments; and the Baltic Procurement Initiative, which is concerned with the joint procurement of vaccines, and with countries lending each other medicines in case of shortages. These initiatives often have wider remit beyond price negotiation, including joint horizon-scanning and health technology assessment capacity, but their goal is to scale up joint actions and increase collaboration and capacity. The success of such initiatives has been hard to measure,⁷ for even where successful price negotiations may have taken place, this does not automatically imply either a much cheaper price or greater patient access (which is also dependent on domestic factors such as prescribing behaviours). But the principle of collaboration based on sharing data and information between countries to reduce information asymmetries and strengthen their ability to make informed selection and purchasing decisions remains one that some stakeholders are keen to explore.

A second point of discussion has been about changes to current approaches to external reference pricing (ERP) / international price benchmarking and comparisons. Although widely used in Europe, there are several perverse consequences of ERP^{8,9} and its effectiveness is increasingly unclear across a number of parameters, including not least overall expenditure on pharmaceuticals.¹⁰ Coupled with other

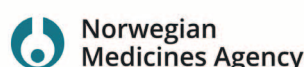
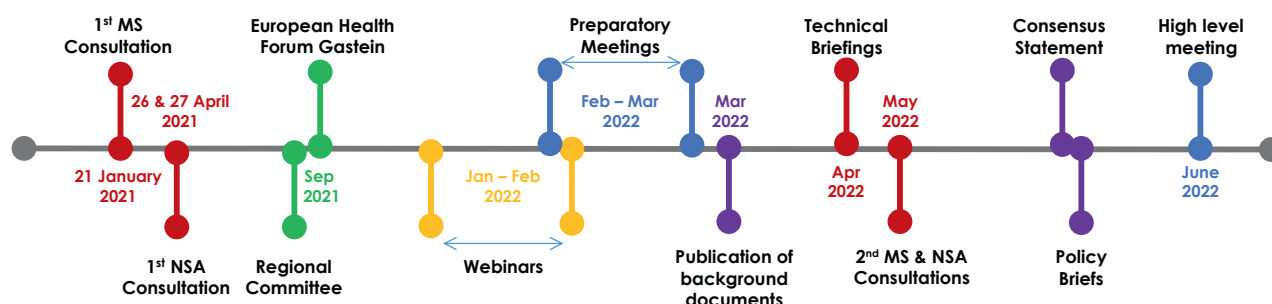
frameworks, such as parallel importation in the European Union (EU), externalities associated with its use reportedly outweigh the benefits. Moreover, industry argues that governments have sometimes sought to use ERP to artificially control prices,¹¹ by benchmarking to inappropriate countries. Yet a revised ERP model, one which seeks to involve not only industry in its design but also the other key actors (given that ERP systems can have unintended consequences such as the de-registration of medicines in cheaper markets), may be something that stakeholders can work on together as part of a wider set of policy tools.

aims to help all parties work together to find common ground

Finally, tiered- or differential-pricing, represents a tool that stakeholders all see as having potential, but as also requiring considerable development to make it feasible and beneficial in practice. While the notion of segmenting markets and charging different prices according to ability to pay would help promote access to certain products for less wealthy countries, and may help reduce the wait time in some countries associated with staggered market entry, this does not necessarily address the issue of affordability of the treatments themselves, and some would argue that promoting generic competition is more effective in lowering prices.¹² Introducing an equity-lens to take into account both ability and willingness to pay from a ‘fairness’ perspective may be a way forward – known as equity-based tiered-pricing – but some feel that the approach is still too imbalanced in favour of manufacturers¹³ and that risks would need to be carefully managed.

Mentioning these three policy options is not to endorse them, nor to say that they will be taken forward by the stakeholders. The OMI provides a platform, based on

Figure 1: OMI timeline



Norwegian Ministry
of Health and Care Services

Source: Authors

the available evidence, to explore potential policy options that will increase access to medicines in the European region to the benefit of patients. In this, the OMI stresses the need for workable indicators to measure genuine access and patient benefit; all stakeholders have their own metrics. But it is ultimately up to the stakeholders whether, or how, joint solutions can be agreed and pursued.

What the OMI is doing in convening the stakeholders and promoting discussion is prompting them to consider their wider roles and duties in this area. More specifically, given the solidarity pillar, the OMI is asking whether a new relationship between the stakeholders to the benefit of patients can be forged, defined loosely in terms of a ‘social contract’. The question at the heart of this is whether medicines are simply another traditional market commodity, or do they have a wider societal value that merits a more careful approach to shaping markets, managing innovation and determining selection and purchasing decisions? Do payers and industry have a duty of care to patients and society which comes with expectations and responsibilities towards each other in support of this, and for which they should be held accountable?

The major milestone of the OMI will be a high-level meeting scheduled to take place in Oslo on 13–14 June 2022, and this question will be very much on the agenda. Building on the OMI work

(see Figure 1), the meeting will present a unique opportunity for the stakeholders to discuss progress made on some of the major challenges and consider ways of overcoming them jointly. It is envisaged to agree a consensus document on behalf of the stakeholders which will set out an agreed starting position and highlight some new opportunities for improving access to novel medicines for patients in the European Region based on this wider social understanding of roles and duties.

The OMI is underpinned by three pillars: transparency, solidarity, and sustainability

Looking ahead

Since its launch in 2020, the OMI has continued to attract attention. Not just the stakeholders themselves, but the representatives of the Norwegian government and WHO/Europe have been invited to various international meetings and fora to outline the initiative

and its progress. Earlier this year, the European Commission and the OECD, along with the French Ministry of Health joined the OMI Steering Committee. Ensuring consistency with the EU Pharmaceutical Strategy,¹⁴ technical coherence with the OECD work on access and specific issues such as managed-entry agreements¹⁵ and alignment with the French Government’s EU Presidency priorities around health,¹⁶ allows for a strong voice across Europe and its Member States. This is a strong sign that the OMI is on the right track, and so too is the fact that the industry is willing to engage in a meaningful way. Indeed, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has been onboard with the OMI from the outset, participating in not just the formal consultations with non-state actors (political stream), but also contributing alongside other stakeholders in the webinars (technical stream). The OMI has made it clear that real solutions will only be possible if all stakeholders work together, and the engagement with originator firms is thus crucial.

Earlier, we noted that the record development of effective, quality vaccines for COVID-19 has been a bright-spot in the pandemic, and that the optimists have been proven right. As optimists ourselves, we are similarly hopeful for the emergence of concrete solutions around sustainably improving the affordability of novel, effective high-priced medicines

in Europe and, ideally, beyond. For while those behind the COVID-19 vaccines have been rightly lauded for their success, the success story goes beyond the accomplishment of individual scientists and companies. What those of us involved in the OMI would point to as the real lesson, is what is possible through close cooperation between public and private sectors, between stakeholders and between countries, in the generation and supply of new treatments for priority health issues. We would argue that the same spirit of solidarity between key stakeholders in the COVID-19 vaccine story must extend to ensuring access to innovative treatments more broadly.

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