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- Online Consultation with non-State actors: Nongovernmental organizations and philanthropic organizations - 26 April 2021
- Online Consultation with non-State actors: Private sector - 27 April 2021

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AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

WRITTEN STATEMENT - OSLO INITIATIVE

FORMAL INPUT PAPER

Brussels, 11/05/2021

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WRITTEN STATEMENT TO THE OSLO INITIATIVE

Affordable Medicines Europe strongly support the ambitions and objectives of the Oslo Initiative. In this context, our sector will primarily focus our input on our own key objective – which is to bring more affordable medicines to healthcare systems and patients across Europe. The current lack of transparency of medicines prices is one of the key obstacles to reach this objective. We therefore call for real transparency in prices of medicines.

Ensuring a competitive pharmaceutical market in Europe

Affordable Medicines Europe believe, that one of the main obstacles to access to effective, novel, high-priced medicines is indeed the price of said medicine. We therefore strongly believe, that more competition in the on-patent pharmaceutical market is needed, as increased competition will put a downward pressure on prices. Parallel distribution is based on the principle of free movement of goods. Parallel importers find products that are less expensive in one Member State and import to a Member State where prices are generally higher. They then sell the medicines at a lower price than that offered by the pharmaceutical companies in the importing country. This spurs competition and bring significant savings to healthcare systems and patients.[1] Unfortunately, in Europe, the lack of transparency on prices hamper our sectors ability to increase competition in the market.

In an EU/EEA context, Affordable Medicines Europe call for a revision of the Transparency Directive to remedy this. However, we believe that also the Oslo Initiative could be a driver for similar changes in the market – i.e. real price transparency. We therefore strongly encourage WHO Europe to consider price transparency as a key driver to obtain the objectives of the Oslo Initiative.

Ending secret agreements

In some European countries (e.g. Germany), voluntary agreements between e.g. health insurers and pharmaceutical companies are a key component in setting the prices of medicines. In fact, in Germany alone, more than 50% of all procedures are concluded through co-called 'voluntary' agreements.[2] Hence, these agreements are already part of the formalised pricing procedures.

In Sweden, "side agreements" with secret refunds have been growing in importance since 2014. Here, the Dental and Pharmaceutical Benefits Agency (TLV) coordinates negotiations between companies and the Regional County Councils (SKR). In the agreement between the Swedish government and SKR on government grants for the pharmaceutical benefits, the government and SKR share the refunds that the managed entry agreements generate.

Another example of such agreements is the so-called 'rebate contracts', which are not disclosed. This means that list-prices are known, but the actual price paid by the health insurer is unknown. The lack of transparency on voluntary agreements makes it impossible for parallel importers to know at what prices they may bring products to the market at more competitive prices. This reduces the downward pressure on prices brought on by competition. In this case, the lack of transparency potentially stabilises prices at a higher level than the market would otherwise have dictated.

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[1] *Mendez, S. J. (2016). Parallel Trade of Pharmaceuticals: The Danish Market for Statins. Melbourne: Melbourne Institute of Applied Economic and Social Research. Retrieved from https://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf, Enemark, U., Pedersen, K., & Sørensen, J. (2006). The economic impact of parallel import of pharmaceuticals. Odense: University of Southern Denmark. Retrieved from https://pdfs.semanticscholar.org/92f1/eb32d32370ea06ae76abd7d009d7759e62ce.pdf, Posada, P. (2019). Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases. Madrid: NERA Economic Consulting, and Verband der Ersatzkassen. (2019, April 16). Keine Streichung der Importförderklausel für Arzneimittel. Retrieved from https://www.vdek.com/presse/pressemitteilungen/2019/ streichung-importfoerderklausel-arzneimittel.html.*

[2] *BPI Pharma-Daten 2019, page 62, https://www.bpi.de/fileadmin/user_upload/Downloads/Publikationen/Pharma-Daten/Pharma-Daten_2019_DE.pdf.*

Another example of voluntary agreements is the UK Pharmaceutical Pricing Regulation Scheme (PPRS). This voluntary scheme implements a system of retrospective volume discounts. Any spending of the NHS above an agreed cap will be paid back to the NHS which leads to a subsequent discrepancy from the list price at an unknown level. According to the industry association, the payback amounts to around one million pounds per day.

The number of secret agreements between public authorities and pharmaceutical companies is growing in a number of Member States.[3] Examples of such agreements in which prices remain untransparent are claw-backs, secret price discounts e.g. for new molecules and patented medicines, and cost-volume contracts. There is a tendency to suggest that the 'rebates' given are equal to savings. However, this is not the case, as most often pharmaceutical companies start price negotiations at fictively high levels, only to give 'rebates' based on this. By the lack of transparency, every Member State may think they have struck "the best possible deal", while in fact, they have not. The savings are as fictive as the initial list-price proposed.

Finally, since External Reference Price systems applied by many Member States are based on list prices, setting a fictitiously high list-price in e.g. Germany, upon which a 'rebate' is then given to German health insurers, allow pharmaceutical companies to keep the reference prices high (the list-price), translating into higher price levels in other Member States.

Recommendation:
The winning prices of public tenders should be transparent and accessible to all market players.

A similar procedure is applied in Italy, where a given MAH and the national agency agree to a price similar to the one in other Member States and which is published in the Official Gazette accordingly. In fact, the parties agree on a secret discount during these negotiations which will only be indicated in a confidential document agreed and signed between the two parties. In the Netherlands, there are two forms of secret agreements on patented products. The government negotiates secret agreements with MAH's where the public price is higher than the real price. This so called "sluis" procedure is applied before the product enters the market in case the costs of the product is in total more than 40 euro million per year or when the costs are more than 50.000 euro per year per patient. Furthermore, insurance companies can negotiate secret agreements with manufacturers regarding reimbursement prices leading to deviations of the real prices from the listed prices.

Transparency in public procurement

In many Member States, public procurement of medicines provides transparency of the prices paid for medicines. However, this is not the case for all Member States, which constitute a significant barrier to more efficient competition in these countries. Especially parallel importers are discouraged from participating in tendering if winning prices are not known over time. This is due to the fact, that in effect having no transparency on prices over time, makes it very difficult for parallel importers to know if e.g. investing in a parallel import license of the given product is relevant.

In its 2012 Impact Assessment the Commission (preparing for a revision of the Transparency Directive) assessed that public procurement mainly affects generics and represents 8% of the market.[4] However, since then, this volume has increased and today patented medicines also play a more prominent role in the tendering. Hence, the advantages of including public procurement in the scope of any transparency of prices initiatives should be recognised. For those Member States where the winning prices are already transparent, such an inclusion would have no practical implication.

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[3] *In Bulgaria, 216 million BGN (approx. 110 million euro) were announced to be saved due to secret agreements in 2019. In 2020, more than 80 MAH were invited to make secret agreements with the insurance fund. In Romania, the budget allocated for secret cost-volume contracts in 2019 was 4,49 billion leu (approx. 965 million euro) for 44 contracts including 25 medicines. In Sweden, there are secret "side agreements" for 50 medicines to date. Pharmaceutical companies will pay 2.9 billion SEK (approx. 282 million euro) in bonus for medicines covered by side agreements between companies and regions for 2020.*

[4] *European Commission, SWD(2012)30 final, p. 7, para. 4.2., Tendering*

Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for patented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.

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26 April 2021

The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines –

A new vision for collaboration between the public and private sectors

Consultation with non-State actors: nongovernmental organizations and philanthropic organizations

On behalf of the Association of European Cancer Leagues, I thank you for the opportunity of being here today. ECL is a non-profit, pan-European umbrella organisation of national and regional cancer societies, representing over 500 million citizens. The ECL Secretariat is based in Brussels and our vision is to free Europe from cancer, for this we work across the entire cancer continuum including cancer prevention with our advocacy support to the European Code Against Cancer.

We create opportunities to advocate for cancer prevention, access to medicines, and patient support and we shape recommendations to contribute constructively to policy and legislative processes in the EU. However, it is important to highlight that the policy developments and talks happing in Brussels cannot be limited to the so-called EU-bubble, but it is essential that national stakeholders, including NGOs and patient organisations, are aware and informed of these conversations because ultimately the EU Member States have the responsibility to effectively transfer these into their setting. So inclusion is key.

ECL welcomes the Olso Medicines Initiative for Better access to effective, novel, high-priced medicines.

This year much is happening and much has been changing. The WHO Fair Pricing Forum has just concluded its sessions, the Global Health Summit will take place in a few weeks - on 21 May. And we are here today to continue this journey towards fair, just, equitable, and sustainable access to affordable medicines through a fair pricing system.

We all need to shape a forward-looking ecosystem based on international collaboration, solidarity, transparency, and sustainability of the healthcare systems. These are different concepts but strongly intertwined.

When it comes to Solidarity: The pandemic has been challenging the status quo and forces the European Union to move towards a fairer "new normality". When the World Health Organization characterized the COVID-19 as a pandemic, the Member States found themselves alone in fighting an unknown disease. Soon, they realised that solidarity and cooperation were *vital*. Therefore, building on the lessons learnt from COVID-19, ECL calls for a stronger collaborative framework among countries, beyond COVID-19 crisis. Member States should *systematically* join forces to overcome common challenges. The spirit of solidarity and multilateral cooperation experienced during the pandemic need to be nurtured with concrete policy changes. We need to understand which multi-country mechanisms of collaboration worked, why these worked, and what shall be improved.

Moving to Transparency: Health must be discussed as a public good and not as a marketing product or this will even undermine the citizens' trust in science and institutions. Instead we see skyrocketing prices, inequalities, lack of transparency and non-disclosed data on cost and not only. It is important to support data and knowledge sharing, to disclose critical information that impact on the current unequal access to medicines. It should be clear who is producing what – when- and how, who receives what - when and how. Little information is available on this.

26 April 2021

Finally, Sustainability: Member States are facing heavy socio and economic distress, and the current health and pharmaceutical system are not sustainable in the long run.

Pool resources and enhance collaboration throughout the entire medicines access pathway is critical, to prepare health systems for (i) the arrival of new medicines and technologies, (ii) conducting high quality Health Technology Assessment (HTA) and (iii) sharing information about prices and pricing & reimbursement strategies so that countries are able to (a) prioritise medicines with higher clinical value, (b) review and adjust prices based on new evidence and setting, and (c) fairly negotiate the prices of medicines.

To conclude, a common objective should be avoiding monopolistic system, we should support fair competition which would ultimately benefit innovation and scientific improvements to the benefit of patients.

Thank you for the opportunity to make this intervention. ECL looks forward to cooperating with the WHO and Member States moving forward.

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The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines

Written statement of Dr. Ward Rommel, member league chair of ECL Access to Medicines Task Force

- The ECL Access to Medicines Task Force represents 30 cancer societies in 25 countries. Our mission is to make safe and effective medicines available to all cancer patients in Europe.
- ECL Access to Medicines Task Force welcomes the Oslo Medicines Initiative. It is a timely and necessary initiative to tackle these challenges. We are grateful for the opportunity to participate in the consultation.

- Regarding access to oncology drugs, we identify 5 challenges:

  1) Notwithstanding progress, some cancers still have very low survival figures. The relative 5-year survival of patients with lung cancer and brain tumours is well below 30%, to take just 2 examples. **There is an urgent need for better drugs**, **but we should not forget that cancer care is not only about drugs.** We also need better prevention, diagnosis, surgery, radiotherapy, psychosocial support and palliative care. We cannot invest all our resources in cancer drug development.

  2) There are **big disparities in access to and uptake of new cancer drugs**. A recent OECD report made clear that countries such as Germany and Denmark have a more comprehensive and faster access than countries such as Hungary and Latvia.

  3) The **price** of new oncology drugs keeps increasing. With the arrival of **cell & gene therapies,** they have reached a **new order of magnitude**. CAR T therapies cost several 100.000 euro.

  4) It is unclear where these prices come from. Research shows firstly, that there is no link between price and clinical **benefit** and secondly, that some expensive cancer drugs have very low clinical benefit. In addition, it is not transparent whether these **prices** are legitimized by R&D costs, because these costs are not transparent and the amount of public funding that went into R&D is not clear.

  5) Increasingly, drug shortages are becoming a problem in oncology.

- As a way to move forward, ECL Access to Medicines Task Force proposes a definition of fair price and fair pricing: **A fair price has to be justifiable, predictable and cost-effective** within the aims and priorities of health care systems and the available budget. At the same time, a fair pricing policy that takes into account the ethical and financial dimensions of patient access to care, affordability and sustainability of healthcare systems should be encouraged and rewarded.
  - Whereas '**justifiable'** means a price that reflects the documented and clinically relevant benefit of the medicine, and a reasonable relationship between the cost of bringing the product to market (including R&D, production, marketing) and the price.
  - Whereas '**predictable'** relates to the need for health payers, policy makers and systems to be able to predict the total costs of investing in the treatment.

- '**Cost-effective'** (ness) could be a common criterion for evaluating whether the price seems 'justifiable', as it links benefits with costs in a systematic way and provides a comparable decision-making tool across healthcare interventions.
- **Within the aims and priorities of health care systems:** a fair price may depend on the available budget and other urgent needs in the system.
- Finally, '**affordability'** addresses the financial side of the sustainability of health systems.

- A prerequisite for obtaining fairer prices is a higher level of **transparency** and access to information about end-user prices, documentation of product value and the cost of developing and bringing the pharmaceutical product to market, as well as reimbursement decision-making processes.

- ECL Access to Medicines Task Force has several proposals **to arrive at a situation of fair prices and fair pricing (see our fair price paper and our paper on the EU Pharmaceutical strategy).**

  We call on WHO/Europe to support our recommendations and to take initiatives to develop and bring them about:
  - We suggest establishing a High-Level Working Group on fair price and fair pricing connecting all relevant stakeholders, in order to define a fair price and identify opportunities and challenges connected to different pricing models;
  - Public funders should attach conditionalities to public funding and ensure that medicines resulting from publicly funded research are available at a fair and affordable price;
  - There is a need for new business models in drug development. Initiatives organizing drug development in a new way should be supported. Inspiration can be taken from existing initiatives such as DNDi, Health Impact Fund and Fair Medicine. Essential features of these new business models should be: (i) a strong focus on needs driven R&D; (ii) new ways of approaching intellectual property, for example by using the framework of socially responsible licensing, and (iii) patient groups and academics need to have a stronger role in the research and development process.
  - We need to step up the level of cross-country collaboration, because that is the only way to tackle some of the challenges ahead, such as performing high quality HTA, collecting real-world data and real-world evidence and creating more transparency in the drug market (for example, about real prices, about R&D costs).
  - For new cancer drugs, we need to ensure high quality benefit-risk assessments of patient-relevant endpoints. There is a need for surrogate endpoints in clinical trials to be accompanied by hard endpoints reflecting improvements in overall survival and quality-of-life measures. The R&D-process has to be developed in such a way that data about patient relevant outcome measures, such as overall survival and quality of life, become available as soon as possible.
  - **To prevent shortages, we need** legally binding shortage management and prevention plans for all medicines. The EU needs to develop early warning shortage systems, building on the SPOC system experience.

Statement for Consultation on *The Oslo Medicines Initiative* 2021

EuroHealthNet is a leading partnership bringing together agencies and authorities with responsibilities for public health, health promotion and tackling health inequalities at national and regional levels across Europe. These bodies are at the frontlines of preventing diseases and tackling public health consequences for people who struggle to access effective, high quality and affordable new medicines and medical products.

EuroHealthNet welcomes the *Oslo Medicines Initiative* and its aims to help to remedy the lack or inadequacy of effective "social contracts" and regulations establishing and ensuring clear rights and duties of all involved in medicines development processes. This is needed to ensure critical and innovative products are equitably available for people in need, and to apply lessons of the COVID-19 syndemic, particularly on effective cooperation between stakeholders at all levels of governance and supply.

What does EuroHealthNet see as the main issues affecting access to effective medicines?

The importance of WHA Resolution 72.8 has been underlined by recent disclosures of significant variations between prices for innovative vaccines and therapies in Europe, thus reinforcing the importance of the transparency imperative in the Oslo Initiative. EuroHealthNet firmly reiterates the need for equitable public health priorities to be placed at the forefront of research and development for public good and recognises the work of other major European organisations, including the European Public Health Alliance, the European Patients Forum and organisations representing health system professionals.

We again emphasise the importance of intrinsically ensuring equitable and informed patient, professional and public involvement throughout medicines development processes, from design to implementation. This includes new and more transparent approaches for clinical trials that should be inclusive for non-commercial actors including authorities and agencies and in accordance with public health priorities. Improving health and digital literacy for all is a keystone of that approach, on which we are working in several dimensions. The importance of defining and setting clear criteria for unmet medical needs and how to address them equitably in diverse global and European contexts will be vital in ensuring equity and universal access.

It is unsustainable that only 3% of average health budgets are allocated for public health, and prevention research often averages only around 5% of health research spending. To "build back fairer and better" that must change. We note and commend the new model of the *EU4Health* Programme which will allocate a minimum of 20% to prevention and promotion, the achievement of which has been largely based on public demand.

We also note the significant example of increasing health system restrictions on medicines for people suffering chronic pain, for which physical and mental health promotion measures will be advised. That is partly for sustainability and cost reasons, but mainly because emerging evidence

shows certain medicines may not always be as effective as claimed. This is an example why new social contracts between public decision makers and private supply chains are needed on effective prevention measures and distribution of research, development, and implementation budgets.

What promising actions is EuroHealthNet undertaking to help improve access?

We coordinate IMMUNION, a new EU-funded consortium on vaccination, which will:

- Strengthen the *Coalition for Vaccination*'s long-term sustainability and visibility.
- Improve use of validated training materials and resources for health professionals, provide training opportunities and enhance collaboration between public health institutions, health professionals, students, and the media.
- Understand drivers of vaccine inequalities within countries and address vaccination coverage issues in vulnerable and underserved populations.

Comparable and high-quality data is fundamental to monitor health inequalities and identify the pathways through which such inequalities originate. By building the world's first *Global Burden of Health Inequalities* data warehouse and by adding a health equity dimension to the *European Social Survey,* the CHAIN research consortium will lead in collecting such data and making it publicly available. This initiative, already well known in Norway and the UN agencies, includes ongoing studies into, *inter alia*, ethics and global justice in medicines, including TRIPS.

EuroHealthNet is also engaged in a new EU funded research project called RIVER-EU *('Reducing Inequalities in Vaccine uptake In the European Region - Engaging Underserved communities'*). The project will work to improve access to MMR and HPV vaccines among specific underserved populations by identifying and removing health system barriers, identify promising interventions that will be piloted, and convert results into evidence-based guidelines to address equitable access to vaccination across Europe.

We have also established the *European Health Inequalities Portal* at https://health-inequalities.eu/ as a comprehensive information hub for Europe on actions to improve equity.

How can WHO Europe and EuroHealthNet collaborate in further efforts to improve population access?

EuroHealthNet will help to connect these and other actions with WHO Europe and the *Oslo Medicines Initiative* and disseminate knowledge with stakeholders, policy makers and the public.

We have an established and active long-term liaison with WHO Europe Regional Office, its Geographically Dispersed Offices, and via our members to the Regional Committee. This is now being enhanced to systematically support and mutually collaborate on taking forward effective implementation of the WHO Europe *Programme of Work* and the EuroHealthNet *Strategic Development Plan 2021-26*. Further joint announcements on these developments are imminent.

We welcome the opportunity to include in these actions support for the *Oslo Medicines Initiative* and add the value of the EuroHealthNet Partnership to contribute to progress on common aims of Equity, Solidarity, Transparency and Sustainability.

For further information on our work please see www.eurohealthnet.eu

Consultation for non-State actors on the Oslo Medicines Initiative – 26 April 2021
Intervention of the European Association of Hospital Pharmacists (EAHP)

Thank you very much for inviting the European Association of Hospital Pharmacists (EAHP) to this very important exchange. Hospital pharmacists across the world are working every day for their patients to ensure that they receive the medication they need to improve their health and to cure and prevent diseases. However, sometimes the medicine that is suited for an individual patient is not accessible. Growing healthcare expenditure has become a problem for many European countries. Innovative drugs, in particular, place an additional strain on already tight hospital budgets. Patients are directly affected and increasingly faced with avoidable accessibility and affordability issues. Besides the constraints faced by public health budgets, there are other barriers to treatment access. These include the growing problem of medicines shortages, delayed market access for new treatments in some European regions or increased out of pocket costs for patients. In light of these challenges, EAHP very much welcomes the Oslo Medicines Initiative and its vision for collaboration between the public and private sectors for better access to effective, novel, high-priced medicines for our patients.

The pillars on which this initiative is built – transparency, solidarity and sustainability – are also important for hospital pharmacists across Europe as they have a direct stake in the efficient functioning of the medicines supply chain and the operation of medicines reimbursement systems that enable patients in hospitals to benefit from sustainable and equitable access to the medicines they require.

Transparency between stakeholders is a very important element to bring about change. Thus, it would be valuable if the Oslo Medicines Initiative evaluates how the implementation of World Health Assembly resolution WHA72.8 on transparency has advanced and how further advancements can be fostered in the future. This should be paired with providing concrete suggestions as to how transparency could be increased to build trust and support access.

Concerning, solidarity, I would like to highlight how collaboration and cooperation can contribute immensely to the improvement of health and care in Europe. EAHP has made good experiences in the field of medicines shortages where we collaborated with different actors concerned by this issue. Facilitating best practice sharing and exchanges between non-State actors and Member States on already existing activities linked to fostering access to medicines and therapies should consequently be put into the focus of the pillar on solidarity.

Touching on sustainability, I would like to emphasise that not only the overall financial sustainably is important, but also a balance between providing access to new treatments and keeping old and essential ones available and accessible needs to be ensured. Existing treatment options are very often needed to support novel therapies and should thus not be forgotten in discussions linked to access to novel and high priced medicines. Also, competencies of healthcare professionals should be utilised for achieving sustainability, like the pharmacoeconomic skills of hospital pharmacists and their expertise in the area of medicines procurement, which could enable better treatment access procurement policies, avoiding treatment barriers, such as market concentration and dependency on one single supplier.

In conclusion, it can be said that all stakeholders – be it, non-State actors, supply chain operators, Member States, WHO or other European institutions – have a role to play when it comes to ensuring equitable and sustainable access to safe, effective, affordable and quality-assured medicines for patients across Europe. It is clear that there is no one-size fits-all solution to meet the needs of all patients across Europe. Emphasis should be put by the measures on patient-centredness, a key element for the delivery of high-quality, effective and safe care. Also, cooperation and communication via a structural dialogue should be fostered in relation to a variety of access to medicines issues since collaboration can contribute immensely to the improvement of health and care in Europe. Thus, we all should play our parts and contribute to make the Oslo Medicines Initiative on better access to effective, novel, high-priced medicines a success.

Nenad Miljković, EAHP Director of Finance

EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

27 April 2021

EUCOPE STATEMENT

PRESENTED AT WHO EUROPE 'OSLO MEDICINES INITIATIVE' CONSULTATION WITH PRIVATE ACTORS

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) is the voice of small to midsize innovative companies active in the field of pharmaceuticals and medical technologies at the European level.

We welcome the efforts from WHO Europe to organize this meeting and hear the perspectives of the different stakeholders on the topic of access to effective and higher priced medicines in order to increase patients access across Europe.

These dialogues are important to us not only because of the opportunity to exchange views around topics such as 'affordability' and 'sustainability', which can take different meanings for different people, but most importantly because these dialogues can help build trust between stakeholders who in the end share the same goal: bringing therapies to patients based on their medical needs.

Discussions on spending on healthcare often ignore the connections with other areas of society as well as the medium to long term health and economic benefits. A recent paper from the WHO titled "*Rethinking policy priorities in the light of pandemics*" which was prepared by an independent commission made up of former heads of state and ministers highlighted that many European health systems suffered from "*chronic underfunding and underinvestment*" as a legacy of austerity policies from the 2008 financial crises.

The same report affirms that evidence-based investments in health systems have repeatedly demonstrated value for money and should form the core of measures to strengthen health systems going forward, with intensified efforts to create a climate that is supportive of innovation in health.

We must avoid myopia and time discounting in spending decisions and aim for sustainability in the longer term. Despite health being viewed as a standalone issue, perhaps due to governments' budgeting practices, the pandemic has made it painfully obvious how health spending is intricately linked to a healthy and vibrant economy. In our opinion, a European vision for this sector should reflect the long term effect of healthcare decisions, from the incentives we design to further attract R&D, to how we reward innovation and the value that it brings for patients, healthcare systems and society at large. Healthcare spending should be seen as an investment in future and effective health technologies, rather than a cost. We believe that access and sustainability ultimately depend on a working system, which cannot be addressed through a narrow focus on just medicines expenditure. All stakeholders, including purchasers, payers and HCPs must incorporate sustainability in their decision.

The objective of improved access to innovative medicines should be central when discussing transparency. We think more information sharing around new pricing and payment models can help countries and manufacturers implement those models that best suit their specific situation. We think pricing transparency, i.e how prices are set, is of fundamental importance, but we caution against moving towards transparency of the actual net prices. Net price transparency would ultimately increase price levels especially in lower income countries which would exacerbate differences in patient access rather than reduce inequalities.

As the COVID-19 pandemic demonstrated, investments and appropriate incentives are crucial to ensure healthcare systems remain resilient in the long term. Investing in healthcare systems and setting the right policies at national level are prerequisites to ensure access to innovative medicines.

We thank you for this opportunity and look forward to further substantiating these points in the coming discussion in what we see as a unique chance to work towards increased access for European patients.

The Consumer Voice in Europe

Statement by The European Consumer Organisation (BEUC)

Oslo Medicines Initiative - Consultation for NGOs

26 April 2021

Ensuring affordable access to medicines is essential to improve health outcomes. However, there are important inequalities in terms of patient access across Europe and high medicine prices are a key contributor.

On the one hand, new innovative medicines are placed on the market at exorbitant prices that threaten access and the sustainability of public healthcare systems. At the same time, some medicines that have long been on the market undergo huge price hikes. This might happen, for example, after these medicines gain orphan designation and are approved to treat a rare disease.

There is reason to believe that these prices are not only high, but excessive, and go well beyond what is necessary for pharmaceutical companies to recoup development costs and harvest a reasonable profit.

To a great extent, excessive prices are the result of information asymmetries in medicine pricing negotiations that weaken the bargaining power of governments. This situation undermines their ability to set medicine prices that are fair for consumers and the public sector. To fix this, it is necessary to:

1. Shed light on research and development costs and on net prices paid by other countries for medicines, so pricing authorities can have an accurate benchmark when they use tools such as external reference pricing.

2. Attach conditions to public research funding that contribute to the availability and affordability of end products, such as vaccines and treatments. This will help maximise public return on public investment.

3. Enhance country collaboration on health technology assessments, joint medicine price negotiations and procurement. By teaming up, governments can increase their negotiating power vis-à-vis the pharmaceutical industry and get better deals.

BEUC recommendations to improve medicine affordability through enhanced pricing transparency are further outlined in our publication '*Time to lift the blindfold. Abolishing price secrecy to help make medicines affordable*'.

We look forward to working with the WHO Oslo Medicines Initiative and other stakeholders to advance this agenda and the goal of equitable access to affordable medicines in Europe.

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efpia
European Federation of Pharmaceutical Industries and Associations

Written statement on the WHO/Europe Oslo Medicines Initiative

Author: EFPIA ● **Date:** 12/05/2021 ● **Version:** final

Introduction

EFPIA, representing the interests of the research-based industry operating in Europe, welcomes the Oslo Medicines Initiative and the opportunity to engage in dialogue between the public and private sectors on how to improve access to medicines in Europe. EFPIA has for a long time been engaged in the issue of unequal access to medicines across Europe, and has been calling for a High-Level Forum on Better Access to Health Innovation within the European Union, to be able to discuss barriers to access and co-create solutions together with all Member States, EU institutions and all relevant stakeholders. EFPIA believes that the Oslo Medicines Initiative would be a valuable starting point for such discussions, even if some issues might need a separate, follow-up discussion in a European Union context. Though access to medicines to a large extent depend on a number of factors that are unique to each country, there are also some common themes and interrelated issues that would benefit from a more joined-up discussion across countries in order to find sustainable solutions.

Scope and objectives of the Oslo Medicines Initiative – access to medicines in the European region

When aligning on a situational assessment as a basis for finding solutions, it would be important to reflect on the relation between the concepts of value, affordability, budget impact and price. The price of an individual medicine is only one factor affecting the overall budget impact on the annual pharmaceutical budget, and more importantly the long-term impact on the overall health system budget and resource use should be taken into account when looking at affordability and value. We would therefore encourage a holistic, long-term and value-based approach to the issue of access to and financing of innovation, and health system budgeting and efficiency, also considering broader benefits to society and the economy.

EFPIA has investigated the root causes of unavailability and found there are 10 interrelated factors that explain unavailability and delays. These are rooted in the medicines access systems and processes in the EU member states and the corresponding impact on commercial decision-making. They range from a slow regulatory process to late initiation of market access assessment, to duplicative evidence requirements, to reimbursement delays, and local formulary decisions. As the root causes are multifactorial, they can only be solved by different stakeholders working together.

To address these factors across countries, EFPIA considers that the industry and public authorities should work together to identify:

- Proposals to speed up the regulatory process, delivering safe and high-quality diagnostics, vaccines and treatments to patients as fast as possible;
- Proposals that aim to increase transparency of information regarding placing on the market [of centrally approved products];
- Proposals to facilitate a process that allows prices to align with value and ability to pay;
- Proposals to improve the efficiency and quality of value assessment;
- Proposals to ensure equity of access and solidarity across EU member states.

EFPIA's Patient WAIT indicator is invaluable for documenting delays and unavailability of centrally approved products but only provides a partial picture of how these delays are constituted. EFPIA is exploring how more granular information can be provided through a 'Patient Access Innovation Index' explaining the cause of delay and unavailability.

Principles of the Oslo Medicines Initiative

EFPIA believes that the principles of Solidarity, Transparency and Sustainability are appropriate for anchoring this initiative.

Solidarity:

The industry is positive towards collaborations between countries that serves to increase efficiency, remove duplication and enhance access to innovative medicines for patients. Joint horizon scanning and setting up joint high-quality registries/data collection for monitoring real-world effectiveness are examples of objectives where synergies could be achieved also in the short term. In the area of Health Technology Assessment, EFPIA has supported the proposal for a Joint Clinical Assessment in the EU, as a tool to accelerate HTA procedures, to increase efficiency and predictability in the process for all parties by reducing unnecessary duplication at a member state level. Collaborations that seek to conduct joint price negotiations should consist of countries with a similar economic status and health needs, as it is challenging to coordinate negotiations between countries with very different ability to pay and the result may be sub-optimal in terms of equal access. For the industry to interact with these collaborations, legal certainty and predictability is important as well as a clear governance framework.

One important factor affecting patient access across the European region is the differences in economic levels of countries and thereby different levels of healthcare expenditure (and ability to pay for innovation). Pharmaceutical companies are trying to mitigate these factors by adapting to the local context when entering into P&R negotiations with individual countries. Even so, there would be value in a dialogue on how to create a more sustainable framework for Equity-Based Tiered Pricing, and this needs to be anchored in the concept of solidarity – including a recognition that wealthier EU Member States should not benefit from the lower prices that ought to be available, in the interests of patient access, to less resourceful Member States.

Transparency:

EFPIA supports a thorough and informed discussion about in which areas improved transparency can facilitate patient access, and where it would not or even be counterproductive. More transparency and information sharing around market access hurdles in European countries – i.e. an analysis of the various factors that negatively impact time to patient access and availability of specific products or classes of products in a specific country, could serve as a good basis for tailored policy solutions, and EFPIA is taking concrete steps to contribute to such a transparency. We already publish a yearly WAIT report, highlighting the delays to patient access across the EU as well as a report on the 10 most common root causes of unavailability and access delays, and we are exploring how more granular information on this topic (e.g. through a Patient Access Innovation Index) can further stimulate a solution-oriented dialogue.

We also believe that more information sharing around implementation of pricing and payment models, including Novel Payment Models such at outcomes-based agreement and staggered payment models can help countries to (together with industry) implement those models that best suit their specific situation. We should together explore how the existence of these agreements and how they function can be disclosed to improve information sharing and best practices. Furthermore, EFPIA published on April 30 a White Paper on transparency of evidence from novel payment models, to launch a discussion on how data and evidence collected under such schemes could be disclosed to the benefit of other countries and stakeholders.

We do not believe transparency of net prices is the answer. It can have unintended consequences and may increase net prices in poorer countries. It would also work against the possibility of applying Equity Based Tiered Pricing.

Sustainability:

EFPIA welcomes that the framework for this initiative recognizes the need of both, sustainable health systems and a sustainable European based research industry, as one is not possible without the other. EFPIA believes that the way to combine sustainable health systems with sustainable industry, sustainable economies and innovation is to embed a holistic value approach in the assessment, pricing and procurement of innovative medicines, adapted to the national context in terms of health system organization, public health priorities, epidemiological situation and level of economic development.

Pharmaceutical policies for innovative medicines that only focus on cost containment and driving down prices will not provide the necessary incentives for the industry to invest in innovation in Europe that brings value to patients and health systems. At the same time, society, health systems and payers need to be reassured that they are getting value for money for their investments, both in terms of patient outcomes, health system efficiency and broader societal benefits. To apply a value-based approach to the assessment, reimbursement and financing of innovation and of healthcare in general do require development of capabilities and capacity in health systems, including for the collection of data needed to monitor the effectiveness of medicines in real life, and on this point collaboration and capacity-building can be of great value.

Finding joint solutions through the Oslo Medicines Initiative

Access to innovative medicines is largely driven by factors at a national level, such as level of health spending, healthcare infrastructure, pricing & reimbursement policies, health policy priorities and epidemiology. However, through this initiative, WHO/Europe could help shed more light on how the situation looks in each country in terms of access and availability to medicines. Improved transparency around access and availability across countries as well as of access hurdles would enable WHO/Europe to facilitate an evidence-based discussion and tailored solutions to identified problems. Greater transparency on the R&D pipelines of the industry, including through horizon scanning tools, could also enable better planning for health systems, and is another area where the WHO and the industry could collaborate to spread insight and build capacity.

WHO/Europe could furthermore assist countries with capacity building and spread of good practice, including through harnessing digital tools, when it comes to implementing various types of access solutions, including Novel Payment Models such as outcomes-based agreements, indication-based pricing and staggered payments, that help payers manage the relation between value (including clinical effectiveness), reimbursement and overall budget impact. More transparency around the existence of these schemes, as well as disclosure of some of the evidence that is collected in the framework of the models, is something that could benefit health systems and payers in many countries.

When it comes to access hurdles stemming from different levels of healthcare expenditure across the region, and the ability to align prices with the economic level of each country, the concept of Equity Based Tiered Pricing is one where a discussion involving all Member States would be needed, as it is strongly linked to the concept of solidarity between countries. Such discussions need to take into account also the broader global context and interdependencies with developments in other regions.

EFPIA is looking forward to the continuation of the Oslo Medicines Initiative, and engaging with WHO/Europe, Member States and stakeholders in a dialogue to find joint solutions.

The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors Consultation with non-State actors: nongovernmental organizations and philanthropic organizations

EFMA Intervention

The European Forum of Medical Associations (EFMA), thank the WHO European Office and the Government of Norway for organising The Oslo Medicines Initiative and for the online consultation with Non-State Actors.

We congratulate them on this forward-thinking project and for taking advantage of the collaborations made during the Covid-19 pandemic with a much-needed new vision for cooperation between the public and private sectors. EFMA welcomes the opportunity to be part of the consultation.

EFMA believes that there is a necessity for collaboration with all stakeholders, which highlights the importance of the initiative. If this year has taught us anything, it has taught us that you need to cooperate on a global scale with ALL stakeholders.

The concept of access to medicine, health products and potential solutions has a lot to do with the issue of equality in health. As we have learnt throughout this pandemic, you must want to achieve access for everybody, as if you do not, in the end, you don't have protection for anyone. It is important that every region find different ways to reach access for everyone. Each area faces different challenges, a problem to access to medicines in UK, is different to problems of access in Serbia or in Azerbaijan. It is imperative that stakeholders work to identify barriers in each country and see how to tackle these. We believe that they must build a mechanism that will create the proper incentives in order to achieve access to medicines. This will help to strengthen the solidarity of the region.

With the rapid technological advances worldwide, which have transformed the global landscape with regards to access to information, only highlights even more the need for transparency. It is clear to us, in order to engage people, you need complete transparency. Particularly when you are bringing in changes, stakeholders and service users need to see and believe that the system is transparent. It is a core component of an effective health system while a lack of trust can be its downfall.

EFMA calls for a review of patent laws, which would help to achieve better access to medicines, supply of quality medicines at more affordable prices, which meet patients' needs, thus increasing equality in the region. We believe that incentives should be formulated in order to encourage collaboration, particularly with regards to clinical trials.

EFMA stressed the need for mechanisms that will be sustainable and robust in order to facilitate the movement of knowledge, data and engagement. We would encourage

governments to establish clear standards and mechanisms which will work to ensure the stability and the supply of medicines.

Non-State Actors can work with the WHO in all of the key areas of the initiative by presenting information to stakeholders and acting as a sounding board to the WHO. We believe that if the WHO understand that there are many layers to gaining information and if they can reference data that they receive from Governments with the information from NSA's it will help to provide a much clearer picture. EFMA calls on the WHO Euro to facilitate collaboration between Non-State Actors and stakeholders in both the public and private sectors in order to ensure the effective flow of clear, transparent information and communication to the professionals in the health sector and the public. This will assist to increase transparency and strengthen solidarity.

European Forum of National Nursing and Midwifery Associations

Европейский форум национальных сестринских и акушерских ассоциаций

EFNNMA

Written statement by European Forum of National Nursing and Midwifery Associations at non-State actors consultation on The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors

April 26, 2021 – Virtual Meeting

The European Forum of National Nurses and Midwives Associations (EFNNMA) thanks WHO Euro for the opportunity to participate in the Oslo Medicines Initiative. EFNNMA represents the over 7 million nurses and midwives in the WHO European Region. Nurses and midwives comprise 59% of the health workforce globally, work in all settings of the health service, and are essential to ensuring access to medicines, vaccines and health products.

EFNNMA and the nursing and midwifery professions support the European Program of Work to achieve Universal Health Coverage by 2025. Achieving this vision requires access to safe, effective, high-quality and affordable essential medicines and vaccines. Already today an exceedingly large share of healthcare budgets is allocated to the purchase of high-priced novel medicines and health products. High cost is undermining equitable access to novel medicines and health products not only for low and middle income countries but also for high income countries. High-priced medicines break health system budgets, leave fewer funds necessary to support human resources, pose a major ethical dilemma for clinicians in day to day practice and undermine the principles of social justice when life-saving treatment exists but cannot be provided to each and every one.

High priced medicines may also mean financial hardship to patients and their families. New approaches to controlling cost are greatly needed. Thus, EFNNMA fully supports the scope and purpose of the Oslo Medicines Initiative.

EFNNMA supports multiprofessional collaboration between nurses and midwives, physicians and pharmacists to improve access to safe, effective and high-quality medicines and vaccines. Proper diagnosis, treatment, prescription of novel medicines and health products requires highly qualified health professionals with up-to-date knowledge. EFNNMA calls for adequate education, training and continuous professional development of nurses and midwives and other health professionals to ensure safe and effective use of medicines and health products. Education and training should also include ethical and policy related issues regarding access to high cost health products.

Already today nurses and midwives in many countries in Europe have authority to prescribe medicines and health products. EFNNMA calls for the expanded scope of practice of nurses and midwives to include prescription authority as this would extend the reach of effective, safe health products and medicines to vulnerable populations especially in rural areas.

The COVID19 pandemic has put the spotlight on solidarity between countries with both good and bad examples. Solidarity must be a guiding principle because noone is safe, until everyone is safe. The OMI can serve to highlight the good examples and bring member states together for dialog and sharing of experiences in the search for effective methods to control the cost of medicines and health products. Cooperation and coordination between member states is critical to shift the balance of power in a market that appears to be controlled by the pharmaceutical industry. The OMI can serve to strengthen solidarity between MS.

Cooperation and collaboration are strengthened when WHO Euro convenes public and private stakeholders to joint action. WHO Euro and stakeholders should utilize this 18 month initiative as an opportunity to collect and explore the various strategies individual member states and groups of MS have utilized to controll costs. This would start with developing a common understanding of the challenges faced and collecting experiences with various strategies and methods such as regulation, joint horizon scanning, procurement and assessments.

Lack of transparency with regard to pricing of medicines and health products currently undermines trust and cooperation. EFNNMA supports focus on transparency as a basic principle underlying the OMI starting with developing a common understanding of the current situation as critical foundation for improved dialog between MS and stakeholders.

EFNNMA thanks the Norwegian Government and Ministry of Health and the WHO European Regional Office for establishing the Oslo Medicines Initiative and look forward to participating.

EFNNMA
Submitted 10th May 2021

GIRP Statement at the online consultation with non-State actors on the Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines - a new vision for collaboration between the public and private sectors
27 April 2021 (11:30-14:30 CEST)

GIRP welcomes the Oslo Medicines Initiative and the opportunity to share our ideas and input on the topic of better access to effective, novel, high-priced medicines with the World Health Organisation, the Norwegian authorities and with all other relevant participants, including national authorities and supply chain partners.

GIRP and its members fully applaud the effort by WHO and the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency to bring together supply chain stakeholders and national competent authorities in a discussion on ensuring safe and fair access to novel therapies and high-priced medicines to all patients across Europe.

In the context of this initiative, GIRP would like to outline the core function of full-service healthcare distributors (also referred to as pharmaceutical full-line wholesalers), being the vital link for the fair, efficient, timely and safe distribution of all medicinal products, including medical devices and other medical supplies, to patients across Europe. Full-service healthcare distributors, through their stockkeeping and financing function, their extensive web of distributions centers and warehouses, as well as, through their logistic excellence are able to deliver any medicine in Europe within a very short time span to even the most remote location (average delivery time in Europe is 2.5h).

The continuity of supply and guaranteed availability of medicines are key necessities and therefore unique dynamics are required within the pharmaceutical market. Full-service healthcare distributors are committed to ensuring that even the most isolated patients can receive even the most specialised medicines via their pharmacist in a safe and timely manner.

In doing so, full-service healthcare distributors also ensure the integrity of the medicinal products upon dispensation through full compliance to a comprehensive set of national, EU and international level regulations, including but not limited to the WHO and EU Good Distribution Practice guidelines as well as all relevant EU and national legislative frameworks.

Full-service healthcare distributors continually adapt their infrastructure and their practices to fulfil requirements of new specialty products as they enter the market. GIRP members are acutely aware that systems of specialty distribution have become increasingly complex and require a much higher amount of agility, flexibility and innovation from the supply chain. Supply chain actors need to analyse their levels of mobility to be able to cater to the specific patients' needs. As such, full-service healthcare distributors leverage their unique position in the supply chain to be able to provide tailored services.

That said, this new model requires a high-functioning level of communication between all partners of the supply chain. Digitalisation of the supply chain and use of data in a safe and up-to-date regulatory framework are key to develop the structure for safe, fair and sustainable specialty distribution. From the pharmaceutical industry down to the payor, supply chain networks need to build platforms to discuss the specific needs of patient groups and tailor solutions to their individual needs. The WHO could support discussions and progress on the development of such structures to ensure all elements of access to high-priced medicines be considered including refitting of the downstream supply chain from distribution to dispensation.

GIRP calls on the instigators of the discussion to ensure that the downstream supply chain and the challenges brought by new specialised, high-priced medicines are not overlooked and that the existing supply chain mechanisms are not bypassed.

GIRP also calls for the sustainability of the healthcare supply chain to be considered when addressing the issue of medicines pricing. The remuneration models of full-service healthcare distributors vary across Member

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States, although in most countries they highly depend on an extremely slim percentage of products' prices with a maximum cap placed on the delivery of high-priced medicines. Unfortunately, in some countries, full-service healthcare distributors are reaching breaking point in the sustainability of the distribution sector where the remuneration is insufficient to cover the costs of pre-financing, risk assumption, storage, picking and delivery. A key factor for a healthcare system's overall resilience and its capacity to adapt to new healthcare models is based on ensuring full-service healthcare distributors' financial sustainability.

Full-service healthcare distributors are the only ones to assume a financing function towards manufacturers and pharmacies. They finance the quasi-entire medicinal product market (on average EUR 11.6 bn over a period of 45 days[1]) and thus support the development of novel therapies without distinction between smaller or larger players. In doing so, full-service healthcare distributors enable SMEs which do not have the infrastructure or the resources to organise the complete supply chain of their innovative products themselves.

Conclusion

Safe and fair access to high-priced medicines to all patients across can only be guaranteed through considering the specificities of the requirements for such products and the impact of the transformation throughout the supply chain and through ensuring a seamless-communication and cooperation between supply chain stakeholders and with the competent authorities.

1 Calculation based on the data of the 6 main markets, DE, ES, FR, IT, NL, UK

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The draft Scope and purpose document for the Oslo Medicines Initiative is a relevant step forward in the inclusion of the perspectives and voices of non-State actors in sensitive topics of health care. The European Medical Association is focusing to the barriers of the access to effective, novel, high-priced medicines and health products, including medical devices. The complexity of the situation, and the efforts of all Health professionals, worldwide, for facing, counteracting and mitigating the most ominous consequences of this situation, must be analyzed, looking forward for potential solutions.

The scenarios reducing the access to effective, novel, high-priced medicines are related to

- the different health care systems (public or private, universal or segmented),
- the level of information of health professionals and of the general population in regard of the cost-benefit balance of the need of using different diagnostic and therapeutic approaches,
- the marketing pressure of Companies,
- the productive, delivery and administration capacities of different Countries, Areas, sub-health systems (such as limited resources contexts)
- the political use of health care delivery.

The actions of non-State actors for advocating to improve access are few, weak, sporadic and sparse, worldwide. Even if, in abstract, price negotiation, public-private partnerships, novel financing mechanisms, price volume arrangements, risk-sharing, and advance purchase arrangements may follow some position or intervention undertaken by non-state actors, such effects are not relevant nor clearly visible. Official positions of Scientific-Medical Associations, of Universities and research centers, of health professionals associations are seemingly absent and their comments or contributions are not explicitly asked, until now. The model of the open and transparent contribution to the European Commission decisions, at all the stages of any process, should be taken into account also by WHO/Europe offices.

There are different non-State actors that may collaborate with WHO for increasing the success of their efforts to provide access to the population to effective, novel, high-priced medicines. The point is that the need of moving along law, industrial, marketing and effective delivery boundaries can reach limited effects in any Country due to the asymmetry of human and financial resources. Existing mechanisms for cooperation and coordination between Member States and areas to be strengthened, including joint horizon scanning, procurement and assessments, need a greater support with explicit and recognizable ethical, scientific and educational contributions.

WHO/Europe may begin to support active and meaningful dialogue between stakeholders operating with a sustainable model, such as “Have your say”, the open platform where Citizens and businesses can share their views on new EU policies and existing laws. The timely report of the contributions and of the surveys will be mostly important. The key feature of this approach is the transparent input of any actor, mainly non-state actors that are usually silent, even if they may have something to say. This is a basis for envisaging any likely and sustainable support to the implementation of World Health Assembly resolution WHA72.8, and to pursue any other important joint action. The commendable goal of reconciling sustainable pharmaceutical policies and procurement practices with industry and innovation can be nullified without a visible contribution of people and organizations, presenting their points of view, credibility and expertise.

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Drawing lessons from the COVID-19 pandemic, general national or federal legislation on medicines, aimed for human use to ensure a future-proof and crisis-resistant medicines regulatory system must be revised. The revision should aim to: ensure access to affordable medicines; foster innovation, including areas of unmet medical need; improve security of supply, adapt to new scientific and technological developments, reduce red tape, i.e. reduce bureaucracy.

At the heart of this problem is the taboo on the patentability of drugs and vaccines, in particular. This topic, at our knowledge, is not yet proposed as a topic of discussion in official and public contexts, and not even at an academic level. This seems to take place in the awareness that the chain of proprietary patents and the effective availability of know-how and facilities prevents serene proposals and discussions, while there is the need of guaranteeing competitiveness of innovation, research and development.

The upstream problem, that a large part of these patents derive from research financed with third parties or public funds, is equally strongly overlooked. The shared scientific and intellectual contribution leading to novel drugs and devices is hidden.

To reach a basic level of information on the field experience of doctors belonging to EMA, we have developed and distributed among our member associates a questionnaire for a basic survey, of which we are focusing here on three key issues, presented below as a synthetic analysis of answers:

1. The current opinion among the interviewed is that the patents are barriers for drugs and vaccines wide use, being at last disadvantageous element for public health in the world and therefore for the global world economy.
2. Most interviewed answered that the patentability of drugs is a condition that can be abolished or mitigated, at least in some specific cases, and this is considered not detrimental to research and the quality of drug production.
3. For most interviewed it is not clear if there are already legal spaces that in emergency conditions, such as the current pandemic, allow the free production of patented drugs, even with a very short period of validity of the patents themselves (namely a few months / one year) by reducing or eliminating the cost of the related royalties.

CONCLUSION. One of the position points that EMA already agrees inside its working groups refers to promote sustainable global health ethics and transparent economy strategy in research, teaching, production and delivery of drugs and medical devices. Political ethics and economy must enhance free cultural interactions at the level of study, research and medical procedures, assuring everywhere and for everybody freedom, human rights for life and health, free mobility, also allowing access to the better possible care. EMA endorses any effort for joining medical professional for assuring affordable delivery of innovative and salvaging medicine as a primary preventive tool, beyond the barriers of patents, if any. Mostly relevant is that European and National Governments clarify if there are already the international legal conditions, secured by International treatises, which will allow overcoming the barriers of patented drugs and of the know-how of relative production, at least in specific conditions and still guaranteeing the appropriate gains to producers. The suspension of intellectual property rights in emergency contexts is already possible. Among the legal instruments allowing the widest possible access to medicines, in emergency contexts, 'patent suspension' should be considered vs. 'compulsory licensing' and ‘statutory

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license' (as in UK). Such concepts and information need effective dissemination actions, including a greater specific focus inside the educational-academic schemes, such as the Erasmus actions in Europe. Most teaching actions are still transiently substituted by distance- e-learning courses. Not all e-learning platforms, and not all delivered contents are suitable for spreading information actively among members, followers and any sensitive social media network. A WHO's open platform where Citizens and businesses can share their views on new national or international policies and existing laws can and should be developed. The timely report of the contributions and of the surveys will be mostly important.

On behalf of European Medical Association.

Guglielmo M. Trovato, MD. Director

April 26, 2021

NSA consultation convened by WHO Europe for the Oslo Medicines Initiative - contribution by the European Public Health Alliance (EPHA)

Good afternoon, ladies and gentlemen,

I am Dr Milka Sokolović, Director General of EPHA, the European Public Health Alliance.

EPHA is the leading public health stakeholder in Brussels, involved in advocacy towards the European Union institutions, agencies, as well as the WHO. With our diverse civil society membership from the WHO European region, we advocate across issues of public health, including policies for better and affordable medicines. We receive no funding from pharmaceutical companies.

In June 2016, EU Health Ministers acknowledged that there was a series of imbalances in pharmaceutical systems in Europe[1]. Five years later, excessive medicines prices remain a systemic problem for health systems, and a key access barrier for patients across Europe[2].

We hence **strongly agree and warmly endorse** the objective of a new "social contract" with pharmaceutical manufacturers, and we are grateful for this opportunity to contribute to the Oslo Medicines Initiative.

Increasing transparency in pharmaceuticals and strengthening collaboration amongst member states go hand in hand and should both be prioritised[3]. **Secrecy** undermines governments' leverage in the negotiations with the companies, as demonstrated by the first round of EU covid19 vaccines procurement. Governments suffer from the information asymmetry, which contributes to the power imbalance between them and pharmaceutical manufacturers, and often results in market failures[4]. To this end, **the pooling of resources**, the exchange of information and expertise need to be fostered, in order to build capacity and reinforce the negotiating power of countries.

Regional intergovernmental initiatives of joint negotiations, like Beneluxa and others, are an irreversible political choice for the countries involved, in the face of unreasonably high medicines'

[1] https://epha.org/dutch-pharma-policy-a-groundbreaking-presidency/
[2] https://ec.europa.eu/health/sites/health/files/human-use/docs/pharma-strategy_report_en.pdf.
[3] https://beneluxa.org/benefits
[4] https://www.euro.who.int/en/publications/abstracts/cross-country-collaborations-to-improve-access-to-medicines-and-vaccines-in-the-who-european-region-2020

prices. That said, the ongoing EU negotiations with pharma over covid19 vaccines highlight the potential for joint negotiations on an EU level. In order for such negotiations to be effective, be they regional or pan-European, we need a paradigm shift: **today's passive payers need to become empowered, better informed buyers**. To achieve this, buyers need to organize themselves, overcome fragmentation, work closely with regulators & HTA bodies, gain foresight through horizon scanning, define unmet needs, set priorities. The sharing of information combined with the joint determination of the willingness to pay and its public announcement in advance, can be beneficial in this direction. We need to move towards a system which is **demand rather than supply-driven**.

WHO Europe as well as the European Commission have a key role to play in enabling public-public partnerships to improve capacity, effectiveness, tackle policy fragmentation, limited know-how and resources. This is a prerequisite for rebalancing pharmaceutical systems.

As the AMR threat keeps growing, the development of new antibiotics is an area where the shortcomings of current market-based approaches are painfully tangible. Medicines for rare diseases, orphan drugs, is another area where access, affordability, availability issues are clearly visible. These are two areas where governments can decisively steer innovation driven by public health needs. This will prevent from once again finding themselves before "done deal" created by the industries. Also, public support into biomedical R&D is substantial and multilayered and can provide governments with further considerable leverage.

Whilst pharmaceutical industries are indispensable partners, we urgently need a new social contract, a new equilibrium with them. In light of the current pandemic, it is undeniable that companies' power grows. It is important that governments counter-balance it, invest wisely, and steer meaningful innovation to serve public health.

With this, I would like to thank you for your attention and for the opportunity to share EPHA's views.

ESMO Statement
Oslo Medicines Initiative
Online Consultation with Non-State Actors
26 April 2021

The European Society for Medical Oncology (ESMO) represents more than 25,000 members from over 160 countries and welcomes the Consultation with Non-State Actors on the Oslo Medicines Initiative.

With the incoming wave of high-cost cancer treatments, WHO Member States need to be able to choose medicines appropriately. Therefore, ESMO continually addresses the topic of access to medicines at the European and global level through its public policy efforts and by developing freely available tools and resources based on our expertise in the management of patients with cancer.

To support WHO Member States in addressing issues that affect access to effective, novel, high-priced medicines, and health products, ESMO would like to provide the following 6 suggestions:

1. **Harmonise the standard of cancer care:** ESMO has over 80 ESMO Clinical Practice Guidelines, updated in real-time, and used globally. In many countries, there is no measure of the implementation of standard of care. Therefore, it is essential to invest in implementation of guidelines, to ensure that national and local care pathways are in line with them, and that the medicines recommended for the evidence-based treatment of patients are included in national essential medicines lists.

2. **Prioritise cancer medicines with the highest magnitude of clinical benefit:** ESMO has developed the ESMO-Magnitude of Clinical Benefit Scale, which uses a rational and structured approach to score the clinically meaningful benefit of medicines approved by the European Medicines Agency. ESMO publishes those scores on its website and references them in its guidelines. The scale is used by various countries to prioritise cancer medicines and to help frame the use of limited public and personal resources. The WHO uses the scale to evaluate cancer medicines for the WHO Model List of Essential Medicines.

3. **Determine the appropriate use of biosimilars:** With many expensive cancer medicines coming off patent, ESMO believes that biosimilars present a necessary and timely opportunity because they can positively impact the financial sustainability of healthcare systems while improving access to medicines for patients. ESMO has a biosimilars portal and has published its views in the ESMO Position Paper on Biosimilars. The WHO prequalification process also provides a potential solution to tackle safe and effective biosimilars, where countries lack robust regulatory practices.

4. **Harmonise the Health Technology Assessment process at the EU level:** ESMO has recommended using cancer medicines as a pilot for joint clinical assessments under the draft EU Health Technology Assessment Regulation. The ESMO-Magnitude of Clinical Benefit Scale may help facilitate the process.

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Additionally, ESMO is currently developing a geographically adapted value-based reimbursement model to tackle issues related to the reimbursement of expensive, innovative cancer medicines. ESMO will share the model's details with the WHO and the European institutions in due course, and as input to feed into the Pharmaceutical Strategy for Europe.

5. **Address issues related to the availability of cancer medicines to patients:** ESMO has gathered data on the availability of cancer medicines in Europe and internationally through two surveys, whose findings were published in ESMO's journal Annals of Oncology. The two studies were cited as the most comprehensive assessment on the availability of cancer medicines globally in the 2018 'WHO Technical Report on the pricing of cancer medicines and its impacts'. ESMO will be re-doing the survey and will be sharing the results with the WHO and the European institutions, to feed into the Pharmaceutical Strategy for Europe and other relevant policy initiatives.

6. **Promote multistakeholder collaboration to implement the Initiative:** WHO can collaborate with Non-State Actors by inviting them to participate in well-defined aspects of the Oslo Medicines Initiative based on their areas of expertise. ESMO welcomes the opportunity to share its knowledge and resources. We contribute to EU and WHO meetings and consultations, and provided input into Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, and all other relevant policy initiatives. ESMO was invited by WHO to participate in an imPACT mission in Kazakhstan. Supported by ESMO tools, we worked with WHO and national health authorities to review the country's cancer treatment protocols. The assessment supported the Ministry of Health to optimise its cancer treatment protocols and to link them to the national essential medicines list. Incorporating the project recommendations into the 2018-2022 Kazakhstan national cancer control plan allowed the country to maintain its commitment to offer evidence-based comprehensive cancer care as part of universal health coverage.

ESMO is pleased to support the Oslo Medicines Initiative and thanks the organisers for their consideration of our suggestions.

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STATEMENT

18 May 2021

HAI Statement on The Oslo Medicines Initiative at the WHO Virtual Consultation with Non-State Actors, 31 March 2021

Health Action International (HAI) welcomes the Oslo Medicine initiative and commends the leadership of the government of Norway. We thank the European Regional office of the World Health Organisation (WHO) for allowing Non-State Actors to contribute to the early stages of this project.

The issue of high prices of medicines have been atop of the public agenda for some time. The fact that it is now affecting wealthier countries has given the issue a renewed sense of urgency. As some speakers have already noted, there is a correlation between IP-based monopolies, through patents and other mechanisms, and high prices. We need to counter IP misuse and abuse and subordinate its enforcement to public health interests. Norway has a good opportunity to advance in this direction when guiding, as chair of the TRIPS council, the discussions around the TRIPS waiver proposal submitted by India and South Africa. In a time of pandemic there should be no room for production-limiting market exclusivities.

While we welcome the participation of all stakeholders and concerned parties in discussions around access to medicines, we ask that stringent conflict of interests and high transparency standards be upheld in all partnerships and cooperation instances between governments and multilateral organisations with industry and private interest groups. Transparency can not only be a goal but needs to be a strategy to achieve, defend and promote global health by, for example, making clinical trial information widely accessible and research and development costs independently assessed. That is why, together with many other organisations, we believe that WHO Covid-19 Technologies Access Pool can not only make a difference in the fight against the pandemic but also enable a more collaborative and participative thus efficient research, development, and manufacturing of health technologies.

Finally, we believe for this initiative to be successful it is needed to be framed, regionally, within ongoing initiatives and resolutions specially the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property and the transparency of markets for medicines, vaccines, and other health products; simultaneously it needs to align itself with ongoing discussion within the European Union, especially around the European Pharmaceutical Strategy and European Health Emergency Preparedness and Response Authority (HERA) with specific attention to such critical issues as how to eradicate shortages and ensure public return on public investment.

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Briefing Note

To:	**Medicines for Europe Board**
Subject:	Contribution to WHO transparency initiative
Date:	**20 May 2021**

Please find the Comments from Medicines for Europe

3. The objectives of the Initiative are to:
a) reflect on the state of the market for effective, novel, high-priced medicines in Europe from diverse stakeholder perspectives;
It is important to understand the European pharmaceutical market as a system that requires competition – not to focus exclusively on the prices of individual medicines. Competition has been the only effective tool to ensure sustainability. This can be verified by looking at the evolution of pharmaceutical prices over a 15 period. You will note that most originator drug unit prices have increased over time. Only in situations where there is head-to-head competition have prices declined (this is usually competition from an off-patent molecule but this may also be competition between similar originator patent protected molecules as seen for hepatitis C drugs.
All country efforts at controlling originator prices have failed from a systemic point of view. For many years, European countries have negotiated discounts per product through health technology assessments (HTA) and managed entry agreements (MEAs) but the total cost of originator drugs in pharmaceutical budgets is increasing while volumes are decreasing. The only measure that has lowered costs has been first competition from generic medicines and then biosimilar medicines (and to a lesser extent competition between similar on-patent molecules). There is an opportunity to stimulate a new wave of competition on innovation with value added medicines – innovation applied to off-patent molecules. This can bring dynamic competition to the on-patent drug market in addition to improving the management of chronic or infectious diseases which is a major cost-centre for healthcare systems and/or patients.

b) 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;
Looking exclusively at lowering originator drug prices has inherent limits because even with important discounts or differential pricing, poorer European countries will need to make choices about what expensive drugs to reimburse. Most of these countries do this already by only reimbursing expensive drugs for large population infectious (i.e. hepatitis) or chronic diseases (i.e. diabetes or asthma). If these countries would reimburse expensive rare disease drugs, they would overwhelm their pharmaceutical budgets. From an equity point of view, this is also a more sensible approach – to target finite resources at the biggest number of patients – especially as there are often inequities inside countries (favoritism for well-connected patients in big cities versus less well-connected patients living in rural areas or small cities). There should be a realistic approach to this that recognizes the economic limitations of some European countries. I realise this is difficult to do ethically but this is reality.

Another point for consideration is how to encourage competition from generic and biosimilar medicines to targeted (small population/indication drugs). The current EU regulation on orphan drugs does not consider the importance of follow-on competition. First, the policy can be misused to unduly extend exclusivities on originator orphan drugs as demonstrated by the "Gleevec" dispute. In addition, there are no efforts to encourage follow-on orphan development. For example, for a biosimilar orphan development, there is no effort to tailor clinical requirements (even though it is difficult to conduct comparative clinical trials and there is limited scientific justification for this) and there is no agreement to allow single global development (say to develop for the EU & US & Japanese market with the same clinical programme) for biosimilar medicines. This multiplies the clinical requirements for biosimilar developments without scientific reason. This is not cost-effective and not ethical (repeating clinical trials when the results are already known).

c) exchange experiences on voluntary multi-country/area collaborations as a mechanism to enable collaboration;

European countries have the most sophisticated procedures to control the high prices of originator drugs. These can be fine-tuned but there are inherent limits to how far this can be pushed. By focusing on ways to stimulate competition to the originator segment from the off-patent industry, there are limitless opportunities to generate a more sustainable market. Most European countries are very slow at stimulating competition. For example, it took most countries (except Germany) about 8 years (2006-2014) to introduce policies to encourage biosimilar uptake. The big biosimilar policies of Denmark and Norway were in this timeframe 2014-15 while the first biosimilar was on the market in 2006 – even these frontrunners were in practice latecomers to biosimilar competition. The amount of investment in these biosimilar policies was very low but governments chose to wait many years anyhow. In poorer European countries, they are still waiting to encourage biosimilar uptake despite the obvious benefits for their patients that lack access to biologic therapies. Concretely, the WHO could encourage EMA regulators to engage more on the science of biologics (including biosimilar medicines) in poorer CEE countries. None of these countries have experts in the EMA biosimilar medicines working party so their regulators have less credibility on the issue. This small step could support efforts to introduce competition from biosimilars. Additionally, there should be recommendations from WHO for these countries to use the savings from biosimilar medicines to increase access to therapy. In countries like Poland, Hungary or Romania, the per capita access even to first line oncology treatment is dismally low – with the health outcomes that you can imagine. The savings from biosimilar medicines should be reinvested into treating the whole patient population.

In some European countries (ie Greece), there is almost no generic medicine competition because the pharma system is designed to penalise generic competition instead of encouraging it. These problems are well known and international bodies like the WHO Europe or the Commission have not seriously engaged to ask why generic competition rates are so low. We see similar situations in countries like Romania which applies a similar policy to Greece.

Most European countries also ignore the potential of competition in the innovation (on-patent) space because they believe that off-patent molecules are not "innovation". This is because governments have fallen into the trap of believing that a medicine that is expensive and protected by a patent is somehow miraculous and necessarily innovative. You can see this in the language of many government policy documents that read like the marketing information of originator companies. Consequently, the focus of pharma policy on "innovation" is exclusively on new chemical or biological entities – ignoring the possibility of off-patent innovation (repurposing, reformulation, drug/drug or drug/device combinations) –

which is far less costly than NCE/NBE development. There are no incentives in Europe for this kind of innovation (except for orphan repurposing) in contrast to the US where there is a clear pathway for off-patent innovation called the 505(b)2 pathway. By encouraging value added medicines innovation, there can be dynamic competition between the 2 different forms of pharmaceutical innovation (on & off patent molecules). The off-patent innovation will be less costly to develop but could be equally effective (consider remdesivir & dexamethasone for the treatment of Covid-19 infected patients). Why should governments only reward the costly form of innovation?
By dynamic competition, we mean two forms of competition. First, physicians may prefer the outcome of either the on or off-patent innovation and increasingly may consider the cost-benefit – this will drive price competition between the two forms of innovation. Second, having a second off-patent molecule in competition with the on-patent molecule will generate a more dynamic HTA calculation – likely lowering the overall treatment cost of the relevant patient population.

d) continue the dialogue and allow the exchange of experiences to advance the implementation of World Health Assembly resolution WHA72.8 on transparency;
There should be a clear objective of transparency and its purpose. What governments in Europe really mean with the term transparency is the ability to compare individual drug prices and then to apply external reference pricing to reduce those prices to the lowest in Europe. This does not take account of the fact that the cost to market varies considerably across EU countries for both on-patent and off-patent medicines.
For off-patent medicines, there are significant differences in volumes, purchase guarantees, marketing costs (whether industry pays hospitals wholesalers and pharmacists through rebates or whether governments do through service fees). Applying lowest prices policies leads to the withdrawal of older generic medicines from markets as has been witnessed in wealthy countries (withdrawal of large generic companies from countries such as Norway), mid-wealthy countries (consolidation of hospital markets and around 10-15% of tenders with no bidders in Southern EU countries) and poorer countries (over 2000 generic medicines withdrawn from the Romanian market due to reference pricing and clawback policy). It is noteworthy that many European countries temporarily suspended reference price cuts on generic medicines (BG, RO, BE, PT, IT, FR) during the Covid-19 pandemic – which shows they understand the link between these price cutting measures and supply problems.

Governments should also consider whether price cuts on pharmaceuticals are really achieving savings. For the off-patent industry, payers usually refer to the price of the medicine but not the cost of dispensing or administration (multiples of the cost of most generic medicines) so in practice they are no real savings. For example, in Germany, the average DDD price of a generic medicine is €0.06 or €1.80/month of treatment. But you must add a wholesaler fee of around €1.80 and a pharmacy dispensing fee of around €9 to this price. So in practice, the cost of the medicine for the insurer (or the patient that pays for the insurance) is not low – it is only low for the manufacturer.

Many European countries misuse this policy and apply external reference pricing to the competitive (off-patent) market even though the WHO, Euripid (the EU database to compare prices) and academics warn of the nefarious effects of ERP on competition from generic medicines. Notably, this leads to a double price reduction for generic medicines (first the reference product price is reduced then the generic price which is linked to the reference product price is reduced a second time). This discriminatory and anticompetitive behaviour by payers across Europe is well tolerated because payers are exempt from competition law scrutiny. This anticompetitive discrimination would be totally illegal if a private buyer (say a supermarket chain) would every apply such a discriminatory policy. It also explains why so many generic

medicine licences are withdrawn across Europe – reducing the level of competition on the market. Just look at Greece or Romania for a confirmation of this of this trend. Please note that the costs of medicines is actually higher on these two markets as governments reimburse a maximum price and patients pay the rest through co-payment schemes. This policy therefore increases costs directly for patients.

e) share successful initiatives undertaken during the COVID-19 pandemic;

During the pandemic, there was a massive surge in demand for certain ICU emergency medicines that were widely used in treatments of infected patients. The surge was so big that countries and hospitals panicked and started to hoard medicines at the expense of their neighbouring country/hospital. The Commission had to intervene on multiple occasions to prevent hoarding practices – that would have been incredibly harmful to patients for Europe as a whole. The WHO (international) has done the same but it has no real legal authority over its members unlike the Commission so its impact was more limited. The pharmaceutical industry has aligned with these international institutions against hoarding which is something to be fought against permanently in healthcare. Solidarity is a genuine health issue in Europe and institutions like the Commission or the WHO need to enforce it against egregious behaviour that undermines efforts to deal with public health which always requires cooperation.

Recognising the urgency of the situation, Medicines for Europe with the support of EFPIA obtained a competition law comfort letter to allow cooperation to expand production output. Although the competition law elements were never used, the project was able to calculate the number of patients and average consumption/patient across all of Europe. This enabled a clearer dialogue between the EU, MS and industry to calm the situation and enable a rational allocation for patients. In addition, industry proposed numerous regulatory flexibilities (mainly a shift to digital forms of regulation, temporary reimports of what had been exported, possibilities to increase output or the speed of production, more flexible packaging/labelling to facilitate the flow of products across countries). We should note that industry was totally transparent in this process and shared all data with the EU and MS as per the agreement with the Commission. Industry would welcome a more transparent policy from the EU in relation to such projects or data submissions in the future. For example, the EU organised a highly secretive joint procurement for ICU medicines (using the regulatory data supplied by industry for shortage prevention). The procurement criteria were incomprehensible because this was applied to mostly nationally licenced medicines (not centrally approved medicines) and the Commission was unable to respond to clarification requests from manufacturers which delayed the decisions making process by several months – critical time in a pandemic situation. Member states refused to make purchase commitments to build up reserves for a second wave of Covid-19 (predicted with total accuracy by the industry) and many MS organised parallel procurements national for the same medicines to maximise their pricing leverage in this process. This forced industry to keep extra stock for two different procurement processes (one for the joint procurement and one for the national procurement) – and probably led to shortages of medicines in poor countries outside of Europe that needed those medicines in Latin America.

The EU and MS were also unable to assess actual demand needs during this pandemic (even though our industry was able to make such calculations with 95% accuracy in the project) and surprisingly had almos no visibility on inventories held by hospitals. Understanding demand and inventories is critical to ensure solidarity-based allocation in a crisis and Europe must improve its digital capabilities to do this in the future.

The EU and MS were also unable to use shortage reporting data in any meaningful way because the collection of this data is not standardised across the EU so it cannot be aggregated to EU level during a crisis. The EMA tried to collect this data through a voluntary system called i-SPOC. Companies submitted lots of reports but there was no follow up. All of this points to the need for European governments to implement coherent and interoperable digital tools on pharmaceuticals – something that has been planned (and delayed) for the last 10 years in the field of telematics and the interconnection of relevant data sources (hospital inventory systems, EMVS data, etc).

There is final critical point related to cooperation between governments and industry to maximise efficiency in a crisis. Some European countries wasted ICU medicine API by directly purchasing API for hospital compounding – leading to short shelf-life product that was wasted. This API could have been used by manufacturers to produce more medicine with long shelf life for use in patients. On the flip side, the use of regulatory flexibility and the move to digital regulatory tools by the EU and the UN (for narcotics control) was critical to prevent shortages of medicines. Many of these measures could be applied permanently to improve the efficiency of the regulatory system.

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

Governments play a critical role in ensuring good regulation (high standards, low administrative burdens) and promoting competitive markets so that industry can deliver innovation and price competition – and sustainable and secure supply. Europe struggles in this area because individual countries are too small to truly impact the pharmaceutical sector and to take account of certain costs like security of supply. This is where international institutions like the EU or WHO Europe can facilitate a European-wide coordination to tackle some of these issues. Some critical questions are are:

- Do I have competition and secure supply in my market (how much generic, biosimilar competition is there on my market? If the level is low, why. Do I have a lot of stock outs of cheap medicines? If so why?)?
- Do I have a good HTA system to manage pricing of expensive originator drugs? If not, can I adapt the assessments of other countries to my situation (to my different healthcare cost base)?
- Can my system realistically afford all new expensive originator drugs? If I don't have the resources, which originator drugs are population level priorities and which ones are not? For population level, how do I maximise the use of generic, biosimilar and value added medicines to ensure affordable access and reduce any wasteful spending?

g) discuss potential future actions to address collaboration challenges; and

Most European countries except maybe Denmark do not do forecasting of the costs of the future pipeline of originator drugs and the future generic or biosimilar pipeline (which can be utilised to increase access or drive price competition – usually both). This is necessary to adapt the budget the level of competition/innovation in the market rather than constantly scrambling for resources as overspending on originator drugs typically overwhelms annual budget planning. Government should avoid applying discriminatory clawback taxes on the generic industry as this pushes generic companies to withdraw from the market and reduces competition on the market (think Greece, Romania, the Portuguese Hospital market). This can easily be achieved by establishing innovative drug funds that are separate from the competitive pharmaceutical segment. Where there is over-spending in the innovative drug fund, the originators participating or being paid from that fund can pay back through a clawback or payback mechanism without penalising the off-patent segment (that delivers almost all savings in the system).

Reminder: fewer competitors leads either to higher spending on originator drugs or to no availability of the molecule.
h) to issue a joint WHO and Member States outcome statement.

Themes
4. In line with the Sustainable Development Goals (SDGs) and the European Programme of Work, 2020–2025, the Oslo Medicines Initiative 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 collaborations between the Member States and areas and the private sector 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.

There should be solidarity in healthcare and pharma policy – recognising that there are different levels of wealth across European countries. As stated above, for poorer EU countries, there needs to be recognition that they cannot afford all expensive originator drug – choices must be made. For population level health – which should be the priority, there should be clear policies to support uptake of generic and biosimilar medicines as these cover the overwhelming majority of first line treatments for most diseases. This is where real health progress can be made. Consideration should be given to value added (off patent) innovation which is much less expensive for patients and the NHS. This can deliver in a lot of therapy areas like AMR, cancer, better management of chronic respiratory or neurological diseases. This is low-cost innovation that can make a difference for large patient populations and contribute massively to improve population level health. By focusing on the high prices of a few rare disease drugs (which is a concern for wealthy European countries but hardly a concern for poorer countries that don't even provide full access to first line off patent, inexpensive cancer medicines), the WHO should prioritise its efforts to improve access in poorer countries – including access to off-patent medicines that are inexpensive but for lack of pro-competition frameworks are not reaching patients.

• TRANSPARENCY – understanding how transparency can be used to build trust and support access.

Yes there should be transparency but also responsibility. Individual European countries want transparency to obtain 'cost of goods' prices for medicines and to avoid paying for the other costs associated with medicines (development, regulation, manufacturing, security of supply, IP litigation). For generic medicines, European countries want the lowest prices globally combined with EU quality, regulation and security of supply.

And they want our industry to develop as many biosimilars as possible to lower biologic drug prices – knowing this costs €100 million/development – and then European countries want to pay generic prices for biosimilars.

There are clear cut and well documented cases of misuse of the IP system to evergreen monopolies in Europe – with massive costs for healthcare systems.

- The Commission competition authority has published reports that the European Patent Office (EPO) divisional patent policy support anti-competitive misuse of the patent system to delay generic entry – yet the EPO continues this policy.
- The Commission competition authority has called for an EU-wide legal ban on patent linkage where originators mix civil law (patent enforcement) to delay regulatory and administrative procedures required for the launch of a generic or biosimilar medicine. EU law did not ban this practice and it is expanding to new administrative areas.

- The Commission called for the expansion and harmonization of the Bolar exemption to facilitate day-1 launch of generic and biosimilar medicines in 2015 but this has not been acted upon.

WHO Europe could play a supportive role here by helping poorer European countries establish specialised IP courts. In most CEE countries, general courts deal with IP disputes which leads to the over-protection of weak patents as these courts cannot deal rapidly with patent disputes (in contrast to countries with specialised IP courts). For example, the launch of the oncology biosimilar medicine rituximab was delayed in several CEE markets due to the lack of specialised courts to invalidate a national patent that had been invalidated at the EPO level (obviously a weak patent) for western Europe. This led to West European countries getting quicker access to this medicine than poorer, East European countries (whose access levels to this molecule are very low on a per capita basis).

• SUSTAINABILITY – considering how to ensure a sustainable industry and health care systems.
There needs to be a balance that accepts the role of market forces to drive sustainability. European governments (including this initiative) believe that they can dictate prices lower and lower and that nothing will go wrong. This will not work in practice. By encouraging competition, European countries will experience lots of price competition and patients and the NHS will benefit from that. But applying permanent price cuts to generic and biosimilar medicines or using single winner procurement to maximise buying power – will lower prices but eventually companies stop selling medicines in those markets. Many of our companies have withdrawn products because this is commercially unviable –due to extreme pricing or procurement policies. In many southern EU countries, there are hospital tenders for critical anti-infective or cancer medicines with no bidders because of a negative risk-reward criteria.

On the other hand, we still have clear discrimination against the entry of new generic and biosimilar medicines in many of the poorer countries in Europe – meaning these countries are losing the benefits of competition. In Romania, the NHS is losing huge savings opportunities because it hesitates to stimulate biosimilar competition in the market.

European countries are also failing to see the opportunities to bring competition to on-patent molecules by encouraging competition with off-patent innovation. Look at Covid-19, where dexamethasone was repurposed to treat infected patients and it was indirectly in competition with another treatment (remdesivir) that was on patent. This gave governments a choice of treatments (on & off patent) for patients – this is totally acceptable to both sides of the industry by the way. Reformulations, repurposing and combinations of off-patent innovation could deliver lots more competition in the innovation space in areas like cancers, rare diseases, AMR, respiratory conditions – basically everywhere. In some cases, expensive new chemical or biological entities will be better and investments should be made. In other cases, value added off patent innovation will work just as well or better and (much lower) investments should be made there. Let the best and most cost-effective innovation win. But to do that, there must be a framework to allow my industry to invest in that off patent innovation – currently this does not exist in Europe. Concretely, there is a discussion on how to incentivise this innovation in the EU but it will take some discussions to clarify how this will advance.

Questions for the consideration of non-State actors, to facilitate exchange of views and positions:
5. **Scope and purpose of the Oslo Medicines Initiative**
a) Do non-State actors have any comments on the draft Scope and purpose document for the Oslo Medicines Initiative?
A focus on the price of individual drugs will fail. You need to look at this as a problem of a lack of competitive dynamics in the system(s). If you look at the pharmaceutical market, you can see that most

innovation focuses on targeted (small patient population) developments and around 50% of this in oncology. This translates into higher unit costs almost automatically – so more NHS spending on fewer patients. This can be balanced by determining the total budget governments want to spend on targeted therapies and separating that from the competitive pharmaceutical market to prevent over-spending beyond what society agrees with.
For the competitive market, measures can be taken to encourage uptake of generic, biosimilar medicines to reduce spending or increase access as soon as exclusivities expire. Where we are witnessing shortages and withdrawals of older generic medicines, there should be market reforms as this is largely driven by extreme procurement and reimbursement policies.
Another avenue is to consider the link between pharmaceuticals and major healthcare challenges that are cost-drivers in the NHS. For example, chronic disease management, AMR and cancer are major public health challenges and cost drivers in the system. Value added innovation can play an effective (and cost-effective) role in managing these challenges through reformulations, repurposing or combinations with digital technologies. Bringing cost-effective solutions to these public health challenges would free up resources for more funding of rare disease drugs.

6. **Issues affecting access to effective, novel, high-priced medicines, and health products, and potential solutions**

a) What do non-State actors see as the major issues affecting access to effective, novel, high-priced medicines? Not all EU countries can afford all innovation. Even with a price discount, there are simply budgetary limits. Countries should define separate innovative drug budgets for oncology and rare diseases to manage this. This establishes a democratically decided funding of these drugs that is not perfect but is at least transparent.
b) What promising actions are non-State actors undertaking or advocating to improve access? Examples could include price negotiation, public-private partnerships, novel b) What promising actions are non-State actors undertaking or advocating to improve access? Examples could include price negotiation, public-private partnerships, novel financing mechanisms, price volume arrangements, risk-sharing, and advance purchase arrangements.
These are all fine but there should be a clear mechanism to enable generic and biosimilar companies to bring competition to the market at patent expiry. Confidential MEAs should be accessible (under clear rules) to companies targeting those molecules or bringing competition to the market. In addition, procurement arrangements like APAs should always contain a requirement to reopen the process at entry of the first follow on competitor to the market. Otherwise, originators will extend the duration of contracts beyond patent expiry to extend de facto their monopoly. This is common in the pharma sector and it is incredibly costly and wasteful.

c) How can WHO/Europe collaborate with non-State actors in their efforts to provide access to the population to effective, novel, high-priced medicines?

7. **SOLIDARITY**
a) How can existing mechanisms for cooperation and coordination between Member States and areas be strengthened, including joint horizon scanning, procurement and assessments?
Horizon scanning should also look at how to encourage competition from generic and biosimilar manufacturers. Most poor European countries delay this competition rather than embrace it. In addition, patent courts in CEE countries are highly unfavourable to access to medicines because they are not specialised and very slow. This leads to many generic and biosimilar delays in these countries compared to

rich West European countries (i.e. cancer medicine rituximab – biosimilar launch delayed in CEE countries because patent courts too slow to invalidate a patent already invalidated in W. Europe).
b) How can WHO/Europe continue to support active and meaningful dialogue between stakeholders?
WHO Europe should collaborate with the EMA to educate about biosimilar medicines and increase their use in CEE countries where it is very low and where savings are not invested in increasing (the very low) access to these therapies – even for first line lifesaving cancer medicines. This is another reason why cancer survival rates are so low in these countries. This is a quick fix that could literally save tens of thousands of lives.

8. **TRANSPARENCY**
a) What actions can Member States and areas and non-State actors take to further strengthen the implementation of World Health Assembly resolution WHA72.8?

This project should focus on how to improve population level health in the WHO Europe region. To what extent will this genuinely improve access to medicines? The EU already has databases to compare medicine prices so there is nothing that can be added here. What is missing is an analysis at the extremely low levels of patient access to some first line treatments and to prioritise the areas where the WHO can make the biggest difference quickly.

i. encourage generic & biosimilar 'first' policies and reinvestment of all savings to increase access levels in poor countries to the West European average. This is financially achievable for poor European countries and the health outcome gains will be multiples of anything that can be achieved related to higher discounts on originator drugs.
ii. encourage competition between on and off patent innovation by creating a framework for off-patent innovation. Then put the two forms of innovation in competition and let the best innovation win. Competition will save more than any price regulation (as demonstrated by almost every economic study ever made).
iii. Identify the barriers to generic & biosimilar competition at patent expiry (evergreening) and put forward recommendations to remove these barriers. Again, this will save more money and give more access to medicines to the poorest patients that currently have limited access to therapy.
iv. Share best practice on MEAs and provide technical support to poor countries on HTA – most of them cannot do this technically in Europe so they use NICE HTA decisions for this. But NICE is designed for the UK where they have high volumes and high healthcare expenditure – this is not the same as Bulgaria or Moldova.
v. Recognise the limits of Joint Procurement. Every experience our industry has had with generic medicine joint procurement (Norway-DK-Iceland; EU ICU medicines) has been too complicated because generic medicines have national (not EU/CP) licences. This simply does not work for nationally licenced medicines (99% of generics).

b) How can WHO/Europe support the implementation of World Health Assembly resolution WHA72.8?

9. **SUSTAINABILITY**
a) How can WHO/Europe contribute to reconciling sustainable pharmaceutical policies and procurement practices with sustainable industry and innovation?

i. first, especially in CEE markets, encourage competition in procurement from generic and biosimilar manufacturers. Time and time again, procurement is gerrymandered to prevent head-to-head competition at patent expiry (extending procurement just before patent expiry, keeping

one lot for the originator & a separate lot for the generic or biosimilar, shifting patients to slightly different versions without clear additional benefits).
ii. There must be a move away from extreme tendering for older generic medicines. There should be multi-winner tenders and MEAT criteria – especially including security of supply.
iii. Avoid joint procurement of nationally licenced generic medicines.

b) How can non-State actors contribute to sustainability for both health systems and the pharmaceutical industry?

Create a better framework for competition and my industry will deliver, massive increases in access with generic and biosimilar medicines. Value added innovation can improve the management of large population level health challenges: AMR, cancer, chronic disease management. And we will do so by bring dynamic competition to originator innovation. This will lower costs in two ways: offering lower cost alternatives & impacting HTA prices. We need a framework to encourage my industry to invest more in this affordable innovation.

Government regulation of originator drug pricing is not a panacea. We have had HTA in Europe for the last ten years but this has not lowered originator drugs unit prices or cost in pharmaceutical budgets. On the other hand, generic medicines have taken over the volume share of the market and have had their prices reduced drastically to the extent that security of supply is threatened. Europe needs to restore some balance by focusing more on how to stimulate competition and less on how to control individual prices.

PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Oslo Medicines Initiative: PGEU statement

26 April 2021

At the heart of community pharmacists day-to-day mission lies their commitment to the safe, effective and rational use of medicines by patients, ensuring that the right patient receives the right medicine at the right time, along with the appropriate professional advice.

Unaffordable medicines prices can be one of the main barriers to access to medicines by patients and health systems. Community pharmacists are sometimes faced with patients who are not able to pay for the medicine they need due to the high co-payment. Therefore, ensuring equitable and sustainable access to medicines for patients and health systems is an objective that PGEU shares with national governments and health systems, as well as with European[1] and international institutions[2].

In the context of current political priorities, PGEU welcomes the Oslo Medicines Initiative and WHO Europe efforts to ensure the affordability of medicines for patients.

On top of financial and fiscal sustainability pressures to European health systems, the increasing marketing of innovative, specialty medicines has been a major challenge even in high-income countries in Europe over the last years. Although new, innovative medicines may be able to respond to unmet patients' needs, they may pose new challenges as for the capacity for patients to access these medicines without financial hardship and for health systems to be able to reimburse them. As argued by the Organization for Economic Cooperation and Development (OECD)[3], launch prices of new medicines have been increasing in some therapeutic categories, sometimes without commensurate health benefits. Even new effective medicines are not always affordable to patients in need and this puts an additional pressure on healthcare budgets.

The data included in the OECD Health at a Glance 2019 report[4] confirm that pharmaceutical expenditure increased by 1.6% between 2013-2017 across OECD countries. As a result, keeping pharmaceutical expenditure under control has remained a key policy objective for national governments.

PGEU observes that adoption of pure cost-containment pricing models may be detrimental to public health objectives, as they tend to affect availability of medicines[5] and to shift the financial burden of the costs of medicines on patients, by, for instance, increasing co-payment. Lack of financial coverage and protection on medicinal products may jeopardize public health objectives, as it can reduce access to healthcare, worsen health status, for instance by lowering patients' adherence to their medication due to cost concerns, in turn undermining health outcomes, and also exacerbating health and socio-economic inequalities.

P&R policies remain a competence of EU Member States under the condition that they comply with the overall EU legislation such as the Transparency Directive. In this respect, PGEU considers decisions on P&R to be an integral part of health policy and as such a prerogative of each individual Member State. At the same time,

[1] https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/

[2] https://www.who.int/news-room/detail/28-09-2020-who-publishes-pricing-policy-guideline-to-improve-affordable-access-to-medicines

[3] https://www.oecd.org/els/health-systems/pharmaceuticals.htm

[4] https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1602145348&id=id&accname=guest&checksum=BC9EF3892A3528117D6F24E0914AE227

[5] https://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm

PGEU acknowledges that individual pricing decisions in some EU countries may affect other countries. Taking this into account, PGEU believes that promoting better coordination among EU countries[6] to ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another country is an appropriate way the EU can help improve affordability of medicines for health systems.

In line with the European Commission proposal in the Pharmaceutical Strategy Roadmap, we also support EU co-operation on issues related to evaluating cost-effectiveness and measuring added therapeutic value as well. In this respect, we recognize that in recent years, a number of voluntary cross-country collaborations[7] [8] have been established on different areas, including on P&R and on the joint procurement of medicines. We believe these collaborations to be useful and successful experiences to be further promoted.

Furthermore, PGEU considers that the regulation of medicines prices should be operated through a mix of policy instruments and not only leveraging on a single pricing policy tool. It is also desirable for Member States to carry out periodic review of P&R policies, conducting adequate policy evaluation, and taking into account any changing conditions in the pharmaceutical market and in the population.

Pharmaceutical pricing policies are not the sole determinant of affordability of medicines. There are multiple aspects that affect the affordability of medicines and the sustainability of health systems.First of all, we consider that the promotion of the rational use of medicines should be at the core of any policy aiming to enhance the affordability of medicines for patients and health systems. This can be implemented by appropriately remunerating cost-effective healthcare services which improve therapy outcomes and adherence and minimize the risks related to using medicines. Examples of such services are adherence-focused new medicines services[9], medicines use reviews[10], dose administration aid services, common ailment[11] and chronic disease management [12,13] services.

Together with the promotion of the rational use of medicines, more investments in prevention and in strengthening of primary care systems should be strongly encouraged as a measure to promote affordability of medicines for patients and health systems.

As pointed out by the OECD[14], with the share of population aged 65 and above set to almost double to 28% by 2050 across OECD Countries, national governments must reconfigure their health systems to make them more sustainable and make sure that patients can receive affordable, effective and high-quality care for people living with chronic conditions. This would enable to avoid unnecessary use of hospital and specialised healthcare services. In this respect, community pharmacy services should be further integrated in primary care networks to help reducing the pressure on overburdened secondary care. The Covid-19 pandemic has demonstrated that it is more important than ever before to maximise the scope of community pharmacy practice and its integration within the primary care systems, in order to offer rapid, effective and safe solutions

[6] Cross-countries cooperation should be encouraged to establish adequate HTA frameworks, or to promote joint pricing negotiations and/or to promote horizon scanning. Examples of successful cross-countries cooperation include the Beneluxa Initiative on Pharmaceutical Policy and/or the International Horizon Scanning Initiative.

7 https://beneluxa.org/

8 https://journals.sagepub.com/doi/full/10.1177/2399202619852317

9 Elliott, et al. (2016). Supporting adherence for people starting a new medication for a long-term condition through community pharmacies: a pragmatic randomised controlled trial of the New Medicine Service. Pharmacoeconomics. 2017 Aug 3. doi: 10.1007/s40273-017-0554-9

10 Jódar-Sánchez, F. et al. Cost-Utility Analysis of A Medication Review With Follow-Up for Older People With Polypharmacy in Community Pharmacies in Spain: Consigue Program. Value in Health, Volume 17, Issue 7, A511 - A512

11 Watson M, Holland R, Ferguson J, Porteous T, Sach T, Cleland J. Community Pharmacy Management of Minor Illness (the MINA Study) London: Pharmacy Research UK; 2014.

12 Marra C et al. Cost-effectiveness of pharmacist care for managing hypertension in Canada. Can Pharm J (Ott). 2017 Mar 21;150(3):184-197 doi: 10.1177/1715163517701109

13 Hughes, Jeffery David et al. "The role of the pharmacist in the management of type 2 diabetes: current insights and future directions." Integrated pharmacy research & practice vol. 6 15-27. 16 Jan. 2017, doi:10.2147/IPRP.S103783

[14] https://www.oecd-ilibrary.org/sites/a92adee4-en/index.html?itemId=/content/publication/a92adee4-en

to meet patients' needs and maintain continuity of pharmacy services and of medicines supply. This is crucial to make European health systems more sustainable and resilient.

Further expansion of community pharmacy services should be considered by introducing appropriate legislation and/or financial support, for instance to enable services which proven to be crucial during this pandemic, such as the home delivery of medicines to patients who are not able to physically visit the pharmacy, the safe renewal of repeat prescriptions for chronic medications, the promotion of safe and rational use of medicines as well as the prevention, reporting or mitigation of adverse drug reactions (ADRs) and ensuring access to certain hospital medicines via community pharmacies for patients who need them.

Over the next months and years, it will be even more crucial to ensure that the sustainability and resilience of EU Member States health systems. In line with this priority, the wide network of community pharmacies in Europe provides a unique opportunity to access to disease prevention programs, immunization, health screening, etc. through provision of increasing number of health services for all citizens. Therefore, we believe that this crisis suggests that expanding community pharmacy services, as integral part of primary care, promoting prevention and better management of long-term conditions, can help to improve access to health services and ease the burden to the secondary health sector. As recommended by the World Health Organization Regional Office for Europe (WHO Europe)[15] and by the OECD[16] recently many European countries have introduced changes in legislation to expand the role of pharmacists and relieve pressure on the rest of the healthcare system. Some countries have also secured additional funds to empower pharmacists in their vital work on the frontline against Covid-19.

Further key policy levers to advance affordability of medicines for patients and health systems consist in the design of appropriate financial incentives for pharmacists to dispense and promote the uptake of generic medicines in order to make medicines more affordable for patients.

[15] https://www.euro.who.int/en/health-topics/Health-systems/pages/strengthening-the-health-system-response-to-covid-19
[16] http://www.oecd.org/coronavirus/policy-responses/beyond-containment-health-systems-responses-to-covid-19-in-the-oecd-6ab740c0/

CPME statement on the Oslo Medicines Initiative

The Oslo Medicines Initiative
Consultation with non-State actors
26 April 2021

European doctors explicitly welcome the WHO/Europe's and Norway's initiative to develop "*a new vision for collaboration between the public and private sectors*" in order to allow patients better access to novel and hopefully effective and safe medicines.

The initiative's ambition - to reconcile the patients' right to reasonably priced medicines with the pharmaceutical industry's profit-driven business model - is fully supported by European doctors' recent call to restore balance in the pharmaceutical sector on which forthcoming legislative and policy changes in the EU are targeted.

The initiative correctly observes that the increasing number of novel medicines entering the market frequently with high prices and uncertain clinical benefits, poses a great challenge for the sustainability of health budgets. It also affects doctors' and patients' ability to choose the appropriate treatment.

This initiative rightly places a special emphasis on collaboration as the best possible way to address this issue. Timely access to effective, safe and affordable medicines depends on close cooperation among Member States as well as between the public and private sectors.

In my today's short statement, I will briefly focus on three topics where strengthened cooperation among Member States and between the public and private sectors can be particularly beneficial: firstly, the generation of comparable and robust data on new medicines, secondly, their pricing and procurement, and thirdly, health innovations that are accessible, affordable and really meet patient needs.

At first, comparable and robust data are critical for informed marketing authorisations, for assessing the potential benefits and harms of new medicines against existing ones, for making pricing and reimbursement decisions and, finally, for allowing doctors and patients to make the best individual choice of treatment.

Regulatory agencies, HTA bodies and payers working together and supported by patients, healthcare professionals and pharmaceutical companies can lead to the generation of meaningful comparative data on new products. This could happen through the harmonisation of the designs, by choosing reasonable endpoints and outcomes of clinical trials, early dialogues between all stakeholders, encouraging Randomised Controlled Trials with active comparators, and explicitly proven added therapeutic benefit in pricing and payment decisions. Thus, the obvious risk that there is no consistent link between a drug's price and

the associated medical benefit can be avoided. During the last few years, the challenges of the combination "accelerated approvals and high-priced drugs with uncertain clinical benefit" – for example in the field of cancer drugs – were obvious. Therefore, postmarketing studies as a main source of evidence for clinical decision making are of paramount importance.

Secondly, Member States should improve transparency and cooperation on pricing of medicines by disclosing net unit prices, which will allow national pricing authorities to make better informed decisions. It could lead to a level playing field for national governments with varying purchasing powers and market sizes, as well as for pharmaceutical companies. Transparency is a precondition to ensure competition and a balanced market. An effective pricing system should facilitate accessibility but also reflect the public contribution - so taxpayers don't pay twice such as nowadays.

Member States should also draw conclusions from the experience gained during the COVID-19 pandemic, realise how joint procurement has benefited their bargaining strength and analyse whether it has been fully exploited by including all possible public interest conditionalities such as transparency in the contracts. Member States should discuss how to improve and expand the scope of joint negotiations. Importantly, a stronger position of different Member States speaking with one voice should be used to demand high transparency standards in future joint undertakings.

Thirdly, when it comes to creating a more beneficial cooperation with the private sector to provide patients with affordable medicines that bring added therapeutic benefits, the current system of health innovation should be reshaped. Given that the public co-creates and is a major investor in health technologies, Member States should take an active role in defining directions for health innovation to create a system that is aligned with medical and social needs, rather than leaving it to be driven by commercial interests alone.

Moreover, all forms of public investment in the R&D process should be subject to concrete commitments. Medicines benefiting from a centralized marketing authorization at EU level should be launched in all Member States at the same time.

WHO/Europe's and Norway's leadership in advancing collaboration to ensure patient access to novel medicines is strongly supported by European doctors who remain committed to contributing to a sustainable and balanced system that also serves better the public interest. This initiative is of particular importance as during the last decade the current research and development (R&D) system has been biased towards high revenue generating diseases, leading to an increasing gap between so-called innovative medicines and real unmet medical needs.

26th April, 2021

Contribution of Wemos to the consultation with non-State actors by the Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors

Thank you chair,

Over the last year, access to medicines has seen a surge in political attention because of Covid-19. The pandemic has shown the importance of a strong public health system and access to medicines for all. We thank WHO Europe and the Norwegian government for their interest to improve pharmaceutical policies resulting in increased access to medicines.

Many problems surrounding the lack of access to novel treatments can be linked to the power imbalance between pharmaceutical companies and governments. Monopolies and the lack of transparency in the pharmaceutical industry are major contributors to this power imbalance.

Wemos has three recommendations to WHO Europe that will contribute to the rebalancing of power in favour of public health systems, and therefore improve access to effective, novel high-priced medicines.

Firstly, WHO Europe should set up a so-called toolkit with clauses to be used by publicly funded research institutions when licensing intellectual property or knowledge to pharmaceutical companies. This toolkit on Socially Responsible Licensing should contain clauses that ensure availability of pharmaceutical products everywhere, promote affordability for payers and health systems, and create transparency of net prices and R&D costs.

Public funding of R&D of novel treatments plays a central role in the discussion on access to medicines. Wemos is convinced that licensing conditions on affordability, availability and transparency in an early stage of the R&D process, can boost the accessibility of novel treatments.

Three years ago, the former Dutch minister of Health instructed Dutch Medical University centres to investigate the possibility to attach pro-public interest conditions to publicly funded R&D. The result was a toolkit that provides contractual principles universities can include in their licensing agreements with pharmaceutical companies.

Even though the Dutch toolkit should have contained stronger language on affordability, availability and transparency, the concept can act as a blueprint for regional cooperation on conditioning public funding. Wemos recommends WHO Europe to engage with academia and not-for-profit non-state actors, in order to create an effective licensing toolkit that promotes global access to and transparency on novel treatments.

Secondly, we recommend WHO Europe to actively engage with member states and industry to support and utilize the Covid-19 Technology Access Pool, or C-TAP for short. Through this pooling mechanism for data, knowhow and intellectual property, we can maximise manufacturing capacity and decrease inequity in Covid-19 technologies. So far, no government nor pharmaceutical company has shared their technology for Covid-19 vaccines in C-TAP.

Considering the large amounts of public funding from member states into vaccine R&D, it is only fair to expect pharmaceutical companies and governments to share their knowledge.

A well-functioning mechanism for the transfer of data, knowhow and intellectual property is vital to combat the Covid-19 pandemic. Additionally, it will better prepare access to pharmaceutical products in future pandemics. It is therefore essential to make C-TAP work.

Thirdly, we recommend the immediate implementation of the World Health Assembly resolution 72.8 by setting up a European database on net prices of pharmaceutical products. This database resets the current information imbalance between governments and the pharmaceutical industry. Governments negotiate blindfolded as they lack useful information on the actual prices negotiated by other countries.

This WHO Europe database will especially be useful for countries engaged in external reference pricing. When more data is disclosed on R&D costs and public funding, academia, NGOs and governments can analyse whether these net prices are fair and sustainable.

Many countries are interested in ways to increase transparency of net prices, but simultaneously, they are afraid to be first movers in disclosing these prices. Therefore, Wemos recommends to draft an agreement with WHO Europe member states to publish all net prices for pharmaceutical products at the same point in time, annually.

Wemos believes that the three proposed strategies, being socially responsible licensing, C-TAP and coordinated price publishing, will end the disbalance of power, effectively enhance access to medicines, better prepare us for future pandemics, and transform Covid-19 technologies into a global public good. WHO Europe can here position itself as the leading change-maker for the greater good.

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