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Federal Ministry
Republic of Austria
Social Affairs, Health, Care
and Consumer Protection

sozialministerium.at

BMSGPK-Gesundheit - VII/B/5 (Leistungsorientiertes Finanzierungssystem, Gesundheits- und Pharmaökonomie)

Mag. Stefan Eichwalder
Head of Department

stefan.eichwalder@gesundheitsministerium.gv.at
+43 1 711 00-644153
Stubenring 1, 1010 Vienna

Please indicate the reference number in your email and send them to the following email address: post@sozialministerium.at.

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Consultation on the Oslo Medicines Initiative – written statement on behalf of the Ministry of Social Affairs, Health, Care and Consumer Protection

Dear Ms. Azzopardi Muscat,

Please find below the written statement on behalf of the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection to the consultation on the Oslo Medicines Initiative, held online on 21st January 2021 (oral statement by Stefan Eichwalder, head of department VII/B/5).

"Dear (Regional) Director,
dear Secretary General,
dear ministers and distinguished colleagues,

It is a great honour to participate today in the informal online consultation on the Oslo Medicines Initiative on behalf of our Minister of Health, Rudolf Anschober. Unfortunately, Minister Anschober is not able to participate due to urgencies in the national response to the current Covid-19 crisis. Please accept his sincere apologies. However, he would like to convey the message that today's topic is of highest importance to Austria as well as to the WHO European Region. On behalf of the Austrian Ministry I would like to give you a short outline of the most important aspects from our point of view:

All over the world, the pandemic has shown that social structures in general and health care systems in particular are fragile and vulnerable to challenges as the current Covid-19

pandemic. The crisis has also confirmed the fundamental importance of a well-functioning health care system – based on solidarity and mutual support – in addressing such an extraordinary situation. Even though the Covid-19 pandemic has pushed countries all over the world to their limits, we should take the current crisis as an opportunity for reflection and learning in order to strengthen our resilience and to optimize our crisis-response. We can also use important lessons learned for further developments and improvements in the context of equitable and sustainable access to safe, effective, affordable and quality-assured medicines and health products. This is highly relevant for the whole of the European Region.

The development of innovative medicines is essential for making progress in preventing and treating diseases. However, the high price tags put on new medicines do not always reflect the value added for patients. Additionally, persisting unmet clinical need in the population suggests a misalignment of pharmaceutical research and development efforts.

From a national perspective and in regards to the accessibility of safe and affordable medicines, I want to highlight some major points:

1. The price of medicines: As a high-income country, Austria is frequently among the first countries where new medicines are launched. While an early launch of medicines is, in principle, beneficial to patients, it comes at a cost. Even in a high income country like Austria, the price tags of some of new medicines are increasingly challenging the financial sustainability of the health care system. As a result, fewer resources are available to fund other areas within health care and public spending in general.

   In addition to public spending, we must not forget the individual situation of the people: Based on the excellent work by the WHO Barcelona office, we know that financial hardship often stems from expenses on pharmaceuticals and we need to focus on that issue.

2. Availability of medicines: As other countries, Austria was increasingly exposed to medicine shortages during and even before the COVID-19 pandemic crisis. Therefore, it is of utmost importance to consider solutions and measures to foster resilience also by strengthening the production of pharmaceuticals in the European Region.

3. Transparency: To maintain trust transparency is key, transparency about the therapeutic value of medicines but also regarding prices.

4. Research and development: Public funding has a great impact on pharmaceutical innovation. Therefore, a stronger implementation of public interest provisions along the life cycle of pharmaceuticals, including a "fair return of investment", is required.
   Additionally, more actions to improve coordination and priority-setting across R&D efforts are required ideally on a global level, but with further refinement on an European level to reflect regional priorities.

There is a growing consensus that existing policies need to be rethought and new approaches need to be found to strike the delicate balance between stimulating true innovation, particularly towards addressing unmet needs, and ensuring both financial sustainability for health systems and accessibility for patients.

In view of these challenges, Austria strongly supports of cross-country collaborations and international exchange in order to learn about similar challenges and potential solutions and concrete measures. Austria is involved in several initiatives, among others as member of the Beneluxa Initiative. Austria hosts the WHO Collaboration Centre for Pharmaceutical Pricing and Reimbursement Policies, which is working on above-mentioned topics.

During the Presidency to the Council of the European Union in 2018, Austria has also put emphasis on affordable access to essential medicines, transparency and innovation. Two policy briefs on "Ensuring Access to Medicines" prepared by the European Observatory on Health Systems and Policies were published and Austria will continue to prioritize this specific area in the upcoming years.

We are looking forward to working with our friends in the WHO and colleagues in the Member States, who are also present today in order to increase the focus on implementing concrete measures.

We are convinced that international and cross-sectoral cooperation is the way forward. We trust that the Oslo Medicines Initiative will play an important role in strengthening equitable and sustainable access to medicines and health products. Therefore, the dialogue, which involves Member States and central stakeholders, and the discussion on advancing the implementation of the WHA resolution on transparency are of major importance.

We support the objectives of the Oslo Medicines Initiative and endorse the preparation of an outcome statement to pledge our commitment to collaborative actions to ensure solidarity, transparency and sustainability in the innovation process of medicines and in health care systems.

Thank you very much."

8. April 2021
On behalf of the Federal Minister:
Mag. Gerhard Embacher

Enclosure: Beilagen

Elektronisch gefertigt
(signed electronically)

WHO Oslo Initiative - Input Belgium

Ladies and gentleman,

Belgium welcomes with great interest the joint Oslo Initiative of WHO and the Norwegian government.

Indeed, there is an urgent need to set up a work programme focusing on identifying and elaborating a new and innovative approach based on collaboration between all stakeholders aiming at improved access for European patients to novel, effective, high cost medicines.

Belgium wants to contribute actively to the objectives and outcomes of the Oslo initiative. Belgium has already shown and shared its expertise and experience in the matter and plays an active role in international collaborative initiatives like BeNeLuxA and IHSI, the International Horizon Scan Initiative, today involving 7 countries. Also research we mandated has focused on this topic as well, e.g. through the analysis of potential future scenarios about drug development and drug pricing for example.

Let me stress five key elements we should take on board in the process:

Firstly, we believe that the Oslo Initiative can and should be both complementary to and synergetic with the agenda and the goals of the Pharmaceutical Strategy that the European Commission is currently developing together with the member states.

Secondly, Belgium recognises that it is of great importance to set up and to express publicly mutual objectives and commitments with the pharmaceutical industry. Those should be based on an integrated and continuous dialogue that focusses on fair reward and smart commitments broader than pricing issues alone.

Indeed, we need appropriate incentives for the development of innovative medicines, as well as safe-guards preventing shortages. We need to pay attention to managing high cost individual therapies in practice, as well as strategies for long term budget allocation and control. We need to look at alternative financing methods, such as common procurement and innovative payment mechanisms, as well as budgeting techniques for resource allocation and risk sharing. We need a commitment to a number of ethical principles, such as social justice, inclusion and transparency about the motivations behind sequential market

entries and other topics. Commitments should be made public and formalised in a charter so all partners can take up responsibilities, but also can be held accountable.

Thirdly, this WHO initiative is an opportunity for Member States to reflect on and even to rethink their pharmaceutical policies together, taking into account scientific evolutions and the possibilities offered by digitalisation with regard to data. We believe countries are compelled to take an active role and act as investors in health for their population and 'buyers' of innovative solutions for health issues in a demand based setting, rather than act as passive 'payers' in a supply based system. This is easier said than done as such approach pushes competent authorities to a certain degree of introspection. This role requires essentially accountability towards society and its citizens for choices made and priorities set when allocating limited financial resources. It therefore requires clarity in expressing preferences and in willingness or reluctance to invest.

Fourthly, the way forward for such demand driven approach will require international collaboration. Luckily, foundations for this are already in place: robust horizon scanning such as delivered by intergovernmental initiatives like IHSI, gives insight in upcoming challenges, as well as future opportunities. Its deliverables will document transparent priority setting and nurture early dialogues with companies, as well as the much needed societal debates on willingness to pay on investment in health solutions. Intergovernmental collaborative initiatives such as BeNeLuxA, Valletta Group, Nordic Pharmaceutical Forum, Visegrad group, etc. are demonstrating the added value of capacity and expertise building and exchange of information, regardless of national specificities. By fostering the asset of international collaboration, we can steer the agenda in a cooperative fashion for the benefit of patients.

From the COVID-19 pandemic 2 important learnings emerged: First, the "never seen before" acceleration in vaccine development was only made possible by a shared approach of leveraging resources and power, both human and financial. Second, the response to the crisis demonstrated the power of pooling knowledge, evidence, expertise and solidarity.

To end, allow me to comment on WHO's important role in this matter: WHO and the Oslo Initiative are uniquely placed to establish this much needed "integrated" dialogue between Member States, civil society and the industry. Through its unique position, the WHO can play an active role in the agenda setting of this dialogue. The WHO's expertise can support member states and international collaborative initiatives through technical and organisational know-how, convening power, and legal support. By doing so the WHO could act as the network of networks, leveraging interesting and ongoing initiatives in the realm of international and cross-sectoral cooperation to deliver efficient and sustainable pharmaceutical innovation to all.

Thank you.

REPUBLIC OF CROATIA
MINISTRY OF HEALTH

Oslo Medicines Initiative - Written statement HR

The number of new, innovative and usually very expensive medicines, including advanced medicines therapy, is increasing daily, enabling the improvement of the treatment of many malignant, hereditary and chronic diseases. At the same time, the high prices of these medicines limit the availability and pose a potential risk to any healthcare system.

The Republic of Croatia has opted for a health care system based on the principles of solidarity, whereby insured persons treated for the most serious diseases, such as oncological and especially rare and severe diseases, participate minimally or not at all in the costs of their treatment. Therefore, the biggest challenge for the Republic of Croatia in terms of rapid availability of innovative medicines is, as a rule, a very high price of medicines for the treatment of rare and severe diseases.

An additional reason relates to the fact that marketing authorization holders do not even submit a request for inclusion of a medicinal product in the list of medicinal products of the health insurer, whereby the contractual relationship would define the price of the medicinal product, but they rather offer new, innovative medicinal products at prices formed in countries with higher national income, which makes it difficult to access innovative medicines in small markets such as Croatia. The number of newly registered smart medicines is extremely large and is constantly increasing. All these new drugs are extremely expensive, and the financial resources are not limitless.

Procedures implemented in the Republic of Croatia to ensure the availability of innovative medicines to patients are focused on activities at the national level and participation in international initiatives at the EU level.

The common problem of faster availability of safe and high-quality innovative medicines has led to the identification of natural groups of like-minded people among the European Union Member States with whom the Republic of Croatia would fight for the interests of its citizens. Smaller countries have been working together for some time to improve dialogue with the pharmaceutical industry to ensure a level playing field in the EU internal market. A number of more or less successful initiatives, such as Benelux, Valletta, V4+, FINOSE or the Nordic Pharmaceuticals Forum (NLF), have been launched to establish voluntary cooperation between individual Member States with the aim of exchanging and sharing information, identifying best practices, horizon scanning of innovative medicines and therapies and research of possible mechanisms for price negotiation and joint procurement of medicines, and the Republic of Croatia also participated in some of them.

Regarding the measures taken at the national level, to facilitate the financing and availability of innovative and particularly expensive medicines to insured persons in the Republic of Croatia, there is the provision of funds for these medicines and their payment to the Croatian Health Insurance Fund (HZZO) from a special financial position in a way that the cost of these medicines does not burden hospital budgets.

Ksaver 200a, 10 000 Zagreb, Republic of Croatia
T + 385 1 46 07 555 F + 385 1 46 77 076
www.zdravlje.hr

The Croatian Health Insurance Fund puts medicines on the list of medicines in accordance with the prescribed rules. Treatment with an innovative medicine that is placed on the basic list of HZZO medicines is carried out entirely at the expense of a special fund if the established criteria for the medicine use are met, by using medicines in a certain indication for those patients who are expected to have the greatest success in treatment, in accordance with the registration status. When putting such expensive medicines on insurance lists, HZZO concludes special financial agreements with the marketing authorization holders, which define the price of the medicine throughout a certain contractual period.

In this way, two years ago, the Croatian Health Insurance Fun's list of medicines included those for the treatment of several rare diseases, such as mucopolysaccharidosis, spinal muscular atrophy, haemophilia, Duchenne muscular dystrophy, Batten's disease and neuroblastoma, as well as drugs used as immunotherapy in various malignant diseases, medicines for the treatment of rare haematological diseases, medicines used as gene therapy, etc., which made these drugs available in the Republic of Croatia, and increased the standard of treatment of these diseases.

In the current circumstances, to achieve the sustainability of health systems while increasing the availability of new and innovative medicines, it would be necessary to either provide significantly higher funding or change the conditions of approval and conditions under which the pharmaceutical industry proposes and first determines the price of the medicine. In the current situation of the COVID-19 pandemic and the associated costs, this is a great challenge not only for Croatia, but also for all health systems in the EU and beyond.

When it comes to new, innovative medicines, the European Medicines Agency issues approvals for placing medicines on the market, often in the so-called accelerated registration procedures or conditional registration with the aim of making new innovative medicines available to patients as soon as possible. Thus, health insurers who ultimately have to pay for a medicine do not have sufficient data on the long-term efficacy of medicines given that they are approved on the basis of limited data on clinical trial results that are either short-lived or performed on very few patients. In view of the above, we are of the opinion that the rules applicable to pricing and valuation of medicines should be adjusted and that some new procedures need to be established.

Just as the pharmaceutical industry finances the treatment of a patient with a medicine while it is being tested during clinical trials, and health insurance pays for the medicine when the medicine is placed on the medicine list, in a situation where the medicine is administered under an accelerated regulatory authorization or conditional authorization has been granted and the medicinal product is subject to special monitoring, it would be advisable at EU level to consider introducing mechanisms to share the cost of the medicinal product in some way between the pharmaceutical industry and insurers until the new of the regulator confirms that the criteria for unconditional authorization are met for placing the medicinal product on the market, i.e. that the medicinal product is effective and safe for use in a particular indication without restriction.

The crisis caused by the COVID-19 pandemic in the internal market for medicines has reconciled the views of Member States and directed them towards joint decisions and uniform procurement procedures for medicines, vaccines and medical equipment at EU level, and increased cooperation and transparency in general. Our firm view is that such cooperation, to

ensure the sustainability of health systems, needs to be continued in order to ensure the availability of innovative medicines in all Member States. In this context, it is necessary to strengthen the dialogue between the pharmaceutical industry and regulatory structures, both at national and EU level, and we consider necessary the synergistic action of all regulatory structures with a clearly defined goal and how to achieve it. In this regard, we fully support the content and proposals of the Oslo Medicines Initiative.

MINISTRY OF HEALTH

DK Written statement - The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors

Denmark would like to thank WHO Europe and the Government of Norway, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency, for having launched the Oslo Medicines Initiative. An important topic that deserves our focus.

Denmark agrees that reasonable and sustainable access to safe, effective, affordable and quality-assured medicines and health products is critical to universal health coverage and achieving the Sustainable Development Goals.

It is a difficult balance to strike. On the one hand, we need to ensure incentives for companies to continue to develop new and innovative medicines – and on the other hand, we must improve access to medicines and ensure the financial sustainability of health systems in countries around the world.

In this written statement, we focus on how cooperation between countries on joint tendering can contribute to improve access to medicines. We will also focus on mechanisms to slow down the growth in medicines expenditure.

Joint tenders between Denmark, Norway and Iceland

In September 2018, Denmark and Norway agreed on a letter of intent regarding joint tenders and price negotiations for medicines. In April 2019, Iceland also became part of the agreement.

The background for this agreement was the experience of difficulties with:

1) securing access to medicines that have gone out of patent,
2) and challenges with increasing costs for medicines.

The aim of this cooperation is

- to improve security of supply
- to achieve better prices for medicines
- to gain experience that could form the basis for joint tendering for new and innovative products.

Amgros, the Danish regions' procurement organization, has in collaboration with the procurement organizations in Norway and Iceland launched the first joint Nordic tender in February 2020.

The tender included a number of different drugs – primarily older medicines that have gone out of patent and where we have experienced supply failures.

The process of this first joint Nordic tendering procedure took one year and 2 months. This was in part due to differences between the three countries regarding the organizational and regulatory setups.

Despite these challenges, the tender has been a success so far. The procurement organizations have succeeded in getting offers for all the medicines that were included even though the industry was skeptical from the out-set.

The purpose of the tender was to secure the supply of older types of medicines to hospitals. We follow the work closely to assess the results and we are now in the process of preparing the next joint Nordic tenders for medicines.

Joint tenders and joint price negotiations may thus prove to be one way forward to ensure better access and potentially better prices for medicines.

Mechanisms to slow down the growth in medicines expenditure

Use of Generic substitution – a way to increase acces and reduce prices:
Another important approach is the the use if generic medicines. In Denmark, the Danish Medicines Agency decides which generic medicines are suitable for substitution.

Pharmacies are obliged to offer the least expensive products to patient, unless the doctor and/or the patient prefers another product. This allows for competition between the manufacturers of original medicine and several manufactures of generics.

The use of generic medicines has thus led to increased competition, and consequently falling prices for some medicines, which has contributed to Denmark having some of the lowest prices of generic medicines in the EU.

Systematic use of generic medicines is thus also a way of reducing the cost of medicines.

Prioritization of new medicines:
Finally, we would like to raise the issue of prioritization of new medicines. In Denmark, there has been an increased focus on prioritization in recent years, and in 2017, the Danish Medicines Council was established.

The role of the Council is to provide guidance about new medicines for use in the Danish hospital sector. The Council does this through assessments of new medicine by comparing a new drug to the standard therapy used in Denmark. In the assessments, the Medicines Council must ensure that there is a reasonable relationship between the price and the effect of new medicines. If this relationship is considered no to be reasonable, the drug in question cannot be recommended as standard treatment in the Danish hospital sector.

A recent evaluation has shown that The Danish Medicines Council has improved the negotiating position towards the pharmaceutical companies when it comes to the procurement of new medicines.

Systematic assessment of medicines is thus also an important tool in our effort to reduce the cost of medicines.

Finland´s comments on the OSLO initiative

Thank you for the opportunity to comment the OSLO Initiative, "The Oslo Medicines Initiative: Better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors" which was presented in the meeting on 21 January 2021.

In general, we agree that we should more discuss key issues that are affecting access to effective, novel, high-priced medicines and the potential steps to address these. Finland agrees on the importance of the themes of innovative collaborations during the COVID-19 pandemic, on the basis of solidarity, transparency and sustainability.

Finland stresses the importance of controlled introduction of medicines to health systems in order to reduce risks associated with new medicinal products. The marketing authorization is granted to some new medicines on the basis of early and limited evidence. In such cases, the assessment of efficacy, safety and financial risks of the uptake of new medicines are largely shifted to national health systems. This trend has further strengthened with the evolution of personalized medicines. Therefore, the procedures on managed entry require further development.

Answers to some of your specific questions:

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

a) What do Member States and areas see as the major issues affecting access to effective, novel, high-priced medicines?

Medicinal products more often get the marketing authorization with uncertainty regarding evidence, but the price is very high. The effectiveness may be based on changes in surrogate end-points and the follow-up period is short. The marketing authorization is granted with limited information available on whether the medicine should be taken into use and the Member States bear the risk.

b) What promising actions are Member States and areas undertaking to improve access? Examples could include price negotiation, public-private partnerships, novel financing mechanisms, price volume arrangements, risk sharing, and advance purchase arrangements.

In general, it is important to develop risk-sharing agreements; the current models are insufficient. Medicines can come on the market with one indication, but new indications often cover larger or very different patient groups. If evidence is still very uncertain or less effective, health care systems of Member States become major financial supporters of innovations, which should not be their task.

Risk-sharing agreements are steps in the right direction, and we use them in Finland. However, there are problems with transparency of such agreements. We do not know what is or will be the price in other European countries. This was not entirely transparent before, but during risk-sharing agreements, the situation has come even worse. There is a risk that companies will still be able to raise the price level of medicines when, due to risk-sharing agreements, we no longer know what the medicine costs elsewhere in the EU.

c) How can WHO/Europe provide assistance to Member States and areas in their efforts to provide access to the population to effective, novel, high-priced medicines?

Health Tecnhology Assesment – also in the European level - will be one-step forward. We need an objective assessment of the level of evidence, taking into account the risks. Although each country has its own practices and legislation, it would be important for the pharmaceutical industry not to be able to exploit the gaps in the legislation and invoke price secrets. The reduction percentages vary greatly from country to country, which affects the conditions for introduction of the medicinal product.

Solidarity

a) How can existing mechanisms for cooperation and coordination between Member States and areas be strengthened, including joint horizon scanning, procurement and assessments?

There already exist good examples of co-operation, e.g. BeNeLuxA and Valletta co-operations. However, they do not cover all the Member States. Practices in co-operation should be simple enough, but on the other hand take into account the diversity of the needs of Member States.

b) How can WHO/Europe continue to support active and meaningful dialogue between stakeholders?

The active and meaningful dialogue can be supported by providing a forum where different parties i.e. authorities, payers and pharmaceutical industry could discuss and change views. Also sharing of best practices is a good way to foster co-operation and dialogue between different stakeholders.

Sustainability

a) How can Member States and areas contribute to reconciling sustainable pharmaceutical policies and procurement practices with sustainable industry and innovation?

In Finland, growth and renewal in the health sector has been promoted with the National growth strategy for research and innovation announced in 2014. Its implementation has been jointly steered by three ministries (Ministry of Economic Affairs and Employment, Ministry of Education and Culture and the Ministry of Social Affairs and Health) and the providers of funding (Academy of Finland and Business Finland). The aim of the strategy has been systematically develop the sector's operating environment and ensure its competitiveness, boost investments and to achieve economic growth in the sector. Based on know-how, measures have been taken to improve people's health and wellbeing through the opportunities offered by research and technological development.

b) How can WHO/Europe support Member States and areas in this effort with the aim of strengthening effective national governance systems?

Again, providing a forum for discussions and sharing of best practices would be useful tools to support Member States.

საქართველოს ოკუპირებული ტერიტორიებიდან დევნილთა, შრომის, ჯანმრთელობისა და სოციალური დაცვის სამინისტრო

Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

KA030191702897921

საქართველო, თბილისი 0119, აკ.წერეთლის გამზ.144; ტელ.: (+995 32) 251 00 11; ცხელი ხაზი: (+995 32) 251 00 26; 15 05; ელ.ფოსტა: info@moh.gov.ge
144 Ak.Tsereteli ave., 0119, Tbilisi, Georgia; Tel: (+995 32) 251 00 11; Hot line: (+995 32) 251 00 26; 15 05; E-mail: info@moh.gov.ge

№ 01/4441 **29 / March / 2021**

Statement on the Oslo Medicines Initiative

Georgia

Health care policies in Georgia are well align with the objectives of the Oslo Medicines Initiative. We do believe that all three pillars of the Oslo initiative: Solidarity, transparence and sustainability are critical for achieving equitable access to life saving treatment for all in need. Since the initiation of the Universal Health Care Program in 2013, the government of Georgia made access to affordable quality drugs a top priority.

Overall, pharmaceutical care in Georgia featured by the high price of pharmaceuticals locally, and the very high level of spending per capita on pharmaceuticals, which can be catastrophic for households. In 2018, 36% of total-health expenditure was spent on pharmaceuticals in Georgia. The take-up of generic pharmaceutical products is weak as they are not well trusted by patients or professionals, and cost-effectiveness guidelines are not used in most branches of medicine. The cost of outpatient pharmaceuticals is widely seen as the biggest barrier to accessing care. In order to eliminate financial access barrier to essential drugs, in July 2017, the Government allocated substantial financial resources to subsidize costs for chronic disease management drugs for people with disabilities and senior citizens. The program has been fully integrated within the UHC package in 2019 and currently covers up to 200 000 beneficiaries.

In response to the needs and active advocacy by professionals and patient groups, in September 2020, the Government of Georgia (GoG) announced expansion of the groups of cancer medicines covered by the Universal Healthcare Program from chemotherapy and hormone therapy medicines to include monoclonal antibodies, protein kinase inhibitors and bisphosphonates. This allowed for unlimited access to international recognized cancer treatment and provides a good opportunity for improving cancer care outcomes.

Georgia has excellent experience of public-private solidarity and cooperation with stakeholders in providing the population with modern, high-quality treatment for hepatitis C. A multi-year partnership with the Gilead Sciences Inc. which allowed to successfully treat over 50 000 individuals with Gilead Hep C medicines.

We fully realize the importance of transparency to support healthy competition of pharmaceutical market and enable informed decision making by consumers. One of the key mechanisms for the GoG for improving transparency on the pharmaceutical market is introducing digital technologies and registries such as electronic prescription system and a comprehensive listing of authorized pharmaceutical products. A partnership between the Ministry, State Competition Agency and the private pharmaceutical sector is envisioned to develop an online platform for pharmaceutical products for pharmacies and consumers to register online, purchase, compare products and prices of suppliers.

Georgian Regulatory Agency is open to support clinical trials in the Georgian Health Care setting to enable early access to novel and repurposed drugs for treating complex health conditions. A legal framework for authorization of novel drugs relies on WHO

authorization listing and/or authorization by Stringent Regulatory Authorities and does not impose additional administrative barriers to introducing new drugs on the Georgian market. It is important to make data on clinical trial publicly available to build public trust and promote further advancement in science.

These days, when all countries globally make all possible efforts to get access to Covid-19 vaccine the role of transparency becomes even more acute. Countries need to have timely access to reliable data on quality and efficacy of new vaccines as well as pricing.

Sustainability in access to quality pharm products is another key consideration. Work is underway to develop a drug law to ensure the quality of medicines in the country, improve the registration system, regulate prices, introduce GMP standards and to ensure sustainable cooperation between the state and industry. Long-term strategy to strengthen the health care system will be completed by June, one of the priorities of which is to ensure equal access to essential medicines, vaccines and technology. The government was also able to mobilize financial resources for the construction and equipment of a drug quality laboratory.

First Deputy Minister 

Tamar Gabunia

MINISTRY OF HUMAN CAPACITIES
SECRETARIATE OF STATE FOR HEALTH

Questions for the consideration of Member States and areas

5. Scope and purpose of the Oslo Medicines Initiative

a) Do Member States and areas have any comments on the draft Scope and purpose document for the Oslo Medicines Initiative?

We thank the WHO/Europe and the Government of Norway for launching the Oslo Medicines Initiative. We don't have any comments on the draft Scope and purpose document for the Oslo Medicines Initiative.

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

a) What do Member States and areas see as the major issues affecting access to effective, novel, high-priced medicines?

The early access to new innovative products is supported by several ways by the European Medicines Agency. Though market access with less robust evidences is possible the prices of these new medicines do not reflect the uncertainties around their effectiveness and the society's efforts to allow early access thus longer period of exclusivity.

The constitutional right of patients to access appropriate therapy, included the most effective, high-priced medicines and health products, no matter what the price level of a country is. This principle must be taken into account when taking measures.

Finding the right target population for a given medicine e.g. by scientific justification of subgroups by diagnosis, age, background diseases might support rational and optimal use of the medicine. Inclusion of such new information, updates in the Product Information into Continuing Medicinal Educations programs might help spread of not only new information but also of new attitudes of handling drugs by various stakeholders.

Also, high prices can only be accepted by public payers and HTA bodies if the scientific evidence is the highest possible and it is shared amongst Member States to ensure that there is no information asymmetry between them.

b) What promising actions are Member States and areas undertaking to improve access? Examples could include price negotiation, public-private partnerships, novel financing mechanisms, price volume arrangements, risk sharing, and advance purchase arrangements.

The Hungarian health government uses the above mentioned possibilities. Our experience is that the too low prices can be counterproductive, because market authorization holders may lose their financial interest for trade. In our view security of supply is also essential in addition to price.

In Hungary the biggest challenges in drug supply are due to the smallness of the Hungarian market and its low drug prices, especially in a global pandemic situation where there is a competition between the states for effective medicines.

Hungary supports marketing authorization holders of certain essentially important products with low sale data by fee reduction and initiates ex officio (Cyprus Clause) marketing authorization.

In our opinion age appropriate formulations should be encouraged to develop in order to ensure right use of the medicine – thereby ensuring that the active substances are able to reach the body and the site of action and the expected effect can be evoked. It is important to make such „user friendly" formulations widely available.

There are several initiatives within the EU to achieve joint assessment and procurement (BeNeLuxA initiative, the cooperation on Fair and Affordable Pricing of Medicinal Products, the La Valetta Group, the Baltic initiative, the Nordic cooperation for joint procurement of hospital products) and there is the Joint Horizon Scanning project initiated by the Dutch government. Hungary is an active member in EUnetHTA and engages in cooperation with regional countries as part of the cooperation on Fair and Affordable Pricing of Medicinal Products. This cooperation focuses on information sharing and exchanging good practices on the reimbursement decision making procedure.

c) How can WHO/Europe provide assistance to Member States and areas in their efforts to provide access to the population to effective, novel, high-priced medicines?

WHO/Europe can provide assistance with resource research, facilitation of cooperation, development of methodologies that allow as many patients as possible to have access to therapy and with summarisation and publication of international experiences.

WHO/Europe should reflect more openly on potential malpractices in the process of providing access to novel medicines (for example, by highlighting decisions lacking sufficient scientific evidence).

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?

In our view setting up working groups can facilitate the exchange of experiences.

Good example is the SPOC network, forum of cooperation and exchange of information between Member States, especially with the involvement of industry (i-SPOC). It is a great help in planning and identifying critical areas or in identifying those areas that will become critical in the future. SPOC helps to do the better preparation in shaping the critical list of medicinal products.

SPOC places particular emphasis on sharing international experience related to Covid-19 pandemic and is even developing a methodology for planning and calculating the needs for medicines in a pilot study.

WHO/Europe may also contribute by helping regional co-operations to gain more visibility and ensuring that stakeholders are aware of them and able to distinguish them from each other in terms of their objectives. Finally, WHO/Europe can provide assistance with helping to develop and disseminate state-of-the-art examples on cooperation.

b) How can WHO/Europe continue to support active and meaningful dialogue between stakeholders

By inviting stakeholder representatives to the working groups/meeting opportunities for the stakeholder representatives, in order to fruitful cooperation, similar to Shortage-SPOC and i-SPOC system.

WHO should be more actively engaged into discussion on fair pricing (eg. fair pricing model of the Association Internationale de la Mutualité - https://www.aim-mutual.org/ or the fair price discussions organised by the Association of European Cancer Leagues) and facilitate the introduction of fair pricing policies.

WHO could facilitate the coordination of external reference pricing activity of the countries eg. by promoting the Technical Guidance Document of the EURIPID Collaboration on External Reference Pricing.

8. TRANSPARENCY

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

The Hungarian National Institute of Health Insurance Fund Management is one of the founders of the EURIPID Collaboration which maintains the EURIPID website and database. The EURIPID project is globally the most advanced initiative to share pricing information of medicinal products.

In our view the EURIPID project could be strengthened by the following ways in order to help the implementation of the WHA resolution:

- the EURIPID project could be extended to those countries of the European region who are not yet participants in line with the decision of the members of the EURIPID Collaboration

- the sales volume information of the EURIPID database could be extended to those countries who not yet share this information

- the information on the existence of managed entry agreements should be extended to those countries who not yet share this information

The transparency in some areas is a new practice we need to improve our knowledge in it also by campaigns and by coaching. Healthcare professionals, epidemiologists, PR - experts or economists could share new and effective methods in healthcare system.

Translation to the national language ensures wider availability of mentioned resolution.

Hungary disassociated from resolution 72.8 as we maintain that the final text lost the right balance between transparency required from industry and that expected from State Parties though Hungary is open to consider increasing transparency of pricing of medicinal products.

b) How can WHO/Europe support national governments in the development and implementation of World Health Assembly resolution WHA72.8?

WHO/Europe can support national governments in the development and implementation of World Health Assembly resolution WHA72.8 with permanent dialogue between the health government, pharmaceutical authority and other state bodies, stakeholders and healthcare professionals.

In our view involving experts from professional organizations and clinical centers is important to use the experiences of hospital pharmacies, and to know the utilisation data of the medicines.

The Hungarian Medicines Authority (National Institute of Pharmacy and Nutrition) has also established good relations with patient organizations.

Website of The Hungarian Medicines Authority also supports the information to patient.

WHO could facilitate the cooperation between EURIPID and the non-European countries by setting up discussion fora.

WHO could also facilitate discussion within the stakeholders to explore options for sharing the contents of Managed Entry Agreements.

9. SUSTAINABILITY

a) How can Member States and areas contribute to reconciling sustainable pharmaceutical policies and procurement practices with sustainable industry and innovation?

Hungarian experience is that the creation of the list of critical medicinal products helps to make the preparation of the public procurement procedures including the selection of the medicinal products to be subjects for public procurement procedures.

We note that it would be safer from the pharmaceutical supply point of view, if there would be possibility for choosing more than one winner at the end of the tender procedures. Our experiences show that a single winner in case of unexpected hazards might not be able to meet the requirements laid down in their contract which itself presents a risk and could greatly jeopardizes the patient care.

b) How can WHO/Europe support Member States and areas in this effort with the aim of strengthening effective national governance systems?

WHO/Europe can support Member States and areas in this effort exploring and sharing good practice among nations and initiating and organizing trainings to learn and develop best practices.

OFFICE OF THE DEPUTY PRIME MINISTER
MINISTRY FOR HEALTH
PALAZZO CASTELLANIA, MERCHANT STREET, VALLETTA, MALTA

Online Member States Consultation on Oslo Medicines Initiative, 21st Jan 2021

Intervention by Hon Chris Fearne, Deputy Prime Minister and Minister for Health, Malta

Thanks to WHO Europe and congratulations to our Norwegian colleagues. This is an extremely important discussion and as some of you may know a topic which is very close to my heart.

Where are we and where have we started from, where have we come. The argument has been very well made that high-priced innovative measures are putting strains on our budgets and are leading to a risk of decreased access to our patients, which of course no one wants anywhere and from all aspects. One of the ways Member States have been trying to address this by trying to come together as Member States attempting to negotiate and procure jointly. There is the Scandinavian initiative, the Beneluxa, the Eastern European initiative and the Valletta initiative mostly for Southern European States; and over the years these have developed, there have been discussions, there have been one or two successes, but mostly where we are now is debating the issue of transparency.

So on the one hand the pharmaceutical industry maintains that transparency will actually bring medical prices up; the pharmaceutical industry maintains that once there is price transparency they will not be able to give preferential discounts to, they claim, lower income countries, and the reference price will be the price for everyone, and, they claim, that that will mean that prices will come up. Of course, we only have their word for that, because this is all wrapped up in secrecy.

On the other hand, Member States and authorities, have been saying over the years that joint procurement works; that if you negotiate as a region, possibly as a union rather than as a single country or single authority, then your negotiating power is stronger and you can possibly negotiate better prices. And the only way we can negotiate jointly is if we trust each other as authorities and member states and the only way we can do this is if there is price transparency.

So price transparency, in and of itself, is of course extremely important and the point has been made, rightly, that in a democratic society we owe it to our citizens to be transparent in anything we do, including in how we buy and procure our medicines. But equally important, transparency is the keystone to allow us to work together to jointly procure medicines, to jointly negotiate with the pharmaceutical industry and therefore to bring process down.

Up to now there hasn't been a lot of evidence whether the argument for price transparency and joint procurement brings medicines prices up or down. As rightly pointed out there is a document that the European Observatory are preparing that was commissioned by Malta a few months ago and so far, real world evidence seems to be scarce. However, to my mind this has all changed in the last couple of weeks. So yes the pandemic has been a dark cloud over all of us, but this dark cloud has a silver lining, and I think that the silver lining is that the European Health Ministers, European Member States led by the European Commission, have managed to come together to concretely procure vaccines as a block .

We have negotiated with a number of companies as a bloc and we have procured vaccines as a bloc. And this has not only allowed access to a scarce resource, which is the vaccine, to all citizens in Member States, but it also allowed us to negotiate the price, and to my mind, we negotiated the price favourably. And we could only do this because there was full transparency in these negotiations between all Member States. And yes, this has proven without doubt that transparency is extremely important and the only way there can be joint procurement; and that joint procurement through transparency, manages to keep prices down.

So I think the answer is there, it's open, and the model has been set; there is scope in joint procurement, there is scope in coming together: I believe that this is probably the European Union's finest moment, that we've managed to work together in a crisis and do something that we have been talking about and trying to do over the years and never managing. It's now up to us to ensure that this model that works, that seems to have worked for the vaccines is taken forward for orphan drugs, for innovative medicines, for cancer treatments because this is the way forward.

So, price transparency works because it allows joint procurement and joint procurement brings prices down, and I think the jury is in.

I think this is an extremely important development which can be taken forward and once more I congratulate WHO and our Norwegian colleagues because this is a crucial and extremely important topic to be discussing.

Thank you very much.