AVAILABILITY | ACCESSIBILITY | AFFORDABILITY
OF MEDICINES & MEDICAL DEVICES

3A CONFERENCE

29 | 30 APRIL 2021 IN VIRTUAL FORM

CONFERENCE REPORT

This conference is funded by the European Union's Health Programme (2014-2020).*

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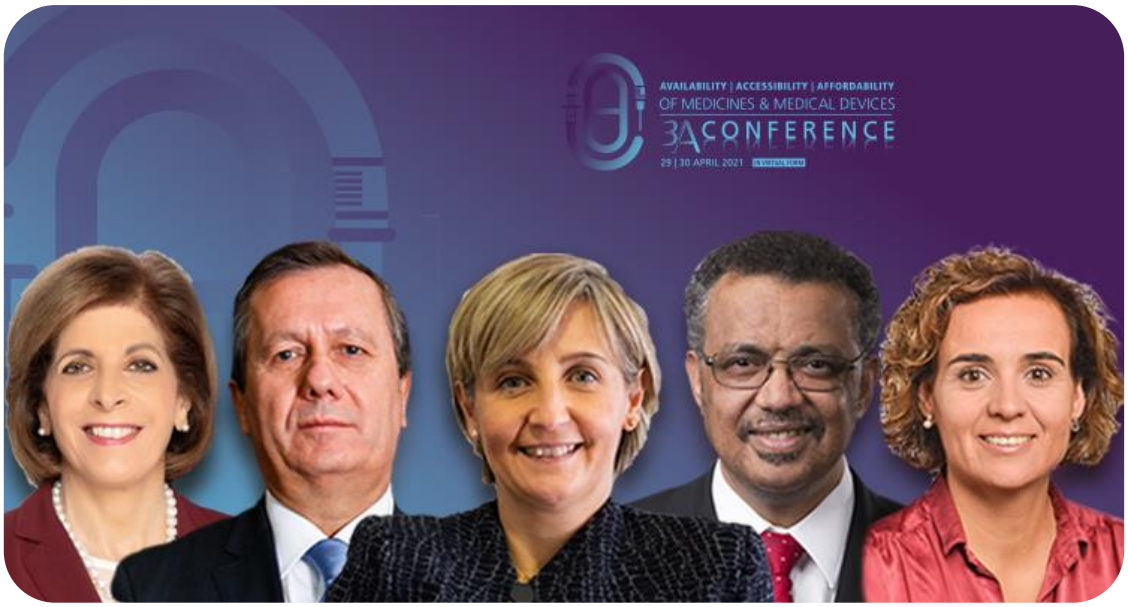
THE 3As CONFERENCE
"Accessibility, Availability & Affordability of Medicines and Medical Devices"



Report on the results and conclusions

The 3As Conference "Accessibility, Availability & Affordability of Medicines and Medical Devices" was held on the 29th and 30th of April 2021. The event took place in Lisbon, in a virtual format, under the Portuguese Presidency of the Council of the European Union, co-organised by the Ministry of Health and INFARMED - National Authority of Medicines and Health Products, I.P., in collaboration with the European Commission.

The objectives

One of the priorities identified by the Portuguese Presidency is "Supporting Sustainable, Equitable and Universal Access to Medicines and Medical Devices". This priority was built on structured discussions around three main pillars: availability, accessibility and affordability. In this context, the Conference aimed to give a new and renewed momentum to the discussion on how to address these longstanding topics that have been on the agenda in the European pharmaceutical policy. Therefore, it is necessary to continue the debate in the field of pharmaceutical policy at EU level, addressing European and national developments and challenges in the various aspects of the subject in an integrated, ethical, and sustainable manner.

Enhancing cooperation between EU countries is a key factor in the improvement of the accessibility, availability and affordability of medicines and medical devices. Hence the need to promote a discussion on pricing and

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reimbursement policies, cost effectiveness of medicines, how public incentives are translated into the price of the product, regional collaborations, the transparency throughout the value chain and the overall sustainability of health systems. During the Conference, it was also discussed how ensuring access and accessibility when meeting needs and unmet needs and how to improve the market launch of centrally authorised products. In this sense, to achieve a more equitable and adequate patient access to health technologies, it is fundamental to keep working and promoting accessibility.

The 3As Conference promoted a multi-stakeholder debate on these specific issues pertaining to the identified topics to inform collaborative approaches, define priorities and policy options to be translated into concrete actions, aiming ultimately to contribute on promoting a European Health Union, through a larger and better cooperation between the different national competent authorities (NCA) and stakeholders in the EU, namely, in the area of medicines and medical devices.

The speakers

In order to engage in these priorities, it was essential to gather those with the highest responsibilities in the European pharmaceutical policy and bring together the stakeholders that produce the knowledge and make the decisions on these specific issues. To this extent, the keynote speakers invited were the World Health Organisation (WHO) Director, Tedros Ghebreyesus, the European Commissioner for Health, Stella Kyriakides, the Member of the European Parliament, Dolors Montserrat, and the Portuguese Health Minister, Marta Temido. Additionally, 40 high-level speakers from NCAs and associations participated in the Conference. These include the Executive Director of the European Medicines Agency (EMA), Emer Cooke, the representative of DG Santé, Andrzej Rys, different Heads of Medicines Agencies, such as Christa Wirthumer-Hoche, Head of the Austrian Medicines and Medical Devices Agency (AGES), Kristin Raudsepp, Director General at State Agency of Medicines in Estonia (SAM), Karl Broich, President of the Federal Institute of Drugs and Medical Devices (BfArM) Momir Radulović, Executive Director of the Agency for Medicinal Products and Medical Devices in Slovenia (JAZMP) and Maria Lamas, Director of the Spanish Agency of Medicines and Medical Devices (AEMPS). The Director General of EFPIA, Nathalie Moll, the President of Medicines for Europe, Christoph Stoller, the President of the European Patients Forum, Marco Greco, Serge Bernasconi from Medtech Europe and Annabel Seebohm, the Secretary General from the Standing Committee of European Doctors (CPME), as well as Yannis Natsis, Policy Manager from the European Public Health Alliance (EPHA), the Director General from the European Healthcare Distribution Association (GIRP) and Illaria Passarani, the Secretary General of PGEU were a few of the other presenters during the Conference.

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OPENING SESSION

OPENING SESSION

Marta Temido
Portuguese Minister of Health

This conference is a crucial moment in the pursuance in the set of priorities defined by the Portuguese Presidency in the field of health.

Health threats know no-boarders. For this reason, their handling requires increased cooperation, expertise and solidarity. We must increase our cooperation at the European and global level by ensuring better quality of life for our citizens.

The pandemic has underlined the urgency of making sure the readiness of medicines and medical devices. In that light, broadening cost-effective and equitable access to health care, particularly in accessing innovative health technology is a keep tool in pursuing the ambitious project for a true European health system.

Our collective challenge has been made clear, we must work together to build a stronger Europe and reinforce the citizen's trust in the European social model, by promoting a Europe rooted in cohesion and cooperation.

We need a strong and coordinated Europe to respond to future crisis. This context serves a stepping stone in organising this Conference that will bring forward these issues to the forefront of our response to collective challenges.

Tedros Adhanom Ghebreyesus
Director-General, WHO

Access to medicines and medical products have always been a central element of health.

The COVID-19 crisis has exposed the need for more resilient health systems that can ensure uninterrupted affordability, availability and equitable access to medicines and medical technologies.

We now need to expand the efforts to close the gaps and overcome the limitations of current incentive models for research and innovation. WHO welcomes the Pharmaceutical Strategy for Europe and the EU4Health programme that will finance strategies aiming to reduce the fragmentation and vulnerability of medical products supply chains.

Creating an environment for a competitive and efficient European Pharmaceutical Industry is of strategic interest for public health, not only in Europe but globally to stabilize supply chains and deliver quality assured products.

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The pandemic has shown that health is not a luxury for the few but a human right and the foundation of social, economic and political stability. We must work in the world in which all people have access to all medicines and medical products they need.

Stella Kyriakides
European Commissioner for Health and Food Safety

We are building the foundations of a stronger European Health Union in which 27 will work together to detect, to prepare and to respond collectively to cross-border health crisis. The EU health union will equip the EU and its Member States to better prevent and address future pandemics, to improve the resilience of Europe's health system and hence it will enable us to protect the health of our citizens.

In November 2020 we put a series of proposals to create a patient-centered and future-proof and crisis resilient pharmaceutical system in the form of the pharmaceutical strategy for Europe. It draws on lessons learnt from COVID-19 crisis, but primarily addresses the long-standing challenges of availability, accessibility and affordability of medicines across the EU.

This is a period of rapid change and innovation, but medicines are often unaffordable or unavailable for those who need them the most, the patients. The objective is clear, the strategy needs to support patient-driven innovation, security and continuity of supplies, resilient supply chains, reduction of systemic shortages, availability and affordability. No patient in Europe should be deprived of the medicines that one needs.

Dolors Monserrat
Member of European Parliament, ENVI Committee Representative

Reflection on the future of the Union is a key moment and it is clear that the pandemic has propelled our work and our agenda.

Building a strong European health sector, strengthen European health policy, promote equal and affordable healthcare for all European citizens is a top priority, especially concerning the future of Europe.

When we look back at the European Union performance on the vaccines, there will be a positive story to tell and a wider lesson to learn. Simultaneously, we are working together with the WHO in the Covax platform which is very important since it will help to provide vaccines around the world.

Europe has shown resilience and strength during the COVID-19 pandemic. The critical point of our health systems has also been exposed. Consequently, it is crucial to draw on the lessons learned from the pandemic in order to strengthen on the European health

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policies and legislative frameworks to increase preparedness and better meet the medical needs of European citizens.

The European Parliament and in particular the ENVI Committee, have been in the forefront of these regulatory processes.

A thriving and technically advanced European healthcare industry and a competitive research community are vital. This requires an ambitious, clear and up-to-date regulatory framework.

INTRODUCTION TO THE CONFERENCE

Rui Santos Ivo
President of Executive Board INFARMED, PT

This is the moment for us to come together and discuss the challenges regarding availability, accessibility and affordability of medicines and medical devices. We need to address them in an integrated ethical and sustainable way, in the spirit of European solidarity and leave no one behind.

We have promoted dialogue and co-operation to enhance knowledge, trust, confidence and transparency between all the relevant actors in the pharmaceutical area, in order to strengthen public health in Europe.

The COVID-19 pandemic has shown us the need to work together to jointly address the challenges we face as Europeans and that go far beyond the pandemic.

Our conference aims to give a renewed momentum to the discussion on how to address these longstanding topics that have been on the agenda of those with the highest responsibilities in the European pharmaceutical policy and look to the future, to a post-COVID pharmaceutical and health sector.

To hear the opening remarks, please click here.

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PANEL I

AVAILABILITY OF MEDICINES AND MEDICAL DEVICES

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Panel I: Availability of medicines and medical devices

Moderator: Christa Wirthumer-Hoche
AGES, AT

Addressing shortages: Preliminary results from the Commission study

Andrzej Rys
European Commission

Availability of medicinal products

Nuno Simões
INFARMED, PT

A common understanding for a list of critical medicines and medical devices

Noël Wathion
EMA

The first panel focused on the challenges of shortages, with much input from the lessons learned from the fight against COVID-19. Andrzej Rys, of the European Commission, presented the preliminary results from the Commission study. The pharmaceutical strategy discusses the revision of the current pharmaceutical legislation to address shortages through specific measures, such as the strengthening of supply obligations, greater transparency, earlier notification of shortages and stronger EU coordination. The strategy will also consider the contribution of results from the on-going study on root causes of shortages, which is expected to be concluded in the third quarter of 2021. The main goal of the study is to look for solutions to guarantee the regular and continuous supply of the market. The Commission is identifying and evaluating the current strategic dependencies, in order to propose measures to reduce the respective dependencies, including the diversification of production and supply chains, strategic stockpiling, fostering production and investment in Europe. The first step is to map vulnerabilities, including dependencies, of the supply chains and gain good understanding of the supply chain situation in order to propose concrete actions. Furthermore, Mr. Rys emphasised the ongoing work of the Structured Dialogue which involves actors of the pharmaceuticals manufacturing value chain, public authorities, patient and health non-governmental organisations and the research community. This initiative is a key priority for the Commission with the purpose of strengthening the resilience of the pharma supply chains as well as ensuring

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the security of supply of medicines. To this extent, the first phase of this process includes an in-depth understanding of the functioning of global supply chains and consequently identify the precise causes and drivers of different potential vulnerabilities. The second phase ecompasses a set of measures to address the identified vulnerabilities and formulate policy options to be considered by the Commission and other authorities in the EU accordingly.

Nuno Simões, from INFARMED, spoke about the availability of medicinal products. He touched upon shortages being a global concern. There are various reasons as to why shortages are multifactorial, manufacturing and quality problems; active pharmaceutical ingredients and raw materials; unexpected increase of demand; logistic (delays); parallel trade; non-compliance of legal responsibilities; commercial strategies and pricing and reimbursement legislation. To this end, stakeholders must provide regular and continuous market supply tools, give an early notification of shortages (at least 2 months), a minimum safety stocks (of at least 2 months), create shortage prevention plans, design a shortage risk management strategy as well as avoid discriminatory practices. Moreover, Mr. Simões explained how the ongoing initiatives such as the Pharmaceutical Strategy for Europe, the Structured Dialogue, the legal proposal on the reinforced role of EMA or the Commission's study on shortage aim at tackling such issues. Furthermore, Mr. Simões reiterated the need for action to better understand the drives and vulnerabilities of supply chain and the importance of promote the sharing of information between public authorities. As such, strengthening partnerships between all stakeholders and have a proactive approach is key for a stronger cooperation at the EU level. In summary, regulatory flexibility, transparency of supply chains, better information and communication tools are key to address shortages. To manage the availability of medicines on a national level, INFARMED, I.P., has created a dedicated an inter-institutional and Health System Projects Unit (USS) that focuses and exchanges information and coordination with Heads of Medicines Agencies (HMA), wholesalers and pharmacies. INFARMED also utilises regulatory instruments to mitigate the impact of shortages in public health: such as exceptional authorisations, import authorisations, export controls and liaises with the National Commission of Pharmacy and Therapeutics.

Lastly, Noël Wathion, from EMA, presented a common understanding for a list of critical medicines and medical devices as well as the importance of the reinforced EMA mandate. The two key ideas identified in this panel were the relevance of cooperation and transparency. Mr. Wathion highlighted that shortages are a global and growing problem related to manufacturing or quality (GMP) and/or economical (marketing / reimbursement decisions) factors. This impacts both patients and health systems and may lead to the rationalisation of medication, delays in treatments and use of potentially less effective therapeutic alternatives. Henceforth, the availability of medicines and medical devices are priorities of EMA mandate. The reinforced EMA role will underline a greater presence in the management of critical shortages as the majority are managed at national level. Furthermore, Mr. Wathion explained how regulatory authorities - within and outside Europe - are increasingly working together to prevent shortages and to limit their impact whenever they occur. To this extent, in December 2016, a joint HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM) was established to provide strategic support and advice to tackle disruptions in supply of human and vet medicines and ensure their continued availability. Concerning the EU response to shortages during the COVID-19 pandemic, Mr. Wathion explained that the EMA was requested by the Commission and the Member States to increase its involvement in

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the handling of medicine shortages and it initiated a number of activities, which include, amongst others, the creation of an EU Executive Steering Group (ESG) on shortages of medicines caused by major events; the increased cooperation between the EMA in cooperation with the Commission, HMA and CMDh to establish a list of critical medicines for use in COVID-19 patients; the EMA programme on the i-SPOC (Single Point of Contact) system in April 2020, in relation to COVID-19 medicines (ICU setting); the common framework for forecasting demand data in the EU/EEA (ad hoc Working group on forecasting demand data) and the EMA use of the EU SPOC network for sharing information between Member States, EMA and the Commission on critical medicine shortages in the context of COVID-19.

The new legislative proposal establishes obligations for companies and Member States to report to the Agency information about shortages, supply capacities and demand data, in order to facilitate the establishment of recommendations and coordination of measures to prevent or mitigate shortages. Furthermore, when dealing with shortages of critical medicines, essential substances need to be available at all times. The legislative proposal for a reinforced EMA role in the shortages management reflects much of the processes that EMA had put in place already for the COVID-19 pandemic (and even before) but formalises these systems making them more robust. The new legislative proposal puts clear obligations to companies and Member States for reporting on shortages, supply capacity and demand data to the Agency, which will facilitate setting recommendations and coordination of measures to prevent or mitigate potential or actual shortages.

In the short Q&A section at the end of the panel, Christa Wirthumer-Hoche emphasised the importance of communication and cooperation between Member States to have a clear exchange of what is happening amongst Member States to ultimately avoid duplication of work. Additionally, it is crucial to have a more centralised and analytical approach in the EU to really improve the resilience of the supply chain and the health system overall to increase cooperation, collaboration and transparency.

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PARALLEL BREAKOUT SESSIONS

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Parallel breakout sessions: Stakeholders solutions to medicines shortages

Moderator: Kristin Raudsepp
SAM, EE

Rapporteur:
Hugues Malonne
FAMHP, BE

Breakout session 1: National experience on shortages management

In this breakout session, the case study of Belgium was discussed. The case study discussed the Belgium working group on medicines shortages where patient and continuity care entities are involved, such as FAHMP, Ministry of Health, Social security entity NIHDI, FPS Economy, industry, wholesalers, parallel traders, hospital pharmacists and public pharmacists. This platform was put in place to exchange and interact with information. Belgium introduced of a new act to combat medicines shortages in 2019 and it included a definition of shortages, mandatory notification of shortages that allowed the FAMHP to publish guidance.

The need to define and identify what critical medicines and critical issues are was also a topic of discussion. Prices are indeed a problem in this context due to its a powerful driver for parallel trade which is very often is seen as a gateway. Furthermore, the significance of not blocking parallel trading was considered, whilst being careful that this is not an incentive that may cause a disruption in the market. This needs to be dealt in a common and unified way to protect EU citizens.

Rapporteur:
Josipa Cvek
HALMED, HR

Breakout session 2: Shortages management plans to avoid availability problems

Initiatives focusing on the stability of pharmaceutical supply chain are key to address shortages. There is no quick solution to implement a single measure to prevent shortages but early communication strategies on possible supply disruptions between stakeholders within the supply chain, management of shortages with patient-oriented focus and the prioritisation of specific patient groups are ways to address this issue.

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Regulatory and strong focus should be moved from safety and efficacy to quality and strong policies. To take advantage of forecasting, it was suggested the creation of an EU platform to monitor manufacturing stock levels to ensure manufacture responsibilities. For example, to have buffer stock for procurement procedures. The priority should be always patient focused approaches, especially towards those who are most vulnerable.

Rapporteur:
Aida Batista
EAHP, PT

Breakout session 3: Hospital pharmacy solutions for availability problems

Hospital pharmacies have a direct effect in the efficient functioning of medicines supply chain and operation of medicines in the reimbursement system. This enables patients in hospitals to benefit from sustainable and equitable medicines. However, there are barriers to treatment assessment, one of them being the procurement practices and policies leading to pricing and reimbursement which can tackle medicines shortages.

Additionally, national policy choices linked to procurement, value assessment and price mechanism should safeguard the patients' needs. It should be ensured that innovation is used in patients that need a specific medicine. More resources should be invested to accomplish this outcome. Hospital pharmacies are involved in the Structured Dialogue initiative to address shortages in two dimensions: critical medicines and the vulnerabilities of the supply chain.

Rapporteur:
Monique Goyens
BEUC

Breakout session 4: Consumers and patients' perspectives on medicines shortages, the case of small volumes and limited use medicines

From the consumers and patient's perspective, Ms. Goyens explained that shortages could be linked to the commercial strategy of a company to withdraw a product from the market, creating an artificial shortage and consequently putting the product at a much higher price.

Solutions to address shortages could additionally focus on parallel import as an option. For this reason, companies need to regularly notify the NCA when there is a situation of shortages and there should be a public report on such shortages via a database that is accessible to all stakeholders.

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Moreover, Ms. Goyens suggested creating a high-level forum with stakeholders, patient and consumer representatives to address shortages and increase transparency throughout this process.

To conclude, it was discussed the need for stronger obligations on companies in terms of presenting the market authorisation process and also introduce a medicines shortage projection management. Once a company has a marketing authorisation holder, there should be an obligation to the market too.

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PANEL II

INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS

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Panel II: Innovation and accessibility of medicines and medical devices to patients

Moderator: **Karl Broich**
Bfarm, DE

HMA-EMA joint strategy 2025

Emer Cooke
EMA

Svens Henkuzens
ZVA, LV

The second panel focused on the implementation of the EMA Network Strategy 2025. Emer Cooke, Director of EMA presented the set of goals for the coming years. The EMA/HMA agreed on six strategic focus areas for the next five years which are: availability and accessibility of medicines, data analytics, digital tools and digital transformation, innovation, antimicrobial resistance and other emerging health threats, supply chain challenges and the sustainability of the Network and operational excellence. On the theme of availability and accessibility of medicines, two goals were presented: strengthen availability of medicines to protect the health of EU citizens and animals and optimise the path from development and evaluation through to access for beneficial medicines through collaboration between medicines regulators and other decision makers. To strengthen the availability of medicines an efficient and targeted regulatory measure will be made possible through an in-depth understanding of the root causes of unavailabilitu of patented and off-patent products. To optimise the path from development to access of medicines, it will be done through evidence planning, engagement in the evidence review and methodologies and collaborate on horizon scanning.

On the theme of innovation, the goals presented by Ms. Cooke, were to catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support

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innovators in various phases of medicines development. A few objectives are to support the integration of scientific and technological progress in the development of medicines (e.g. precision medicine, biomarkers, 'omics and ATMPs) and ultimately into patient treatment and implement an EU-level model for efficient, timely and coordinated horizon scanning and priority setting that fulfils the needs of both regulators, HTA-bodies and payers. Another goal is to foster collaborative evidence generation – improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities.

Some objectives are to foster innovation in clinical trials and develop the regulatory framework for emerging clinical data, develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance. Additionally, it is fundamental to foster collaboration, whilst improving the scientific quality of evaluations and ensuring useful generation of evidence for all actors in the lifecycle of medicines, including Health Technology Assessment (HTA), and pricing and reimbursement authorities.

Svens Henkuzens, on behalf of the HMA, presented the vision and mission of the Network which ultimately aims at protecting and promoting public health in Europe. Furthermore, its misison includes fostering an effective and efficient European medicines regulatory system. Mr. Henkuzens, explained the close cooperation with EMA and the Commission and how the HMA is committed to being trustworthy by being receptive to new knowledge and sound argument whilst adapting its positions and strategies. Additionally, the HMA is committed to securing the efficient and effective operation of both the European Medicines Regulatory System and the Network and wants to ensure that there are sufficient available resources are to support the work of the network. Mr. Henkuzens also presented the six focus areas of implementation of the European Medicines Agencies Network (EMAN) Strategy to 2025. These include: antimicrobial resistance (AMR) and emerging health threats; availability and accessibility of medicines; innovation; supply chain challenges; data analytics, digital tools and digital transformation; sustainability of the network and operational excellence. Mr. Henkuzens also illustrated the scheduled timeline on the implementation of the strategy: The Programming Document for 2020-2022 which has already been approved and the conclusion of the HMA Multi Annual Work plan 2021-2025. Plans for the implementation of the strategy consist of continued collaboration between the EMA/HMA in order to identify and translate actions into the relevant work-programmes/implementation plans, the EMA multi-annual programming 2021-2024 which has 3 main pillars: products related activites, strategies and public health activites, programmes and projects, another implementation method. An overall review of the strategy will be conducted every 18 months to ensure that all goals and objectives are still applicable.

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PARALLEL BREAKOUT SESSIONS

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Parallel breakout sessions: Panel II

Moderator: **Karl Broich**
Bfarm, DE

Rapporteur:
Helena Fonseca
PDCO

Rapporteur:
Violeta Stoyanova-Beninska
COMP

Breakout session 1: Access to medicines for special populations - Orphan and Paediatric Regulations & Revision of the system of incentives

This breakout session addressed the EU regulation regarding orphan and paediatric medicines. It was recognised that many therapeutics have become available, but they are not enough, especially when the needs are higher. In 2000 and 2006, the EU introduced two regulations to foster the development of medicines for rare diseases and for children. Both regulations address the lack of medicines available for the patient groups concerned. The objectives of these regulations partly overlap as most rare diseases may appear already within the paediatric age range and many diseases that affect only children are rare. Professor Fonseca reflected on the recent outcomes on the joint evaluation of both regulations, published in August 2020, which identified an insufficient development in areas of greatest unmet medical needs (UMN), particularly for mental health and neonatal care.

Additionally, the outcomes also recognised that scientific and technological developments may not be fully exploited. The paediatric regulation has promoted an increase in clinical trials in paediatrics and currently there are more therapeutic alternatives available in the market. Market incentives directed towards pharmaceutical companies play a role on increasing the development of these medicines and its availability. It is crucial to explore medicines that are dedicated to conditions affecting children. Incentives should be attractive but also lead to rapid availability of medicines in the Member States.

Professor Fonseca, presented a summary of options to avoid bureaucratic processes and simultaneously address the modifications proposed to the current system of rewards. For example: the 6-month extension for supplementary protection certificate (SPC) should remain the main reward provided by the legislation. This also

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gives the possibility to link this reward to a timely completion of paediatric investigation plan (PIP) as well as to place on the market in most/all Member States on assessment. This option builds on the above-mentioned but particularly for products addressing unmet needs for children, a novel reward would complement or replace the SPC extension. Possible novel rewards could involve the extensions of regulatory rewards (data and market protection) or various types of transferable "vouchers" (e.g., priortiy review or regulatory rewards vouchers).

To conclude, Professor Fonseca expressed the importance of a coherent approach through potential combinations of options; possible synergies, overlaps and common solutions for both areas of rare and children's diseases and a holistic reflection on the pharmaceutical sector.

Dr. Stoyanova-Beninska took the floor to discuss the problems identified in the evaluation of the Orphan regulation, where there is no link between incentives in the current provision and placing a product on the market (orphans). Currently, under discussion on UMN, experts are discussing where there is a need to incentivise on two levels: the seriousness of the disease and the available treatments in place.

Additionally, Dr. Stoyanova-Beninska discussed options available to the modifications to the current system of rewards which include: market exclusivity and extension, changes to the current threshold (building on the option above-mentioned), address UMN in rare diseases and rare paediatric diseases to explore novel incentives, more variation of UNM and market exclusitivity can be one of the incentives but combinable with the other options presented in the discussion.

Rapporteur:
Elisabeth Kasilingam
EPF

Breakout session 2: Unmet medical needs- medicines and medical devices research in view of patients and health systems needs

During this session, the need to better define UMN was identified. There is still a lack of a common definition and a meaningful patient involvement. It was identified that all patients need to be considered during a crisis. The current Governance Model is not enough to address the patient needs. From a European Patients Forum (EPF) perspective, further understanding on real world evidence (RWE) is needed to better understand the patient's priorities and needs. How to consider RWE should also be

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considered by understanding priorities better and creating a more patient centric approach. There is a need to reinforce the strategies in place and develop stronger coordination. There is also a need to better explain the strategies that already exist and to align the coordination of these strategies too. Futhermore, there is a need to find ways to keep pushing for full patient intervention and expand on the tools that allow for this.

Rapporteur:
Cesar Hernandez
AEMPS, ES

Breakout session 3: How the repurposing of old medicines may add new value on patients' access to new therapies

In this session, experts discussed the need to focus on regulatory pathways to recognise indications for old products and its importance when it comes to repurposing old medicines. The discussion between participants around what should be done to have regulatory pathways recognise indications regarding old products led to the following ideas: pharmaceutical legislation invites for more repurposing whereas outside the normal regulatory arena, other factors make repurposing less attractive, such as, substitution when the medicinal product is marketed. Repurposing is often a difficult topic to discuss and find solutions for as there to be a pathway established through pharmaceutical legislation.

Furthermore, many challenges are seen outside of the regulatory pharmaceutical system as well. There are many substituitions for medicinal products in Member States and these may undermine the repurposing systems. As this is mostly national competence, it is difficult to make alterations and is still less attractive for companies to repurpose even if there are incentives. Moreover, price and reimbursement are also other factors that affect the repurposing of old medicines. Another issue is if it remains as an off-label product, it then becomes an issue regarding privacy and reimbursement for the country. Most of the HTA payers rely on licences which come under strict regulations. By repurporsing, the question then becomes who will hold the marketing authorisation for that particular product.

Academia is a great asset regarding the repurposing of medicines as they learn from various branches of civil society, gather all the available information to support the repurposing. However, they do not have the necessary experience to apply for marketing authorisation which could be a very complex process for academic organisations. A possible solution would be to integrate academia and the pharmaceutical industry together as both have opposite strengths and combined,

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could result in new methods to repurpose medicines. For companies, high incentives might be needed but these should also not be excessive. Use of observational data for regulatory approval and HTA depend on the medicines and where the biases are.

The future of medicines may be around clinical trials which can be complemented with other data. Regarding the amount of data, repurposing would not work if the cost would be the same as the new indication for a new medicinal product. Another possible solution would be to create a repurposing ecosystem with adequate incentives created. For instance, the WHO has ongoing discussions about fair pricing. In the past, there are a number of examples where medicines have been bought and repurposed which led to prices becoming very high. The difficulty with repurporsing is going beyond the legislation currently available and finding a new pathway that will change prices and benefit both label and off-label products.

Rapporteur:
Xavier Kurz
EMA

Breakout session 4: Generation of evidence for a better patient access & Health data space and big data - shared data for a better communication and coordination

In this breakout session it was discussed the importance of data and the way it could be displayed to be useful for everyone. The HMA/EMA Join Task force on Big Data recommends ensuring a secure and ethical data sharing culture by creating a trusted environment with transparency concerning the use of the information and compliance with data protection laws. Secondly, both data privacy and data sharing can and should co-exist whilst considering data ethics. Thirdly, data ethics studies and evaluates moral problems related to data, algorithms and corresponding practices in order to formulate and support morally good solutions.

Rapporteur:
Nikolai Brun
DKMA, DK

Secure and ethical data sharing culture will support data discoverability by helping to signpost Industry and regulators to the best data source to address a particular regulatory use case whatever the regulatory procedure. It aims to Improve the evidence available to reach benefit/risk decisions and facilitate getting better medicines to patients.

Also, it wants to make data findable, accessible, Interoperable and reusable through automated data processing algorithms that efficiently identify appropriate data sets. The breakout session was guided by a series of questions based on themes such

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as, creating a trusted environment, the sharing of data and the rapport between data ethics, "data stewardship expertise" and the FAIR principles compatibility with data.

The discussion around the levels of trust in data and whether the process of data sharing is trustworthy. Analytical data and whether it can be shared, even if it is anonymous. A common standard for the European Health Data Space (EHDS) is to establish processes to extract data however, at this stage it is not at the level of data sharing. The DARWIN EU model was promoted in order to have harmonised fast data analysis on one database. One of the criteria that should be present in this model is the conversion into a specific data model. This could lead to better sharing of aggregated data, consistent data quality assessment and a data quality framework across different data sources.

Overall, applying a common data model could be beneficial. To better enact health data governance some example was given such as having EMA promote post-authorisation studies. However, sharing data could impose some challenges as GDPR must be considered as well as, national legislations which defer from Member State to Member States.

Parallel breakout session conclusions: Panel II

The breakout session conclusions summarised the debates that were considered throughout all 4 of the abovementioned sessions. For breakout out session 1, the problem at variously stated at the paediatric committee is having to administer a waiver for certain medicines created for adults. This mechanism of action should also be used for other diseases in children, even though that is currently not the case. Some of the incentives to push the regulation in a different direction of development are the prioritisation of ultra rare conditions and provide other incentives to those already on the market. Furthermore, the simplification of the HTA assessment process impacting vulnerable populations could also aid in the access to medicines.

Breakout session 2 was mostly focused on the definition of UMN and highlighted that this notion has been repeated and set as an objective in many strategies. There is a lack of a common definition and understanding of the concept. An agreement is that a more concrete definition, that pushes for meaningful patient engagement with defined priorities needs to be created. To create this definition, it was concluded that the HTA, WHO, European Commission's definitions should be brought together and understand if the definition is the same. In addition, creating safety nets such as incentives and better governance models would allow for equal partnership,

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both at European and national levels. An interesting debate was whether the concept of UMN has helped to drive innovation or is used as a tool to justify lower standards.

The third breakout session concluded that repurposing is clearly a major issue in the health sector. There was an overall agreement from the participants that work on all products out of their protection periods would be beneficial and could provide a route for better incentives. Moreover, the repurposing of medical products should not just be done through the regulatory route, but should also be affordable for various sectors. Academia and not-for-profit organisations are key to repurposing of medicines due to the amount of research and information they obtain. However, it must be noted that they are not willing to insert themselves into marketing authorisation arenas.

The final breakout session shared experiences of various national competences on their experiences on data sharing. It is ideal for data to be made publically available but it is a difficult process to put into practice as data would need to be shared with all realms of civil society. For data to be shared equally, it would be done so by regulators to companies and vice-versa. It was also concluded that there is a certain complexity when attempting to share data in "real-time" as some countries can take months or years to do this efficiently. Lastly, data stewardship is the procedure that has been promoted to provide adequate expertise to data ethics and data protection whilst allowing them to follow fair principles.

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PANEL II (CONT)

INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS

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Panel II (cont): Innovation and accessibility of medicines and medical devices to patients

Moderator: **Maria Lamas**
AEMPS, ES

The new regulation of medical devices: State of play – Are we ready?

Anna Eva Ampelas
European Commission

Will the new regulation promote accessibility of MD: Coordination, complexity and stringency vs. the need for regulatory flexibility?

Thomas Wejs Møller
Chair CAMD

The technological, scientific and regulatory convergence between medicines and medical devices (digital technologies, companion diagnostics, combination products).

Niall MacAleenan
HPRA, IE

The second part of the panel II focused on the medical devices. Anna Eva Ampelas presented the state of play of the new regulation of medical devices. It was noted that this was the first-time medical devices were high up on the political agenda. The COVID-19 was extremely challenging on the sector of medical devices. The European Commission has turned its focus onto the shortages and potential shortages and in order monitor these they set up the Commission Clearing House, put in a place a joint procurement agreement, produced a list of critical medical devices, managed to ensure the European Standards were made freely available to facilitate the manufacturing of COVID-19 related devices and have fought against export restrictions. One of the impacts of the pandemic was felt on the daily work required by all stakeholders for the implementation and subsequent application of the Regulations, with the postponement of the date of application of the Medical Devices Regulation (MDR) (UE) 2017/745 (MDR) to 26 May 2021.

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Together with the Member States, the European Commission has created a large number of guidance documents such as: guidance on placing medical devices and personal protective equipment (PPE) in the EU market, guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices (IVDR) in the COVID-19 context, commission guidelines on COVID-19 IVD tests and their performance, a working document on the performnace of COVID-19 test methods, commission guidelines on Union-wide derogations.

One of the opportunities coming out of the pandemic, which was clearly shown, is the need to develop tools for crisis management and shortages mitigation applicable to medical devices. Furthermore, the proposal for the reinforcement of EMA's role, also aims to strength the Union-level crisis management to address future crises with impact on medicines and medical devices, to monitor and mitigate potential and actual shortages of medicines and medical devices and also provide a permanent secretariat for medical device experts panels within the EMA.

The main achievements of the MDR/IVDR Implementation thus far are 24 notified bodies that have been designated under new regulations, the set up of the Medical Devices Coordination Group (MDCG), with 13 technical subgroups operating to produce guidance documents. Since April 2021 the expert panels under the MDR regulation are involved in the assessment of higher risk medical devices.

Thomas Wejs Møller addressed how the new regulation can promote accessibility of medical devices. There are changes occuring in the medical devices sector, which became visible due to the new legal frameworks, triggered by new technologies and mediatic scandals related to medical devices (breast implant, vaginal meshes). The driving force behind the regulation is a massive growth in technology and complexity, political attention and awareness which both demand an increase in authoritative capacity and to adjust the authority framework to the needs of the environment. Another incentive is access to market and the need to increase patient safety. COVID-19 brought new and additional challenges. Among them the necessity to balance the need to urgent access to essential medical devices (such as face masks, PCR testing, self-testing), the quality issues about the devices and the patient safety. Mr. Møller underlined some of the limitations presented throughout the new regulation by comparing the medical devices system to the pharma system. For instance, the capacity issues in notified bodies and authorities will remain for many years to come and posed the question if there is a need for further coordination and collaboration between the two sectors. There are also strong interdepencies between national authorities and the industry.

Niall MacAleenan, presented the technological, scientific and regulatory convergence between medicines and medical devices. Mr. MacAleenan addressed convergence from three perspectives: products which are physically combined (drug-device or device-drug combination), products used in combination (companion diagnostics or biosensors and therapeutics) and convergence of regulation (common objectives, expectations, and challenges).

Precision medicine has the possibility of changing healthcare paradigms allowing for much more personalised and independent care, as well as more control as a patient. Precision medicine affords many opportunities for real time diagnosis and therapies that may be required, it can target and monitor therapeutic interventions, help to resolve issues regarding unmet clinical needs. With more digitalisation and better analytical tools, there is undoubtedly the

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need to rethink how to regulate products and review traditional approaches. Although there is significant discussion on new technologies and convergent products, consideration should be given to a need for appropriate regulation for these products and an open and honest exchange of views between Member States, the EMA and the European Commission to avoid any misunderstandings or differences in interpretations between authorities.

One particular challenge is the speed of innovation that is developed by an iteration of existing technologies. One is also challenged by finding ways to appropriately regulate converging technologies and combination products that innovate very quickly. Applying proportionate regulation without unduly compromising on the scientific and technical rigour as well as safety of the products is another challenge.

In summary, this session on medical devices focused on the availability, accessibility and safety of medical devices, particularly during the COVID-19 pandemic. Thus, the medical devices area is characterised as a free and innovative market where the price has a relevant role on accessibility and availability. The panel agreed on the complexity of EUDAMED system, introduced by the medical devices regulations which may not be fully operational at the time of application of legislation. Additionally, the collaboration between centralised assessement systems applicable to medicines and the decentralised assessement systems of the medical devices will only be possible with more efforts, being essential in the context of combined products and convergent technologies. Moreover, reflection is needed on how to ensure the availability of medical devices when the current system does not have the same tools as the medicines systems, namely with regards to shortages management. Overall, the COVID-19 pandemic highlighted how challenging the medical devices sector is and deserving of a higher focus on this field.

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PANEL III
AFFORDABILITY OF MEDICINES

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Panel III: Affordability of medicines

Rui Santos Ivo
President of Executive Board
INFARMED, PT

Developing an "affordability" agenda under the pharmaceutical strategy for Europe to keep the sustainability of health systems

Sylvain Giraud
European Commission

Effective ways of investing in health and patient access

Pedro Pita Barros
NOVA SBE, PT

Sustainability of healthcare systems: What costs? What value?

Francisco Ramos
ENSP, PT

This panel gathered three different approaches on how to face the topic of affordability. Sylvain Giraud, from the European Commission, addressed the issue of developing an affordability agenda under the Pharmaceutical Strategy for Europe to keep the sustainability of health systems. Mr. Giraud announced that the Pharmaceutical Strategy proposes to verify how the legal framework affects the market competitivity and simultaneously aims to revise the legislation. The change in the business model from selling blockbusters to marketing "niche-busters" has risen drastically the prices and the demand for early access grows up uncertainty as to their real-life effectiveness and related overall costs. Sustainability is a challenge to all health systems and the medicines contribute increasingly and exponential to their budgets. The Pharmaceutical Strategy also proposes to verify how the legal framework affects the market competitivity blocking the affordability and aims to revise the legislation accordingly, namely in generic and biosimilar access whose uptake has several differences between Member States. It was underlined the pharmaceutical strategy proposal to further increase EU level cooperation, namely on developing cooperation in a group of national competent authorities for pricing and reimbursement and public health care payers (NCAPR).

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In this sense, Mr. Giraud highlighted that building on existing structure and past experience in NCAPR, the strategy brings new momentum to stability, continuity and concrete actions to this cooperation. Continuity across presidencies through an agreed long-term rolling agenda and action plan, stability in membership but flexible to allow holistic approach and dialogue and cooperation with others, such as Pharma Committee, EMA/HMA, HTA. And finally, concrete actions focusing on specific actionable issues to support and help national policy-making. To that extent, the pharma strategy proposes to develop further cooperation not only between national competent authorities, based on mutual learning and best-practice exchange, but also on pricing, payment and procurement policies. Overall, its aims to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Comission reinforced its willingness to support this group that can also be financially supported by EU programs such as EU4Health.

Professor Pedro Pita Barros, from Nova School of Business and Economics (Nova SBE), presented effective ways of investing in health and patient access. The proposals were to advance with new approach, not just "fine-tuning" existing arrangements, to find a common direction in the cooperation between countries, accepting the differences that naturally exist and to explicitly recognise market power issues. Mr. Pita Barros states that the basic problem Europe is facing is the increasingly high prices of medicines. The search for fast access for patients hopes to bring innovation that matters to the patients and affordable products to the health care payers. The difficulties in place include the regulatory time approvals and the fact that the submission process is lead by the industry, and that companies decide the introduction of innovation in the market. Potential solutions to address these issues have to be identified but they will require trade-offs between these different goals, different movement in prices according to our needs. For instance, price differentials are required for bringing innovation that must receive better prices, while affordability is favoured by lower prices. The cost-based prices are not the solution and net price transparency, as promoted on World Health Assembly resolution in 2019, may not be enough to respond to the critical issue of market power. Additionally, with HTA, the economic evaluation and value-based pricing approaches deal mostly with relative prices but seem to fail to deal with market power. These mechanisms could contribute to get higher prices and thus go against the affordability goal. It is necessary mechanisms that keep differential prices but at a low-price level. It is important to recognise market power issues and deal with these at institutional design level and at operational level. Professor Pita Barros gave a glimpse on possible ways forward to deal with these issues. On the one hand, in terms of cost transparency to payers, information disclosed can be treated as confidential commercial information, and not be publicly available – and still some idea about margins earned to payers. On the other hand, use HTA and economic evaluation as a necessary but no sufficient condition – negotiation for lower prices will be a fact of life. In this regard, define and develop new ways to fund and reward R&D, in particular when a certain unmet need is clearly identified as a target for innovation. Other tools may include innovation procurement arrangements, set an assessment of exercise of market power in price negotiations, explore non-linear payment systems (including multi-indication and/or multi-geography pricing, ensuring that market power concerns are addressed), joint negotiations by buyers to curb on market power.

Professor Francisco Ramos, from Escola Nacional de Saúde Pública (ENSP), addressed the costs and the value of the sustainability of healthcare systems. In the context of sustainability of the healthcare systems, it is important to consider that the needs and investments in the health sector grows faster than the economy, presenting

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challenges to Member States, which often results in different economic capacities of the countries to support health innovation. Additionally, there is a growing trend in health spending. It may largely be a choice of national policies that reflect decisions about how much the government budget should be allocated to health and coverage policy aimed at reducing out-of-pocket expenditures. Transparency remains an issue and it is quite important to not let the discussion fade especially at European level. It is worrying to have on the pharma market a complete non-transparent information and market on fixing of prices, a compromise of keeping the secret on that issue which in his view is completely against the competition rules that are quite important to the existence of this common market and also with the political and social project of the European Union.

The HTA assessment should be transparent, supported by evidence, which leads to the need to develop new decision-making tools, namely in specific areas in health, such as rare diseases/ orphan drugs and pediatric medicines. Despite the different national methodologies, there are European initiatives that allow harmonisation and knowledge sharing concerning HTA assessment, such as participation in EUnetHTA, Horizon Scanning Initiative and joint procurement of vaccines. The need for decisions and additional funds allocated to COVID-19 will have impact in health and economic systems, which can be an opportunity to build more resilient health systems. This pandemic showed it was possible to find extra money and it was clear that well-designed public policies can be effective in improving health and showing that health systems are resilient even in times of pandemic. Perhaps now in economic crisis it is hard to invest more in health, in public terms, but clearly austerity is not a good solution. The pharma strategy is certainly a relevant tool but there is need to strive for more transparency, more clear rules and effective on health on HTA and also a clear pathway to fund research and development in order to get better value at an affordable cost.

On drawing up the concluding remarks of this part of the panel, the chair, Mr. Santos Ivo, highlighted that these presentations had in common the «architecture» of dealing with affordability and on how to improve the available tools and also in some specific issues, such as transparency and competition.

On this final exchange of views, for Mr Giraud, in the aftermath of the COVID crisis, thre is a recurrent discussion of national competence reform, it is important incentives will work better. Repurposing of old dugs could also be an important source of innovative and affordable treatments. The question of whether non-profit developers could be supported with public money also arised. Mr. Giraud agreed with Professors Pita Barros and Ramos, it is for the authorities to be able to exchange information the way they want to the extent that it helps and facilitate their own work on defining their willingness to pay on defining their policy. It was highlighted the need to work collaboratively rather in silos, in order to share experiences that others find useful.

Professor Pita Barros pointed out that in relation to non-profit developers being supported by public money, Professor Pita Barros underlined that it will fit in these other ways of trying to get the innovation and it just means adding more ways to the current ones. It does not eliminate the possibility of having a reward through the traditional patent system, so if a player or a group of countries are a player who have a clear target, they should work for that target in a more explicit way and should work in a way that eventually they retain the intellectual property of that innovation that they have supported in a particular way. Professor Ramos stated that there is

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plenty of room for a European intervention without questioning the issues of Member States health competences, so an information review, such as the European semester on health with possible recommentations. Innovation is crucial on the issue of the small markets.

The chair, Mr. Santos Ivo, underlined that the idea brought in relation to incentives that they would not go only to the profit sector but also to the non-profit sector, this was related to the repurposing of medicines. Finally, the chair conveyed that there is a need to make changes in a way that all speakers was converging into the needs to reinforce joint collaboration.

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ROUNDTABLE

ROUNDTABLE
Collaboration and priorities for accessibility and affordability

Moderator: **Marcel van Raaij**
Moh, NL

This roundtable session brought together the perspectives of the NCA, the industry as well as patients and health professionals. It was guided by a series of set questions that encompassed the practice problems with unequal access to innovative medicines in European Member States. It also looked at how the affordability of new medicines are a worldwide issue. It also addressed the topics that require priority in the European Pharma Strategy to guarantee sustainable access, availability and affordability of medicines and discussed ways to deal with upcoming developments such as, the HTA, collaboration between Member States on a European level and market authorisation.

The perspective of National Competent Authorities

Momir Radulović
JAZMP, SI

The Pharmaceutical Strategy is a key pillar of the Commission vision' on building a stronger European Health Union. From the perspective of the national competent authority of a new Member State of 2 milion people with the universal healthcare system, a well-functioning and strong EU regulatory framework in medicines is key for accessibility and affordability.

Both the accessibility and affordability of medicines are linked with the shared values of universality and access to good quality care, equity and solidarity of EU health system. Slovenia faces accessibility problems at different levels and in case of critical shortage, mitigation actions mostly considers some flexibility in packaging requirements, exemption from the application of the sunset clause provision and parallel import and different therapeutic options. In Slovenia the majority of shortages

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comes in therapeutic areas as oncology, central nervous system and infectious diseases which is from the public authority perspective not acceptable for the patients.

In relation to the analysis of what causes these shortages and largely Slovenia is affected as a small Member State. In this sense, the economic factor of shortages and less attractiveness of small markets for industry is a very significant issue that needs to be tackled.

The European Union needs to really develop its strategic autonomy and ensure robust supply chains, so Europe can actually really work as a single market. Because if there is one market authorisation for instance for a centralised procedure, it is not acceptable that there is not equal access to this medicine across Europe. Mr. Radulović pointed out that some incentives to market authorisation holders should be better linked with the obligations to secure and ensure supply. On the other hand, he argued that additional organisational and cost issues for the industry should be avoided which is sometimes an obstacle for the supply of medicinal products to the small markets. The lack of commercial interest tends to favour bigger markets leaving smaller markets exposed to shortages. COVID-19 experience can be an inspiration to find a new approach at EU level to ensure the accessibility of those medicinal products that lack, but that are of strong public health interest like antimicrobials, generics or other medicines in oncology.

On affordability, in Slovenia there is a growing trend of medicine's expenses and looking into how the future would look like up to 2000 and 2030there will be 40 to 60 Advanced medicinal therapy products (ATMPs) on the market. Either gene therapy tissue engineering or any gene modifying cell therapies will be extremely hard to utilise in the sustainable way. There is room for improvement on the utilisation, for instance, of biosimilars, so this pressure of sustainability of pharmaceutical budget and continuous need to ensure and improve accessibility to patients have left the different forms of the regional collaboration of countries which boost mutual trust and transparency for a better access to medicines. The future of Europe is multinational and as the second largest market in the world for pharmaceuticals it has the foundations to ensure and improve accessibility of medicines for patients, as well as boost mutual trust and transparency between all stakeholders.

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The perspective of the industry

Nathalie Moll
Director General, EFPIA

From an industry perspective, innovation is transforming healthcare and helping tackling unmet medical needs. New shared solutions are needed to make the most of the disruptions in access and ensure best outcomes for patients and a more equitable and speedy access. Furthermore, after the COVID-19 pandemic, there is an opportunity to shape the future of the pharmaceutical system. Despite COVID-19, the volume of initiated clinical trials has increased year on year since 2015 with oncology having the most expensive pipeline which can only be successful if it reaches patients in a timely mannner.

Overall, several innovation areas have appeared on the horizon, with a potential to gain importance in the coming years. It is fundamental to co-create solutions to address access barriers, as suggested by the EU Health Coalition[1] that recommended the setting up of an EU Forum for better access to health innovation, including stakeholders (healthcare professional; patients, civil society; industry, regional authorities) and Member States. There is a need to have a shared vision on health and to build back the European healthcare systems in a sustainable way after COVID-19. The first step is to agree on what needs to be fixed by identifying at early stages what are the root causes, barriers and delays in access to treatments. Consequently, finding possible solutions is the next step to achieve an improved access to health and innovation.

The industry's commitment to work constructively with the Euorpean Commission and stakeholders to align on principles for the disclosure of evidence from novel pricing and payment models was emphasised. Furthermore, the commitment to continue the conversation with Member States to improve the transparency of novel pricing and payment models (to develop a transparency mechanism that promotes good governance and accountability, indentify the most appropriate platform for data collection, the mechanisms of evidence disclosure and how this is going to be used) was highlighted.

[1] "The EU Health Coalition Is a multi-stakeholder initiative looking at mapping the future of healthcare in Europe in order to make the most of the innovation at our fingertips, at the role of the European Union in addressing the challenges we face and critically at how can different sectors converge to deliver the best outcomes for patients in Europe." (https://www.euhealthcoalition.eu/, Accessed on 7 July 2021)

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Christoph Stoller
MfE

There were several policy recommendations discussed to reach equitable access, namely: removing on day-1 of generic or biosimilar competition, promoting the uptake of off-patent medicines for competition and invest savings from competition into better access/treatment for patients as a way to foster equitable access.

Also, ensuring availability of medicines via smart and sustainable market reforms promotes a diversity of supply chain and manufacturing; smart procurement, multi-criteria from cost to value-based procurement.

In terms of digitalisation of healthcare, one method that can be utilised is by promoting and advancing the digital regulatory network (telematics), implementing the e-leaflet (ePI), and promoting an ecosystem for continuous off-patent innovation such as Value-Added Medicines (VAM)[2].

Furthermore, the possibility of introducing new tender models where the price is not the only criteria could be beneficial. For instance, criteria could consider the environmental aspects and cause-and-effects in the tender.

Serge Bernasconi
Medtech Europe

What to achieve behind the principle of accessibility was one of the questions posed. Some of the suggestions includeed the need to be aware of the HTA regulation that is currently undergoing discussions in the EU and assure it does not decelerate the access to innovation. Mr. Bernasconi warned about the differences between countries on certain requirments which at times might go agaisnt the European system. There is a need to work on a fair and objective way towards accessibility and innovation. Regarding affordability, The COVID-19 crisis emphasised the need to invest on healthcare and health systems. Digital health will move forward and how systems will absorve digital health in the sense of making a useful tool to improve systems and make systems more affordable should be the focus.

[2] "Value Added Medicines contribute to addressing unmet patient needs. Moving from a one-size-fits-all to a much more tailored and patient specific approach, value added medicines are one of the key components of the customisation of healthcare. By answering patients' unmet needs, they represent a new horizon for those who are currently looking forward to a better quality of life with their treatment." (https://www.medicinesforeurope.com/value-added-medicines/our-5-pillars/, Accessed on 07 July 2021)

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Monika Derecque-Pois
GIRP

The supply of medicines and medicinal products across Europe was the main issue addressed to mitigate shortages as much as possible and ensure a transparency build up process from Member States to the European level is fundamental that there are different obligations for industry and wholesalers and these have to clerly identified. Medicines can only take effect when it accesses the patients in a timely way. However, ensuring timely accessibility of medicines and medical devices is only possible with enforcement of the obligations imposed on the industry. In this respect, it is crucial to be supplied by the industry. Public services obligations are fundamental to ensure wholesalers equip hospitals and pharmacies. Implementation is key to ensure a smooth availability of medicines and medical products to patients. The COVID-19 vaccines distribution process is an example of the importance of a resilient supply chain.

The perspective of patients and health professionals

Yannis Natsis
EPHA

With the current vaccine negotiations, the EU has found itself on several occasions largely dependent on company's business plans. Mr. Natsis believes the EU is still capable of counterbalancing the companies and mitigating the effects of excessive concentration of power in a single business sector. To address these issues, it was suggested to have complete activation of the regional initiatives such as BENELUXA.

As with the ongoing EU vaccines procurement negotiations, there is a potential for the joint negotiation for price to take place at EU level. Thus, for such negotiations to be effective and successful, there is need to have a paradigm shift. Nowadays, COVID-19 vaccines are available across the Union and this is something that should be put in action in other areas as well, for example, across orphan drugs for rare diseases.

The review of the respective legislation, the orphan legislation is a prime opportunity to show that Europe is serious about the overall policy change. The revision of the general pharmaceutical legislation and the flagship initiatives included in the Pharmaceutical Strategy is another area where the "orphanisation" of the pharma environment and its framework should better use data at the early stages of the process at the time of the approval of medicines.

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Annabel Seebohm
CPME

The national medical associations across Europe stated that collaboration is essential to affordability and accessibility. It is acknowledged that patients across Europe suffer from an unequal access to medicines which poses severe ethical questions to doctors. Therefore, close cooperation between Member States, public health authorities and stakeholders is a precondition for timely access for safe, effective and affordable measures. From Ms. Seebohm's point of view, there are three areas for collaboration and cooperation that can be improved:

Member States could benefit from improved cooperation in the areas of medicines data generation. There is a need for better and more comparable robust data on new medicines for informed marketing authorisation accessing potential and harms of new medicines against existing ones. These can be achieved through better cooperation between regulatory agencies, HTA bodies and payers, supported by patients' health professionals and marketing authorisation holders. Such cooperation could perhaps cover a better comparability in the designs of clinical trials and/or early dialogues.

Pricing and reimbursement decisions- For a functioning EU market in which countries are not played against one another, we need transparency on medicines and pricing of medicines. Demanding such transparency rests with the payers or the competent agencies. Member States should better cooperate towards this transparency and initiatives such as BENELUXA are a beginning. Prices are subject to confidentiality and this should be discussed because some countries might be paying more than others.

Medicines procurement- The Commission and Member States need to explore ways to improve and expand joint negotiations, especially in health emergencies. The Commission and Member States should demand high transparency standards in future joint procurements. Moreover, contracts with marketing authorisation holders should be published because only transparency can build on trust and confidence in the management of public resources and ensure accountability.

Ilaria Passarani
PGEU

The European pharmacist group, highlitghed that community pharmacists are sometimes faced with patients who are not able to access to their medicines due to lack of payments. Therefore, ensuring equitable and sustainable access to medicines is an objective that must involve national governaments and European institutions.

On top of financial sustainability pressures to european health systems, the increasing marketing of innovative speciality medicines has been a major challenge, even in high income countries in Europe over the last years. New innovative medicines may be able

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to respond to unmet patient needs but it also poses new challenges when it comes to the capacity for patients to access these medicines without financial hardship and for health systems to be able to reimburse patients. This is because the launch price, especially for some therapeutical categories, has been increasing significantly. This is an issue since it may jeopardise public health and hinder access to healthcare systems by lowering patient's adherence to their medication due to cost concerns. This also means undermining outcomes and exacerbate health, social and economic unequalities.

The EU pricing and reimbursement policies are a competence of Member States but simultaneously individual pricing decisions in some countries may affect others. Therefore, promoting better coordination amongst Member States to ensure pricing decisions taken by one country do not lead to a negative impact on patient access in another country, is an appropriate way for the EU to help improving medicines' accessibility and affordability.

In addition, Ms. Passarani emphasised the need to promote better coordination between Member States that is in line with the Pharmaceutical Strategy and it is important to support issues related to evaluating cost-effectiveness and measuring added therapeutic value. It is essential to encourage a variety of policy options that lead to an increase in accessibility and patient-centred careCOVID-19 has shown the importance of investing in primary care, to move away from hospital centered perspectives to a patient centered care Community pharmacies are stronger and ready to take up the challenges by offering a number of advanced services to patients, including health screenings and disease prevention programmes that can improve both quality of care and sustainability of healthcare systems.

The general agreement was that the resources should be focused on the real innovation needs. Upon identifying UMN, there is a need to find solutions to promote innovation. The focus should be on finding new tools such as innovation in procurement, incentives for profit or non-profit organisations driven to the patient needs. Collectively, there should be a better use of research and development (R&D) generated in Europe allowing it to end the cycle and bring to the market such innovation. The COVID-19 vaccines were a pragmatic example of the investigation capability of Europe.

These strategies strengthen the need to reinforce EU collaboration. The Network of Competent Authorities on Pricing and Reimbursement (NCAPR) is an adequate forum for a fruitful collaboration regarding these issues. Robust and better data along the lifecycle of health technologies in early stages is crucial to facilitate the work of the agencies. Affordability is directly linked with the rational use of the health technologies. Affordability measures

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should be accomplished with rational use measures. Europe should be able to translate different clinical outcomes into differential prices to pay those different results. The negotiations should be strengthened with the concrete results of clinical assessments. The repurposing mechanisms should be adopted particularly on the oncology field where several off-label products are used.

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29 | 30 APRIL 2021 IN VIRTUAL FORM

CLOSING SESSION

This conference is funded by the European Union's Health Programme (2014-2020).*

CLOSING REMARKS

Rui Santos Ivo
President of Executive Board INFARMED, PT

Ultimately, we aim to promote a European Health Union, through a larger and better cooperation between the different NCAs and stakeholders in the EU, namely, in the area of medicines and medical devices.

INFARMED, with its integrated scope of competences, remains fully committed to constructively participate and collaborate on the development of a model that would reinforce EU sovereignty to ensure a continuous and safe supply of medicinal products in Europe, by adapting the EU regulatory framework as required while focusing on the needs of health systems and patients. We have to be persistent in our collaboration and firm in pursuing our objectives.

Diogo Serras Lopes
Portuguese Secretary of State of Health

These difficult months have shown us that health challenges are not constrained by borders, creeds or flag colors. That is why we need greater knowledge, cooperation and solidarity.

We addressed the threat of scarcity and how different countries; agencies and hospitals faced that risk. We have set the stage for innovative initiatives in order to seek answers to rare diseases and unmet needs. We discussed how new technological tools can support us in providing better care for our citizens.

We need to improve strategic regulatory and scientific aspects in the area of medical devices, which will allow us to increase access in a safe and effective way throughout the European area.

To hear the closing remarks, please click here.

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CONCLUSIONS

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Conference Conclusions

The Conference had the purpose of discussing key topics in the different domains of the trinity of Availability, Accessibility and Affordability and the moderators, speakers and rapporteurs were asked to identify, deliberate and debate some of the most pressing concerns in the pharmaceutical and health sector.

The availability panel identified that on one hand it is important to not block parallel trading which may lead to disruption in the market. On the other hand, the priority to always be patient focused, especially towards the most vulnerable populations. It is crucial not to dismiss the importance of hospital pharmacies when dealing with solutions for availability issues and more resources should be invested on this. Additionally, it is important to be sure that innovation is used in patients that really need a specific medicine. Communication between all stakeholders is key to increasing transparency and offset any possible disruptions to the supply chain. The latter is not a quick solution to prevent shortages, but a potential long-term one, that if implemented with cohesion between Member States and the Commission, could become successful.

Another potential solution to address shortages of limited use of medicines, could involve setting up high level collaborative forum with stakeholders, patient and consumers representative and the different regulators that are involved in medicines to increase transparency. There are several of solutions to address, prevent or manage shortages and the Pharmaceutical Strategy as well as the EMA's reinforced mandate should be used as the momentum to improve and push for stronger action in tackling shortages in Europe.

In relation to shortages of medical devices, actions to mitigate them is through joint procurement to promote the availability of some essential medical devices. Availability should be ensured via smart and sustainable market reforms such as the diiversity of supply chain and manufacturing, smart procurement with multi-criteria, and the optimisation of the regulatory processes, from onerous to cost-effective.

An opportunity that arose from the pandemic that one should take advantage of is the need to develop tools for crisis management and shortages mitigation applicable to medical device. Under discussion is the proposal for reinforce EMA's role regarding monitoring and mitigating shortages of critical medical devices. Another opportunity is the availability of financial tools to support these initiatives (in particular "EU4Health"). A consensus about medical devices is that notified bodies need to support availability of medical devices and the constellation around medical devices is complex, but must be brought closer to medicines.

The accessibility discussions address both medicines and medical devices, as a whole but also individually. It was concluded that it is essential to focus on the needs and priorities of special populations and this can be done through a public-private partnership and by identifying the existing coalitions and through international foruns, better define the concept of unmet needs. A major conclusion was the needed to establish a definition agreed upon by all Member States on what are UMN.

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There is also harmony between participants to work on products that are out of their protection periods and develop these medicines accordingly to ensure affordable access. It was also considered that HTAs have a very complex assessment period and it would be beneficial to simplify the process for rare medicines. It was also suggested to create mechanisms related to the differentiation of incentives for medicines development and within this, guarantee that products brought to the market will be made available and accessible to more or all Member States. For ultra-rare conditions, there should be some additional incentives introduced to help and accelerate the developmental process.

To ensure data discoverability, one should guide the industries and regulators towards the best data source to address a particular regulatory use case whatever the regulatory procedure. They should also improve the evidence available to reach benefit-risk decisions and facilitate the delivery of better medicines to patients and make data findable, accessible, interoperable and reusable through automated data processing algorithms that efficiently identify appropriate data sets. Regarding the data that should be ideally shared to create a trusted environment: data sharing and data privacy must coexist. Data should be shared according to General Data Protection Regulation (GDPR), but national requirements differ across EU countries. In some countries it is not possible to share data at patient-level, even anonymised. Nevertheless, there are mechanisms that should be promoted to allow sharing information across borders, such as federated network of databases, as the Darwin EU project is an example. Regarding to whom and by whom should data be shared to demonstrate data ethics, it should be visible to researchers and regulators.

The affordability panel debated possible solutions to tackle some of the most pressing concerns in the health sectors of Europe. There is a need to co-create solutions between stakeholders (healthcare professionals; patients, civil society; industry, regional authorities) and Member States to address access barriers. One way to develop this initiative is to reference the EU Health Coalition recommendation on the establishment of an EU Forum for Better Access to Health Innovation. The creation of a new high-level forum, with an intergovernmental framework that aims to create solutions on a value-based assessment was highly supported, namely by industry representatives. Furthermore, there is a need for a shared approach to codevelop new, flexible and collaborative solutions to ensure faster, more equitable and sustainable access to medicines across Europe.

Another form of steering innovation and not being dependent solely on the pharmaceutical industry, is by investing in the development of new antibiotics to tackle AMR, under public leadership eventually through the future European Health Emergency Preparedness and Response Authority (HERA). This initiative has the potential to go beyond the traditional industry-driven, public-private partnerships that have been seen before, such as the Innovative Medicines Initiative (IMI). The need for regional collaborations to be revitalised was also underlined. For example, joint treatment facilities, especially when discussing gene therapies, could complement European reference networks in rare diseases. To achieve this, there would need to be some joint legal basis to help create such facilities among Member States willing to participate.

The focus should be on resources for the real innovation needs. Upon agreeing on the concept of UMN, the aim should be towards innovation and to find solutions to promote it, and without relying on the industry. Industry

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driven market must be shifted. There is a need to find new tools such as innovation procurement, incentives to profit or non-profit organisations driven to the prevent patient needs, such as antibiotics. Innovation in off-patent markets should be done through the repurposing drugs. The repurposing mechanism must be adopted particularly on the oncology field, where several off-label products are used. Moreover, the link to cost-effectiveness and payment or reimbursement can be assured as long as fruitful conversations are being held across all national competent authorities and across the whole product lifecycle. All the authorities such as those designing, funding, assessing the safety and efficacy should establish a multilateral relationship as a means to improve transparency.

A strong breakthrough for the Council Conclusions written by the Portuguese Presidency were based upon the abovementioned discussions and conclusions. The debates were pivotal to identify the main issues for each pillar, its specificities, needs and complementarities as well as possible ways forward tackle them.

The presidency will endeavour to translate the conference conclusions into a set of actions under each pillar to pave the way for concrete measures to be implemented at European and national levels in the near future. In particular, those highlighted under the pandemic, as well as the need to act beyond COVID-19 namely on the structural needs. Also, it will ensure timely access to innovative medicines and medical devices along with reinforcing the convergence of tools and methodologies, whilst taking measures to assess in an increasingly rigorous manner the effectiveness of new and complex technologies.

Overall, the conference provided a holitistic view of the pharmaceutical sector policies, the positions of its main players and political leaders. They all converged on key issues to enable concrete actions in each of the three pillars of the trinity of 'Availability, Accessibility and Affordability' through increased communication coordination and transparency as well as on identifying sustainable solutions for a more robust, agile, future-proof and crisis-resistant regulatory system.

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BIOGRAPHIES

BIOGRAPHIES

Marta Temido
Portuguese Minister of Health

Marta Temido was born in Coimbra in 1974. She holds a PhD in International Health from the Institute of Hygiene and Tropical Medicine of the New University of Lisbon, as well as a Master's Degree in Health Economics and Management from the Faculty of Economics of the University of Coimbra and a Law Degree from the Faculty of Law of the University of Coimbra. Specialized in Hospital Administration by the National School of Public Health of the New University of Lisbon, she held the positions of deputy director of the Institute of Hygiene and Tropical Medicine of UNL and non-executive President of the board of the Portuguese Red Cross Hospital. From 2016 to 2017, she was President of the Executive Board of the Central Administration of the Health System. She was Minister of Health from October 2018 to October 2019. She held management and administration responsibilities in several hospitals of the National Health Service, as well as other health-related entities. Namely, from 2013 to 2015 presided the Portuguese Association of Hospital Administrators. Marta Temido was also member of the advisory board of the Grupo de Ativistas pelo Tratamento (GAT) and of the Institute of Hygiene and Tropical Medicine.She taught in several health institutions and is the author and co-author of scientific publications on health.

Tedros Adhanom Ghebreyesus
Director-General, WHO

Dr Tedros Adhanom Ghebreyesus was elected WHO Director-General for a five-year term by WHO Member States at the Seventieth World Health Assembly in May 2017. In doing so, he was the first WHO Director-General elected from among multiple candidates by the World Health Assembly and was the first person from the WHO African Region to head the world's leading public health agency. As Minister of Health from 2005 to 2012, he led a comprehensive reform of the country's health system, built on the foundation of universal health coverage and provision of services to all people, even in the most remote areas. Under his leadership, Ethiopia expanded its health infrastructure, developed innovative health financing mechanisms, and expanded its health workforce. A major component of reforms he drove was the creation of a primary health care extension programme that deployed 40 000 female health workers throughout the country. A significant result was an approximate 60% reduction in child and maternal mortality compared to 2000 levels. As Minister of Foreign Affairs from 2012 to 2016, he elevated health as a political issue nationally, regionally and globally. In this role, he led efforts to negotiate the Addis Ababa Action Agenda, in which 193 countries committed to the financing necessary to achieve the Sustainable Development Goals. Prior to his election as Director-General of WHO, Dr Tedros held many leadership positions in global health, including as Chair of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, Chair of the Roll Back Malaria Partnership, and Co-chair of the Partnership for Maternal, Newborn and Child Health Board. After taking office as WHO Director-General on 1 July 2017, Dr Tedros initiated the most significant transformation in the Organization's history, which has generated a wide range of achievements.

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Stella Kyriakides
European Commissioner for Health and Food Safety

In her capacity as the European Commissioner for Health and Food Safety since December 2019, Ms Kyrriakides is leading the Commission's work on various portfolios including the Europe's Beating Cancer Plan, aiming to improve cancer prevention and care while also she is in charge of developing a new Pharmaceutical Strategy to ensure that Europe can meet its needs relating to affordable medicines. During the COVID-19 crisis, the Commissioner took on the responsibilities of coordinating the EU's health response and of supporting Member States to tackle the outbreak. Ms. Kyriakides has previously worked as a clinical psychologist for 28 consecutive years, in the Mental Health Services of the Ministry of Health of the Republic of Cyprus in the area of Child and Adolescent Psychiatry, from 1979-2006. Ms. Kyriakides was elected to the Cyprus Parliament in 2006 and was then re-elected in 2011 and 2016 for the Democratic Rally Party, for which she served duties as Vice-President. In 2012, Ms. Kyriakides was appointed Head of the Cyprus Delegation to the Parliamentary Assembly of the Council of Europe (PACE) and in 2017 she was elected as President of PACE, thus becoming the 30th President of the Assembly.

Dolors Monserrat
Member of European Parliament, ENVI Committee Representative

Dolors Montserrat is a Member of the European Parliament since 2019. Amongst her parliamentary activities in Brussels is the membership of the Committee on the Environment, Public Health and Food Safety, the Special Committee on Beating Cancer and Head of the EPP Spanish Delegation. She is also a member of the EP Conference of Committee Chairs, and she chairs the Committee on Petitions. She has also served as Minister of Health, Social Services and Equality of Spain from 2016 to 2018. In addition, she has also been Member of the Congress of Deputies in the Cortes Generales between 2008 and 2019 by Barcelona. She was a practicing Lawyer from 1997 to 2011, specialized in civil, property and family law, attended the C.O.U in the United States (Memphis, Tennessee), has a Postgraduate in Urban and Real Estate Law taught by Pompeu Fabra University and a Postgraduate in Family Mediation and contractual negotiation taught by the University of Barcelona.

Rui Santos Ivo
President of Executive Board, INFARMED, PT

Rui Santos Ivo is the current President of INFARMED – National Authority of Medicines and Health Products, I.P., since June 2019. Member of the Management Board of the EMA, since March 2016. Member of the Executive Board of EUnetHTA - the European Network for Health Technology Assessment, since June 2016. Vice-chair of the Valletta Permanent Technical Committee/Valletta Declaration, since July 2017. He is also an Invited Assistant Professor of Medicines Regulation, at the Faculty of Pharmacy of the University of Lisbon, where he is a member of the School Council. He is an external elected member of the General Council of the University of Coimbra, since 2017. Previously he was President (2014/2016) and Vice-President (2011/2014) of the Central Administration of the Health System (ACSS, IP) at the Ministry of Health, in Portugal. He was Coordinator of the Hospital Reform Project Team (2012/2015) and chaired the Governance College for the Public Health Subsystems (2015/2016). Santos Ivo initiated his professional career as a hospital pharmacist at Hospital de Egas Moniz, in Lisbon. In 1993 he joined INFARMED, where he held various responsibilities, namely vice-president (1994-2000; 2016-2019) and President (2002-2005). In 2000 and 2002

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he worked as Administrator at the Directorate of the European Medicines Agency (EMA), in London, and in 2006 and 2008 he worked for the European Commission as Administrator at the Pharmaceuticals Unit, Directorate General for Enterprise and Industry, in Brussels. He was a member of the Management Board of the EMA (2002/2005) and the first Chairman of the European Union Heads of Medicines Agencies Management Group (2004-2005). Between 2008 and 2011 he was Executive Director of the Portuguese Association of the Pharmaceutical Industry (APIFARMA).

Christa Wirthumer-Hoche
AGES, AT

Besides is role at the Austrian Medicines and Medical Devices Agency, he is also Chair of the Austrian Scientific Board since 2009. Member of the EMA-Management Board (topic coordinator for the AR of the EMA annual activity report and for the report on the annual EMA Budget from 03/14 - 12/15) since 03/2016 Chair of the EMA-Management Board HMA full member (HMA alternate 2000 - Oct. 2013) Co-Chair of the EU-Training Network Centre Member of the Pharmaceutical Committee. Until 2013 he was Head of Institute for Marketing Authorisation of Medicinal Products. He was a member of the CMDh (Nov 2005 - Oct. 2013) and Chair of the ASMF-Working Group. He was also a member of the European Risk Management Strategy Facilitation Group (ERMS-FG) 10/2010 - 10/2013. Until 2005 he was Head of Unit for Pharmaceutical Affairs of the Federal Ministry of Health (Austria).

Andrzej Rys
European Commission

Andrzej Rys is a medical doctor (radiology and public health) graduated from Jagiellonian University (JU) Krakow (PL). In 1991 established a School of Public Health at the JU. SPH's Director till 1997. In 1997 to 1999 he was appointed as Krakow's city Health Department Director. In 1999 till 2002 he was appointed as Health Deputy Minister (PL). He is a member of the Polish accession negotiators team. In 2003 established and ran as Director the Center for Innovation and Technology Transfer at JU. In 2006 joined the EC as Public Health and Risk Assessment Director in the Directorate-General for Health and Consumers in LUX. In 2011 he was appointed as Director for the directorate of Health Systems, medical products and innovation in the Directorate-General for Health and Food Safety in Brussels.

Nuno Simões
INFARMED, PT

Nuno Simões is the director of interinstitutional and health system projects at INFARMED, since April 2020. Previously, Nuno worked as head of unit for executive support, communication and information at the Central Administration of the National Health System. Between 2018 and 2019, he was the national representative at the EU Social Protection Committee. He was an advisor of the Executive Board of INFARMED from 2003 to 2012 and member of the permanent secretariat of the Heads of Medicines Agencies Management Group between 2007 and 2012. He has a degree in International Relations and a Masters in Political Science as well as post graduate studies on European Studies and Political Journalism. Nuno also holds a National Defence course at the Instituto de Defesa Nacional in 2019.

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Noël Wathion
EMA

Noël Wathion is the Deputy Executive Director of EMA (European Medicines Agency) since 1 February 2016. He also exercises the function of Chief of Policy. He is the Chair of the EMA ORP (Operations and Relocation Preparedness) Task Force, set up since June 2016 following the United Kingdom's decision to leave the European Union, responsible for overseeing all Brexit consequences for the Agency and coordinating the Agency's response, including the Agency's relocation from London to Amsterdam. He is also the Chair of the Agency's COVID-19 Steering Group, set up in March 2020 to coordinate the Agency's activities related to the COVID-19 pandemic, hereby ensuring EMA's preparedness for any possible scenario during the pandemic. He joined the Agency in August 1996 and was appointed over the past 20 years to several senior managerial positions. He is a qualified pharmacist from the Free University of Brussels (VUB).

Kristin Raudsepp
SAM, EE

Kristin Raudseppis a graduate of the University in Tartu as a physician - general practitioner. She has been working in the Estonian drug regulatory agency from 1994, from 2002 Director General of the Estonian State Agency of Medicines, and is also the estonian representative in the EMA Management Board since 2004, the representative in the Pharmaceutical Committee, European Commission, an Expert for World Health Organization in the field of regulation of medicinal products (2011, 2013) and Co-chair of the HMA/EMA Task Force of the availability of authorised medicines (TF AAM). Kristin Raudsepp has been the leader in international working groups (Heads of Medicines Agencies, Task Force of Availability of Medicinal products, HMA/EMA strategy 2020 lead for priority theme Availability of appropriately authorised medicinal products), theme leader and member of the organizational committee of international conferences (DIA Euromeeting, ICDRA, PERF), team leader of international working groups (Heads of Medicines Agencies Management Group) and is having lots of experience as a speaker and session chair at international conferences.

Hugues Malonne
FAMHP, BE

Hugues Malonne, has more than 25 years of experience in mature and emerging markets delivering significant business results through Market Access, Public - Private Partnerships, Medical and Governmental affairs initiatives. Strong R&D background in oncology, pain and supportive care as well as modified-release dosage forms. Extensive academic experience in pharmacokinetics & pharmacodynamics, pharmaceutical technology, clinical pharmacy, ethics and pharmaceutical regulation (registration and market access). He is Director-General of FAMHP, the Belgian competent authority for the quality, safety and efficacy of medicines and health products, since 2017. The DG Post Authorization (>150 FTEs) is in charge of all the activities taking place after the first marketing authorisation for a medicine or a healthcare product. The DG regroups 4 divisions: The Post Authorization Division, the Vigilance Division, the Healthcare Products Division (MD & IVD) and the Proper Use Division. NON-EXECUTIVE DIRECTOR, Board of Directors, LIH, Luxembourg Jan 2015- Dec 2019. In January 2015, the Integrated Biobank of Luxembourg and the Centre de Recherche Public- Santé were merged into a new entity called Luxembourg Institute of Health. The Luxembourg Institute of Health is a Public Research Centre under the "Loi du 03 décembre 2014 ayant pour objet l'organisation des centres de recherche publics". The Board of Directors oversees both IBBL and former CRP-Santé activities.

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Josipa Cvek
HALMED, HR

Josipa Cvek, is a Senior Advisor for Distribution of Medicines in Croatian Agency for Medicinal Products and Medical Devices (HALMED). Dr. Cvek has a University Degree and PhD in Pharmaceutical Science from Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia. In 2020, Dr. Cvek was nominated as a NCA SPOC person and she is actively involved in activities within the EU regulatory network related to shortages of critical medicines.

Aida Batista
EAHP, PTE

Aida Batista holds a degree in Pharmaceutical Sciences, from the Faculty of Pharmacy, University of Lisbon (1987). Aida has a specialisation in Hospital Pharmacy (1994), has a postgraduate course in Management and Leading of Health Services, Faculty of Economics, University of Porto (2006). She has been a hospital pharmacist since 1987, senior pharmacist at the Vila Nova de Gaia Hospital since 2003, member of the drug and therapeutic committee (2004-2019) and director of the Pharmacy Department (2013 -2019). She was board member of the Portuguese Association of Hospital Pharmacists - APFH (2002-2005) and President of APFH, (2008- January 2015). Aida is the Vice-President of the European Association of Hospital Pharmacies (EAHP) since June 2017.

Monique Goyens
BEUC

As Director General of BEUC, Monique Goyens represents 45 independent national consumer associations in 32 European countries, acting as a strong consumer voice in Brussels, ensuring that consumer interests are given weight in the development of policies and raising the visibility and effectiveness of the consumer movement through lobbying EU institutions and media contacts. As a consumer expert and advocate, and on behalf of BEUC, Monique is a member of the EU Platform on Sustainable Finance and of the Euro Retail Payments Board. She is Vice-Chair of the European Advisory Board of the Open Society Foundations. She is also a member of the Advisory Group on Noncommunicable Diseases of WHO-Region Europe. Since March 2021 she is a member of the Consumer Policy Advisory Group, DG Justice. Previously, she was a member of the expert group on "Online Disinformation" (2018), of the expert group on "trade agreements" (2018-2019), the EU High Level Forum for the Capital Market Union (2020) and sub-group on Artificial Intelligence, Connected Products and other new Challenges in Product Safety (2020). In her capacity as BEUC Director General, Monique is currently EU co-chair of the Transatlantic Consumer Dialogue (TACD) a network of EU and US consumer organisations, and she also represents BEUC at Consumers International, the international consumer organisation.

Karl Broich
Bfarm, DE

Prof. Dr. med. Karl Broich absolved a Study of Human Medicine at the Medical Faculty of the Rheinische-Friedrich-Wilhelms-Universität Bonn. Since 2014, Karl Broich is President of the Federal Institute for Drugs and Medical Devices in Bonn. His current activities in the European

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network of regulatory authorities are member of the European Medicines Agency's Management Board (EMA MB) and Chair of the EU Telematics Management Board (EU TMB). In addition, he is member of the Heads of Medicines Agencies (HMA) Management Group; since March 2021, he also took over the role as Chair of the HMA Management Group. His scientific focus is clinical psychopharmacology; advanced imaging in neurodegenerative diseases, biomarkers, dementia, and methodology of clinical trials. In addition, Karl Broich is author and co-author of over 190 essays (original scientific papers, reviews, book contributions).

Emer Cooke
EMA

Emer Cooke is as of 16 November 2020 the new Executive Director of the European Medicines Agency, based in Amsterdam. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for a term of 2 years. She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies. Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

Svens Henkuzens
ZVA, LV

Svens Henkuzens is the Director of the Latvian State Agency of Medicines since 2015. He joined the Heads of Medicines Agencies (HMA) Management Group in 2019. He was for a brief period Deputy Head of the Department of Investments and Monitoring of the European Union Funds at the Ministry of Health. During 2015 he was Chair of the European Union Council Working Group on Pharmaceuticals and Medical Devices. Before that he was the Health and Pharmaceuticals Attaché at the Permanent Representation of Latvia to the European Union. He has a bachelor's degree in European Public Health from Maastricht University and a master's degree in Healthcare Policy, Innovation and Management from the same University.

Helena Fonseca
PDCO

Helena Fonseca is an Associate Professor in Pediatrics at the Faculty of Medicine, University of Lisbon. She is also a PDCO member of the EMA, a senior consultant at the Department of Pediatrics, Santa Maria Hospital, head of the adolescent medicine division and coordinator of the paediatric obesity clinic at the Lisbon Academic Medical Centre (CAML).

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Violeta Stoyanova-Beninska
COMP

Violeta Stoyanova-Beninska is Chair of the Committee for Orphan Medicinal Products at the European Medicines Agency (EMA) since 2018. Before that she has been member of the COMP representing The Netherlands, Chair of the National Scientific and Regulatory Advice at the Medicines Evaluation Board, member of CNS working party and Scientific advice working party at EMA. She is also member of scientific and advisory boards of international projects related to rare diseases, personalised medicine and orphan drug development. Along with the regulatory work, Violeta is active as an academic being supervisor of PhD and master students, guest lecturer at several universities, member of editorial board/reviewer panel in scientific journals.

Elisabeth Kasilingam
EPF

Elisabeth joined the EPF Board in May 2018, and began her position as Treasurer in April 2019. With a background in law and European Affairs and a special interest in Human Rights, Elisabeth started her professional experience as assistant policy officer with Brussels-based NGOs Eurochild and the European Patients' Forum (EPF). In September 2016, she was appointed as the new Managing Director at EMSP.

Cesar Hernandez
AEMPS, ES

MD, PhD, specialist in rheumatology. Head of the Department of Medicines for Human Use at the Spanish Agency for Medicines and Medical Devices.

Xavier Kurz

EMA

Xavier Kurz graduated in 1982 as a Medical Doctor at the University of Liege, Belgium. He specialised in Tropical Medicine and worked for several years in public health projects in Africa and Asia. He obtained a MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He then joined the Department of Pharmacology of the University of Liege and the Belgian Centre for Pharmacovigilance (Ministry of Health) as scientific expert. He joined the European Medicines Agency on 1st September 2005. He is currently Head of Data Analytics within the Data Analysis and Methods Task Force.

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Nikolai Brun
DKMA, DK

MD, PhD Nikolai C. Brun, has background and experience in the clinical field and afterward in research and development of pharmaceuticals in the Biotech and Pharmaceutical Industry for 17 years with a long list of publications in high-impact journals. He has worked for 4 years as Director of Division responsible for Medical Evaluation and Biostatistics – both Human and Veterinary Medical Evaluation, Danish Medicines Agency. As of 1st of January 2021 Director of Division responsible for Medical Strategy and Innovation, Danish Medicines Agency. he is Co-Chair of the joint HMA/EMA Big Data Steering Group. Member of the Board of Directors, Copenhagen Centre for Regulatory Science, University of Copenhagen Member of the Scientific Advisory Board, EHDEN, European Health Data Evidence Network.

Maria Lamas
AEMPS, ES

Maria Lamas is the Executive Director, Spanish Agency of Medicines and Medical Devices (Spain) since 2018. From 2013 until 2018 she was Chief of the Pharmacy Department, Xerencia de Xestión Integrada of Santiago de Compostela. Before that she was the Area Coordinator of "Platforms and methodology", Institute of Health Research (IDIS) of Santiago de Compostela and responsible for the Oncology Pharmacy Unit Oncology Pharmacy Unit XXI of Santiago de Compostela. She was also the Research Director Spanish Society of Hospital Pharmacy and Senior Clinical Pharmacist Conxo Hospital (Santiago de Compostela).

Anna-Eva Ampelas
European Commission

Anna-Eva Ampelas is Head of Unit for Medical Devices and Health Technology Assessment in Unit B6 in DG SANTE, European Commission. In this capacity, she is managing files on medical devices, including in vitro diagnostic medical devices, and Health Technology Assessments (HTA). She has almost fifteen years of experience working on health policy and legislation in the European Commission and five years in managerial positions in the Commission. Before taking over the Unit on Medical Devices, Anna-Eva was heading units dealing with pharmaceuticals, substances of human origin, tobacco control and global health. She was Health Counsellor at the Permanent Representation of Sweden 2002-2006 before joining the European Commission. Anna-Eva has a Master of Laws from Uppsala University.

Thomas Wejs Møller
Chair CAMD

Thomas Wejs Møller is Head of medical device division in the Danish Medicines Agency and Chair of the competent authorities (CAMD).

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Niall MacAleenan
HPRA, IE

Niall MacAleenan is the Director of Medical Devices at the Health Products Regulatory Authority (HPRA) in Ireland. As a member of the HPRA's senior management team, he is responsible for the operation and development of HPRA's regulatory activities and capabilities for medical devices and leadership of its Medical Device Department. His work over the next number of years will focus on ensuring effective operation and consistent application of the new EU Regulations on medical devices and optimising the HPRA activities for medical devices.

Niall MacAleenan qualified as a medical doctor at Trinity College Dublin in 1999. Niall worked in a variety of clinical and research roles across the Irish health care system. He also attained a business degree from University College Dublin. Since joining HPRA Niall has held a variety of different roles at senior level within the organisation both in the area of medical devices and human medicines. In 2018, Niall was appointed as the Head of Medical Devices to establish and lead the HPRA's new medical devices department.

Niall is a leading European expert on medical devices. He represents HPRA and Ireland at the EU Medical Device Coordination Group (MDCG), the EU Regulatory Committee, the Executive Group of the Competent Authorities for Medical Devices (CAMD) network and, when required, at the European Council's Working Party on Pharmaceuticals and Medical Devices. Niall is also a member of the European delegation to the Management Committee of the International Medical Device Regulators Forum (IMDRF).

Sylvain Giraud
European Commission

Sylvain Giraud is since last year the Head of Unit "Medical products: quality, safety and innovation" in the Directorate General for Health and Food Safety of the European Commission (DG SANTE). The unit is in charge of EU level policy developments on quality, availability and affordability of medicines and supervises important aspects of the implementation of EU legislation, the implementation of the Pharmaceutical Strategy for Europe and the coordination of international cooperation on medicines policy. In previous Head of Unit, positions in DG SANTE in the last 10 years Sylvain has been dealing with Health Systems, global health and EU health policy coordination.

Pedro Pita Barros
NOVA SBE, PT

Pedro Pita Barros is a Professor of Health Economics at Nova School of Business of Economics, Universidade Nova de Lisboa. He is a member of the European Commission's "Expert panel on effective ways of investing in health", a member of the Portuguese National Council of Ethics for the Life Sciences, a member of Portuguese National Health Council, past-President of the Portuguese Association of Health Economics, and past-President of the European Association of Health Economics. His research focuses on health economics and on regulation and competition policy which appeared in many academic journals. Pedro Pita Barros also has several books on health economics (in Portuguese and English). He served as Member of the Board of the Portuguese Energy Regulator (2005/2006), on the Governmental Commission for the Financial Sustainability of the National Health Service (2006/2007) and on European Commission Mission Board for Cancer (2019-2020). Pita Barros served as vice-rector of Universidade Nova de Lisboa (2013-2017). He

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serves on the editorial boards of academic journals in the field of Health Economics. He acted as consultant for both private and public entities, in Portugal and at the European level, in the areas of health economics, competition policy and economic regulation.

Francisco Ramos
ENSP, PT

Francisco Ramos has a Degree in Economics, from the University Institute of Lisbon, Portugal, 1978, with a specialisation course in Hospital Administration, from the National Public Health School. He is the President of the Board of the Red Cross Hospital, since 2020, and associate professor of Health Economics of the group of social sciences disciplines at the National Public Health School, New Lisbon University, since 1987. He was Deputy Minister for Health of the XXI (2018-2019) and XVII (2008/2009) Constitutional Government. He was also President of the Board of the Portuguese Institute of Oncology of Lisbon Francisco Gentil and Chairman of the board of directors of the National Administration Institute (INA), 2009/2012. Prior to this, he was Deputy Director-General of Health and Deputy Director-General of the Health Studies and Planning Department (1997).

Marcel van Raaij
Moh, NL

Since October 2014 Marcel van Raaij is the Director of Pharmaceutical Affairs and Medical Technology at the Ministry of Health in the Netherlands. The Directorate is responsible for the policy making on pharmaceuticals (from innovation, market access, safe use to pricing and reimbursement), medical devices and technology and tissues and cells including organ donation policy. The Netherlands presented a new Pharma policy in January 2016 and proposed an active agenda on pharmaceutical policy during the Dutch Presidency of EU council in 2016. From 2016 until May 2019 Marcel van Raaij was the first chairman of the Steering Committee of the BeNeLuxA initiative where The Netherlands, Belgium, Luxembourg, Austria and Ireland are working together on sustainable access to medicines in their countries. After his PhD he moved to the National Institute of Public Health and Environment (RIVM). He worked in the toxicological risk assessment and was active in various international working groups and commissions (EU, WHO, OECD, US EPA). He became acting director for Nutrition, Medicines and Consumer Safety. From 2011 to 2014 he was Director of Environment and Safety at RIVM dealing with environmental policy and physical safety including preparedness and response activities.

Momir Radulović
JAZMP, SI

Momir Radulović leads the Slovenian Medicines and Medical Devices Agency since December 2018. He is a member EMA Management Board, a member of EC Pharmaceutical Committee and a member of High-level Group on the Health Emergency Preparedness and Response Authority. His previous work experience includes Hospital and Community Pharmacy and Pharma industry, where his work focused on oncology medicines, HIV and vaccines. By living in 6 and working in 10 different countries with diverse health systems and cultural environments and through different work areas, projects, and assignments he has learned to adapt swiftly to changes and to seize the opportunities that those can offer.

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Nathalie Moll
Director General, EFPIA

Nathalie Moll joined the European Federation of Pharmaceutical Industries and Associations (EFPIA) as Director General in April 2017. EFPIA represents the pharmaceutical industry operating in Europe. Together with its direct membership 40 leading pharmaceutical companies, 33 national associations representing over 1,900 companies and in collaboration with health and research players, EFPIA's mission is to create an environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Prior to joining EFPIA, between 2010 and 2017 Nathalie was the Secretary General of EuropaBio ranked as the most effective European Trade Association in Brussels in 2013. She spent over 20 years working for the biotech industry at EU and national level in associations and corporate positions and held the position of Chair and Vice Chair of the International Council of Biotech Associations (ICBA). In 2013, Nathalie won the Technovisionaries Women Innovation Award organised by Women & Technologies while in 2009, Nathalie and the Green Biotech Team of EuropaBio were presented with the Leadership and Excellence in Advancing Ag-Biotech and Food Issues Award. Nathalie was also named one of the 15 leading women in biotech in Europe in 2017. Nathalie holds an Honours Degree in Biochemistry and Biotechnology from St Andrews University, Scotland.

Christoph Stoller
MfE

Christoph Stoller has been a member of the Board as well as of the Executive Committee of Medicines for Europe, the European committee for generics and biosimilar companies, responsible for nearly 70 % of the pharmaceutical supply in Europe, since 2014. Furthermore, he has been pivotal in setting up the sector group on Value Added Medicines and chaired that sector group until 2017. In his current role as General Manager for Teva´s cluster Germany & Austria, he is responsible for Teva´s Generics, OTC and Specialty Medicines businesses and he is Managing Director of all Teva´s legal entities in Germany. Until June 2017, he served as Chief Operating Officer Global Generic Medicines Europe. As part of that role, he also led all activities integrating Actavis Generics into Teva in Europe as Chief Integration Officer Europe. In addition, he was responsible for the negotiations to get the approval of the European Commission and all associated divestment activities. Christoph has been working for Teva Europe in various roles with increasing responsibility since 2011 after having joined Teva as General Manager in Switzerland in July 2008. Before joining Teva he worked for Zur Rose Group as member of the Executive Board and General Manager Helvepharm, DSM, F. Hoffmann-La Roche and Swiss Re.

Serge Bernasconi
Medtech Europe

Mr Bernasconi has 40 years' experience in the world of pharmaceuticals, medical technology and trade association leadership. He has worked in senior leadership position in companies such as Johnson & Johnson, Schering Plough (now Merck), and Medtronic. He has exercised his leadership in various geographical areas around the world, including, the US, Europe (France, Italy, Belgium, Switzerland), Turkey, the Middle East and Africa. Throughout his career he has been involved in trade association activities and responsibilities both for the pharmaceutical industry and the MedTech Industry. Prior to become the

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CEO of Eucomed and EDMA and then MedTech Europe, he had been elected President of APIDIM (The French Association for the Promotion of Innovation in Medical Devices), and Vice President and Treasurer of SNITEM (French Medical Technology Industry Association).

Monika Derecque-Pois
GIRP

Monika Derecque-Pois is the Director General of GIRP, the European Healthcare Distribution Association, which brings together over 750 pharmaceutical full-line wholesaling companies and their national associations from 34 countries. Monika was appointed to her current position in 2001, having previously served as European Affairs Consultant for GIRP. Monika Derecque-Pois was born in Graz/Austria and holds a master's degree in Economics from the University of Economics in Vienna, where she specialised in International Trade and Marketing. She has over 25 years of experience in European public affairs and healthcare distribution. Prior to her engagement with GIRP, she served as a director in a European affairs consultancy company, and she also held a six-year post as Marketing and Client Support Manager at IQVIA Austria.

Yannis Natsis
EPHA

Yannis Natsis currently leads the advocacy for better and affordable medicines at the European Public Health Alliance (EPHA), the leading public health stakeholder in Brussels. Before joining EPHA in January 2016, he worked at the European Parliament, the Greek Ministry of Foreign Affairs, the UN and the private sector in Brussels and Athens. Between 2013-2015, Yannis was Advocacy Advisor for the TransAtlantic Consumer Dialogue (TACD) focusing on access to medicines. Between 2006-2010, he was an investigative reporter for Greece's award-winning TV news programme "Fakeli" and a contributor to the Greek daily "Kathimerini". He has a Master's degree in International Conflict Analysis from the University of Kent, UK and a Bachelor's degree in European Studies from Pantion University of Social and Political Sciences, Greece. A Greek national, he is fluent in Greek, English and French. Yannis is committed to fighting for transparency, accountability and defending the public interest in health and medicines policies.

Annabel Seebohm
CPME

Prior to joining CPME in 2016, Annabel was head of the Brussels office of the German Medical Association (GMA) and legal advisor in the joint legal department of the GMA and the National Association of Statutory Health Insurance Physicians (NASHIP). From 2007 to 2016 she was also general counsel of the World Medical Association (WMA). Annabel studied law at the University of Bonn, undertook her judicial service training in Hamburg and obtained a Masters' degree from the University of Auckland, New Zealand. She is admitted to the Berlin Bar and a Member of SCIANA, the Health Leaders Network.

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Ilaria Passarani
PGEU

Ilaria Passarani is Secretary General of PGEU, the organization representing European community pharmacists. She provides strategic direction and leadership to the organization while managing the day to day operations of PGEU, its ongoing relationships with member associations and other stakeholders, as well as representing the pharmacy sector in various European and national fora. She is Vice-President and member of the Board of Directors of EMVO, the European Medicines Verification Organization. Before joining PGEU Dr. Passarani worked as Head of the food and health Department at the European Consumer Organization BEUC. She also served as a member of the European Medicines Agency (EMA) Management Board. She graduated cum laude in Economics from Bocconi University (Italy) and holds a PhD from the Faculty of Health, Medicine and Life Sciences at the Maastricht University (The Netherlands).

Diogo Serras Lopes
Portuguese Secretary of State of Health

Diogo Serras Lopes is the Secretary of State for Health since September, 2020. With a degree in Economics by the Business School of Universidade Nova de Lisboa, he also attended the Masters in Political Sciences at the Instituto Superior das Ciências do Trabalho e da Empresa – Instituto Universitário de Lisboa. Since 2005 he is also a CFA Charterholder (CFA Institute). He began his professional career in 1998, as a journalist at the Economia Pura Magazine, and, from 1999 to 2014, also worked in asset management in a series of private institutions such as MC Fundos, Santander Asset Management and Banco Best. From May 2014 to November 2015, he worked in the Regulatory Policy and International Affairs Department at Comissão do Mercado de Valores Mobiliários (Portuguese Securities Market Commission). From December 2015 to August 2017, he was also adviser to the Secretary of State Assistant to the Prime Minister and from August 2017 to April 2019, he was appointed adviser for economical affairs to the Prime-Minister, in the first Government of Prime Minister António Costa. From April 2019 to September 2020, he was Vice President at the Central Administration of the Health System (ACSS).

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ANNEX

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ANNEX

The Conference contents and dissemination

The Conference reinforced that the 'Conference on Availability, Accessibility and Affordability of Medicines and Medical Devices for a Stronger and Resilient EU' is one of the flagship events in the health sector during the Portuguese Presidency. It aimed to impact key stakeholders in the health area for the importance of the topics discussed and the conclusions obtained at this conference. Some of these key stakeholders were participants from the EU Governments and Parliaments, EU regulatory entities, EU public and private health organisations, health industry, patients, traditional media and social media, key opinion leaders (KOL) and public opinion. The strategy was to disseminate information on three moments: one week before the Conference by creating expectations of what the Conference will achieve, on the day of the Conference by promoting coverage and after the Conference, by sharing results and discussions.

For the Conference, an innovative website was created. The customised page had the official Conference image, explanation of the Conference and themes, the programme, list and biographies of the speakers and the abstracts and presentations. A customised platform that integrated and interacted with two other platforms, namely Streaming and Zoom, was used by for the speakers and participants to interact and create fruitful discussions.

Simultaneously, all contents related to the event were made available, and will remain as archive, on the public website dedicated to the topics of discussion (ppeu2021.infarmed.pt).

Programme

The Conference was divided in three different panels, some of them splitting into parallel breakout sessions. At the end of the Conference there was a roundtable that brought together stakeholders.

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AVAILABILITY | ACCESSIBILITY | AFFORDABILITY
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3A CONFERENCE
29 | 30 APRIL 2021 IN VIRTUAL FORM

FINAL PROGRAMME

DAY 1: 29 APRIL | 08:45 - 17:00 WEST

OPENING SESSIONS

08:45 - 09:00 | Marta Temido
Portuguese Minister of Health

09:00 - 09:05 | Tedros Adhanom Ghebreyesus
Director-General, WHO

09:05 - 09:10 | Stella Kyriakides
European Commissioner for Health and Food Safety

09:10 - 09:15 | Dolors Montserrat
Member of European Parliament, ENVI Committee Representative

INTRODUCTION TO THE CONFERENCE

09:15 - 09:30 | Rui Santos Ivo
President of Executive Board, INFARMED, PT

PANEL I: AVAILABILITY OF MEDICINES AND MEDICAL DEVICES | *Moderator: Christa Wirthumer-Hoche, AGES, AT*

09:30 - 09:45 | Addressing shortages: preliminary results from the Commission study
Andrzej Rys, European Commission

09:45 - 10:00 | Availability of medicinal products
Nuno Simões, INFARMED, PT

10:10 - 10:15 | A common understanding for a list of critical medicines and medical devices
Noël Wathion, EMA

10:15 - 10:40 | Q&A

10:40 - 10:50 | BREAK

PARALLEL BREAKOUT SESSIONS

10:50 - 11:40 | **Stakeholders solutions to medicines shortages**
Moderator: *Kristin Raudsepp, SAM, EE*

PARALLEL BREAKOUT SESSION 1:
National experience on shortage's management
Rapporteur:
Hugues Malonne FAMHP, BE

PARALLEL BREAKOUT SESSION 2:
Shortages management plans to avoid availability problems
Rapporteur:
Josipa Cvek, HALMED, HR

PARALLEL BREAKOUT SESSION 3:
Hospital Pharmacists solutions for availability problems
Rapporteur:
Aida Batista, EAHP, PT

PARALLEL BREAKOUT SESSION 4:
Consumers and patients' perspectives on medicines shortages, the case of small volumes and limited use medicines
Rapporteur:
Monique Goyens, BEUC

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11:40 - 12:00 | Breakout sessions' conclusions
12:00 - 12:25 | Q&A
12:25 - 13:30 | LUNCH

PANEL II: INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS
Moderator: *Karl Broich, Bfarm, DE*

13:30 - 14:00 | HMA-EMA joint strategy 2025
Emer Cooke, EMA
Svens Henkuzens, ZVA, LV

14:00 - 14:10 | Short break

PARALLEL BREAKOUT SESSIONS | ***Moderator:*** *Karl Broich, Bfarm, DE*

14:00 - 14:50

PARALLEL BREAKOUT SESSION 1:
Access to medicines for special populations: Orphan and Paediatric Regulations & Revision of the system of incentives
Rapporteur:
Helena Fonseca, PDCO and Violeta Stoyanova-Beninska, COMP

PARALLEL BREAKOUT SESSION 2:
Unmet medical needs: medicines and medical devices research in view of patients and health systems needs
Rapporteur:
Elisabeth Kasilingam, EPF

PARALLEL BREAKOUT SESSION 3:
How the repurposing of old medicines may add new value on patients' access to new therapies
Rapporteur:
Cesar Hernandez, AEMPS, ES

PARALLEL BREAKOUT SESSION 4:
Generation of evidence for a better patient access & Health data space and big data: shared data for a better communication and coordination
Rapporteur:
Xavier Kurz, EMA and Nikolai Brun, DKMA, DK

15:00 - 15:20 | Breakout sessions' conclusions
15:20 - 15:50 | Q&A
15:50 - 16:00 | BREAK

PANEL II (CONT): INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS
Moderator: *Maria Lamas, AEMPS, ES*

16:00 - 16:15 | The new regulation of medical devices: State of play – Are we ready?
Anna-Eva Ampelas, European Commission

16:15 - 16:30 | Will the new regulation promote accessibility of MD: Coordination, complexity and stringency vs. the need for regulatory flexibility
Thomas Wejs Møller, Chair CAMD

16:30 - 16:45 | The technological, scientific and regulatory convergence between medicines and medical devices (digital technologies, companion diagnostics, combination products)
Niall MacAleenan, HPRA, IE

16:45 - 17:00 | Q&A

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DAY 2: 30 APRIL 09:00 - 12:45 WEST

PANEL III: AFFORDABILITY OF MEDICINES | *Moderator: Rui Santos Ivo, INFARMED, PT*

09:00 - 09:15 | Developing an "affordability" agenda under the pharmaceutical strategy for Europe to keep the sustainability of Health Systems | *Sylvain Giraud, European Commission*

09:15 - 09:30 | Effective ways of investing in health and patient access | *Pedro Pita Barros, Nova SBE, PT*

09:30 - 09:45 | Sustainability of healthcare systems: What costs? What value? | *Francisco Ramos, ENSP, PT*

09:45 - 10:00 | Q&A

10:00 - 10:10 | Break

ROUNDTABLE

10:10 - 12:30 | **Collaboration and priorities for accessibility and affordability**
Moderator: *Marcel van Raaij, MoH, NL*

| The perspective of National Competent Authorities
Momir Radulovic, JAZMP, SI

| The perspective of the Industry
Nathalie Moll, Director General, EFPIA
Christoph Stoller, MfE
Serge Bernasconi, Medtech Europe
Monika Derecque-Pois, GIRP

| The perspective of patients & health professionals
Yannis Natsis, EPHA
Annabel Seebohm, CPME
Ilaria Passarani, PGEU

CLOSING SESSION

12:30 - 12:45 | Closing remarks
Rui Santos Ivo, President of Executive Board, INFARMED, PT
Diogo Serras Lopes, Portuguese Secretary of State of Health

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Media Coverage

Throughout the Conference, over 700 participants assisted different panels and sessions. Additionally, during this two-day event, the press reported on the speeches and debates being held. There were 36 news pieces produced regarding the Conference, resulting in an outreach of more than 1 million of a potential cumulative audience.

https://sicnoticias.pt/especiais/presidencia-da-ue/2021-04-29-Conferencia-internacional-no-Infarmed-para-debater-a-disponibilidade-e-o-acesso-aos-medicamentos-na-UE-a3fdce43

https://observador.pt/2021/04/28/responsaveis-nacionais-e-europeus-analisam-politica-do-medicamento-na-ue/amp/

https://www.publico.pt/2021/04/29/sociedade/entrevista/uniao-europeia-quer-criar-lista-medicamentos-essenciais-1960446

https://www.atlasdasaude.pt/noticias/infarmed-junta-comissao-europeia-oms-e-estados-membros-em-conferencia-sobre-medicamentos

https://www.netfarma.pt/infarmed-organiza-conferencia-internacional/

https://www.google.pt/amp/s/observador.pt/2021/04/28/responsaveis-nacionais-e-europeus-analisam-politica-do-medicamento-na-ue/amp/

https://www.rtp.pt/noticias/mundo/responsaveis-nacionais-e-europeus-analisam-politica-do-medicamento-na-ue_n1315956

https://jornaleconomico.sapo.pt/noticias/ue-presidencia-responsaveis-nacionais-e-europeus-analisam-politica-do-medicamento-na-ue-732217

http://m.destak.pt/artigo/475991?switcher=mobile

https://www.rtp.pt/noticias/covid-19/marta-temido-considera-urgente-melhorar-estrategia-europeia-de-acesso-a-cuidados-de-saude_a1316071

https://www.noticiasaominuto.com/mundo/1742872/oms-sublinha-urgencia-de-acesso-igual-para-todos-aos-dipositivos-medicos

https://observador.pt/2021/04/29/vacina-alema-curevac-pode-estar-aprovada-em-dois-meses-aponta-presidente-do-infarmed/

https://www.dnoticias.pt/2021/4/29/259485-saiba-que-noticias-marcam-a-agenda-de-hoje/

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https://portocanal.sapo.pt/noticia/262603/

https://portocanal.sapo.pt/noticia/262653

https://www.rtp.pt/noticias/mundo/ministra-da-saude-considera-que-europa-tem-de-retomar-lideranca-mundial-na-producao-de-medicamentos_v1316142

https://observador.pt/2021/04/29/oms-sublinha-urgencia-de-acesso-igual-para-todos-aos-dispositivos-medicos/

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