"Redefining the Unmet needs in Healthcare and the Regulatory Challenge"
EAPM Autumn Presidency Conference
Wednesday, November 10th, 2021
08.30 – 15.00 CET

This event will be the third Presidency conference that EAPM will be holding during 2021. All three events reflect the nature of the relative presidency policies in the healthcare arena, but also act as major events during what will be the second full year of the two new legislative bodies - the European Parliament and the European Commission.

And, of course, since the start of the year we have been dealing with impact and fall out of the Covid-19 crisis. We need to look ahead to try and understand what a post-Covid world will mean for healthcare readiness and sustainability, health data gathering and sharing, cancer treatments and personalised medicine. The latter three topics are already being addressed, at least in part, by the European Commission et al, while the first issue cannot be dealt with in any way properly without Europe quickly bringing innovation into its healthcare systems. .

Regulators, industry and healthcare professionals really need to step up to this new reality, and this also applies to citizens, who have a certain degree of responsibility for their own healthcare. Lifestyle changes will be paramount, and could amount in many cases to the best form of prevention.

Key topics that will be addressed include:

- In vitro diagnostics regulation.
- Pharmaceutical Strategy of the EU
- Digital Health Europe - Data space for Genomics
- EU Beating Cancer Plan

Expected outcomes

It is necessary to formulate a patient-centred strategy to takle the unmet needs in healthcare involving national decision makers and regulators in the arena of public health, to enable the EU and Member States to contribute to integrating personalised medicine into clinical practice while enabling much-greater access for patients. In order to provide a clear focus and to devote sufficient space to analysis, discussions during the conference will concentrate on how Portugal can contribute to this at the EU level and how this can be enhanced at the national level:

- to assess and address obstacles to the integration of personalised medicine into Europe's healthcare systems
- to identify best practices and their added value
- to outline the potential benefits of personalised medicine on public health and its impact on policymaking in the EU

The main outcome will feed into activity that will support this action at the national level.

Participants

Attendees will be drawn from key stakeholders whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. These participants will include public health decision makers, representatives from the European Commission, Members of the Parliament, patient organisations, and umbrella organisations representing interest groups and associations actively engaged in the field. Each session will comprise panel discussions as well

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08.30 – 09.45 **Session 1:EU's in vitro diagnostics regulation.**

On October 14th, the European Commission has proposed a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation to prevent disruption in the supply of these essential healthcare products. The unprecedented challenges of the COVID-19 pandemic have diverted resources from Member States, health institutions and economic operators towards addressing the crisis, thereby hampering the capacity to comply on time with the changes introduced.

The proposal does not change any requirements of the In Vitro Diagnostic (IVD) Regulation in substance but only changes the transitional provisions to allow the Regulation's progressive rollout.

How will this impact the patients, stakeholders and the different healthcare systems?

Chair: Denis Horgan, *Executive Director, European Alliance for Personalised Medicine*

Olga Tkachenko, *Policy Officer, DG for Health and Food Safety, European Commission (Confirmed)*

Petra Zoellner, *Industrial Policies, Senior Manager In Vitro Diagnostics, Medtech Europe (Confirmed)*

Marta Carnielli, *IVD Technical Officer – TÜV SÜD (Confirmed)*

Christian Hübner, *Director of the Institute of Human Genetics in Jena, Germany*

Bastiaan Tops, *Head of Diagnostic Laboratory, Prinses Máxima Centrum, Utrecht, Netherlands (Conformed)*

Discussion

Q&A

09.45-11.00 Session II: **Pharmaceutical Strategy**

Patients need safe, efficacious and high quality medicines that are available at an affordable price. Patients across Europe do not have the same access to medicines, health systems and people paying out of pocket have budgetary difficulties, and some medicines are in shortage.

Regulators see the limits of the legislation when it comes to keeping up with the rapidly changing technological environment and businesses need to operate in a system that fosters innovation. The COVID-19 pandemic has raised the vulnerabilities of the EU pharmaceutical system in sharp relief but has also given the opportunity to adapt and learn in order to correct any misgivings.

The Pharmaceutical Strategy includes flagship initiatives and other actions to ensure the delivery of tangible results. As a part of the implementation of the strategy, the Commission is evaluating the current general pharmaceutical legislation2 and assessing the impacts of changes intended to address the following objectives:

- Ensure access to affordable medicines for patients, and address unmet medical needs;
- Enable innovation for the development of high quality, safe, effective medicines, harnessing the benefits of digital and emerging science and technology while reducing the environmental footprint;
- Enhance the security of supply of medicines and address shortages;
- Reduce regulatory burden and provide a flexible regulatory framework.

The session will discuss the different aspects of this issue.

Chair: D. Horgan, *Executive Director, European Alliance for Personalise Medicine*

Alastair Kent, *Former Director, Genetic Alliance UK (Confirmed)*

Frédéric Destrebecq, *Executive Director, European Brain Council (Confirmed)*

Joanna Chorostowska, *Secretary General of the European Respiratory Society, Head of Department of Genetics and Clinical Immunolog, National Institute of Tuberculosis and Lung Diseases, Warsaw, Poland (Confirmed)*

Ivana Cattaneo, *Executive Director, Oncology Policy & Healthcare Systems, Novartis Oncology Region Europe (Confirmed)*

Philip Van Kerrebroeck, *EAU Policy Office Chairman, Maastricht, Netherlands. (Confirmed)*

Discussion

Q&A

11.00 -12.30 Digital Health Europe - Data space for Genomics

Recent advances in knowledge and technology, exemplified by the improvements in genomic sequencing, enable the shift to a personalised, predictive, preventive, and participatory health system. A system that can provide the right information and treatment to the right people at the right time.

Genomics has been a 'game-changer' for clinical and translational research over the past decade, and has improved success in drug discovery and development . Major genomics programmes are also recognised as having stimulated significant economic return. According to the European Commission, the upcoming Digital Europe Programme will reinforce EU critical digital capacities by focusing on the key areas of artificial intelligence (AI), cybersecurity, advanced computing, data infrastructure, governance and processing, and their deployment.

The central construct will be an immense body of information on the genetic, molecular, clinical and social characteristics of a million participating European citizens, along with the required infrastructure and capabilities to underpin this. It will institute a central coordinating body to link across region, member state, and European bodies and infrastructure.

What framework should this take? The session will focus on the elements that can guide policy makers

Veli Stroetmann*, Director empirica, Bonn, Germany (Confirmed)*

Mark Lawler, *Queen's University Belfast, Faculty of Medicine, Health & Life Sciences (Confirmed)*

Benjamin M. Horbach *Global Policy Leader, F. Hoffmann-La Roche Ltd. (Confirmed)*

Volker Liebenberg, *Director Medical Affairs EMEA, Illumina (Confirmed)*

Gary Saunders, *Data Director at EATRIS (Confirmed)*

Fabrizia Galli, *Vice-President, aBRCAdaBRA (Confirmed)*

Discussion

Q&A

12.30 – 13.30 Lunch

13.30-15.00 EU Beating Cancer Plan – Unmet Medical Need

On 3 February 2021, the European Commission presented its long-awaited Europe's Beating Cancer plan. The plan is major initiative under the European health union, a process launched by the Commission on 11 November 2020 with a first set of proposals to reinforce the EU's preparedness and response during health crises. The aim of Europe's Beating Cancer Plan is to tackle the entire disease pathway. It is structured around four key action areas where the EU can add the most value: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors

1,537 amendments to the Parliament Report on the EU beating Cancer Plan were proposed by European Parliament as of Oct 15th, 2021.

The purpose of this session is to discuss common elements of these amendments.

Tit Albreht, *Coordinator, Joint Action Innovative Partnership For Action Against Cancer*

Luzia Travado, *President-Emeritus, International Psycho-Oncology Society (IPOS) And Clinician & Researcher Of Psycho-Oncology, Champalimaud Foundation, Lisbon, Portugal (Confirmed)*

Nicolae Stefanuta MEP, *Co-Ordinator, Special Committee On Beating Cancer (Beca)*

Ivica Belina, *President, Coalition of Healthcare Association (Confirmed)*

Ken Mastris, ECPC, President *(Confirmed)*

Christine Mayer-Nicolai, *Head of Global Regulatory & Scientific Policy Merck (Confirmed)*

Lydia E Makaroff, *CEO, Fight Bladder Cancer (Confirmed)*

Discussion

End of Meeting