



9th Presidency Conference:

**Forward together with innovation: The why, what and how of tackling the
Implementation Gap for healthcare in the EU
Portuguese Presidency of the EU**

**Brussels, Monday, March 8th, 2021
09.00 CET - 16.00 CET**

Overview:

Successful development and deployment of healthcare innovation depends on a policy framework in which countries would find it easier to reach consistent decisions and to provide clearer funding arrangements, thus boosting access and continued development.

Recent demonstrations of wide support for EU initiatives such as its Beating Cancer Plan or its Cancer Mission, as well as numerous declarations made by the EU institutions both before and during the coronavirus crisis, suggest a growing recognition of the need to innovate – at the level of both policymakers and of the health community. The renewed attention to disparities in health care and access across Europe is also driving new assessments of obstacles and new pursuits of solutions and promoting greater networking and collaboration among cancer institutions.

But nothing will happen by accident. Constructive change to the health care context could ensure better use of the potential offered by new technologies in testing, in diagnosis and in treatment of cancer, through development and use of biomarkers and the advanced treatments.

But this will result only from vigorous debate among all stakeholders, and agreement on recommendations of a technical and political nature that will result in a better deal for patients and a more sustainable approach to healthcare.

Target Audience

Attendees will be drawn from key stakeholders from the community whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. These participants will include healthcare professionals, decision makers, patient organisations, and European umbrella organizations representing interest groups and associations actively engaged in the field of Personalised Medicine. Each session will comprise panel discussions as well as Q&A sessions to allow best possible involvement of all participants

Expected outcomes

It is absolutely clear that it is necessary to formulate a personalised healthcare-centred strategy involving 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

- 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 policy making



Monday March 8rd, 2021

09.00 – 10.30 **Opening Plenary Session: Propelling healthcare through an effective Governance framework**

The scope and potential of personalised healthcare are under-appreciated and under-realised, often because of resistance to change. The consequence is that many inadequacies of healthcare in Europe persist unnecessarily, and many opportunities for improvement are neglected. This article spells out some of the options – in terms of identified challenges, possible approaches to resolving them, and benefits that could result from greater adoption of personalised healthcare.

It locates the discussion in the context of European policy, focusing particularly on the most recent and authoritative reviews of healthcare in the EU Member States, and on the new spirit of readiness among European officials to embrace change and technology in a new decade. It highlights the attention now being given by policymakers to incentives, innovation, and investment as levers to improve European citizens' prospects in a changing world, and how these themes contribute to a renaissance in thinking about healthcare in Europe. It explores the chances offered to patients by specific initiatives on cancer or antimicrobial resistance, and by new science, new therapies, new diagnosis, and deeper understanding of health promotion and prevention.

Chair: Denis Horgan, EAPM Executive Director

Setting the Framework for the EU policy Frameworks

EU Health Data Space

Ceri Thompson, DrPH, Deputy Head of Unit DG CNECT H3: eHealth, Well-being and Ageing (Confirmed)

EU Beating Cancer Plan

Solange Peters, Chair Medical Oncology, Oncology Department – CHUV, Lausanne University, ESMO President 2020-2022 (Confirmed)

Member State Perspective:

Ortwin Schulte, Health Attaché, Permanent Representation of Germany to the EU (Confirmed)

Attitudes toward genomics: design, delivery and methods

Anna Middleton, PhD MSc RGC Head of Society and Ethics Research (Confirmed)

Keeping the person in personalised healthcare

Zorana Maravic, Acting CEO - Digestive Cancers Europe (Confirmed)

Role of Innovation to drive forward collaborative healthcare

Benjamin M. Horbach. Health Systems Strategy Leader -- Personalised Healthcare (PHC), Roche (Confirmed)

Q&A



10.30 – 12.00 Session 2: **EU Beating Cancer Plan**

Europe urgently needs a renewed commitment to cancer prevention, treatment and care that recognises the growing challenges, and opportunities to overcome them, including the developments in cancer care. We need a whole-of-government approach that focuses on the patient and maximises the potential of new technologies and insights; strengthens co-operation and opportunities for EU added value; eradicates inequalities in access to cancer knowledge, prevention, diagnosis and care; and delivers improved health outcomes to patients. Europe's Beating Cancer Plan is the EU's response to these needs.

It reflects a political commitment to leave no stone unturned to take action against cancer. Mobilizing the collective power of the EU to drive change to the benefit of our citizens, the Cancer Plan contains concrete, ambitious actions that will support, coordinate and complement member states' efforts to reduce the suffering caused by cancer. It marks the beginning of a new era in cancer prevention and care, where patients have access to high-quality screening, treatments and the latest state of the art technologies, with support at EU level that allows scale and specialisation, while fully respecting member states' responsibilities in health policy.

Chair: Denis Horgan, *EAPM Executive Director*

Setting the Framework:

Politics Meeting Science

Vytenis Andriukaitis, *WHO Special Envoy for European Region (Confirmed)*

Partnership on Personalised Medicine and the Cancer Mission Boards

Christine Chomienne, *Vice-Chair of the Mission Board Cancer at the European Commission & Professor of Cellular Biology at the Université de Paris, France (Confirmed)*

European Reference Networks

Birute Tumiene, *Lithuanian representative at the ERN Board of Member States (Confirmed)*

Role of Data and Access

Francesco Florindi, *Strategy & Partnership Manager, BBMRI-ERIC (Confirmed)*

Knowledge Centre on Cancer

Ciaran Nicholl, *Head of the Health in Society Unit, Joint Research Council (Confirmed)*

Q&A

12.00 -13.30 Session III: The why, what and how of promoting innovation to tackle rare diseases.

In considering what sort of change the regulation may need, it is crucial to recall the intention that regulators and policymakers had when it was developed and introduced. If the aim was indeed that "patients suffering from rare conditions should be entitled to the same quality of treatment as other



patients”, then it must be concluded that the objective has not yet been met. Far from it.

If it has not yet delivered on its aims, does that mean that the regulation is misguided and misconceived? That would hardly be a conclusion consistent with the evidence, given that in the relatively short (in the context of drug development timetables) period of its existence it has in fact led to the generation of a large number of highly effective new therapies.

It therefore remains the case, as it was in 2000, that it is “necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry.”

And again, in the spirit and letter of the regulation, this means it is still necessary “to provide incentives” for the process, through mechanisms through which “orphan medicinal products eligible for incentives should be easily and unequivocally identified,” and on the basis of “objective criteria”.

If the aim is to be pursued, what may be appropriate two decades on is to review the operation of the regulation, in light of imperfections that have been identified as inimical to its objectives, and in light also of the changes – often dramatic – that have occurred in the underlying science and technology and that have opened up new dimensions to the understanding of disease and of therapy.

Chair: Antonio Montserrat, Former Senior Expert on Cancer and Rare Diseases, DG Public Health, European Commission, Brussels, Belgium

Role of Coordination

Daria Julkowska, Co-ordinator of the European Joint Programme on Rare Diseases (Confirmed)

Role of high-quality information on rare diseases

Alastair Kent, Former Director, Genetic Alliance UK

Incentivising Innovation and the role of Regulation

Maciej Gajewski, Head of International Government Affairs & Policy, Alexion (Confirmed)

Putting Patients at the center

Simone Boselli, Public Affairs Director, European and International Advocacy, EURORDIS

European Parliament

Tilly Metz, Member of the European Parliament

Q&A

13.30-14.00 Break

14.00-15.15 Session IV: Role of Biomarkers and Advanced Molecular Diagnostics

Rapid and continuing advances in biomarker testing are not being matched by uptake in health systems, and this is hampering both patient care and innovation. It also risks costing health systems the opportunity to make their services more efficient and, over time, more economical. The potential that genomics has brought to biomarker testing in diagnosis, prediction and



research is being realised, pre-eminently in many cancers, but also in an ever-wider range of conditions – notably *BRCA1/2* testing in ovarian, breast, pancreatic and prostate cancers. Nevertheless, the implementation of genetic testing in clinical routine setting is still challenging. Development is impeded by country-related heterogeneity, data deficiencies, and lack of policy alignment on standards, approval – and the role of real-world evidence in the process - and reimbursement. The acute nature of the problem is compellingly illustrated by the particular challenges facing the development and use of tumour agnostic therapies, where the gaps in preparedness for taking advantage of this innovative approach to cancer therapy are sharply exposed. Europe should already have in place a guarantee of universal access to a minimum suite of biomarker tests and should be planning for an optimum testing scenario with a wider range of biomarker tests integrated into a more sophisticated health system articulated around personalised medicine. Improving healthcare and winning advantages for Europe's industrial competitiveness and innovation require an appropriate policy framework – starting with an update to outdated recommendations. We show herein the main issues and proposals emerged during the previous advisory boards organized by the European Alliance for Personalized Medicine which mainly focus on possible scenarios of harmonization of both oncogenetic testing and management of cancer patients.

Chair: Denis Horgan, EAPM Executive Director

Germany Perspective:

Reinhard Buettner, Director of Department of Pathology, University Hospital, Cologne, Köln (Confirmed)

Italian Perspective

Ettore Ettore D. CAPOLUONGO, Professor of Clinical Biochemistry and Clinical Molecular Biology, Federico II University - CEINGE, Advanced Biotechnology, Naples.

European Parliament Perspective

Nicolas Gonzalez Casares, Member of the European Parliament

Pathology Perspective

Gilad Vainer, Molecular Pathologist, Hadassah Medical Center, Israel (Confirmed)

Industry Perspective

Stephen Hall, Regional Director, Precision Oncology (CDx), Oncology Region Europe, Novartis (Confirmed)

Q&A

15.15 -15.30 **Closing Session: Integrating innovation into healthcare: Next Steps**