European Alliance for Personalised Medicine

European Parliament
Taking Stock: Navigating the Legislative Labyrinth for EU Healthcare that promotes the European Way of Life

Tuesday, November 15th
09.00 – 11.00 CET
Room: 3E-2
European Parliament

Setting the Scene:

Recent advances in biomedicine are opening the door to new approaches – particularly for diseases such as cancer and rare diseases, where limited or no alternative treatment options exist and unmet need remains high. But despite the unique possibilities of these technologies, there are some outstanding challenges across regulatory, scientific, manufacturing, and market access fields that still hamper the ability to deliver the potential. EU industrial policy has a key role here.

Additionally, the field of regulatory affairs in the European Union is by its very nature a complex one. Perhaps nowhere more complex than in the arena of health – and certainly extremely complicated when it comes to legislating for the exciting advances and growing expectations being brought about by personalised medicine. The issues and rules surrounding, for example, in vitro devices and data protection are labyrinthine. Yet they need to be addressed swiftly and effectively if we are to be able to give the right treatment to the right patient at the right time while, at the same time, offering every European equal access to the best treatment available.

There are 27 Member States and the welfare of 500 million citizens to consider, plus so many disciplines, industries and other stakeholders involved that it is often a struggle for legislators to formulate regulations (and even definitions, as we will see) that are satisfactory for all, are up-to-date and progressive, and do the job they are supposed to do. This despite the best efforts from all involved.

The event will focus on two legislative files which includes:

- EU's general pharmaceuticals legislation
- In Vitro Diagnostic Medical Devices Regulation

Objectives of the sessions

The over-riding goal in all areas today is to identify and fill the implementation gap that exists when aiming to introduce innovation into Europe's healthcare systems..

Expected outcomes

- to assess and address obstacles to the integration of personalised medicine into Europe's healthcare systems

Attendees:

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 Commission, Members of the European Parliament, patient organisations, and European umbrella

organizations representing interest groups and associations actively engaged in the field of Personalised Medicine

Programme (draft)

09.00 – 11.00	**Taking Stock**

Chair: D. Horgan, *Executive Director, European Alliance for Personalised Medicine (5 minutes)*

Ms Olga Solomon, Head of Unit Medicines: policy, authorisation and monitoring, *European Commission (confirmed)*
Stelios Kympouropoulo MEP *(EPP), European Parliament (Confirmed)*
Tomislav Sokol, PhD MEP, *European Parliament*

Pharmaceutical legislation

- **Deirdre CLUNE MEP (EPP),** *European Parliament (Confirmed)*
- **Mark Lawler**, *Associate Pro-Vice-Chancellor and Professor of Digital Health, Faculty of Medicine,Health and Life Sciences, Queen's University Belfast (confirmed)*
- **Daniela Morghenti,** *RCE Secretariat & Patient Advocacy Lead, Public Policy, European Society of Medical Oncology*
- **Frédéric Destrebecq,** *Executive Director, European Brain Council. (Confirmed)*
- **Luana Banu,** *Head of Public Policy, Communications and Patient Advocacy, Europe and Canada, Takeda Pharmaceuticals (Confirmed)*
- **Charis Girvalaki, MPH, PhD,** *Director, European Cancer Patient Coalition (confirmed)*

Discussion (10 minutes)

In-Vitro Diagnostic Regulation: Importance of Diagnostics

- **Cristian Busoi MEP (EPP),** *European Parliament (confirmed)*
- **Jörg Engelbergs,** *PhD. Scientific Regulatory Expert Biomedicines at Paul-Ehrlich-Institut (PEI) (confirmed)*
- **Marta Carnielli**, *IVD Technical Officer – TÜV SÜD (Confirmed)*
- **Prof. Pieter Demetter,** *Society President, Belgium Department of Pathology Institut Jules Bordet (Confirmed)*
- **Hans-Peter Dauben,** *Secretary General, EUROSCAN (confirmed)*

Discussion (10 mins)

End