

On 12 October 2015 as part of the World Health Summit, a distinguished group of panelists discussed in an open workshop how decisions taken on patients' access to medicines could be improved through further European cooperation. Today, highly developed cooperation exists in the regulatory field within an EU legal framework coordinated by the European Medicines Agency (EMA). A positive opinion by the EMA about the benefit:risk balance of the medicine is the basis for an authorization that allows the product to be marketed in all member states in Europe. However, the decision to pay for and use the new medicine within the national healthcare system lies with each individual Member States and is, in most countries, informed by national processes of health technology assessment (HTA) to determine the added value of the new product compared with the current standard of care. Panelists representing patients, healthcare professionals, politicians, regulators, HTA bodies and the industry came to the shared conclusion that national HTA bodies should continue to join forces in the interest of patients and create a system to develop European assessments of clinical effectiveness to inform subsequent national decision making. Panelists agreed that such European assessments should only look at the clinical aspects, which are largely based on international evidence and that economic and budget issues that are specific to a health system must remain a national consideration.

As all concurred that such cooperation would be a great step forward, the audience wondered why this has not been put in place yet, despite ongoing activities in this area by the European Commission and member states. There was general view that divergent standards across member states are a key barrier but discussants proposed ways to drive the debate forward:

- Patients and their representatives are calling for full participation in healthcare policy decisions, with a recognition that their unique knowledge and perspectives can identify what adds value to patients and help identify priorities.
- Regulators see opportunities for more scientific convergence between HTA and regulatory evaluation, in order to ensure information and data generated are relevant for all decision-makers
- HTAs recognize that in the current context of stretched healthcare systems, collaboration makes even more sense. Joining forces will lead to efficiencies and form a consistent basis for decision-making.
- Physicians are calling for a common and clear understanding of what is valuable innovation, so as to guide clinician decision-making and do not understand why there is such difference in reimbursement between neighbor countries eg cancer ...
- Politicians recognize that Member States are strongly resistant to any change in EU competence in the health area but that politics should not get in the way of rational and evidence-based decision-making. However financial considerations also play a role, and should be looked at in Europe
- Industry sees the opportunity of European cooperation to improve a predictable environment that enables good investment choices and makes a highly fragmented environment in Europe more manageable

Concluding the debate, all workshop participants launched a call to Member States and the European Commission: **just do it!**

The discussion concluded with a feeling that we should take more proactivity in European HTA collaboration, learning from regulators; after 9 years of European HTA projects and joint actions of Member States, it is time to get tangible results, and take action for improving the

sustainability of healthcare systems and patients' access to treatments that add value. This requires not just collaboration of HTA bodies at a new level, but also the meaningful engagement of HTA bodies with patients, healthcare professionals, politicians, regulators and the industry.

The session was moderated by Karen Facey from the University of Edinburgh and featured the following panelists:

- Bettina Ryll, Founder – Melanoma Patients Network Europe
- Claire Le Jeune, Professeur de Thérapeutique, Université Paris Descartes (former Vice-President of the Commission de la Transparence and member of the Jury for the 2015 Prix Galien)
- Ricardo Baptista Leite, MD, National Assembly and member of the Assembly's Health Committee, Portugal
- Michael Berntgen, Head of Scientific and Regulatory Management Department, European Medicines Agency,
- Elisabeth George, Associate Director, NICE
- Andrea Rappagliosi, SP-MSD, chair HTA WG EFPIA