

Harmonisation of European HTA

—

a round table discussion

MEDVANCE, a unique health care consultancy based on five independent local consultancies, also leads local market access system debates and has invited key opinion leaders in the field of a potential European joint HTA for a round table discussion in Barcelona on 11.11.2018. The following speakers discussed the current proposal by the European Commission and its potential impact for individual EU member states:

- **Dr. Inaki Imaz**
 - Health Technology Assessment Agency, Institute for Health Carlos III, Spain
- **Dr. Ansgar Hebborn**
 - Head of Payer Policy, F- Hoffmann-La Roche AG, Germany
- **Dr. Entela Xoxi**
 - Research Consultant, ALTEMS Catholic University of Rome, Italy and former AIFA member
- **Prof. Dr. Peter Zweifel**
 - Emeritus Professor of Health Economics, Socioeconomic Institute, University of Zurich, Switzerland
- **Flora Giorgio**
 - Head of Sector HTA, European Commission

*„HARMONIZATION UNDERSTOOD AS
CORE COMPETENCY OF EC“*

Dr. Inaki Imaz

Dr. Inaki Imaz stated that the potential HTA harmonization is a key topic in Spain and also in other EU member states as it merges the challenging political and economic interests between member states and its related reimbursement decisions, which are based on health technology assessments. He also added that Europe is in the position of being the first part of the world in which HTA could be harmonized. However, as there are still key differences in terms of process and methods applied Imaz suggested starting in building a closer network, the follow on of the EUnetHTA project, and that the details of any processes or structures could then follow.

Giorgio explained that she would hope to see a sustainable, legally embedded framework for co-operation and an opportunity to take the proposals further if these wish do so by member states and European Parliament.

Dr. Ansgar Hebborn explained that the industry association was involved in EU-level HTA collaboration initiatives for many years and since the beginning. He personally, as well as the industry association EFPIA, felt it was time to build a sustainable foundation for HTA cross country collaboration with focus

on clinical-scientific benefit assessments. Therefore, Hebborn supported the European Commission's proposal to begin the process, as its proposal had in place many of the features necessary for such an arrangement. Hebborn also noted that this was because the collaboration would focus clinical side of the HTA and not on the more context-specific aspects of HTA like social, ethical, organizational, economic and affordability consideration, appraisal and decision-making. All these aspects of HTA and decision making continue to be covered by Member States. As there is basically, or at least should be, a common understanding of clinical assessment methods („Evidence based Medicine“) there should not be any rationale for more than 30 organizations in a joint European Union repeating the same clinical assessment at the time of launch of a new medicine. Finally, Hebborn said that capacity and capability constraints leave no choice but to collaborate, given that the complexity of the medicines is growing and so too the evidence to support those medicines.

„ALREADY CLINICAL DEVELOPMENT IS GETTING MORE COMPLICATED, MORE EXPENSIVE AND MORE CROSS-BORDER, THE INDUSTRY SUPPORTS THE HARMONIZATION WAY“

Dr. Ansgar Hebborn

„IT IS ONLY A SCIENTIFIC APPROACH“

Dr. Entela Xoxi

Dr. Entela Xoxi opened by explaining that she supported the proposal from a scientific point of view, because the subject in question is related to the technical aspects of a relative effectiveness assessment. She referred to the centralized marketing authorization as example of unified European

process and said that the Commission is proposing to align on the scientific aspects to avoid duplication of work at Member State' level. Xoxi said that it would include evidence from clinical trials as well as real world evidence, leaving Member States to have their own conversations about cost-effectiveness & budget impact analysis, pricing and reimbursement decisions. Based on previous experience done in HTA network, the implementation of the proposal should take in account the differences (preferences) for each Member State.

Prof. Dr. Zweifel stated that his point of view was entirely different, and that given the fact that (potential) patients finance the different health care systems in Europe, either through taxes and/or insurance premiums, their preferences need to be accounted for in the assessment and decision processes. He argued that preferred clinical outcomes already vary by country and therefore, patient preferences should be central to decision making. Zweifel went on to explain that there was a cost-benefit assessment of uniform regulation to be performed, the benefit being for industry to have one route or assessment process and for governments to avoid the risk of litigation by deferring to a supra-national body. However, he warned that there are also costs in that learning from the experiences of others would be stifled if there is only one assessment process in the future. Zweifel, as a Swiss citizen living in Austria, also asked himself why everybody assumes that regulation proposed by the EU is the best possible.

„IT IS SCIENTIFIC, BUT WHAT ABOUT THE REGIONAL SCALE?“

Prof. Dr. Peter Zweifel

Hebborn responded to Zweifel on the critique of patient preference inclusion that the preferences of the collective care systems may still make their own decisions, but that the efficacy, safety and effectiveness was already assessed at that stage based on internationally accepted methods. Although for a different decision purpose, EMA conducts such EU-level clinical-scientific benefit/risk assessments for more than 25 years. Regarding preferences of each member state, he believed that the proposal leaves the matter of choosing how to best spend money to the member states.

„30 YEARS AGO NOBODY BELIEVED THAT A HARMONIZED REGULATORY FRAMEWORK COULD WORK AT ALL – WHY SHOULD THE CLINICAL ASSESSMENT WITHIN A JOINT HTA NOT ALSO BE A SUCCESSFUL STORY?“

Flora Giorgio

Flora Giorgio, responsible for the topic at the European Commission, reiterated Hebborn's and Xoxi's statement on the fact that the EU would look at clinical evidence only, and in fact has been doing so for many years through the EUnetHTA Joint Action . She also stated that the Commission would propose to build on member states existing processes rather than start from the beginning, and leading European organizations, such as the German G-BA or the French HAS, would be asked to contribute and take responsibility on this. There is no intention in the proposal

to delegate power to a supernational body, but rather to enable national HTA agencies to work together Giorgio said that being able to rely on the existing network would be advantageous. However, she also noted that the alignment of HTA is important for patients as it would give greater accountability and transparency to the decisions taken as it is planned to involve patients in the assessment. Finally, Giorgio said that member states as well as the European Parliament had several times asked the Commission to continue the cooperation on HTA in a sustainable manner and the proposal is a response to such call.

Xoxi asks the important point if the EC proposal on HTA includes only innovative drugs. **Giorgio** confirmed, saying that centrally authorized products are the focus in the proposal, and that for medical devices there is a different plan to reflect the market access differences. Expanding on medical device proposals she added that the focus would be on implantable devices and products that have undergone scrutiny according to the new regulations for medical devices.

Zweifel stated that, according to the Lisbon Treaty, health is in the domain of member states and that in extending the EU's reach in this way the Commission gains authority where it has not been granted. Imaz disagreed and said that one should look to the competencies of the member states and think about solutions in this context. Furthermore, Imaz added that this initiative could support EU countries, which do not have robust processes themselves in place. Giorgio concurred stating that the proposals have been highly scrutinized from a legal perspective reiterating that they have nothing to do with organization or delivery of care and hence is in the remit of the EC responsibility.

„DID ANYBODY READ THE LISBON TREATY? I ASKED TO GET A SENSE OF UNDERSTANDING OF THE COMPETENCIES OF EU MEMBER STATES ...“

Prof. Dr. Peter Zweifel

Giorgio finally stated that the Commission was trying to give a stronger evidence base for national decisions.

The audience brought up that such a new process might in theory be easier. However, a core issue would start if the standard of care would differ between countries – so the system may be better used in innovative products where there is no standard of care. However, **Giorgio** answered that this is why there was a need to understand what existing systems look like, as well as emphasizing that this is only one part of the whole HTA assessment.

*„TAKE HOME MESSAGES REFLECT ON
THE BENEFITS AND POWER OF
COOPERATION AND THE LONG-TERM
VISION OF EUROPE“*

Flora Giorgio

Giorgio suggested the take home message, as concluding remarks, was to reflect on the benefits and power of cooperation, to think about the long-term vision of Europe and reflect on the benefits that cooperation on scientific issues have brought to society. **Xoxi** agreed that member states should look to the future and the rapid effect of this proposal with positivity in order to strengthen the cooperation. Brussels' proposal has this ambitious aim.

Hebborn concluded that as progress is made, he hoped this would move forward and disentangle the economic decision from the clinical evaluation. **Imaz** ended by saying that members states should be given space for further assessment on top of what is done at European Level.

Anyway, **Zweifel** warned that the joint clinical assessment could just be the entry to the core competency of member states, with the power of cooperation resulting in a binding HTA assessment at the European level.

*„BUT POWER CAN BE USED TO UNDERMINE
THE AUTHORITY OF MEMBER STATES ...“*

Prof. Dr. Peter Zweifel

*„FEEL THE CHALLENGE. WE AT MEDVANCE
ARE WORKING AT THE EDGE OF EUROPEAN
HEALTH CARE MARKETS“*

Vincent Cheney

Vincent Cheney from **MEDVANCE** France summarized the discussion: On one side with a European Assessment for local appraisal, there is no need for duplication, but also with more differentiated appropriate comparator therapies, there will be also bigger assessments. On the other side, there are

concerns, which have to be considered. Feel the challenge of the European work. **MEDVANCE** stays on top of local and European health care political debates.



MEDVANCE is a European Group (EEIG) of five health care market access consultancies in France, Germany, Italy, Spain and the UK.

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