

INTERVIEW

with

Wim Goettsch, MD, PhD,
Executive Board Chair,
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Professional Background:
Between 2010 and 2015, Wim Goettsch was the Project Leader of WP5 of the EUneHrTA JA1 and JA2 on Relative Effectiveness Assessments. Until the beginning of 2013, he was also the Deputy Secretary of the Medicinal Products Reimbursement Committee at Dutch National Health Care Institute. He has a PhD in immunology and an advanced education in (pharmaco)epidemiology and pharmaco-economics. He has more than 70 publications in peer-reviewed international journals.

Reporter: It is a great pleasure and honour for me to discuss an important and current topic, given that HTA is one of the main action points and a strong, frequent issue for health policy agendas at the national and international level.

Why do you consider HTA has become such an important issue to health policies around the world?

Wim Goettsch: Without doubt, the rapid progress in scientific and technologic domains may provide benefits at the individual and society level. In medicine, due to the specificity of this field, the number of new products currently occur at a high rate. However, new products do not always mean better products, and therefore assessing the exact value of these treatments is more crucial than ever.

At the societal level, this technological progress puts pressure on governments that are constrained to face the ever-increasing costs of new emerging technologies.

In this context, one of the best solutions is to implement an efficient system of evaluation of new technologies (between them, or with the solutions already in use) in a functional and sustainable organizational framework that can be used on a national level for decision making. Health policies around the world and decision in the healthcare sector need to be based on solid and valid evidence. Decision makers want to decide where to allocate resources so that the results obtained have the maximum effect in relation to expenditures made.

Therefore, I would say that HTA is a process that helps and support decision makers in deciding when they have to choose between two, or even more, technologies.

Why is now an appropriate moment for approaching this issue in a collaborative manner at the EU level?

WG: Since 1993, the European Commission has supported important projects on HTA, which lead to the start of European Network of HTA (EUneHrTA) in 2006 that was also European Commission funded. This collaboration was more officially introduced in Article 15 of the Directive 2011/24/EU of the European Parliament and the Council on the application of patients’ rights in cross-border healthcare.

This Directive was preceded by the start of the first EUneHrTA Joint Action (JA1) in 2010. This also led to the establishment of an HTA Network in which national policymakers could discuss the strategic and political aspects of HTA collaboration, while EUneHrTA would focus on the scientific and operational collaboration between HTA organisations in the different Member States.

Based on solid principles, such as collaboration and efficiency, the development of EUneHrTA has led to concrete, palpable results in different European Commission funded Joint Actions.

Currently, the European Commission is preparing a proposal for structural European collaboration in HTA from 2020 onwards based on the results that are achieved in the different EUneHrTA Joint Actions.
– What would be the common goal of these collaborations?

– What are the main benefits expected to come from developing and implementing extensive and regional collaborations in this area of HTA?

WG: The common goal of the Joint Actions is to contribute to a permanent, sustainable mechanism for EU cooperation on HTA established after the finalization of EUnetHTA Joint Action 3 in 2020. In accordance with the expectations of all actors involved (including but not limited to HTA agencies, industry, stakeholders, MSs, EC), the main benefits should be counted at the Member State level, in the sense that a structural collaboration in the field of HTA will benefit the Member States. In this context, Member States can benefit from the added value created by pooling resources, exchanging expertise and avoiding duplication in the assessment of the same product or intervention. This should support more timely and consistent decision making on the European level.

R: At the European level, EUnetHTA has an essential role in networking and assisting collaboration between members who want to share and achieve effective results through collaborative work in the field of HTA.

– Please briefly describe for our readers what the story behind the development of this network is.

WG: Briefly, the foundation of the network began in 2005, when a group of 35 organisations throughout Europe, led by the Danish Centre for HTA (DACEHTA) in Copenhagen submitted the EUnetHTA Project for a Commission call. This initiative was solidified by implementing the first 2006-2008 EUnetHTA Project. A number of collaborations followed this initiative: EUnetHTA Collaboration 2009, EUnetHTA Joint Action 2010-2012, EUnetHTA Joint Action 2 (2012-2015) and EUnetHTA Joint Action 3 (2016-2020).

The role of the first Collaborations was to build a solid knowledge based on methodologies and information exchange and to prove the ability of national HTA organisations to work together and produce valuable products. The current EUnetHTA Joint Action 3 now proceeds with the final step of contributing to a permanent network on HTA in Europe that will be based on a legislative framework from the European Commission.

R: As you mentioned, the previous collaborations implemented within EUnetHTA Collaboration (JA1 and JA2) had an essential role in advancing and stabilizing the network. JA1 and JA2 also were important steps ahead in fulfilling the network’s mission.

– Could you enumerate the main results of the previous JA2 Collaboration?

WG: The main activities of the EUnetHTA JA2 were structured to address the issues of value assessment of health technologies during their Life Cycle. This was achieved through the development of processes for Early Dialogues, early (rapid) HTAs (Rapid Relative Effectiveness Assessments [REAs]), Additional Evidence Collection and Comprehensive (Core) HTAs, as well as by developing and applying appropriate tools (the HTA Core Model®, POP Database, EVIDENT), methods (Methodological Guidance), and work process supporting tools. As an example of the order of magnitude, I would like to provide you with some figures: 12 REAs (six on pharmaceutical and six on other technologies); three Core HTAs; 11 Early Dialogues (nine on pharmaceuticals and two on medical technologies); five methodological guidelines; Evidence submission templates for pharmaceuticals and medical devices; an updated and upgraded application package of the HTA Core Model® EUnetHTA; over 40 instances of the national uptake; and last but not least a suite of process and procedural guidelines to support various types of joint activities within the framework of European cooperation on HTA. Additionally we provided input to the four EU FP7 funded HTA projects: AdHopHTA, Advance HTA, Integrate HTA and MedTechHTA; joint actions (PARENT), and information and communication (ICT) projects, including (MAST). Specific activities were developed in cooperation with EMA, which lead to a more structured and sustained level of engagement from both parties based on a three-year work plan. This included areas and initiatives to improve the efficiency of the processes and conditions for patients’ timely access to effective medicines. Our interaction with the HTA Network since 2013 has been close, too, EUnetHTA has been actively involved in the preparation of two main strategic documents (HTA Strategy for European Cooperation on HTA and recommendations on the implementation of sustainable European cooperation on HTA).

– What are the defining key elements of the third joint collaboration, JA3, already implemented within EUnetHTA?

WG: Production and implementation are the key elements of EUnetHTA JA3. We have to establish a structural system of production of joint relative effectiveness assessments of pharmaceuticals but also other
technologies, such as medical devices, surgical procedures and diagnostics. Subsequently, we have to ensure that these assessments are used and implemented in the practice of national HTA organisations.

**R:** I assume that collaborations between different countries, with wide variations in practice, different attitudes and different levels of resources, are difficult to coordinate. However, the previous collaborations within EUnetHTA have demonstrated a good adaptation of partners towards a common goal defined in the project.

— What do you think would be the big advantages and obstacles in this collaborative JA 3?

**WG:** Again, the proof is in the pudding. We have to show that we can structurally produce high quality assessments that are timely, consistent and used in national practice. An important obstacle that we see is the willingness of technology producers, such as the pharmaceutical industry to actively participate in these assessments. This is a hurdle that we continually work toward overcoming. Until now we have not seen broad, practical support from many companies.

— Even though we may think it's too early, I still risk wondering what are the results in the first year of the JA3?

**WG:** The start of one system of parallel consultation in July this year between EMA and EUnetHTA where we collaborate on early advice/scientific advice is a big success. It shows the willingness from both regulators and HTA to work together on getting better clinical trials with better data for market authorisation, HTA, pricing and reimbursement. Additionally, there has been production of joint assessments on pharmaceuticals (three assessments ongoing) and more than six on other technologies. We are encouraged by the efforts of all our partners in the EUnetHTA network to see that these continuing assessed will be used on the national level.

— What would be the main key elements to guarantee long-term successful collaboration?

**WG:** Not only commitment from all HTA organisations to participate and contribute to production of the EUnetHTA but also the willingness to use EUnetHTA structurally in their national processes. We also need clear involvement and engagement from all stakeholders in this process. This means not only industry but also patients, healthcare providers and payers need to be actively involved in these activities.

*Interview conducted by: Marius CIUTAN*