Niklas Hedberg – Chair of the Executive Board, EUnetHTA

After almost 20 years of work, [the implementation of EU HTA legislation] will finally become a reality in 2025 with joint work on scientific consultations, clinical assessment, and horizon scanning, among other tasks

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The much-discussed implementation of an EU-wide legislative framework on health technology assessment (HTA) will finally come to fruition in 2025, explains EUnetHTA Chair Niklas Hedberg. He outlines the need for this framework given the sheer influx of new products and the limited capabilities of individual countries and why the intervening two years will be exceptionally busy for all stakeholders as they work to adapt to a unified system with new requirements. Hedberg ends with a rallying cry to not let minor details derail the rollout of this important new legislation which has been two decades in the making and has had the support of both governments and private companies.

Since we last spoke at the end of 2020, a European Union (EU)-wide health technology assessment (HTA) regulation has been passed. Can you begin by explaining the fundamentals of this regulation and how it differs from what has gone before?

The EU now has a legislative framework for cooperation on HTA. This framework has been voluntary and under construction since 2006 and has taken several forms, including joint actions under the EUnetHTA initiative. EUnetHTA Joint Action Three was the final joint action, and the European Commission (EC) instead established a service contract, which was made available for tenders. Several partners from EUnetHTA Joint Action Three came together under the EUnetHTA

2021 banner and won the contract, meaning that we are now a service contractor. However, we try to work very inclusively with as many as possible of the previous EUnetHTA partners, especially national and regional governmental agencies. The service contract has numerous deliverables all based around providing suggestions to the EC that can be used to decide the form of the future HTA system.

The full regulation will only be implemented in January 2025, but the three-year period up to that point will be quite busy, especially for the newly formed Coordination Group. This will be the main decision-making body under the new regulation and includes representatives of each EU member state. Nominations for the stakeholder network have been sent out, with subgroups set to be appointed shortly.

At the same time as these legislative updates, the two-year service contract is running with several other deliverables. While it is up to the EC to decide how much of the guidance produced under this contract will be reused directly, we are attempting to be as inclusive as possible in our work to create as few surprises as possible for external or future readers and ensure a smooth transfer into the new legislative system.

What do you see as the main adaptation challenges for industry sponsors up to 2025 when the new legislation comes into force?

We are engaging in a formal consultation round for each deliverable to ensure that there are no surprises for industry stakeholders. While there will naturally be several big changes which will take some adaptation, the industry has itself been asking for a more converged European HTA system for several years. When I first started working on a European level more closely a decade ago, the question of why there was not a single HTA decision for the entire EU – as there is on the regulatory side via the European Medicines Agency (EMA) – came up frequently, not least from the industry.

The pharma industry has actively lobbied to ensure convergence between EU member states and has launched several activities focused on both EUnetHTA and the EC. The industry now realises that when you go into a new structure, there will be new features and new demands. We try to be as open as possible with what we propose, showing transparently how we deal with the sometimes over 200 pages of comments we get on one draft deliverable and how the comments are individually integrated.

However, while EUnetHTA 21 remains merely a service contractor made up of 13 voting members and a few invited members there is some overlap with the future Coordination Group. Up to the point at which the Coordination Group is fully established and making its decisions, there will naturally be a degree of uncertainty. Nevertheless, once the EU-wide system is established – bringing together 27 national systems as well as several regional systems – it should bring more certainty around HTA assessments of effectiveness and safety, as well as timelines. Health economics and pricing negotiations will *not* be an EU-wide mandate, but rather stay within the national and regional systems.

The pharma industry via EFPIA and EUCOPE has criticised EUnetHTA 21 as having side-lined their concerns and comments, despite claims that it was a collaboratively composed guidance. What is your response and how do you see this dynamic evolving?

We needed to establish a structure for how to include comments and make consultations while ensuring that we aligned with the principles of the European legislative system. I realise that some of the industry stakeholders feel that their comments were not considered, but we have read and thought about every single one. However, when you have 200 pages of comments, there needs to be a trade-off between responding to each individual one and creating something more condensed.

I know that there has been some disappointment expressed that the changes were smaller than expected, especially in the early deliverables, but that criticism is less pronounced with the publication of the more recent deliverables.

Last time we spoke, you talked about building a HTA system that was more "predictable and flexible." Do you believe that the system currently being put in place represents significant progress towards these goals?

That is our intention. The Joint HTA has been entirely voluntary for companies, member states, regions, and payers. Switching to mandatory Joint HTAs will naturally mean a change in the system, although the final decisions on which system to apply lies with the 27-member Coordination Group.

It is not possible to make promises about what this Group's decisions will be, but as EUnetHTA 21 we try to provide clear, transparent, and predictable products to the Commission and are interested to see how they are eventually used by the Coordination Group.

Given the fact that 39 percent of HTA assessments used real world evidence (RWE) in 2021 according to IQVIA's HTA Accelerator, a record number, how well do you feel that RWE is being used today and how effective a tool is it for assessing costly new therapies?

There is a small space for real world data (RWD) in the joint EU regulation. Post licencing evidence generation can be added into the voluntary work, but there is no strict legal framework for it. While post licence evidence generation and RWD capture are not the main pillars in a joint scientific consultation, there will normally be some discussions about them. In effect, this data comes in through the back door and needs to be closely scrutinised in terms of quality and applicability. For the most part, however, this is a national-level question. While interest levels vary across the EU, there is an increasing realisation that RWE is unavoidable in many contexts and will have to be addressed at some point.

There are several ongoing initiatives globally on this topic. In my opinion, we have come together as a community and have made significant progress in terms of hygiene factors. Standard operating procedures and reporting have been established that would be the equivalent of good clinical practice in randomised clinical trials.

However, there is still a lot of work to do, including from the industry side, on how we value the strength of the data being generated. At what point do we agree that this RWD is strong enough to base a decision on, for better or worse? For example, if an industry sponsor needs to cut its prices or shrink its patient group compared to the original size because of the RWD – which differs from the data generated from a clinical trial – will they agree to it?

In the randomised and controlled clinical trial setting, the industry sponsor has the benefit of being able to ask perhaps 99 percent of the research questions. However, in the RWD space they shall be happy to formulate half of the questions. Instead, individual registry holders, national agencies, or groups of agencies can ask different questions about the data and sometimes obtain quite different results.

Up to 2025 what do you see as the main roadblocks ahead, and what are you most excited about?

Naturally, I am most excited to see the EU HTA legislation finally implemented. After almost 20 years of work, this will finally become a reality in 2025 with joint work on scientific consultations, clinical assessment, and horizon scanning, among other tasks.

This is a necessary shift because of the sheer influx of new products. Only a small portion of member states would be able to handle this influx on their own, while most need to utilise the work sharing mechanism because of national level resource constraints.

In terms of roadblocks, the transformational phase will require a lot of work. In that time, we still need to keep up the production on a national level while channelling resources into excellence and know-how to shape the new joint system.

All national agencies need to work hard and smart, as do the companies themselves. They also face resource and headcount constraints in terms of producing files and submitting dossiers on both a national and European level. For all stakeholders, the next two years will be a big challenge.

Do you have a final message for our international, industry-focused audience?

We have been united in a desire, wish, and need for a more collaborative European approach to HTA for several years. There has long been agreement on how beneficial this approach could be to efficiency and equity across the EU. Do not let small details blur that vision, which should still be our guiding star.

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