



## 4 ways that HTA will change under the new European Regulation

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Over many years the European Network for Health Technology Assessment (EUnetHTA) has been working to get HTA bodies into the same room to harmonise and develop thinking around the assessment of medicines from a societal point of view. The approaches to HTA across Europe vary significantly across member states causing confusion, challenges and increased costs for drug development so the work of this voluntary network has been greatly appreciated by industry, payers and politicians alike.

However, the network’s voluntary nature and a lack of a formalized framework for the continuation of the activities have caused issues to progress and harmonization throughout its existence. To stabilise the situation and institutionalise the continued efforts, the European Commission (EC) therefore presented a new HTA regulation back in January 2018 that will be up for decision in the European Parliament in spring 2019.

Should this new regulation be endorsed as it is, it will have important impact on drug developing companies and the way that drugs will and should be developed if drug developers want to optimise their path to market.

The regulation addresses four things that every biotech CEO and industry leader should be aware of.

## 1 Joint Clinical Assessments

Years of experience and significant respect for the subsidiarity principle enshrined in the Maastricht Treaty has enabled a pragmatic approach in the draft regulation. The regulation does not put any restrictions on how health economic decisions should be made or how pricing of products should be carried out. Instead it focuses on the area of commonality that has been agreed and pushed with EUnetHTA (with varying support from different member states). This area is clinical assessment or the assessment of relative effectiveness of the product.

Should the regulation pass as it is this means that all novel products (defined as any medicinal product passing through the centralised procedure or any medical device or IVD that receives an opinion under the new Medical Device Regulation) will be assessed under a new centralised clinical assessment scheme. This would in theory replace national clinical assessments and could straighten a product's road to market.

Once a product has been assessed for its clinical benefits, national authorities would still have to assess its value in the local market but one crucial step in this process would have been eliminated and the outcome would be harmonised across the EU.

At NDA we will be ready to support clients managing this process when / if the regulation kicks in. Through our extensive experience in the market access area and with support of our partners we are ideally placed to work with companies pulling their HTA dossier together.

## 2 Joint Scientific Consultations

The practice of scientific consultations has become increasingly well-established yet is a relatively under-utilised mechanism for companies to improve their understanding of the different stake-holder requirements. One rea-

son why this is the case is because the process is time consuming. Another is because the procedure is under-resourced and to a great extent based on voluntary contributions from the member agencies.

Under the new regulation all scientific consultations would be managed centrally, including the parallel consultations with the EMA.

This is most likely going to have relatively little impact on the use and performance of consultations to begin with, but by establishing a long-term platform for these activities there will be greater room to expand resources, improve the process and harmonise the contributions from the member states.

NDA's Joint Advice service addresses several of the weaknesses of parallel consultations. By relying on the experts that built the European regulatory systems we deliver high quality, high speed advice. This is used by many companies as a proxy for formal consultation when time is tight, or as a way to prepare for the formal process to maximise the value that can be attained from engaging early with HTA bodies.

## 3 Identification of emerging health technology

Horizon scanning as it's popularly called is a resource intensive activity when it is performed at the member state level. Consolidation of this to a central European function will allow more efficient use of resources, but it will also result in an overall higher quality of the output and material that will be used for training and intelligence at the member state level.

In the long run biotechs and pharma companies can expect their HTA counterparts to be more up to speed with emerging health technologies and that the playing field will become gradually more level across countries thanks to this.

## ④ Voluntary Cooperation

A clause that is easy to dismiss in the new regulation is where it speaks of voluntary cooperation. However, this means that the current cooperation, which has been moving slowly but has left important marks in the way assessments are carried out, has a formal home. This is important as it gives legitimacy and encourages the continuation of EUn-ethHTA's activities in a new and more official format.

Expect this to lead to increased cooperation between HTA bodies in Europe and an increased exchange of scientific and methodological ideas across the member states.

NDA continually monitors the regulatory development to cover any relevant regulatory changes. As many changes are not publicised through regulation, but are a matter of practice in the agencies, our exposure to ongoing procedures and 25% of our staff having experience working at a regulatory body are essential in staying on top of the change. Over the last five years NDA has been involved in more than 40% of the new medicinal products approved in the EU.

### Will it lead to harmonisation?

There are still big differences in the legal traditions, pricing and reimbursement systems and the socio-economic circumstances across the member states of the EU. We will not see these things change overnight, hence it

will take substantial time for these collaborative efforts to bear fruits across the range of the spectrum. Since health care systems and financing is a country matter, appraisals of value and decisions if a new medicine should be granted access will remain a country matter. This includes all decisions around pricing as well.

We have however already seen how collaboration, exchange of ideas and development of joint therapeutic area specific methodologies are spreading. This does lead to harmonisation in a few crucial areas around clinical assessment and is important for drug developers across the world, as it has the potential to make HTA more transparent and therefore predictable.

The new HTA regulation builds on these important steps to increase the transparency and predictability even further. Despite the challenges that remain, this is progress.

As a partner, NDA is ideally placed to support drug development companies navigate through the changes that this new regulation entails. By tracking and reflecting the current thinking and practices of the agencies and by providing tailor made, actionable advice and the help to operationalise this we are looking forward to seeing how this new regulation can help increase predictability and improve the speed with which important therapies reach patients in need, all across the EU.

For more information on how we can support your team with HTA and Market Access questions and requirements, please contact [info@ndareg.com](mailto:info@ndareg.com).