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Getting ready for the new HTA Regulation in the EU

What do companies need to do **now** to be ready?

A Deloitte Point of View

Introduction

With the adoption of the new HTA Regulation (HTAR) at EU level in December 2021[1] aiming to drive the harmonisation of clinical assessment at the EU level and reduction of redundant HTA activities, pharmaceutical and MedTech companies need to rethink the way they have historically prepared for HTA submissions. When looking specifically at oncology and ATMP products for which the regulation will be applied as of 2025, there is an increasing urgency to start preparing now.

Taking a step back, the HTAR is introducing key changes in the HTA landscape:

- The introduction of **Joint Clinical Assessments (JCA)**, an additional mandatory EU centralised HTA submission to assess the clinical benefits of a new technology.
- The introduction of **Joint Scientific Consultations (JSC)**, an optional but recommended early HTA advice at EU level to be considered ideally early before Phase 2 or Phase 3 to shape the design of clinical trials.
- A **harmonised methodology development** based on the learnings of EUnetHTA Joint Action 3, including a comprehensive overview of the different Member States needs and requirements (e.g., population, intervention, comparison, outcome) and a consolidated involvement of physician and patient associations.
- A **new timeline for submission** in parallel of the regulatory process for EMA approval, which is still under discussion until the application of the regulation in 2025.
- **A requirement for Member States' HTA bodies to adapt their local HTA processes** to avoid duplication and focus local submissions on economic and complementary clinical benefits

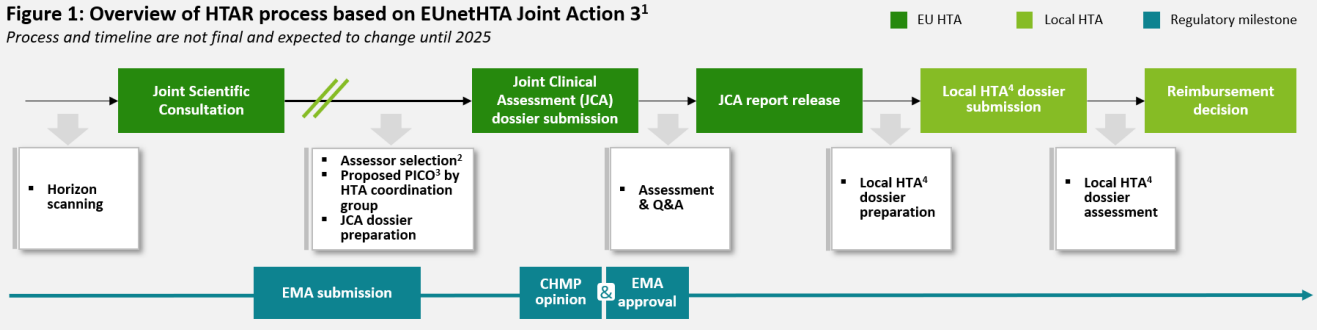
Even though a certain level of uncertainty remains as methodologies and guidelines are being developed until 2025, the impact of those changes on the current ways of working should be addressed now. As the HTA Regulation is restructuring the landscape for clinical benefit assessments, it is currently in the spotlight of many top-level discussions.

While some companies have already gathered learnings by undergoing the EUnetHTA Joint Action 3 process or are currently taking part in EUnetHTA pilots, there is a need to reflect on the scalability and sustainability of new ways of working for multiple asset submissions and therapeutic areas in the coming years, once the regulation is applied to multiple assets and multiple therapeutic areas.

In this paper, we share our point of view on the impacts of the HTA regulation on pharmaceutical and MedTech companies' ways of working. We also discuss how companies can adapt to address those changes on time, while identifying synergies with their current ways of working to improve efficiency and avoid duplication of efforts. Our point of view is mainly based on discussions with industry experts who underwent the Joint Action 3, regular questions from the industry, our observations during external events, and our research on the HTA Regulation.

Figure 1: Overview of HTAR process based on EUnetHTA Joint Action 3[1]

Process and timeline are not final and expected to change until 2025



Note: (1) EUnetHTA has undertaken several waves of voluntary Joint Assessment, with the last one being Joint Action 3. The HTA Regulation JCA process is based on the EUnetHTA JA3 but will be mandatory in nature; (2) Two national HTA bodies are nominated to be assessors; (3) PICO = Population, Intervention, Comparison, Outcome (Standard format for the definition of a research question); (4) HTA = Health Technology Assessment.Source: Monitor Deloitte analysis based on discussions with industry experts who underwent the Joint Action 3 voluntary assessment.

[1] European Commission (2022). Regulation on Health Technology Assessment.

“While there is still a level of uncertainty, we urge our Life Sciences clients to actively prepare and re-shape their ways of working to avoid taking strategic decisions that may negatively impact access and profits.”

Marc Abels, Life Sciences Strategy Leader

Will all industry players be impacted by this?

Yes. The first key impact is on global and regional teams, who need to introduce new activities and adapt their current ways of working, while anticipating a potential opportunity for synergies and reduction of duplication at local level.

Global and regional teams will face a need to address new strategic decisions as well as intensify cross-functional collaboration with local teams. Some activities will need to be executed earlier and capacity challenges will need to be addressed due to an increased workload at peak times. In addition, existing collaboration platforms and tools can be reconsidered to foster co-creation and tighter collaboration within the organisation.

Based on the changes driven by the introduction of the new HTA Regulation, as well as lessons learned by pharmaceutical companies that underwent the voluntary EUnetHTA Joint Action 3 process, we have identified six areas of impact on the internal processes of pharmaceutical companies.

1. Strategic decisions

New strategic decisions will need to be taken at critical points in time throughout the development stages of a product. A few examples include a go/no-go decision for Joint Scientific Consultations, the decision to go for joint consultation with EMA or not, the weight of EU HTA requirements in decisions on early trial design compared to regulatory requirements, etc.

Most of those decisions will need to be taken on an asset-per-asset basis, and companies need to reflect now on when they need to take those decisions and who should be involved, in order to embed those steps in their ways of working.

2. Cross-functional ways of working

Collaboration and coordination with global and regional cross-functional teams will need to be reinforced at key critical points in time, from alignment in the early development stage when drafting early PICO[2] iterations and taking decisions on trial design to the preparation and the submission of the Joint Clinical Assessment dossier.

Specifically, we expect a need to intensify coordination between access and regulatory teams, as the JCA process will run in parallel with the regulatory approval process. Alignment on messages and external stakeholder interactions, such as the Coordination Group and EMA, will be key to success. Looking at the other functions, medical affairs, R&D/clinical and HEOR will need to be heavily involved throughout the end-to-end development stage until the launch.

3. Local involvement

To reduce duplications at country level, one of the key elements to be considered is to build a centralised process where local needs are considered early on in a comprehensive clinical effectiveness approach. Looking at previous voluntary JCA submissions with EUnetHTA, the input and contribution of local teams have been essential at several points in time in the process. Regular updates with affiliate teams were generally implemented with workshops at critical milestones, especially regarding internal scoping decision and EUnetHTA final PICO choice to enable affiliates to start developing their local HTA dossier early on and avoid duplications with the JCA.

However, even though the JCA dossier aims to reflect all EU Member States needs as best possible, regular interactions with all affiliates may seem time consuming and difficult to implement from an organisational perspective. Several approaches may be considered, such as higher interaction in EU4 markets (France, Germany, Spain, Italy), country archetype representatives, or affiliates in which the HTA bodies have been assigned as assessors for the JCA process.

4. Workload and resources

During previous voluntary assessments, several companies expressed a high intensity of work with the need to mobilise global and regional teams in a short timeframe. Looking at the HTA Regulation, the workload for global and regional teams is expected to increase

[2] PICO = Population, Intervention, Comparison, Outcome (Standard format for the definition of a research question)

with mandatory submissions for several assets in parallel. Companies will need to reassess the time dedication of their teams and develop capacity forecast capabilities.

From a capabilities perspective, HTA technical skills at global and regional level are going to be more important in discussions on methodological challenges, SLRs, and indirect treatment comparisons (ITCs) to perform complex analyses, for example.

Lastly, the creation of new roles could be considered to facilitate the process, such as a project management role to coordinate the intensive submission process and deliverables across all stakeholders.

5. Timeline

Looking at the JCA preparation and submission happening in parallel with the regulatory approval process, companies should consider moving up some of their existing pre-launch activities in order to be ready for submission. Not only will certain activities be starting earlier, but some activities may require a longer duration due to more complexity in addressing additional statistical analysis for several PICOs for instance.

In addition to shifting existing activities, internal alignment will be required to decide on when to introduce new activities in the current processes. Examples of such new activities could be PICO preparation and refinement, engagement with EU clinical experts, clinical organisations and patient groups, JCA dossier preparation and submission, etc.

6. Platforms and tools

Lastly, rethinking existing technologies and collaboration platforms will foster JCA submission preparation and delivery. Central user-friendly document repositories and version control could enable companies to save time and efforts.

Other quick wins to be considered are to redefine the global document structure based on the EUnetHTA templates to reduce the amount of re-work to meet eventual requirements, and leveraging the PICO framework internally in early strategic reflection to identify evidence needs and gaps.

The changes highlighted above are expected to impact the entire end-to-end development pathway, but synergies with existing processes can be identified in order to foster efficiency and avoid duplication of efforts, especially when looking at the centralisation of certain activities that can be leveraged by affiliates for local submissions.

Figure 2: Six types of impact on internal processes of pharmaceutical companies

Source: Monitor Deloitte analysis.

Are all countries going to be impacted in the same way?

Not really. By categorising countries into archetypes, we can identify the expected reaction of HTA bodies to the new HTA Regulation and anticipate the level of disruption and opportunities for process efficiency for pharmaceutical companies at affiliate level.

One of the main objectives of the regulation is to reduce redundant HTA clinical assessments across EU Member States, but also to benefit countries which may have less developed HTA capabilities or infrastructures. EU Member States' HTA bodies will be focusing the content of local submissions on economic and complementary clinical benefits only, and will therefore need to adapt their local HTA process accordingly.

From an industry perspective, this change comes with many questions and uncertainties. Affiliates may ask to which extent is their country HTA body going to rely on the JCA report to draw conclusions on the clinical benefits of the health technology, will the local submission process and requirements drastically change, what will be the magnitude of work related to additional complementary clinical analyses required, etc.

In order to anticipate the level of disruption that may be expected at local level, we have built a framerwork to monitor the expected reaction of local HTA bodies, by clustering EU countries in archetypes. This has been evaluated on a matrix looking firstly at the HTA maturity of the country, and secondly at the expected willingness to collaborate. The expected willingness to collaborate is a current snapshot of the HTA body's previous involvement in Joint Action 3, current involvement with EUnetHTA 21, their internal dossier requirements, as well as capabilities and capacity constraints. This snapshot is therefore likely to evolve in the future and the monitoring framework should be updated regularly.

We have clustered countries in four main archetypes for the EU, and one archetype for countries beyond the EU as described in Table 1 below. The table also indicates the level of disruption on already established affiliate market access teams in pharmaceutical organisations, as well as the potential for process efficiencies from an organisational perspective.

Table 1: Point of view – Country archetypes to monitor the expected reaction of HTA bodies to the introduction of the HTA regulation

			Impact for pharma & MedTech	
	Archetype	**Description of the country archetype**	**Level of disruption**	**Process efficiencies**
EU	**Safeguards**	Countries with **mature local HTA**, with a high likelihood to apply limited changes to their current procedure and ask for additional clinical analysis based on their **well-established local value assessment specifications**	◔	◔
EU	**Timesavers**	Countries with a **mature local HTA**, but can **benefit from accelerated process** and aim to minimise the additional data requests	◑	◕
EU	**Discoverers**	Countries with a **limited mature local HTA**, but that would use the introduction of the HTA regulation as a **local capacity improvement** to enhance their HTA procedures or create new ones	◕	◑
EU	**Backbenchers**	Countries with a **limited mature local HTA**, which are more **reluctant to change their HTA process** and will continue to focus mainly on budget impact considerations	◔	◔
Beyond EU	**Observers**	Countries **not impacted by the regulation** but that can **access the published JCA report** and potentially refer to it or its content when going through HTA	◔	◔

Legend: ◔ Low ◑ Medium ◕ High

Source: Monitor Deloitte analysis.

Already established affiliate market access teams can expect different levels of disruption on their current ways of working depending on the HTA body maturity and expected willingness to collaborate

Safeguard countries

Safeguard countries typically have well-established and mature HTA processes and infrastructure with specific requirements to assess the clinical benefits of a new technology. Furthermore, HTA bodies are more likely to be reluctant to change their current processes, either due to strict internal requirements unlikely to be addressed by the JCA report, or because they haven't been actively involved in past joint HTA initiatives.

For example, Germany is an EU country with a mature HTA infrastructure and very strict internal requirements for HTA submissions. Denmark also has strict requirements and a low participation rate in other EUnetHTA initiatives, which suggest that they may be more reluctant to significantly adapt their current HTA processes.

Some other countries also have a highly mature HTA practice, such as France and Italy, but those countries have shown an active involvement in the Joint Action 3 and EUnetHTA21. Therefore, due to their high willingness to collaborate, we can expect them to progressively shift from safeguards to timesavers even though they have strict requirements for clinical benefits assessments.

From a pharmaceutical organisation perspective, market access teams in safeguard countries can expect the local HTA submission process to be lightly disrupted. Therefore, even though this implies they won't need to drastically adapt their internal procedures for local HTA submissions, affiliate teams may not benefit from process efficiencies from the introduction of the HTA Regulation. Moreover, they may need to contribute to the creation of the JCA dossier which may increase organisational complexity at local level in those countries.

Timesaver countries

Timesaver countries also have an established and mature HTA infrastructure, but they are more likely to adapt their current processes in order to benefit from an accelerated HTA process and minimise additional data requests. This willingness to adapt can be due to their less strict requirements to assess the clinical benefits of a new technology, and/or a willingness to collaborate illustrated by their active involvement in past joint HTA initiatives.

For example, Norway and Sweden are two countries that have a highly established national HTA pathway and have shown an active involvement in past and current EUnetHTA initiatives. We can also expect Belgium to fall into this archetype due to their established HTA process, with signs of involvement with EUnetHTA and participation in other joint HTA initiatives such as Beneluxa.

Looking at the Netherlands, this is a particular case where HTA processes are well established for non-oncology/ outpatient products, but they have an insurer-based mechanism for inpatient oncology products which may limit the use of the JCA report. However, the Netherlands is showing a clear willingness to collaborate through, among other, their participation in EUnetHTA and Beneluxa initiatives.

In timesaver countries, affiliate market access teams can expect a higher level of disruption of the local HTA submission process as country HTA bodies may be inclined to adapt their current processes. However, this also comes with an opportunity for faster access to reimbursement and process efficiencies, as the affiliate teams will be able to leverage the JCA report as a basis to build their dossier for reimbursement.

"We expect timesavers and discoverers to benefit from a higher potential to fasten the submission process with the HTA Regulation, even though this implies a higher level of disruption of local HTA dossier submission processes."

Burçak Aydin, Deloitte HEOR specialist

Discoverers

Discoverers are countries that have a less established HTA process and infrastructure, but they see the introduction of the HTA Regulation as an opportunity to enhance or further build their local HTA processes. Those countries have generally shown involvement in previous joint HTA initiatives and we understand they are willing to collaborate.

For example, Spain has a moderately established HTA infrastructure but the high involvement of AEMPS in Joint Action 3 and EUnetHTA21 symbolises their willingness to collaborate and adapt to the new regulation. Looking at Portugal, they have shown great enthusiasm in using JCA reports in recent assessments and they are actively involved in EUnetHTA21. We can also expect Slovenia and Hungary to fall into this archetype.

This willingness to further enhance their HTA capacity may lead to a higher level of disruption in discoverer countries. Driven by the new standard methodologies and guiding documents developed by EUnetHTA, HTA bodies in those countries will adapt and improve their current process for local HTA submissions. Consequently, local market access teams in pharmaceutical companies will need to adapt their current ways of working in order to deliver against those new requirements.

Backbenchers

Backbenchers is our last archetype for the EU and describes countries with a less established HTA process and infrastructure that are more reluctant to change their HTA process. In those countries there is no clear sign of willingness to collaborate under the Joint Action 3 and EUnetHTA21. We can therefore expect them to continue focusing mainly on budget impact considerations.

Lithuania, Estonia, Latvia and Greece are examples of countries with a less mature HTA and no or limited past involvement with EUnetHTA.

In backbencher countries, affiliate market access teams in pharmaceutical companies can expect a very low level of disruption of their local HTA submission process. However, depending on how the global and regional market access teams decide to involve smaller countries in the JCA dossier development, backbenchers may still need to contribute to the creation of the JCA dossier which may introduce some capacity and capability issues at affiliate level.

As a conclusion, we expect timesavers and discoverers to benefit from higher process efficiencies with the introduction of the HTA Regulation, even though this implies a higher level of disruption of local HTA dossier submission processes. The categorisation of EU countries into the different archetypes is illustrated in Figure 3 below.

Observers

When talking about the HTA Regulation, we primarily think about the direct impact on EU countries, looking at how HTA bodies will react, but also how pharmaceutical companies will need to adapt. However, we can also expect an indirect impact on countries beyond the EU.

As the JCA report will be realised under globally recognised methodology standards and available in English, it might potentially become the new reference for the rest of the world.

In this last archetype, we include in observers all countries outside the EU that are not impacted by the HTA Regulation but can use the content of the published JCA report or reference it in their conclusions.

It therefore becomes even more important for pharmaceutical companies to get this right, as a negative opinion in the JCA report might influence the assessment of other countries such as Japan or China, leading to a potential negative commercial impact outside the EU.

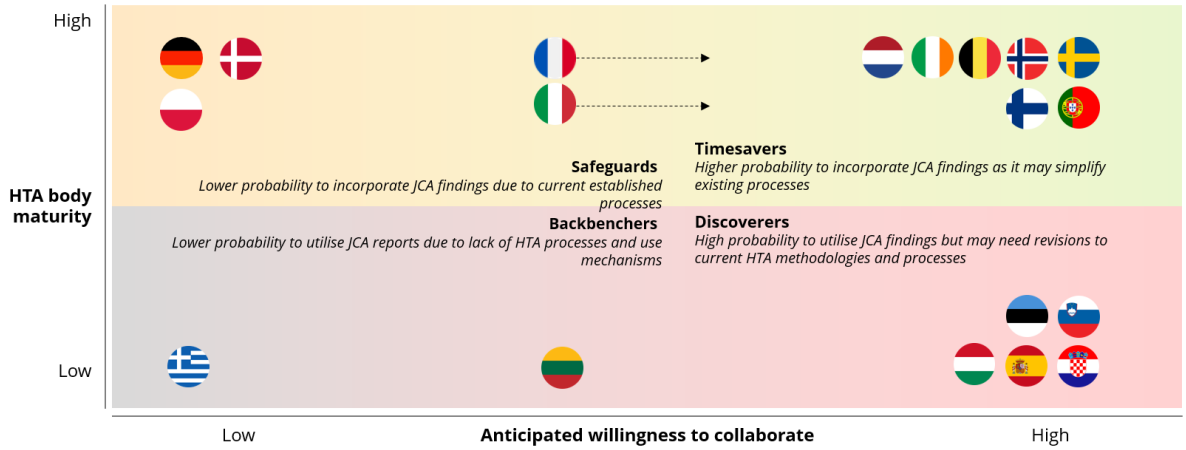


Figure 3: Categorization of EU countries into a country archetypes matrix illustrating the expected reaction of HTA bodies to the introduction of the HTA regulation

"Getting JCA submissions right will be important not only to optimise access in the EU, but the JCA report may also be referenced by other countries and impact access beyond the EU"

Burçak Aydin, Deloitte HEOR specialist

Are you ready from an organizational perspective?

Probably not. So far, most players we have engaged with have taken preliminary steps but none have wholeheartedly analysed the impact front to back and made adequate changes. In order to understand the organisational readiness, access leaders will need to ask themselves some critical questions and act upon those to be ready as an organisation by 2025.

As a pharmaceutical or MedTech company, whether you have already been involved in voluntary joint assessments through EUnetHTA or not, the application of the new HTA Regulation will require your organisation to prepare early enough and scale up to ensure successful submission for multiple assets by 2025 for oncology, but also by 2028 for orphan diseases. But concretely, what do you need to do? To clarify where you are, we are providing a snapshot below of some of the key questions access leaders need to ask themselves to evaluate their organisational readiness.

Key questions access leaders need to answer to evaluate their organisational readiness

"Are the global and regional **access teams aware** of the changes introduced by the new HTA Regulation?"

"Have you already **onboarded cross-functional teams**, such as medical affairs, regulatory, clinical teams?"

"Have you set the **priorities** in terms of critical actions you need to act upon now to be ready for your **upcoming launches in 2025-2026**?"

"Have you already **aligned cross-functionally** to define how to adapt your current **ways of working** in terms of activities and processes?"

"Have you designated a **lead** to drive the **organisational change** and continuously follow the **updates from EUnetHTA**?"

"Have you already defined the appropriate **governance mechanisms** and **roles and responsibilities** cross-functionally in order to successfully deliver JCA submissions?"

"Have you evaluated the impact in terms of **resources** and **capabilities** at global, regional and local level to **ensure scalability** for several asset submissions?"

"Have you explored the opportunity to invest in **enabling technologies** to ensure high **quality delivery** of the Joint Clinical Assessments?"

"Do you have a **change management** plan in place to ensure a **smooth internal transition**?"

"Did you consider the implementation of **performance monitoring** mechanisms (e.g., KPIs)?"

Have you reviewed your **pipeline** and analysed **which assets will be impacted first** and what actions you will take?

Conclusion

Is the HTA regulation only impacting the pre-launch stage?

No. The changes expected will not only impact the preparation of the dossier itself. With the introduction of the new HTA Regulation, it is clear that pharmaceutical and MedTech companies will need to adapt the way they have historically organised internally to prepare for HTA submissions. It will introduce changes along the end-to-end asset development stages and impact all cross-functional teams.

When should companies start adapting their current ways of working?

Now. As the regulation will apply as of 2025, many pre-launch preparation activities should already start now, but should be adapted by e.g., introducing new strategic decisions, adapting the way teams collaborate cross-functionally and how local teams are being involved.

Looking into the future, the HTA Regulation will apply to orphan drugs by 2028 and all drugs by 2030. Therefore, a long-term plan to ensure organisational readiness and scalability in terms of processes, people, tools, structure and governance is a must.

How to adapt when EUnetHTA guidelines and methodologies are still in development?

Plan ahead but stay agile. As many uncertainties remain, it is harder for pharmaceutical and MedTech companies to build a detailed plan ahead. Among other, methodologies and guidance documents are still being finalised by EUnetHTA, the final JCA process and timelines are still subject to change by 2025, and HTA bodies will need to adapt their local HTA processes to take into account the JCA dossier and avoid duplication of efforts. Therefore, companies will need to stay agile and be able to change plans quickly when needed.

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