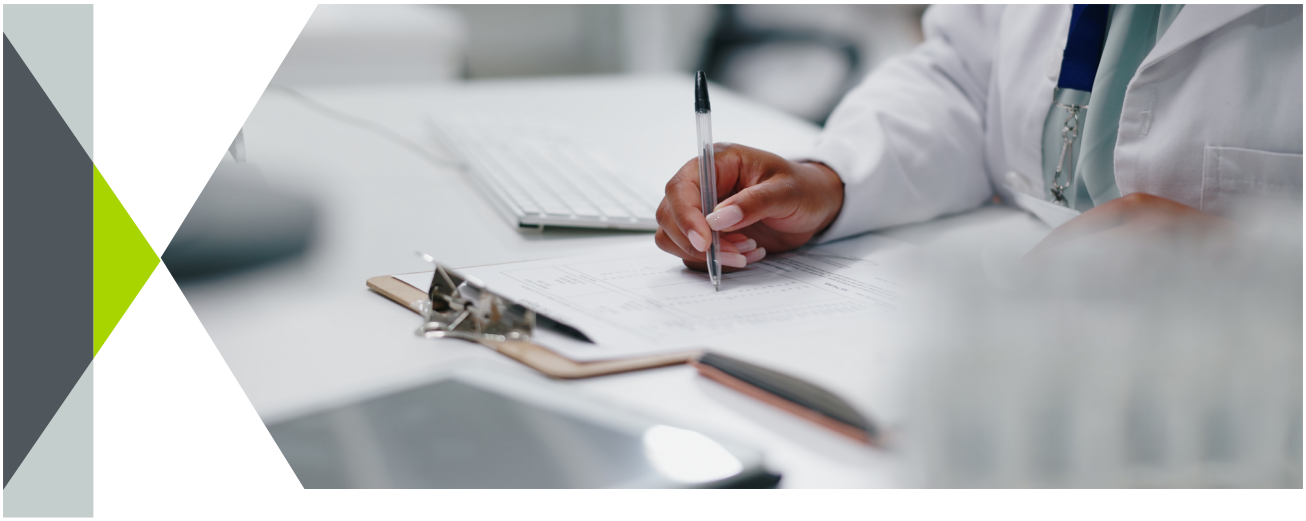


EXECUTIVE INSIGHTS

Transitioning to EU-Wide Health Technology Assessments: Implications for Pharma

Key takeaways

1. The Joint Clinical Assessment (JCA) is now mandatory for oncology and advanced therapies, signalling a major shift in EU health technology assessment processes.
2. Pharma companies can expect faster access to more EU markets, but must balance this with increased complexity and resource demands.
3. Early alignment of clinical trial design with PICO requirements and JCA timelines is essential for streamlined market access.
4. Success under the new framework requires stronger cross-functional collaboration and earlier involvement of market access teams.

Introduction

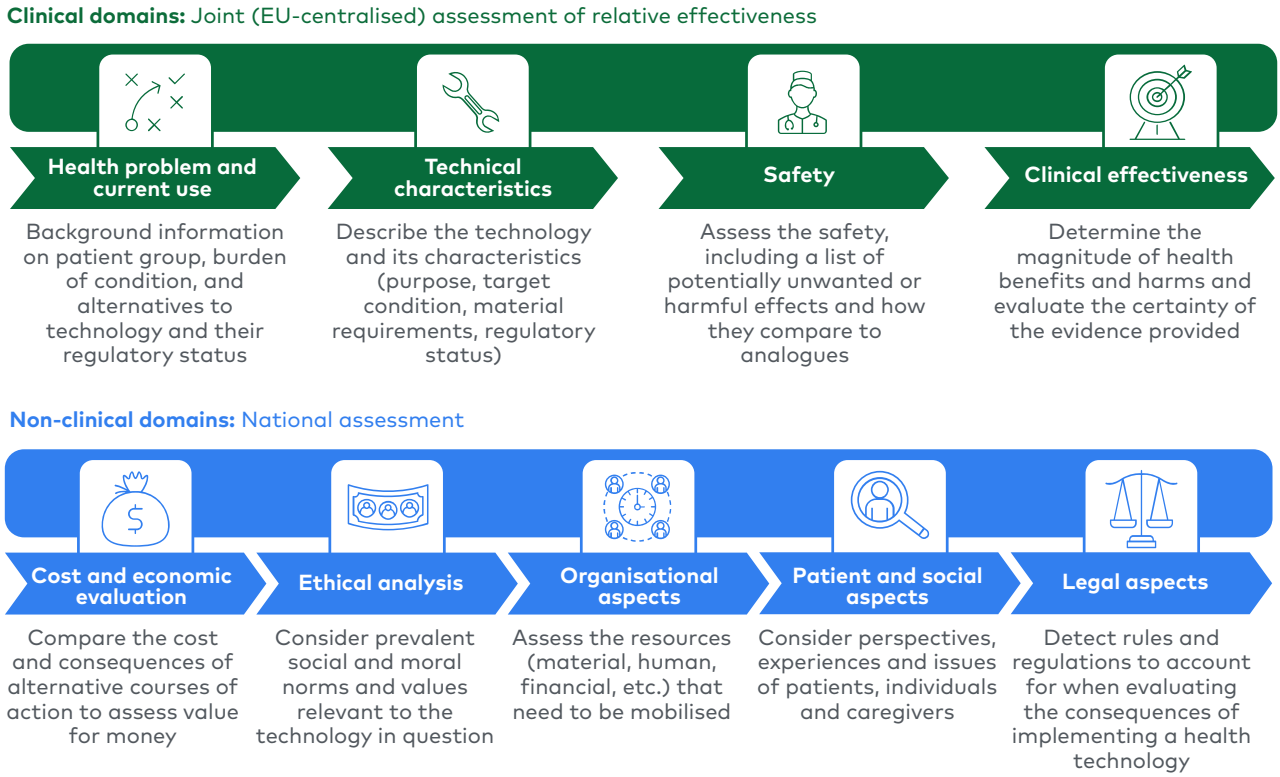
2025 is seeing the gradual implementation of the Joint Clinical Assessment (JCA) as part of the EU Health Technology Assessment (HTA) regulation, which will allow European member states to jointly assess the clinical evidence for new health technologies, with the goal of harmonising clinical assessments across member states and ultimately achieving the timely availability of new therapies across Europe.

From 12 January 2025, JCAs have become mandatory for all oncology drugs and advanced therapeutic medicinal products. This will be extended to orphan drugs in 2028 and to all centrally registered products in 2030.[1]

Under the EU HTA regulation, four clinical domains will be assessed centrally as part of the JCA, while the remaining (non-clinical) domains will remain part of national assessments (see Figure 1). Reimbursement and pricing decisions informed by the JCA and by national HTAs will continue to be made at the national level.

Figure 1

Domains of the HTA Core Model



Note: HTA=Health Technology Assessment
Source: HTA Regulation (2018); L.E.K. research and analysis

While the JCA should replace the national assessment on clinical domains, national HTA bodies will remain free to demand additional analyses on clinical domains that were not evaluated in the JCA if deemed necessary to inform reimbursement and pricing decisions. However, countries are not allowed to request a study that would yield the same data as what has already been submitted as part of a JCA.

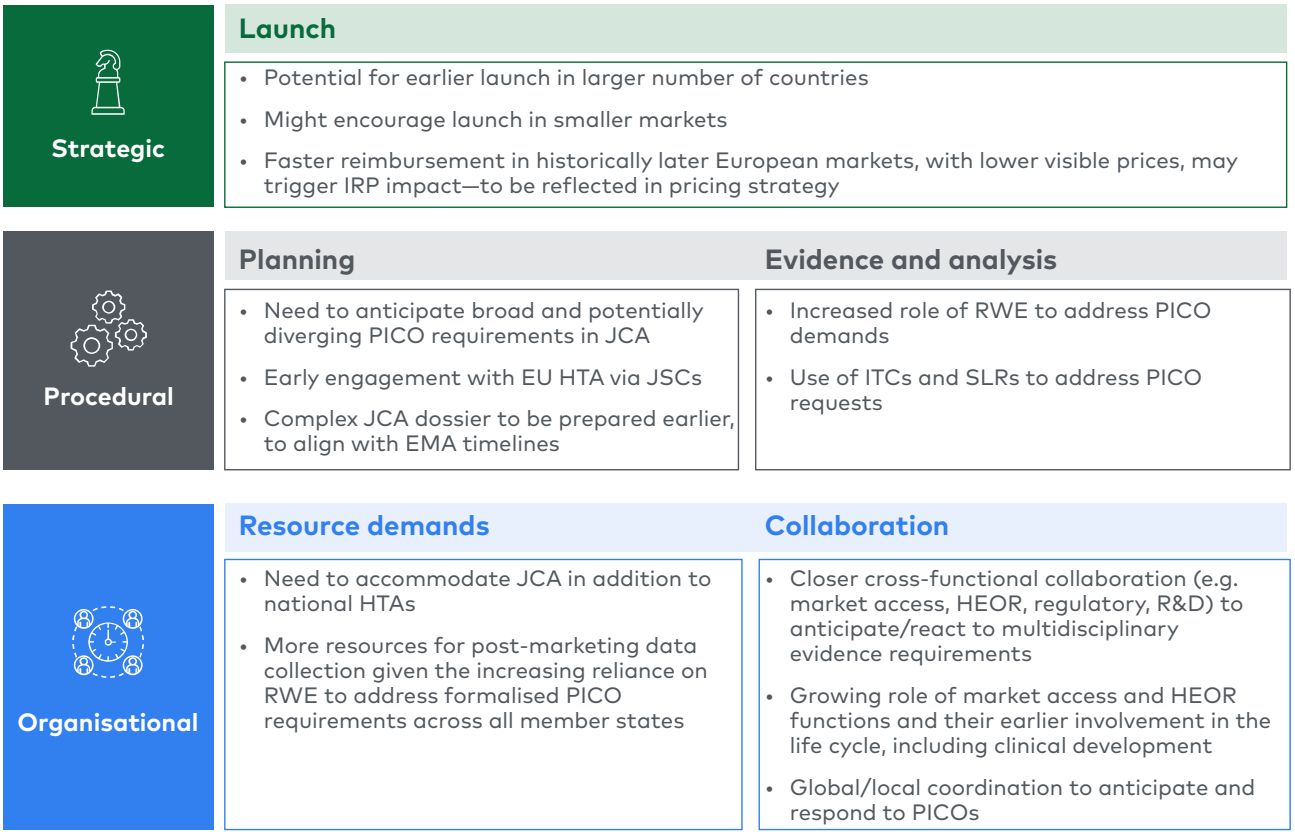
By introducing a central assessment on clinical domains, the EU HTA regulation will substantially disrupt established HTA processes for member states and health technology developers alike.

Building on our previous analysis of the transition to EU-wide HTAs,[2] this *Executive Insights* further explores the implications of JCAs for pharma companies along three dimensions: strategic, procedural and organisational.

We anticipate that the JCA will impact pharma companies' launch strategies in Europe by enabling faster access to a larger number of markets. From a procedural point of view, we expect changes to evidence collection and analysis as well as to pharma companies' engagement with HTA bodies. Finally, the JCA will affect pharma's resource requirements and drive the need for a more access-oriented cross-functional collaboration (see Figure 2).

Figure 2

JCA implications for pharma



Note: HTA=Health Technology Assessment; IRP=international reference pricing; PICO=population, intervention, comparator, outcomes; JCA=Joint Clinical Assessment; JSCs=Joint Scientific Consultations; EMA=European Medicines Agency; RWE=real-world evidence; ITCs=indirect treatment comparisons; SLRs=systematic literature reviews
Source: L.E.K. research and analysis

Implications for pharma: Strategic launch priorities

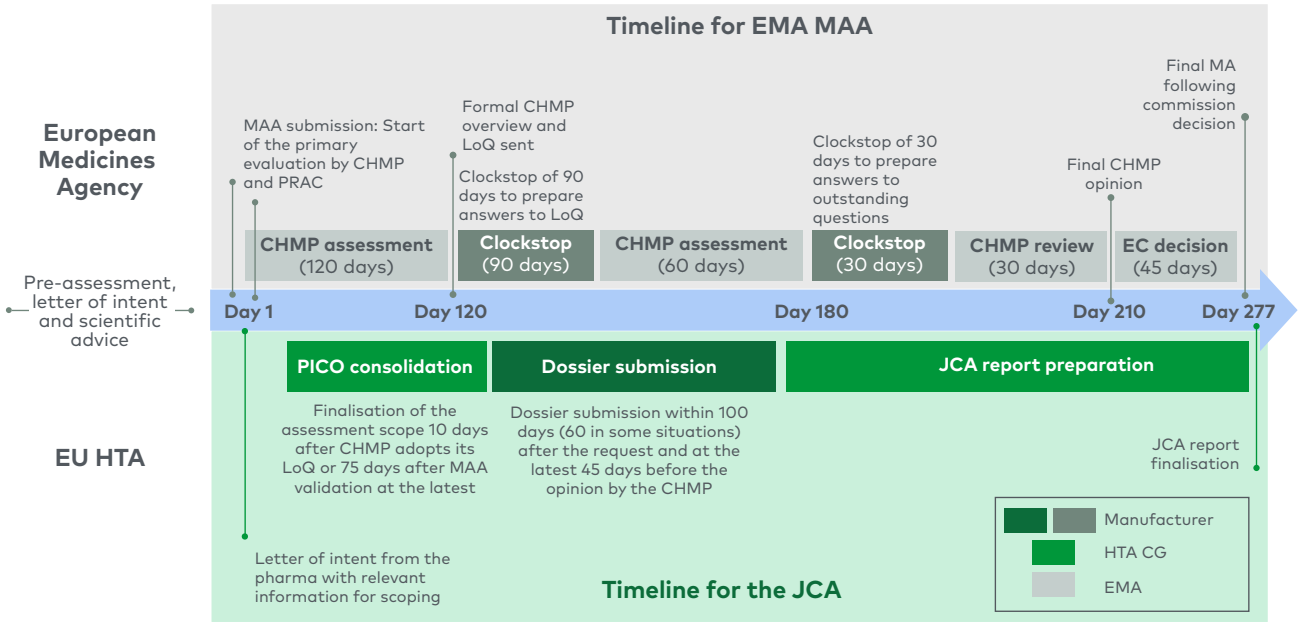
A central tenet of the EU HTA regulation is the alignment of the JCA process with the European Medicines Agency's (EMA) marketing authorisation application (MAA) timeline.

While national HTA processes tend to follow the regulatory procedure, the JCA is performed in parallel: The JCA report is intended to be finalised by the JCA subgroup at the latest on the day when the marketing authorisation is granted (see Figure 3). As a result, the JCA has the potential to accelerate HTA decision-making relative to the established national process.

Further, the availability of central harmonised guidance on clinical domains might eventually make national reimbursement and pricing decisions more efficient, thus shortening the time to reimbursed access.

Figure 3

Timelines of EMA MAA and JCA processes



Note: CHMP=Committee for Medicinal Products for Human Use; EMA=European Medicines Agency; HTA CG=HTA Coordination Group; JCA=Joint Clinical Assessment; MAA=marketing authorisation application; PRAC=Pharmacovigilance Risk Assessment Committee. The PRAC is the EMA's committee responsible for assessing and monitoring the safety of human medicines; the letter of intent should be sent to the Joint Production Team of the EU HTA CG in charge of producing joint assessments
Source: EUnetHTA; EMA; L.E.K. research and analysis

Pharma companies need to keep these accelerated timelines in mind in their launch decision-making as this, together with the coverage of all member states in a joint assessment, will facilitate earlier reimbursed access in a larger number of countries, including smaller markets which have traditionally been deprioritised for launch preparations. Launch readiness and tracking will be more important than ever, given the shortened time frame from regulatory submission to market access.

In this context, pharma companies will have to review their EU launch cadence, with the potential for earlier launch waves in a greater number of markets. However, the opportunity for earlier access needs to be balanced with associated launch costs and pricing implications, as faster reimbursement in historically later European markets, with often lower visible prices, may accelerate price erosion driven by international reference pricing.

> "Most companies have traditional launch waves, going by size of market, but I think [the JCA] will expedite the waves and make midsized markets more attractive. … It will help to prioritise and sharpen the launch sequencing efforts within Europe. I expect that midsized markets will get pulled higher up the launch sequence because a certain amount of the market access work will already be done [via the JCA]." — global head of market access, midsized pharma company

While the JCA might bring smaller markets into closer reach, interviewed experts fear that it will add complexity, which will be challenging, particularly for smaller companies, and might prompt these to reconsider their European launch approaches altogether. This might include deferring European launches or seeking an experienced licensing partner familiar with regional market access requirements.

> "The biggest challenge is to ensure that the process does not hold back smaller pharma/biotech companies from coming to Europe. It could turn out to be so cumbersome and costly that they may just decide not to come." — head of European market access, midsized pharma company

Implications for pharma: Procedural changes will impact evidence generation and analysis

Submission process and timelines

The JCA process will trigger procedural changes in multiple dimensions, including in the way evidence requirements are specified and submitted, as well as in the HTA timeline.

The JCA starts with the scoping process. To this purpose, a population, intervention, comparator, outcomes (PICO)[3] survey is set up to provide each member state with the opportunity to communicate PICO parameters. Disparities between countries in terms of expected endpoints and comparators may initially result in a high number of PICO parameters, but answers will be consolidated and condensed as much as possible.

The consolidated PICO requirements will be transmitted to pharma companies to allow them to gather the necessary data. Assessors and co-assessors will then evaluate the evidence provided and draft the JCA for publication by the European Commission.

A challenge of the PICO scoping process is that it occurs after the pharma company has applied for EMA approval, meaning that requests from the survey cannot be reflected in the clinical trial design. Further, the need to amalgamate PICO requests from 27 member states will bring complexity, particularly in therapeutic areas with significant differences in clinical practice across markets, and could result in requests for analyses which were not specified as part of the trial design.

Pharma will need to anticipate PICO needs and seek guidance on PICO requirements as early as possible. This highlights the importance of joint scientific consultations (JSCs), which can occur ahead of clinical trials to make sure that inputs from national HTA bodies are considered during the design process.

Companies must be prepared to prove eligibility for the JSC in the selection phase. This includes demonstrating unmet medical need, highlighting the expected positive impact on

patients and healthcare systems, aligning with major EU clinical priorities, and applying for the JSC while phase II and III studies are still in the planning stage.

However, concerns remain about meeting the growing demand for scientific consultations given the limited availability of slots. To address this, simulating PICO requirements through other routes — such as early engagement with national HTA agencies, medical organisations and patient associations — will be critical.

> "The JSC in itself is not enough. The JCA isn't binding, and it is on the local HTA body to interpret the data in the JCA as it sees fit and also to request any extra data to meet the national requirements. So I think that even if you get a JSC slot you will still have to take local early advice as well. For example, the German G-BA recently highlighted that a separate consultation at [the] national level is recommended, in addition to the JSC." — head of European market access, midsized pharma company

Pharma companies will need to plan their submission strategies and processes carefully to align with both EMA and HTA timelines, taking into account that the new JCA timeline creates a short window of time from receipt of the scoping document to develop a comprehensive dossier.

> "The JCA is running concurrently with the regulatory process and hence comes way earlier than the national HTA submissions. This means that market access teams need to start their planning much earlier." — head of European market access, midsized pharma company

Evidence collection and analysis

The multitude of scoping requests from member states may create evidence-generation challenges, particularly considering the timing of the scoping process after the initiation of clinical trials. This might strengthen the role of real-world evidence in supplementing the JCA evidence base and meeting PICO demands (e.g. as an external comparator group for single-arm trials).

Further, it is expected that indirect treatment comparisons (ITCs) will play a major role in addressing the evidence needs specified by member states, supported by the methodological guidance on ITCs provided by the Member State Coordination Group on HTA (HTA CG).[4] Planning the necessary systematic literature reviews to feed into the ITCs will be key to addressing diverse PICO requirements across member states.

Implications for pharma: Organisational demands on resourcing and collaboration

Increased resource demands

Pharma companies must allocate resources to meet the EU HTA regulation requirements in the context of tight timelines. This will increase operational demands, particularly for those preparing for assessments in 2025. Companies need to consider how to secure and deploy resources in a cost-efficient manner. If external expertise and/or additional internal resources are used, the budget for this needs to be secured early to avoid delays in accessing support ahead of critical inflexion points.

> "Having the JCA run in parallel with the EMA submission is the biggest change. For local dossiers, the pharma company decides when to submit and where. The JCA is mandatory; you need to prepare it in parallel with the MAA and there are very clear timelines for the submission, so there is less control. This has the potential to increase resource needs at least during peak times." — head of European market access, small pharma company

For smaller companies building up European infrastructure, this means having affiliate market access resources in place earlier to accommodate the JCA timeline.

> "Affiliates need to engage with access stakeholders earlier. They have work to do at a local level much earlier to collect information and feed [it] into the JCA dossier; this is one of the fundamental changes I see. Smaller companies launching in Europe for the first time need to be aware that they can't postpone the local head counts — they need them earlier, no longer just six months before approval." — head of market access, small pharma company

> "The timeline is so crunched for the JCA it means we will need extra staff. Although the JCA and local dossiers should be non-duplicative, I think there is definitely more work, just due to the fact that we need to submit two dossiers — the JCA and then the local one. This means you need local experts who know the country-level HTAs well and then you need a set of experts at the European level. This is almost like adding another large country to your market access organisation." — head of European market access, midsized pharma company

Cross-functional collaboration

The complexity and timing of JCA preparation will require closer coordination between functions, most notably market access, health economics and outcomes research (HEOR), clinical R&D and regulatory. Breaking down silos will be essential for early scientific consultations and for planning the evidence generation, including the anticipation of PICO demands, and in order to develop the dossier.

Companies will need to adapt governance structures to integrate EU HTA regulation capabilities and ensure its strategic importance is clearly communicated across the organisation.

> "We need close collaboration across regulatory, access [and] HEOR at a minimum during the entire process. Any changes in regulatory need to immediately feed into access because the processes are happening in tandem." — head of market access, small pharma company

Further, the EU HTA regulation is expected to shift the market access and HEOR functions into focus and emphasise its centrality for successful launch and commercialisation. Closer collaboration between access and other functions, and in particular the increasing need to consider HTA requirements in clinical development planning, will strengthen the role of market access and reinforce the shift towards an integrated value-and-access function for more effective engagement with HTA bodies.

> "In general, the idea that clinical development will be tailored more to the requirements of HTA bodies is an old one, but I think [the JCA] will put more emphasis on the importance of HTA demands. You need cross-functional teams — access, regulatory and clinical at a minimum — for discussions on trial design early on as part of the scientific consultation."
> — head of market access, small pharma company

> "I think it will motivate clinical development to involve market access earlier and follow their recommendations more closely to ensure that we don't have trial designs that don't meet payer needs." — head of European market access, small pharma company

Conclusions and implications

The EU HTA regulation offers valuable opportunities for harmonising clinical assessments across EU member states, facilitating and accelerating market access in a larger number of countries, and potentially improving HTA outcomes by forcing market access to be a central part of the clinical planning process (via JSCs).

This will come with significant procedural and organisational implications for pharma companies, adding timeline, resource and commercial pressures. Most notably, the alignment of the regulatory and JCA timelines, the need for early scientific consultations and for simulating PICO requirements across member states, and the requirement to accommodate both the JCA and local HTA submissions will add workload and complexity for market access teams and other functions. This requires capacity building, particularly among smaller companies, as well as closer cross-functional collaboration and coordination between local and global teams.

Procedural and organisational changes might present challenges, but they will also create opportunities for a more central, effective and impactful market access function. Earlier and closer integration of market access considerations into the drug development and commercialisation processes might ultimately lead to better reimbursement and pricing outcomes and, hence, improved access for patients.

> "The JCA will be difficult in the beginning because companies aren't used to it and don't have processes in place, but I think it will be a positive in the mid and long term. Some colleagues who have worked in more siloed companies think that it will give market access more power to input into the process earlier, and other functions are more likely to listen. It should lead to better HTA outcomes, as pharma companies are more likely to deliver what is valued by payers."
>
> — head of European market access, midsized pharma company

How L.E.K. Consulting can help

The EU HTA regulation will bring significant changes to EU market access processes. Pharmaceutical companies need to prepare by adapting internal submission processes and templates to meet JCA requirements and timelines, anticipating PICO needs, and engaging in consultations with regional and local stakeholders to embed HTA requirements into evidence generation.

L.E.K. can provide tailored perspectives on the implications of the EU HTA regulation for pharma companies, covering market access strategy, launch preparation and monitoring, and organisational readiness.

To discuss the topic in more detail, please reach out to the authors.

The authors would like to thank Daniel Secker and Charlotte Barthen for their support in writing this *Executive Insights.*

Endnotes

[1]Health technologies subject to a JCA include those undergoing a centralised marketing authorisation that are medicinal products containing a new active substance and/or biotechnology products, class IIb or III medical devices, and class D in vitro diagnostic devices.

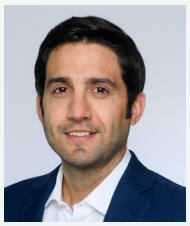
[2]L.E.K. Consulting, "EUnetHTA 21 — Transition to EU-wide HTAs: Implications for Pharma."

[3]The PICO parameters include: population: identification of the relevant population(s) for the assessment scope, based on the claimed indication; intervention: a combination of the intervention to be assessed and the indication or intended use; comparator: pharmacotherapies and/or nondrug interventions that are relevant for the HTA for each of the populations of interest and that serve to determine the relative effectiveness of the health technology assessed; and outcomes: the choice of endpoints of interest and relative improvement necessary to demonstrate the relative effectiveness of the health technology assessed.

[4]HTA CG, "Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons" (adopted on 8 March 2024).

About the Authors

Verena Ahnert | Partner | V.Ahnert@lek.com
Verena Ahnert is a Partner in L.E.K. Consulting's London office, focused on the Life Sciences practice. She advises a wide range of clients in the biopharmaceutical, pharma services and research tool sectors. Verena has extensive experience related to long-term growth strategies and new product expansion opportunities, with particular interest in pricing and market access strategies.



Miguel Mira | Manager | M.Mira@lek.com
Miguel Mira is an Engagement Manager in L.E.K.'s Life Sciences practice, with more than eight years of consulting experience across different therapeutic areas and geographies. His project engagements have focused on pricing, market access, launch sequence optimisation, contracting, price negotiation and value communication across European markets.

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