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European Union - Health Technology Assessment Regulation

MSD is committed to supporting a European Health Technology Assessment (EU HTA) system that delivers predictable, efficient, and meaningful Joint Clinical Assessments (JCAs) to accelerate equitable patient access across Europe. Our position on the EU HTA Regulation (EU HTAR) and the resulting JCA Process is based on the following five key principles:

- **Strengthening dialogue with stakeholders:** MSD calls for structured early engagement and transparent methodology—particularly on scoping and Population(s), Intervention(s), Comparator(s) and Outcome(s) (PICOs) definition—to ensure high-quality evidence preparation, minimize late-stage changes, and improve alignment with European Medicines Agency (EMA) timelines.
- **Ensuring alignment across EMA, JCA, and national processes:** Clear rules for the handling or management of additional evidence which becomes available while the JCA procedure is ongoing, management of EU HTA clock stops, and transparent information-sharing frameworks are essential to avoid duplication and prevent delays in Member State decision-making.
- **Building a system of continuous improvement:** Regular guidance updates, formal stakeholder feedback loops, and robust monitoring will enable a learning, agile HTA framework that supports a thorough evaluation in 2028 and consistently high-quality assessments.
- **Enhancing adaptability to national contexts:** Greater methodological convergence between EU-level JCAs and national HTA practices is needed to reduce fragmentation, increase predictability, and strengthen JCAs as a reliable basis for national appraisal.
- **Positioning EU HTA within a global context:** A future-proof, science-driven framework aligned with evolving EMA processes can serve as an international benchmark, reduce evidence duplication, and maintain Europe's competitiveness as EMA timelines shorten and regulatory innovations expand.

Our Position

The EU HTAR (Regulation (EU) 2021/2282) introduces mandatory JCAs which aim to harmonize clinical effectiveness evaluations at the EU level, reducing duplication, improving efficiency, and expediting patient access.

MSD remains supportive of the EU HTA Regulation and agrees it should be underpinned by

solid Member State commitment to minimize duplication of clinical relative effectiveness assessments at the national level. MSD supports the principle that Member States should use the JCA report as a key resource to understand the clinical value of a health technology. MSD acknowledges that Member States will continue to remain solely responsible for drawing conclusions on the overall clinical value. These conclusions should be based on a holistic evaluation that combines the EU level JCA report with country-specific decisions, incorporating local socio-economic and budgetary considerations. This integrated approach will inform national pricing and reimbursement decisions.

The overarching objective of pan-European HTA is to secure timely and equitable access to effective new medicines that deliver meaningful improvements in health outcomes for patients and the broader EU population. As implementation advances, a number of operational and policy challenges have emerged, underscoring the need for clarity, transparency, and consistent process controls to support predictable market access pathways and timely patient access. Stakeholders, including industry, require clarity, transparency, and reliable process controls to effectively achieve the aims of the EU HTAR. For the JCA process, several conditions must be met, and outstanding issues addressed at both EU and Member State levels during the initial operationalization phase.

MSD therefore calls for constructive action on the following topics, organized under five core themes and detailed below.

1. Dialogue with stakeholders

As a general principle, fostering better dialogue and collaboration with all stakeholders - particularly industry - throughout the JCA process is essential to ensure transparency, alignment on expectations, and the timely resolution of procedural uncertainties.

- Need for **Structured Early Dialogue During Initial Scoping**: To ensure predictability and efficiency in the JCA process under the EU HTA Regulation, MSD calls for the establishment of a structured early dialogue mechanism during the initial scoping phase, including a consultation on the proposed PICOs. Early engagement of the HTA Coordination Group (CG) with Health Technology Developers (HTD), clinical experts, and patient representatives would enable timely alignment on key elements such as population(s), comparators, and relevant outcomes. This proactive consultation would reduce uncertainty, minimize the risk of late-stage scope changes, and support developers in preparing robust evidence packages that meet consolidated EU requirements.

- Establishment of **Specific Criteria to Guide Identification of Relevant PICOs for JCA**: MSD recommends that a set of criteria is established to guide the selection of appropriate PICOs during the JCA scoping process, based on the following parameters:

    - **Clear guidance** is needed on whether a **minimum number of countries** must request a specific PICO for it to be considered valid.

- **Relevance to Clinical Practice**: Comparators identified during the PICO scoping process should reflect main treatments routinely used in real-world practice, next to them being determined by inclusion in guidelines. This approach ensures that the scope aligns with actual standard-of-care practices across Member States and is critical for ensuring that JCAs address evidence questions that are meaningful to support national decision-making.

- **Validity of distinct PICOs for sub-populations**: The inclusion of distinct sub-populations in the PICO process should be based on their clinical relevance and impact on treatment outcomes.

- Provision of **Greater Clarity on the JCA PICO Consolidation Process**: there is a need for greater clarity on how PICOs will be consolidated for JCAs, to help HTDs suitably prepare relevant and proportionate evidence. Without such clarity, there is a risk that HTDs will inevitably have to generate dossiers of excessive magnitude to address the anticipated assessment scope, with potential for much of the content ultimately proving to be redundant, with limited relevance and/or utility. MSD recommends that clearer guidance is issued outlining the steps in the scoping and consolidation process, including selection criteria such as minimum number of Member States requesting a specific PICO and how that influences its inclusion, to enable more predictable and efficient dossier preparation and assessment, avoiding excessive documentation and unrealistic evidence standards, while maintaining JCA utility for national decisions.

- To strengthen the JCA process, the **quality and utility of the assessment scope explanation meeting** should be enhanced by allowing HTDs to submit clarification questions in advance. This would enable the CG to review, deliberate, and form a consolidated position ahead of time, ensuring a consistent and transparent interpretation of scope and evidence expectations. Communicating the CG's position during the clarification meeting would streamline discussions, reduce ambiguity, and provide predictable guidance to the HTD, ultimately improving efficiency, alignment, and the robustness of the JCA outcome.

- **Need to increase predictability on JCA procedural timelines**: Currently, JCAs are conducted in parallel with EMA regulatory procedures. However, the timeline for JCAs can be challenging to anticipate because assessors define and finalize the assessment scope between Day 87 up to shortly after the Committee for Medicinal Products for Human Use (CHMP) list of questions is issued. This creates uncertainty for HTDs in planning the evidence submission and resource allocation. Improving predictability would require clearer alignment between EMA milestones and JCA steps, as well as transparent communication of expected timelines and scope finalization. Greater predictability would enable better preparation, reduce last-minute adjustments, and support timely delivery of high-quality dossiers.

2. Interdependencies impacting EMA, JCA, and national processes

As a general principle, clear alignment and transparency across interdependent EMA, JCA, and national processes are critical to avoid procedural inefficiencies, and uphold the objectives of the EU HTA Regulation by ensuring timely patient access after national processes.

- **Submission of Additional Data Package to EMA and Notification Obligations**: Clarifying obligations and timelines for submitting additional data packages during an ongoing procedure is essential to reduce risk of misalignment, ensure assessors have the most current evidence, and mitigate unexpected issues arising during the process. When an additional data package is submitted to the EMA, the HTD is obliged to inform the HTA Secretariat and submit this if requested by the assessors. Clear guidance is needed on how this data will be considered, as generating additional analyses beyond those submitted to the EMA is unlikely to be feasible within short timeframes.

- **Impact of EU HTA Clock Stops**: As a general principle, the EU-HTA process must be predictable and time-bound so that the JCA report can reliably anchor national appraisals. When EU-HTA clock stops occur—e.g., due to label changes requiring re-scoping—they introduce uncertainty and can cascade into delays at Member State level, where patient access decisions are ultimately made. To remain fit for purpose, the framework should include clear, pre-defined rules for managing such events (including scope adjustments and information flows) without derailing agreed timelines. If timelines are not adhered to, the value of EU-HTA as a coordinating mechanism is undermined; therefore, explicit guidance is needed to ensure continuity of the assessment and timely delivery of JCA outputs, recognizing that resolution of market access issues lies with Member States.

- There is a need to **increase transparency and predictability in information flows** between the EMA, the HTA Secretariat, and national HTA bodies. Specifically:

    - It should be clarified which EMA-submitted HTD materials (e.g., clinical summaries; draft and final European Public Assessment Report (EPAR) elements; risk-management plans (RMPs); and post-authorization commitments) are shared, when they are shared, and for what purposes within and beyond the EU-HTA process.

    - This also applies to horizon-scanning activities: while information is formally requested by and shared with the EMA, no clear or consistent process exists for how such information will be used within the JCA or what the EMA is able or authorized to share with the Coordination Group.

The lack of clarity leads to ad-hoc or informal requests to HTDs, creating uncertainty and potentially discriminatory inconsistency across assessments. Explicitly specifying the scope, timing, and legal basis for information-sharing—including the handling of horizon-scanning data—would support consistent national appraisal, reduce duplicative or informal queries to HTDs, and help align regulatory and HTA evidence expectations. A standardized

information-sharing scheme would strengthen mutual trust, enable earlier planning by HTDs, and streamline both joint and national assessments.

3. System enablement, continuous improvement and monitoring

As a general principle, the implementation of the EU HTA Regulation and its added value should be subject to systematic and continuous monitoring. Any shortcomings identified during this process should trigger timely adjustments, in addition to the formally planned review after the initial application in 2028. This proactive approach will ensure the Regulation evolves effectively and delivers on its objectives:

- **To build an agile, learning EU HTA system**, it is essential to move beyond one-off regulatory revisions and establish permanent technical forums supported by formal stakeholder feedback loops and regular guidance updates. A systematic feedback mechanism should include patients, clinical experts, HTA bodies, and HTDs creating a structured post-JCA cycle with surveys and interviews on scoping, dossier usability, timelines, and report quality. Findings should be summarized in annual public reports and integrated into HTA CG guidance updates, leveraging the Regulation to create a continuous improvement loop that enhances predictability and reduces duplication.

In addition to the above consideration, and to ensure the EU HTA system delivers meaningful, inclusive, and future-ready assessments, two other key areas require attention:

- **Patient organizations, patients and clinical experts** should be involved at EU and national levels with balanced conflict of interest rules, as well as dedicated funding and training, to enable meaningful input that reflects a holistic view in joint EU HTA work.

- **MSD supports Vaccines Europe** in urging the EU HTA system to tailor methodologies and processes for vaccines—engaging National Immunization Technical Advisory Groups (NITAGs) and the European Centre for Disease Prevention and Control (ECDC), adapting JCA/Joint Scientific Consultation (JSC) guidance to preventive, population-level outcomes, and strengthening interoperable real-world data—so that by 2030 and beyond, the Regulation delivers timely, robust assessments that improve vaccine availability, confidence, and public health across the EU.

4. Adaptability to national contexts

As a general principle, JCAs should serve as a facilitator for national HTA processes that ultimately enable timely patient access to medicines, rather than becoming an additional administrative layer. Their role should be to streamline evidence assessment, promote consistency, and reduce duplication across Member States — ensuring that the Regulation delivers on its core purpose of improving efficiency and accelerating patient access, rather than introducing complexity or delays.

- **Greater synergy across Member States** is essential to ensure the relevance, practical utility, and credibility of EU HTA assessments. Stronger alignment of national methodological principles with the European framework will help avoid fragmentation, reduce duplication, and enable JCAs to serve as a reliable foundation for national appraisals. Harmonized approaches—particularly in areas such as comparator selection, outcome prioritization, patient-centered endpoints, and evidence interpretation—will strengthen predictability for stakeholders and reinforce the EU HTA system as a benchmark for high-quality, science-driven evaluations. This requires systematic updates to national HTA methodologies and legislative frameworks to ensure consistency and a truly integrated European approach. By prioritizing European results and implementing more efficient evaluation frameworks aligned with EU HTA standards, Member States can achieve streamlined, less bureaucratic processes without compromising quality. Such changes will enhance predictability, improve patient access, reduce duplication, and strengthen Europe's competitiveness as a leading pharmaceutical hub.

5. EU-HTA in a Global context – interdependencies and market access implications

As a general principle, regulatory and HTA frameworks should be designed with a future-proof, globally oriented approach—positioning the EU HTA as a lighthouse for science-driven, patient-relevant standards that inspire convergence internationally. By ensuring alignment between evolving EMA processes and the EU HTA objectives, Europe can lead with foresight, creating predictable, transparent pathways that accelerate access, reduce duplication, and strengthen its role as a benchmark for high-quality evidence worldwide.

- EFPIA and its member companies share the goals of the EU Pharmaceutical Strategy to increase patient access to medicines across Europe and strengthen the competitiveness of Europe's pharmaceutical sector. Important improvements in the Regulatory assessment procedures stemming from the Pharmaceutical Strategy—such as shortening EMA timelines (evaluation reduced from 210 to 180 days, CHMP-to-Commission decision cut from 67 to 46 days) and introducing regulatory sandboxes—will compress coordination windows and create uncertainty unless clear guidance is provided.

    - **Standard centralized MA**: EMA evaluation period reduced from 210 to 180 days, with no clock-stop. In addition, the time between CHMP opinion and Commission decision will decrease from 67 to 46 days. As the EU-HTAR and JCA process is directly linked to EMA timelines, these changes compress the overall regulatory window, leaving less time for coordination and evidence alignment. Clarification will be needed to ensure that the shortened EMA process does not undermine the ability of the EU-HTA to deliver robust, timely assessments and maintain predictability for national appraisals.

  - Introduction of **regulatory sandboxes** for innovative therapies: Defined in the pharmaceutical legislative proposal, a regulatory sandbox is a time-limited framework, under regulatory supervision, allowing developers to test innovative regulatory solutions in real-world settings for products that are challenging to meet existing MA requirements due to scientific/regulatory barriers. It will be key to better understanding the type of data requirements in these sandboxes, in comparison to the type of data required to meet the needs of the CG as part of the JCA procedure.

- The **EU-HTA** Regulation has the potential to act as a true driver for global health technology assessment, setting a **transparent, science-driven benchmark that others can reference**. By positioning the EU-HTA as a global reference point, Europe can demonstrate leadership and foresight, shaping expectations beyond its borders and promoting convergence on robust, patient-relevant evidence standards. This lighthouse effect can reinforce the importance of consistency and predictability in evidence requirements internationally, giving developers clearer targets earlier in the lifecycle. In turn, greater alignment can reduce duplication for companies operating across regions, streamline development and submission strategies, and accelerate patient access by focusing resources on high-quality, reusable evidence packages.

Outcomes of this dialogue should focus on optimizing the quality, relevance and usefulness of the JCA report, improve predictability for developers, and uphold the Regulation's ambition to accelerate equitable patient access while respecting national competencies.

Background

Patient access to medicines and vaccines in the EU after marketing authorization has become increasingly complex due to varying HTA methods and criteria for evaluation across Member States. This situation mirrors the fragmented regulatory environment before the creation of the EMA, which successfully harmonized regulatory approval processes. To address these challenges, the EU adopted an HTA Regulation aimed at harmonizing clinical assessments, reducing duplication, improving efficiency, and expediting patient access. While regulatory approval determines benefit-risk balance, HTA focuses on relative effectiveness, making alignment essential for faster patient access.

The EU HTA Regulation, developed after more than a decade of collaboration, introduces a Coordination Group of Member State representatives to conduct joint clinical assessments, starting in 2025 and expanding fully by 2030. Its goal is to harmonize clinical evaluations and support timely access to innovative medicines, while fostering competitiveness in the EU pharmaceutical industry.

Harmonization would also strengthen Europe's position by making it easier and more efficient to conduct clinical trials across the region. This could accelerate study setup, reduce duplication and administrative burden, and enhance Europe's attractiveness for global research investments, ultimately improving patient access to innovative therapies.

However, concerns remain that diluted ambitions by a variety of stakeholders could perpetuate complexity and unpredictability. As implementation progresses and first JCA processes finalize with JCA reports being published in 2026, maintaining the focus on expediting patient access, harmonization, and avoiding delays at the national level will be critical to achieving the Regulation's objectives.

Definitions

- CG: Coordination Group
- CHMP: Committee for Medicinal Products for Human Use
- ECDC: European Centre for Disease Prevention and Control
- EMA: European Medicines Agency
- EU HTAR: European Union Health Technology Assessment Regulation (see reference below)
- HTA: Health Technology Assessment
- HTD: Health Technology Developer
- JCA: Joint Clinical Assessment
- JSC: Joint Scientific Consultation
- NITAG: National Immunization Technical Advisory Group
- PICO: Population – Intervention – Comparator – Outcome
- RMP: Risk Management Plan

References

European Parliament. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. Off. J. Eur. Union 2021, 458, 1–32