November 2025

Integrating the European JCA into Joint Nordic Health Economic Assessments

Joint Nordic HTA-Bodies (JNHB) stands well prepared for the tasks of the EU Health Technology Assessment regulation (EU-HTAR) 2021/2282 and to connect the work on EU-level to Nordic and national processes. The Nordic countries are actively involved in the work under the EU-HTAR and have taken on the role as assessor and co-assessor for several of the first products undergoing Joint Clinical Assessment (JCA). After working together for six years, JNHB has experience of joint assessments and foresees several benefits of the regulation. JNHB invites companies to apply for joint Nordic assessments to exploit the full potential of the JCA.

How the HTA Regulation Supports Joint Nordic HTA

The EU JCA process provides a harmonized evaluation of the relative clinical effectiveness and safety of new medicinal products across EU member states. This shared clinical foundation enables more robust health economic assessments, and integrating JCA outcomes into joint Nordic assessments offers several advantages:

- **Early Identification of Relevant Comparators.** The JCA PICO process ensures that relevant comparators are defined for each member state. This enables JNHB to identify products with shared Nordic comparators early, facilitating timely planning for joint Nordic HTAs.

- **Proactive Engagement with HTDs.** With clarity on the JCA scope, JNHB can initiate early and targeted dialogue with Health Technology Developers (HTDs), preparing both parties for a joint Nordic health economic assessment aligned with the JCA conclusions.

- **Clinical Evidence as a Foundation for Economic Evaluation.** The JCA report provides a scientifically validated analysis of relative effects, which can form the clinical basis for joint health economic modelling. This enables the JNHB to focus its efforts on economic evaluation and ensure that national decisions on reimbursement and recommendations are based on transparent and shared evidence.

- **Facilitating Nordic Harmonization.** The HTA regulation and joint Nordic assessments through JNHB support harmonization of HTA methodologies and timelines across Nordic countries, while each country retains national autonomy over decisions on recommendations and pricing.

November 2025

The Role of JCA reports in Joint Nordic HTA

Under the EU HTA regulation, the JCA report must be endorsed within 30 days of European Commission marketing authorization. The JCA report includes an assessment of the relative clinical effect of the new medicine compared to defined comparators.

JNHB uses the JCA report as the clinical basis for joint Nordic HTA, in the same manner as national HTA bodies are required to do. This means that the relative effects and safety reported in the JCA – adapted to Nordic populations and comparators – form the basis for economic modelling. Decisions on pricing, reimbursement, and recommendations remain the responsibility of each individual country. See figure 1 for a schematic overview of the process.

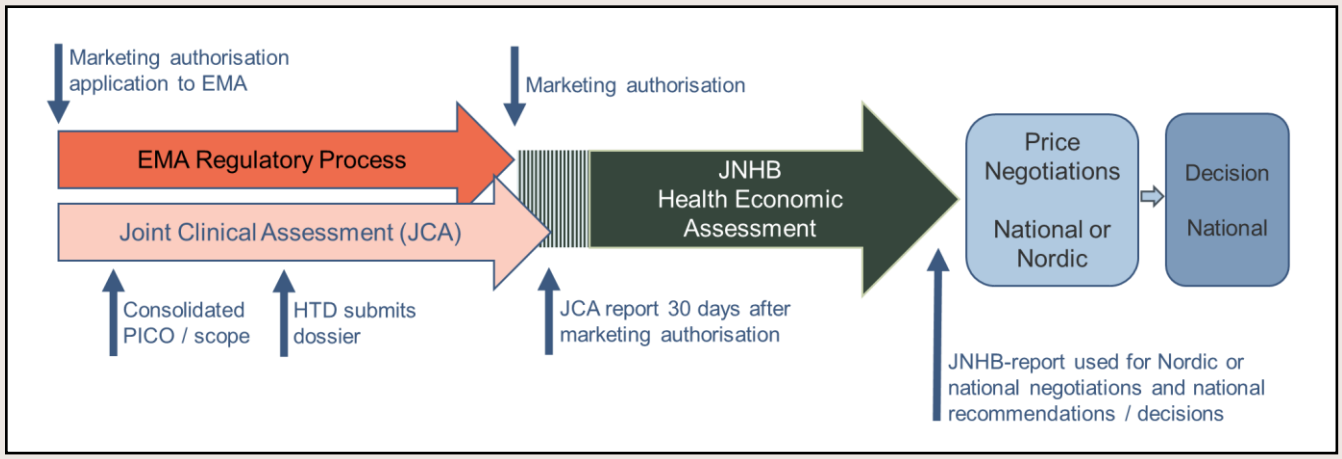

Figure 1. *An outline of how the JCA process connects to the regulatory process, health economic assessments, negotiations and to national decision making. Abbreviations: EMA; European Medicines Agency, PICO; Population, Intervention, Comparator, Outcome, HTD; Health Technology Developer, JNHB; Joint Nordic HTA-Bodies.*

JNHB continues to refine its processes to maximize the utility of JCA reports. In 2026, JNHB will update process guidelines and dossier templates to better accommodate products assessed through a JCA.

A detailed description of the JCA process can be found through the European Commission's website Implementing the EU Health Technology Assessment Regulation

Read more about the JCA process Joint Clinical Assessments - European Commission and about JNHB Joint Nordic HTA-Bodies