

Vaccines Europe response to draft implementing act for EU HTA Joint Scientific Consultations Medicinal Products Public consultation

Vaccines Europe welcomes the openness of the EU JSC for vaccines early January 2025. However, its applicability to vaccines seems unlikely as no specific methodological approaches for vaccines are planned, nor the inclusion of NITAGs (National Immunization Technical Advisory Group), multidisciplinary bodies of national experts that provide evidence-based recommendations to policy-makers and immunisation programme managers.

HTDs see this as a missed opportunity to get advice on their evidence generation plans.

NITAGs assess vaccines in all 27 EU member states, whereas HTA bodies are involved in vaccine appraisals in only 14 EU member states. Including NITAGs in JSCs could increase alignment between the JSC, JCA, and national assessment processes, reducing duplicate efforts. Joint scientific consultations can enable NITAGs to anticipate innovative vaccines and advise developers on appropriate evidence generation plans.

Scientific advice is thoughtfully planned many months in advance as clinical development timelines are tight. Designing and executing a successful clinical development plan for any candidate vaccine requires a solid scientific, medical, operational and regulatory knowledge and expertise, to comply with regulations and assure adequate benefit-risk balance for the product to be used in mass vaccination of healthy populations. Phase 3 studies as well as preparation for regulatory filing can take between 3 and 5 years, meaning that the preparation of the protocol of vaccines that will be eligible for JCA (eg: with a submission to EMA planned after January 2030) is likely to take place in the coming months.

In the methodological guidelines published so far, no specific methodological approaches for vaccines are mentioned. The paper entitled “Guiding Principles for Evaluating Vaccines in Joint Health Technology Assessment in the European Union” recently published in a peer-reviewed journal, proposes standardized and vaccine-specific methodologies and processes that could ensure consistent, transparent, and timely access to new vaccines (Largeron et al., 2024).

Vaccine Europe strongly recommend the involvement of NITAGs as well as the use of the guidelines mentioned above, which were developed using a robust methodology and endorsed by leading vaccine experts, to take in account the unique aspects of vaccines and tailoring the assessment processes to address these specificities.