VE response to JCA implementing act public consultation

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products/F3460187_en

Despite an explicit recognition by the EU legislator (Recital 24 and the art. 4 of the HTA Regulation), Vaccines Europe (VE) is disappointed about the little attention given to the vaccines' specificities in this implementing act. Ignoring them in JCA processes and methodologies would impose serious risks in delaying access to vaccination and result in non-applicability of JCA reports at national level.

Vaccination recommendations and calendars are one of vaccine specificities, which would be essential for e.g. the most efficient development of the PICO survey and timely conclusion of the scoping process. The meaningful involvement of health technology developer, as well as other bodies could mitigate some of risks foreseen.

Please find below key points needed to be addressed as part of this implementing act relevant to vaccines:

1/Ensure appropriate involvement of the NITAGs and the ECDC

National Immunisation Technical Advisory Groups (NITAGs) play a critical role in vaccines' assessment, responsible for recommending whether a vaccine should be included in the National Immunisation Programmes (NIPs). Yet, NITAG members aren't directly involved in the work of the HTA Coordination Group (HTACG).

The implementing act recognises the need for the JCA subgroup members to "consult national authorities and stakeholders in accordance with the procedural rules of the respective Member State" (Recital 17), which could imply a consultation with NITAGs. However, the procedural rules, hence interactions between HTA bodies and NITAGs, significantly vary across countries, suggesting that the JCA reports for vaccines could be taken up differently. Recital 17 and art. 6 should explicitly mention that JCA subgroup members should consult NITAGs.

The European Centre for Disease Prevention and Control (ECDC), given its role in collecting data on infectious diseases, should also be explicitly recognised in art. 6 as one of stakeholders to be consulted.

2/ Define vaccine-specific clinical endpoints and recognise the role of modelling

The implementing act specifies that the dossier and report shall include a section on results, taking into account, if available, the methodological guidance adopted by the HTACG. VE is concerned about potential misinterpretations of vaccine effectiveness and efficacy as the final methodological guidance might not be specific to vaccines.

Vaccine effectiveness is a measure of how well vaccines work in the real world and depends on several parameters, such as disease incidence, herd immunity, cross-protection effect, etc. The full impact of vaccines is often not captured in pivotal clinical trials because population-level data on incidence and disease reduction are usually not available until after market entry. The role of RWE, registry-based follow-ups, digital follow-ups in measuring effectiveness is not defined. Hence, the HTACG shall recognise the role of modelling for these purposes and allow templates to remain generic enough to accommodate various specificities.

3/ Provide clarity on the re-initiation of JCA report

Clinical assessment of vaccines is characterised by the application of specific criteria such as the use of immunogenicity, correlates of protection, surrogate endpoints, etc.

The duration of protection is a critical assessment criterion by NITAGs across the EU. However, there is a limited data on the duration of protection at the time of assessment and clinical trial follow-up is often not adequate to fully capture it. Hence, mathematical modelling can estimate the duration of protection beyond the clinical trial follow-up period, however data used may be limited because of vaccine characteristics and differences in NIPs, seasonality, etc.

RWE proved to be instrumental in refining decision-making processes, e.g. by optimising dosing regimens, enhance guidance on target populations. However, health technology developer needs to be involved in the decision of re-initiating the JCA process.