Developing a specific and coordinated framework for Health Technology Assessment of Vaccines in Europe

Vaccines are one of the **most significant public health advancements** of the past century. They are preventative in nature, aiming to avoid infections in healthy individuals that result in major morbidity and/or mortality. Vaccines are used across the entire age range of the population, from babies to teenagers, adults and older people. They prevent illness in the individual and protect communities from infection via "herd immunity". Vaccines protect millions of people worldwide from infectious diseases and contribute to the socio-economic development of nations on a global scale.

Vaccines lead to a range of direct and indirect benefits that can be broadly categorised in three main dimensions; clinical, economic, and societal. Not only do vaccines protect health, but their **effective use contributes to the sustainability and efficiency of healthcare systems** with preventative spend that reduces clinical burden and costs upstream. This allows for more efficient resource allocation, freeing up resources for areas of unmet needs and healthcare innovation.

The increasing pressure of economic, demographic and societal challenges of higher demand for healthcare has led to more rigorous assessment of novel medical technologies, with stringent processes for the assessment of medicinal products at national and regional levels. Vaccines are classified as medicinal products, but their assessment needs to be quite different. Given their preventative nature, bringing benefits to individuals and populations over a long time horizon, traditional clinical effectiveness assessment is insufficient to determine the value of a vaccine. Furthermore, it is critical that the assessment takes into account the vaccination programme to achieve good adherence that can lead to high uptake and herd immunity.

Currently, populations' access to new vaccines in Europe is slow and heterogeneous. In EU Members States, it takes around six years[1] from marketing authorization of a vaccine to implementation of a vaccination programme. This arises partly due to duplication in assessments used by public health (NITAGs[2]), payer, and regulatory bodies at European, national and regional levels. There is an important need to **streamline assessment practices** and methodologies across evaluation bodies, particularly to **avoid redundancy between assessments conducted by regulatory, public health, and HTA bodies.** Furthermore, in order to ensure rapid implementation of life-saving vaccination programmes there is a need to develop a **specific, coordinated, comprehensive assessment framework that takes account of the unique nature and value of vaccines**.

In recent years, the EUnetHTA Joint Actions have sought to coordinate assessment efforts and avoid duplication in the EU, with specific focus on Relative Effectiveness Assessment (REA) in HTA. This is helpful, but to be relevant for the assessment of vaccines, there needs to be recognition of a series of core vaccines features (see details in Appendix).

Vaccines Europe calls for

1. **A specific and comprehensive framework for HTA of vaccines in dialogue with key EU stakeholders, including the HTA Network and EUnetHTA** with a view to fostering common good practice in method and evaluation throughout Europe to ensure rapid implementation of effective vaccination programmes. In particular, capitalising on the successful experience of the first rapid REA pilot already conducted on a vaccine product within EUnetHTA will be crucial to framing the methodology and improving the quality of evidence generation required for HTA.
2. **The coordination of the different stakeholders involved in vaccine assessment especially NITAGs and HTA bodies, in and among EU Members States, to avoid duplication and foster proper evidence-based policy decisions.** Such collaboration may benefit from the experience of EUnetHTA in establishing joint work in order to maximise the synergies between regulators, NITAGS, HTA bodies and budget-holders in a way that is easily implementable at national level.

[1] Blank P. et al. (2013), Population Access to new Vaccines in European countries, Vaccine 31, 2862-2867, http://dx.doi.org/10.1016/j.vaccine.2013.04.039
2 NITAG: National Immunisation Technical Advisory groups

Appendix:

Vaccines Europe has identified a series of core vaccine features that we think should be considered in a vaccine HTA framework. These include the 4 main EUnetHTA REA domains and the wider HTA domains of ethical, legal, social, and economic considerations, which are integral to a comprehensive evaluation of vaccine effectiveness at national level.

Health problem

- Short and long term consequences of disease and associated burden
- Disease burden at individual and population level (transmission)
- Identification of target population for routine vaccination, based on risk factors and transmission patterns

Technical characteristics of technology

- Targeted biological nature of the product (complexity of research and development process)
- Goal, scope, and intensity of the immunisation strategy within healthcare system
- Dosage and scheduling of vaccination to secure high uptake
- Storage requirements of the vaccine
- Monitoring plans and resources (human and capital) to implement the vaccination programme

Clinical effectiveness

- Clinical endpoints, robust analyses relevant to vaccines (e.g. bridging surrogates to final endpoints)
- Population-based modelling at initial evaluation (to simulate transmission, population dynamics, indirect protection, and long-term effects)
- Relevance of real-life effectiveness (better reflect vaccination effect in the population)

Safety

- Consideration of regulatory requirements specific to vaccines to avoid duplication
- Public views on the safety of the vaccination

Economic considerations

- Population-based modelling e.g. dynamic rather than static model (to simulate transmission, population dynamics, indirect protection)
- Models that use a time horizon and discounting that take account of the long-term effects of vaccines
- Wider perspective in economic evaluation to account for the broad benefits of a preventative intervention for the individual and community: indirect costs, fiscal impact, impact on other sectors and intangible benefits

Ethical, organisational, social and legal aspects

- Extent of equal opportunities for vaccination across social and age groups through healthcare system
- Equal access to information, including in particular for vulnerable populations
- Adaptation of programme implementation strategy to cultural differences, vaccine-specific beliefs
- Implementation of compensation programme for vaccine-related serious adverse events
- Wider stakeholder involvement to design a vaccination programme encouraging high public uptake

Vaccines Europe believes that a more coordinated, inclusive and targeted approach to the evaluation of vaccines would ultimately lead to a **faster implementation of effective vaccination programmes, with benefits for individuals, healthcare systems and society at large.**

We are keen to engage with other stakeholders to discuss these proposals and identify other relevant issues.