

Vaccines Europe's answer to the European Commission's [Call for Evidence](#) on the Single Market Strategy

Vaccines Europe (VE) concurs with the response from the European Federation of Pharmaceutical Industries and Associations (EFPIA) to this consultation. In addition, VE wishes to highlight specific challenges that the vaccine sector face.

1. Divergence in national vaccine access pathways

Challenge

Vaccines follow complicated market access pathways and are subjected to mandatory local standards, which add complexity and time to the recommendation and reimbursement of national immunisation programs (NIP). In a third of EU countries, median time to population access is more than six years.

Not only complex and lengthy, but those pathways are also significantly heterogeneous across EU countries, being at the source of inequity in the availability of vaccines and the gaps in levels of health protection.

In addition, the enormous language diversity of vaccines' packaging and leaflets requirements across EU countries may significantly reduce supply chains' efficiency, slow down emergency response to shortages and limit availability in small markets.

Recommendations

- Ensure an aligned approach to decision-making on vaccination through a common European value framework.
- Enhance the timeliness of national decision-making on vaccination programmes.
- Introduce EU common pack and electronic Product Information (ePIL) for vaccines

2. Lack of vaccine specificities' implementation in the EU HTA Regulation

Challenge

One of the goals of the EU HTA Regulation is to improve the availability of innovative health technologies. However, applying the same processes and methodologies used for the clinical assessment of drugs to vaccines would impose serious risks, such as delayed or limited access to new vaccines.

Recognition of vaccine specificities in the joint HTA activities is necessary for recognizing the broad value of vaccination and improving the time to population access and benefits for public health, the economy, and society.

Recommendations

- Involve NITAGs and the ECDC in appropriate joint scientific consultations and joint clinical assessment steps for their respective roles and expertise
- Address the unique HTA framework and expertise requirements of vaccines in the interim EU HTAR evaluation in 2028

3. Lack of interoperable immunisation information systems

Challenge

In the case of immunisation systems, data and evidence are needed for a wide range of purposes, e.g. to inform decisions on the introduction of new vaccines and vaccination programmes.

However, there are important gaps in the data and evidence currently available to national policy-makers, which need to be addressed in order to optimise vaccination programmes.

Recommendations

- Enhance data collection and evidence generation to support the strengthening of vaccination policies.
- Expand ECDC data collection and reporting on vaccination coverage rates for adolescent and adult vaccines.
- Prioritise digitalisation and interoperability of immunization programmes within the European Health Data Space.

4. Undervalued role of prevention for economic growth

Challenge

Over the last decade, the EU economy has experienced slow growth. The ongoing demographic and epidemiological transition is increasing pressure on public finances, particularly healthcare and social expenditure.

The EU has introduced the New Economic Governance Framework (NEGF), which provides an opportunity to consider investments in the healthcare sector – especially in prevention – as “social security investments”.

Studies suggest that every 1 euro spent on adult vaccination generates a 19 euro return to the health and social care economy.

Recommendations

- Recognise investments in prevention as beneficial for long-term fiscal sustainability and grant greater flexibility within the Member States' fiscal structural plans.
- Exclude prevention and immunisation investments from the calculations of Member States' deficit or debt levels when assessing compliance with fiscal rules.

This is a critical moment for European nations, to rethink the operational models of their healthcare systems. Above mentioned recommendations could contribute to that, but will require substantial and structural investments.