Market Access pathways for vaccines in EU: the need for more transparent & collaborative framework in a context of EU28 to decrease uncertainty and allow faster patient access

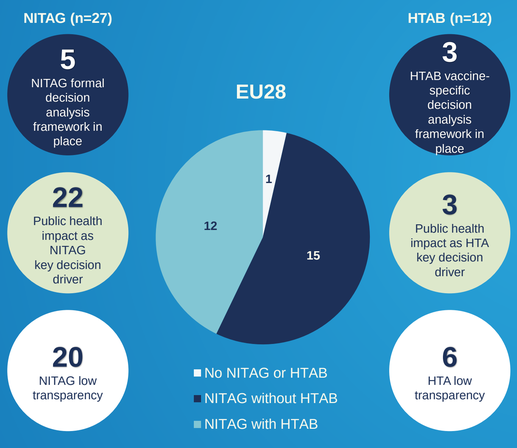
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BACKGROUND

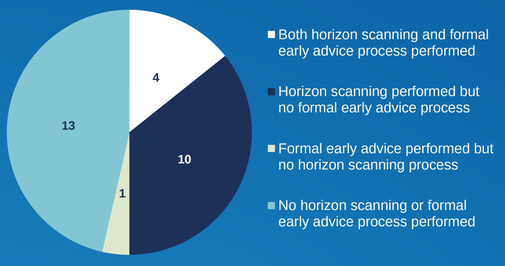
- Despite widespread recognition of vaccination benefits, market access processes for vaccines in the European Union (EU) are complex, heterogeneous and lengthy.[1-3]
- Profiles, roles/responsibilities, decision-analysis frameworks, processes and interactions of stakeholders involved in market access of vaccines are heterogeneous between countries:[1]
  - On top of National Immunization Technical Advisory Groups (NITAGs) available in almost all countries (except Romania), Health Technology Assessment bodies (HTABs) are involved in 12 out of 28 EU countries (Figure 1), but evidence requirements are often unclear and interactions between both agencies seem limited.
    - ➢ NITAG formal decision-analysis framework for issuing recommendation on inclusion of vaccination into immunization program is available in only 5 EU countries.
    - ➢ HTABs apply vaccine-specific frameworks in only 3 EU countries.
    - ➢ Public health impact is a key decision driver for vaccines and utilised as such by 81% of NITAGs (22 out of 27) but only 25% of HTABs (3/12).
    - ➢ Horizon scanning and formal early advice process for vaccines are performed in 14 and 5 out of 28 EU countries, respectively. However, in 13 countries there is no horizon scanning and no early advice available (Figure 2).
  - Sub-national stakeholders are key decision makers in 4 EU countries.

Figure 1. Key aspects related to NITAG and HTA among 28 EU countries[1]



- Transparency of the decision-making process for vaccines (*when considering the key following criteria: formal decision-analysis framework, systematic approach for evidence appraisal in place, and publication of recommendations with rationale)* is low in 26 out of 28 EU countries. When published, rationale for recommendation is not always available (Figure 3).[1]
- As a result, estimated median time to patient access for exemplary new paediatric, adolescent and adult vaccines for diseases with well recognised burden (i.e. pneumococcal, HPV and new influenza vaccines, respectively) from marketing authorisation vary from 2 to more than 6 years.[1]

Figure 2. Availability of horizon scanning and formal early advice in 28 EU countries[1]



DISCUSSION

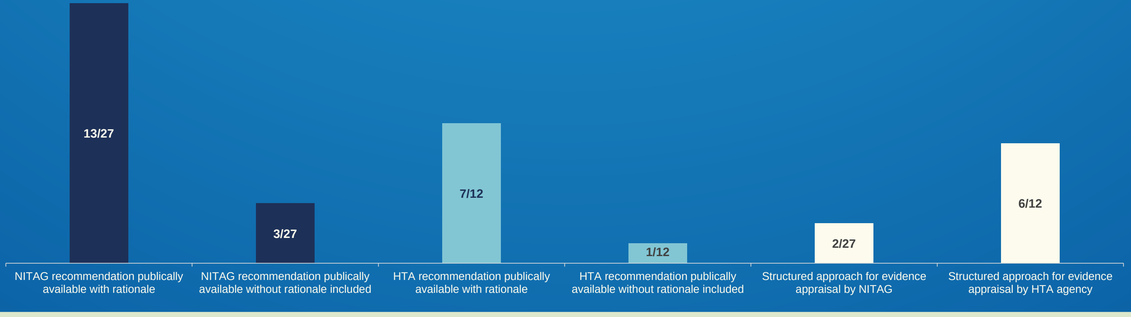
- Vaccines differ from traditional therapeutic drugs in many aspects (Table 1), therefore their assessment framework should be flexible enough to capture all the benefits provided.[2,4]

Table 1. Differences between vaccines and therapeutic drugs[2,4]

Vaccines	Therapeutic drugs
Population treated	
Healthy (relatively large)	Sick (relatively small)
Benefits provided	
Individual & population-based (herd immunity, disease eradication, antibiotic resistance reduction, and outbreaks control)	Individual only
Time of effect	
Future	Present
Duration of effect	
Long-term	Short-term
Acceptance of adverse events	
Lower	Higher

- Heterogeneity and limited transparency in vaccine decision-making process, as well as uncertainty among roles and responsibilities of involved parties in most of EU countries delay patient access to vaccines.[2]
- Time to EU patients access to vaccines may be reduced while considering several aspects:
  - At National level:
    - ➢ Formal decision-making process that should encompass a better coordination and opposable timelines between stakeholders, as well as publication of the recommendations with their rationale, to increase transparency in decision-making and improve time to market access.
    - ➢ Implementation of horizon scanning for vaccines and of a process for early consultation on development plan of candidate vaccines that would help to facilitate earlier and faster adoption of vaccines and addressing the needs of NITAGs and HTABs.
  - At European level:
    - ➢ Development of guidelines for vaccination recommendation assessment framework to support better alignment and understanding of evidence requirements and appraisals.

Figure 3. Key transparency criteria for assessment by NITAG and HTAB (numbers of EU countries out of 27 countries with NITAG and 12 countries with NITAG and HTAB)[1]



RECOMMENDATIONS

- Varying length in time to access for vaccines across EU28 countries indicates that there is room for improvement to allow better predictability.
- At EU level, appropriate European Commission policy and support are needed to reduce time to access for citizens.
- At national level, secured financing of vaccination program and greater collaboration and coordination between stakeholders to drive more transparent assessment guidelines for vaccines should provide opportunity for faster patient access to vaccines.

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