



National and European Union level recommendations to accelerate timely vaccine access

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OBJECTIVE

→ To identify policy changes that may shorten time to population access to vaccinations in the European Union (EU)

METHODS

- Qualitative research conducting semi-structured interviews with experts from exemplary countries of each identified EU Vaccines Access pathway archetype.
- Experts were recruited based on their expertise in the field of vaccines, participation in working groups and authored publications.
- Each exemplar country was chosen based on a previous archetype analysis¹ (Table 1) and being the most representative, i.e. one of 5 main EU markets or the country with the highest population size and number of births.

Table 1. Exemplar countries selected based on archetype analysis¹

Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5
National and sub-national decision-making	National decision-making	Individual reimbursement [†]	National decision-making and mandatory funding and higher GDP/capita	National decision-making and mandatory funding and lower GDP/capita
Mandatory funding	National tendering			

* Selected to represent northern Europe in addition to Italy representing southern countries.
† Individual vaccine procurement based on reimbursement list

RESULTS

- Eleven interviews with experts from European Union (EU) exemplar countries and an EU institution, were conducted in the second half of 2019.
- **Recommendations at European Union Level**
 - Improved collaboration at the EU level is needed to avoid duplication of effort and to reduce access time to vaccines for populations.
 - Experts identified scientific activities and information sharing as key collaboration drivers and recommended their enhancement (Figure 1).
 - Joint clinical assessment and development of framework guidelines for vaccine assessment were considered by experts as having the potential to improve the overall process.
 - Limited funding for scientific groups and the lack of political or health authorities' support were reported as barriers for collaboration at EU level.

Figure 1. Major drivers and barriers of EU-level collaboration



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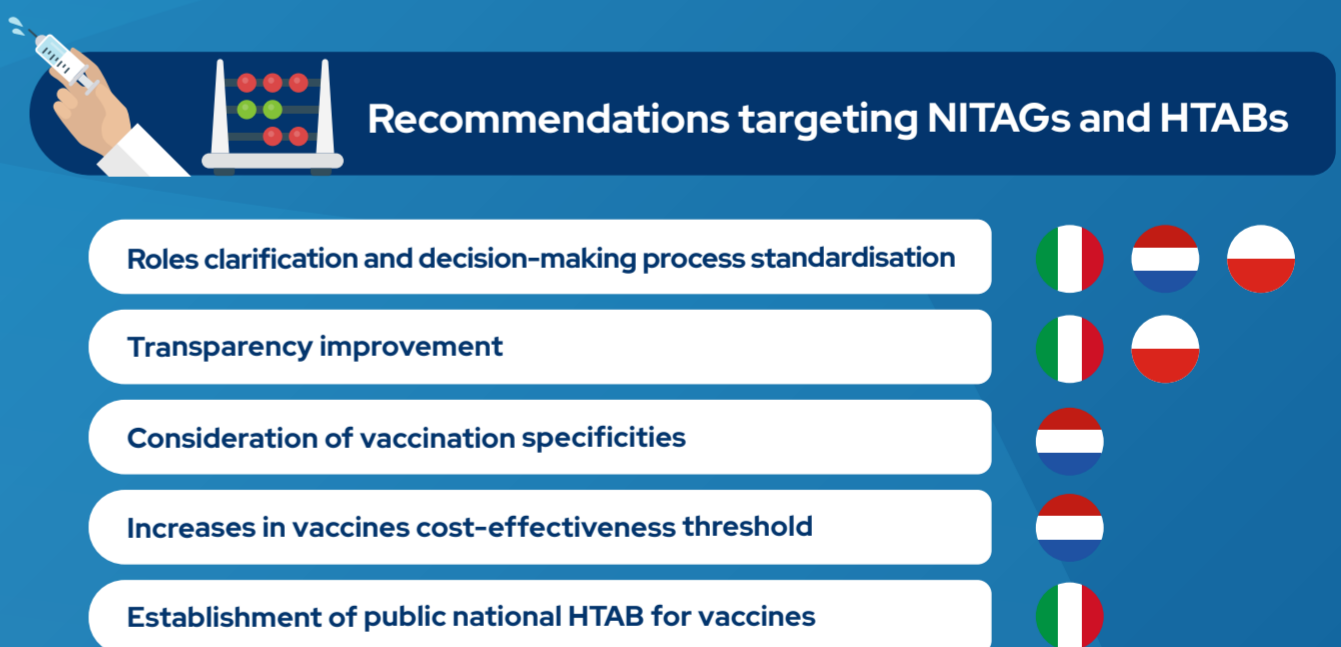
- **Recommendations at National Level**
 - The national level changes recommended by experts to improve vaccine timely access were targeted at National Immunisation Technical Advisory Groups (NITAGs) (Figure 2), NITAGs and Health Technology Assessment bodies (HTABs) (Figure 3) or Vaccine Companies.
- **Recommendations targeting NITAGs**
 - Introduction of formal early advice was indicated by experts from France, Germany and Poland.
 - Involvement of more vaccine experts was recommended by respondents from France, Italy and the Netherlands. Currently some well recognised vaccine experts are excluded from NITAGs due to the rigorous approach pertaining to conflicts of interest.
 - French respondents also recommended formalisation of horizon scanning, definition of recommendation timelines and prioritisation criteria to select in which order to assess dossier, considering that in addition to new vaccines, French NITAG is also involved in assessment of already evaluated vaccines in case of modifications of quality and/or clinical data.

Figure 2. National level expert recommendations targeting NITAGs



- **Recommendations targeting NITAGs and HTABs:**
 - Experts from the Netherlands, Italy and Poland recommend clarification of the NITAG and HTAB roles and standardisation of the decision-making process for these stakeholders.
 - Improvement of transparency was recommended for Italy and Poland.
 - According to the Netherlands' expert, vaccination demographic effect, equity, country macroeconomic development and increases in the cost-effectiveness thresholds should also be considered for vaccines.
 - The expert from Italy recommended that a national public HTAB in charge of independent evaluation of vaccines should be established because it did not yet function at the time of this research.

Figure 3. National level expert recommendations targeting NITAGs and HTABs



- **Recommendations for Vaccine Companies:**
 - Respondents proposed early company engagement in the authorities vaccine assessment process and generation of effectiveness data for recommended vaccines.
 - Other aspects, not directly related to vaccine market access, were raised and were related to vaccine supply and implementation of vaccination programme.

¹Kapuśniak A, Rémuzat C, Laigle V, Beck E, Visic A, Toumi M. EU Market access pathways for vaccines: definition of country archetypes using mathematical clustering. ISPOR 2019, Copenhagen, Denmark, November 2-6 2019. PIN13.

CONCLUSIONS

Vaccine experts' recommendations show a **clear direction for the changes needed to ensure timely access to vaccines in Europe**. Most of these changes pertain to the **decision-making process and include clarification of roles of involved stakeholders (NITAGs-HTAB), standardisation of the process** covering early consultation, formal decision-analysis framework, systematic approach for evidence appraisal **and definition of timelines**. **Experience with drugs indicates that with political willingness and engagement this could be also achieved for vaccines**.