Drivers and barriers to timely access of vaccines for European populations: Expert perspectives on the decision-making process

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Kapuśniak A[1], Rémuzat C[2], Laigle V[3], Beck E[3], Toumi M[4]
[1]Creativ-Ceutical, Krakow, Poland, [2]Creativ-Ceutical, Lyon, France, [3]Vaccines Europe Market Access Working Group, Brussels, Belgium, [4]Aix-Marseille University, Marseille, France

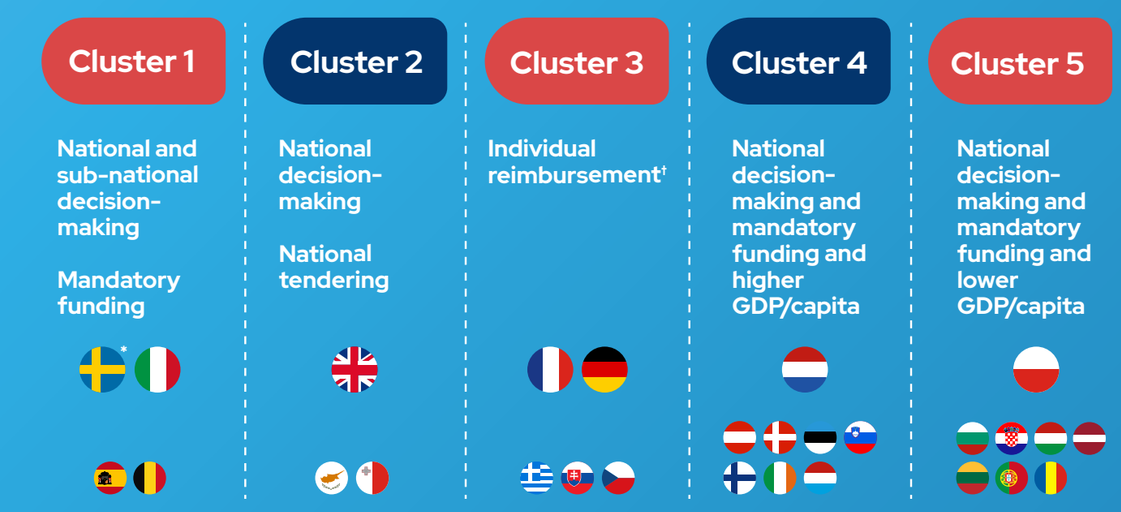
OBJECTIVE

→ To identify drivers and barriers of vaccines market access in Europe from experts in the decision-making process.

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 analysis[1] (Figure 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.

Figure 1. Exemplar countries selected based on archetype analysis[1]



* 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.

→ **Vaccines Access Pathway uncertainties**
- Market access for vaccines was perceived as more complex and complicated than for drugs in all analysed countries except the UK, where guidelines and assessment processes for both are similar.

→ **Transparency of vaccine assessment**
- Experts from France, Germany, Sweden and the UK assessed the overall recommendation process for inclusion of a vaccine into immunisation program and funding as transparent, whereas transparency reported for Italy, the Netherlands and Poland was lower (Figure 2).

Figure 2. Expert's perception of transparency of vaccine assessment

Country	Transparency of vaccine assessment	Reported reasons
France	✓	Overall process is perceived as transparent
Germany	✓	Overall process is perceived as transparent
Sweden	✓	Overall process is perceived as transparent
UK	✓	Overall process is perceived as transparent
Italy	✗	Assessment framework and evidence appraisal are the least transparent parts
Netherlands	✗	Application of assessment criteria is sometimes confused & vague Unclear cooperation between NITAG and HTAB
Poland	✗	NITAG recommendations not published

→ **Vaccines market access drivers and barriers**
- Experts from all countries identified disease burden (or actual benefit) as a decision driver (Table 1); budget unavailability, high vaccine price, lack of cost-effectiveness and vaccination hesitancy were barriers (Table 2).

Table 1. Drivers for vaccine market access reported by experts

	DE	FR	IT	NL	PL	SE	UK
Burden of disease/ actual benefit	✓	✓	✓	✓	✓	✓	✓
Vaccine efficacy/effectiveness/safety	✓	✓	✗	✓	✓	✓	✓
Vaccine cost-effectiveness	✗	✗	✓	✓	✓	✓	✓
Political support	✗	✓	✓	✗	✓	✗	✗
Budget availability/favourable budget impact or vaccine price	✗	✗	✓	✗	✓	✓	✗
Availability of registries/ experience from other countries	✓	✓	✗	✗	✗	✗	✗
Acceptance of vaccination by population	✗	✓	✗	✗	✓	✗	✗

Reported ✓ Not reported ✗

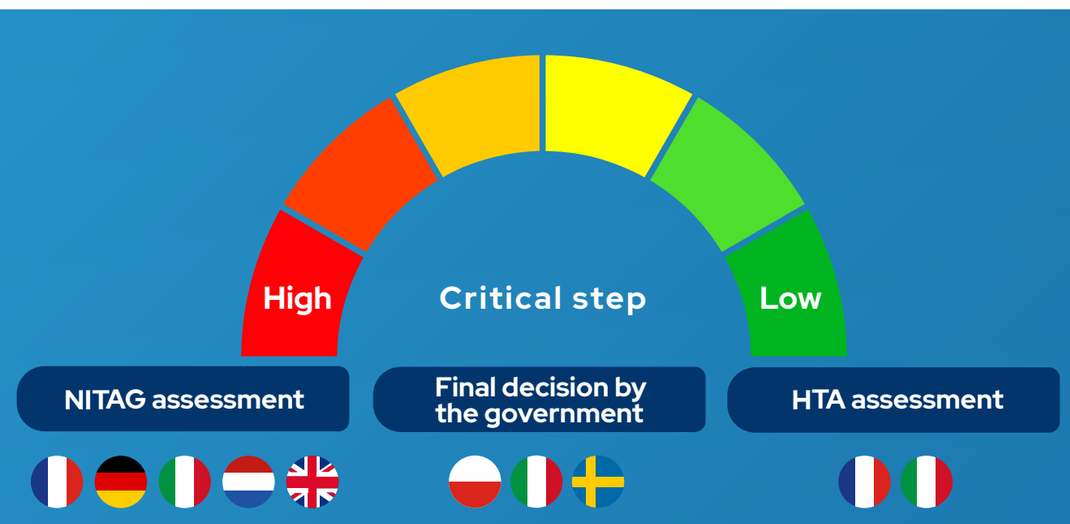
Table 2. Barriers for vaccine market access reported by experts

	DE	FR	IT	NL	PL	SE	UK
Budget unavailability/ high price/ the lack of cost-effectiveness	✓	✓	✓	✓	✓	✓	✓
Vaccination hesitancy	✓	✓	✓	✓	✓	✓	✓
Vaccine safety issues or lack of effectiveness	✗	✓	✗	✓	✗	✗	✓
Unclear market access process	✗	✗	✓	✗	✓	✗	✗
Organization of vaccination at sub-national level	✗	✗	✓	✗	✗	✓	✗
Lack of communication with providers and end-users following vaccination introduction	✗	✗	✓	✗	✗	✗	✓

Reported ✓ Not reported ✗

→ Critical steps in vaccine market access
- NITAG recommendations were perceived as the critical step in vaccine market access in most countries, i.e. France, Germany, Italy, the Netherlands and the UK (Figure 3); challenges include:
  - Rigid exclusion of experts with industry relationships due to potential conflicts of interest (Italy and the Netherlands), limiting the number of experienced participants within some NITAGs.
  - Lack of timelines for issuing a recommendation (France).
  - Reluctance to accept any uncertainty during a vaccine assessment (Germany and UK).
- French and Italian experts identified HTA as a critical step in the vaccine market access process.
  - For Italy, at the time of the research there was a lack of a public body conducting independent HTA which was perceived as a major barrier as HTA for vaccines is required.

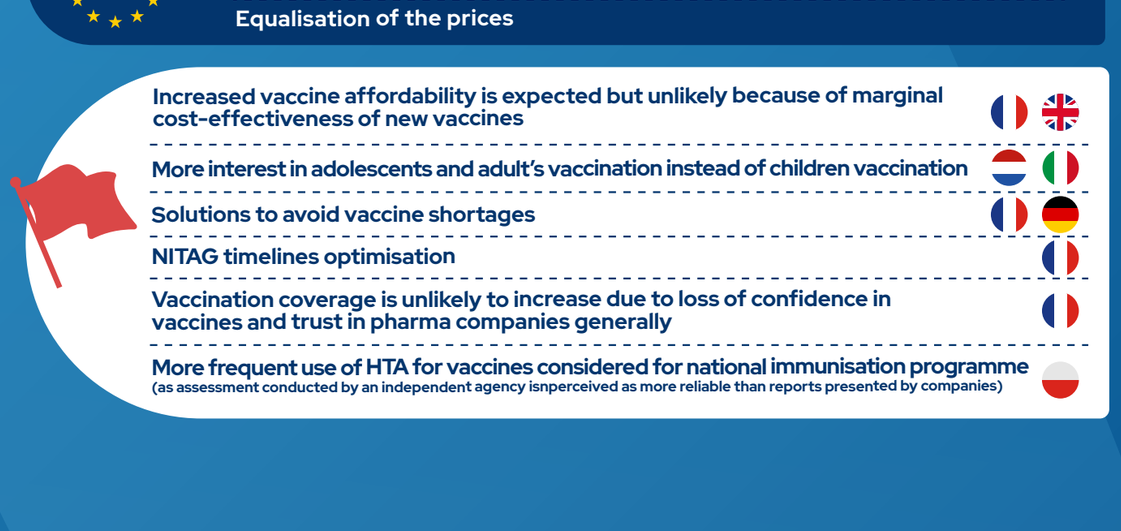
Figure 3. Critical steps in vaccine market access reported by experts



→ The final decision by the government was identified as a critical step for vaccine access for Italy, Poland and Sweden due to:
- Lack of transparency and uncertainty on decision-making in Poland and Sweden.
- Requirement for unanimous Regional consensus to grant final positive decision at the National level in Italy.

→ **Experts' view on the future vaccine market access**
- At EU level, no common expectation regarding future vaccine market access; 3 experts stated single expectations (Figure 4).
- At National level, experts anticipated higher interest in adolescent and adult vaccination and solutions to avoid vaccine shortages. While increased vaccine affordability was expected, experts considered it rather unlikely due to the expected marginal cost-effectiveness of new vaccines.

Figure 4. Changes expected by experts at EU and national level



[1] Kapuśniak 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. PIN113.

CONCLUSIONS

Market **access for vaccines** in European member states is a **highly complex, heterogeneous, lengthy and opaque decision-making process.** NITAG recommendations (and HTA when applicable) and final decision are seen as critical steps and several challenges are encountered during the overall process. In the future, amongst other expectations, life-course immunisation, NITAGs timelines optimisation and implementation of Joint HTA for vaccines are perceived as possible trends.