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BACKGROUND INFORMATION

Present in all EU countries, National Immunization Technical Advisory Groups support immunisation policies, generally applying HTA methodology when providing their evidence-based recommendations.

- NITAGs' role in national decision-making is crucial to ensure that its **independent multidisciplinary vaccine expertise is included, and due attention is given to vaccines** in setting national health priorities.¹
- NITAGs' roles vary among EU countries, exhibiting differences in clarity, formal terms of reference, and use of vaccine-specific frameworks. However, **decision-makers typically align with NITAG's advice.**³
- For the HTA of vaccines, NITAGs provide **technical assistance** by generating evidence-based recommendations for new and updated vaccination schedules, considering national priorities and technical, programmatic logistical, financial, and social criteria.⁴ Their recommendations are often substituting, overlapping, or made in advance of HTA bodies' assessments.

The HTA landscape is evolving in the EU, with the EU HTA Regulation (HTAR) entering into force in 2025, also having vaccines within its scope.

- The EU HTA framework will consist of **4 components**: Horizon scanning, Joint Scientific Consultation (JSC), Joint Clinical Assessment (JCA), and voluntary cooperation on other areas.
- The JCA will start gradually in 2025 and will apply to vaccines starting in 2030.^{5,6} Nevertheless, as of 2025, vaccines might be subject to the JSCs, horizon scanning and voluntary collaboration activities.⁷
- Vaccine market access pathways across EU countries are currently complex, heterogeneous and different to those established for other medicinal products, but they will be equally impacted by the entrance into force of the EU HTA Regulation.

OBJECTIVE & METHOD

Despite NITAG's crucial role and expertise in vaccine assessment, there are still no indications that NITAGs will be systematically involved in the EU HTA framework (JCAs, JSCs, and horizon scanning). A lack of their involvement in the EU HTA framework may limit the utilisation of the JCA reports at a national level and other benefits of the HTAR in the context of vaccines.

This study aims to highlight the gaps that arise when NITAGs are not included in the EU HTA framework and to recommend ways to involve NITAGs therein.

The research methodology consisted of two main points of action:

- Illustrate the impact of the EU HTA framework on a National Immunisation Programme (NIP) vaccine for three countries with different vaccine market access characteristics and identify gaps.
- Provide recommendations for the incorporation of NITAGs in the EU HTA framework.

RESULTS

The varying interactions between HTA bodies and NITAGs in national vaccine assessments across countries suggest that the EU HTA Regulation for vaccines could apply to a different extent in each country.

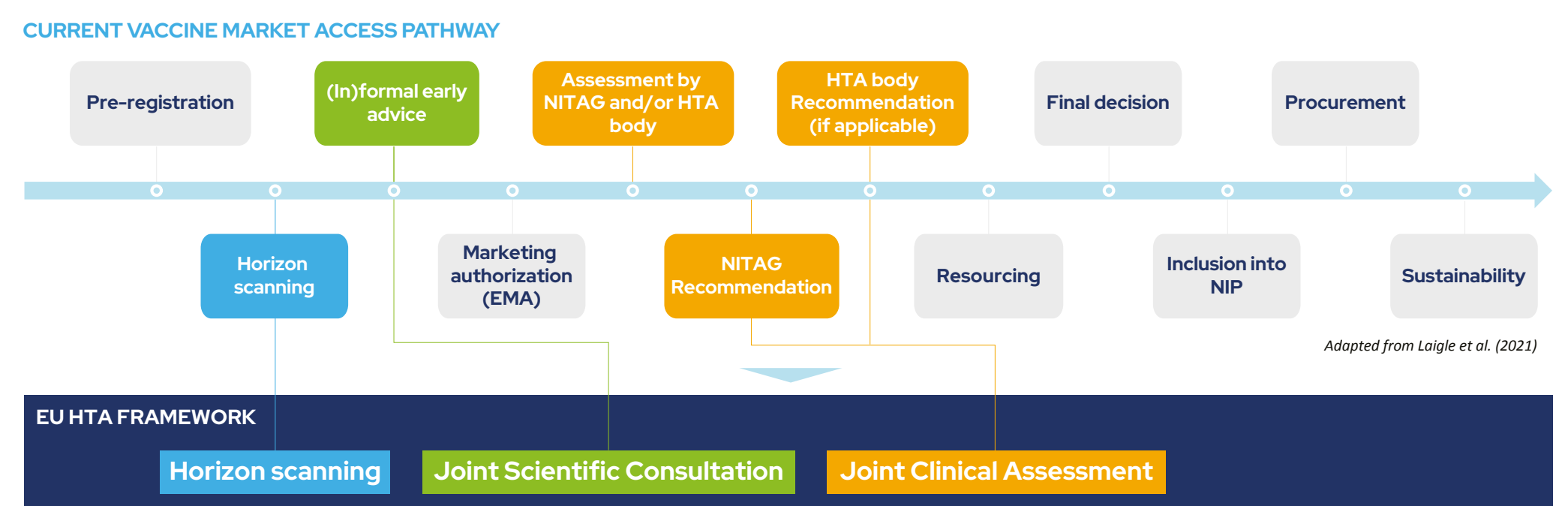
Figure 1. Overview of vaccine HTA landscape in selected countries

	GERMANY	ITALY ¹	THE NETHERLANDS ¹
Level of decision-making:	National	National and regional	National
Vaccine assessment:	NITAG (STIKO), assisted by Public Health Institute (RKI)	NITAG (GTCNV), HTA bodies (AIFA CSE ²)	In parallel by NITAG (GR) and HTA body (ZiN)
Horizon scanning:	Meeting with each manufacturer 1-2 times per year by RKI	National regulatory authority (AIFA)	Meeting with all manufacturers 4 times per year by public health institute (RIVM) ⁶
Formal scientific advice:	Regulatory authority (PEI) ²	Not implemented ^{3,4} (new scientific advice on track)	ZiN, optionally in parallel with regulatory body (CBG) ³
Manufacturer-initiated assessment:	Not allowed (initiated by the STIKO and prioritized according to degree of public interest) ³	Allowed ³	Not allowed for GR assessment; allowed for ZiN assessment; ³
NITAG recommendation based on:	Clinical value (and sometimes economic/cost-effectiveness value)	SmPC, EMA approval, HTA presented by MAH, organization and financial impact ⁵	Clinical value, appropriate use and efficiency ⁷

Abbreviations: PEI = Paul-Ehrlich-Institut; RKI = Robert Koch Institute; STIKO = Ständige Impfkommission
Abbreviations: AIFA = Agenzia Italiana del Farmaco; CSE = Commissione Scientifica ed Economica; GTCNV = Gruppo Tecnico Consultivo Nazionale Vaccinazioni; MAH = marketing authorization holder
Abbreviations: GR = Gezondheidsraad; CBG = College ter Beoordeling van Geneesmiddelen; RIVM = Rijksinstituut voor Volksgezondheid en Milieu; ZiN = Zorginstituut Nederland
¹Limited role, only for specific vaccines

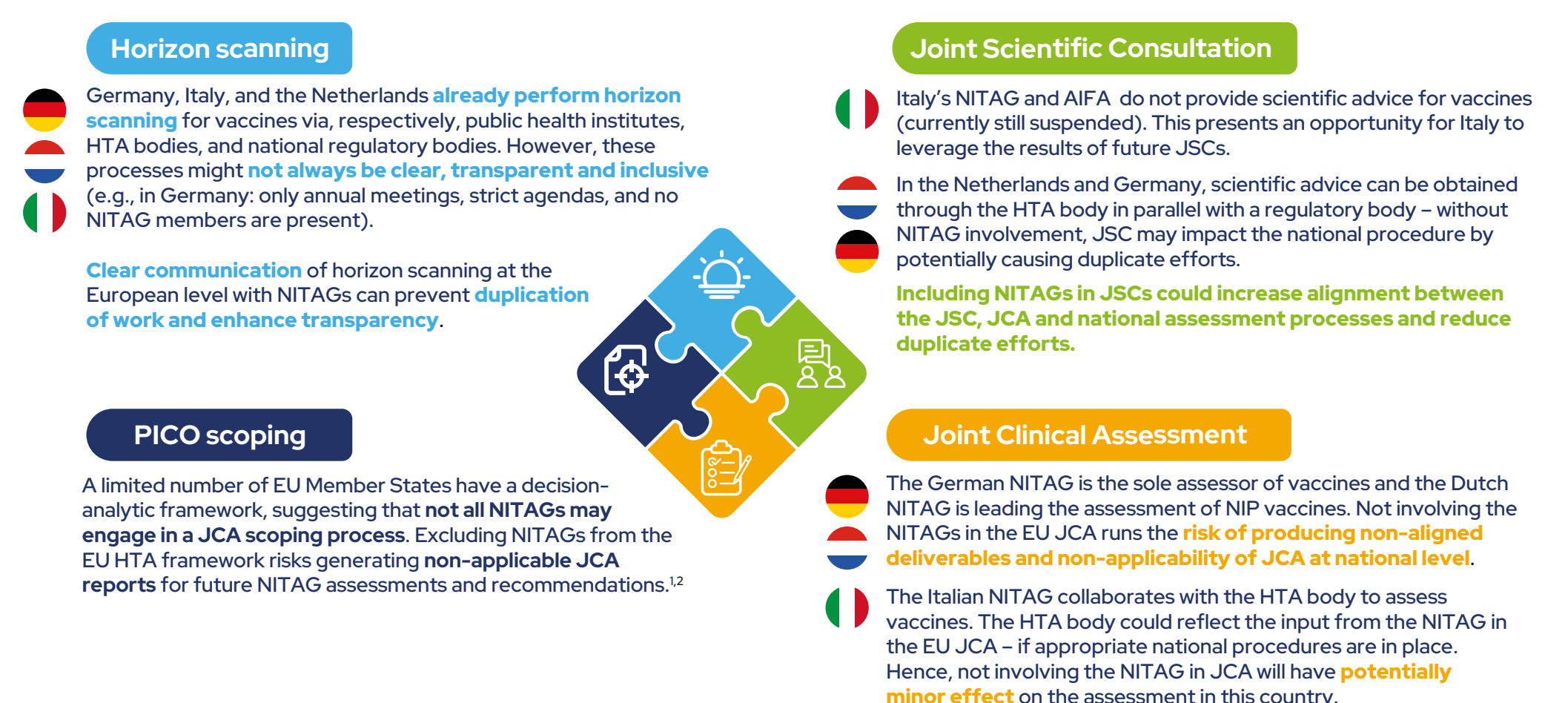
Different steps in the current vaccine market access pathway overlap with the different sections of the EU HTA framework. If there is no communication between the NITAGs and the the HTA Coordination Group/national HTA bodies, this could lead to unnecessary duplication of work, further complexity of the processes, and lengthening of population time to access to new vaccines. This is not the intention of the EU HTAR.

Figure 2. Overlap of EU HTA framework with current vaccine market access pathway



The involvement of NITAGs in the EU HTA framework could positively influence market access for vaccines by enhancing alignment between European and national level processes, shortening time to patient access.

Figure 3. Potential NITAG involvement in the EU HTA framework



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SOLUTIONS

There are possible solutions that the European Commission, HTA Coordination Group and Member States can consider to address vaccine specificities and prevent duplicate efforts:

- Structurally involve NITAGs in the EU HTA framework**
Systematic inclusion of NITAGs in the different EU HTA framework processes avoids unnecessary duplication
- Ensure that NITAGs provide input into the scoping process at national level**
NITAG's involvement in the scoping process optimizes assessment scope applicability and adds resources if needed
- Address vaccines in interim HTAR evaluation**
NITAGs can help incorporate vaccine specific aspects into the JCA
- Provide training to NITAGs to build a common understanding of the EU HTA framework**
Trainings for NITAGs will ensure unified understanding and effective implementation of EU HTA framework
- Consider NITAG members as assessor/co-assessors in the JCA process**
Including NITAGs as assessors in the JCA process ensures the appropriate expertise and quality for vaccine JCA
- Incorporate the ECDC as key stakeholder and partner to facilitate EU HTAR implementation for vaccines**
Incorporating ECDC as key stakeholder can ensure effective oversight and right expertise

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