Assessing the Impact and Strategic Implications of the HTA Regulation 2021/20282 on National Processes: A Scoping Review and Stakeholders Perspectives Through Semi-Structured Interviews.

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Background

- **HTA Regulation 2021/2282** aims to establish a more harmonised HTA framework while fostering cooperation between member states and facilitating equal patient access.
- Introduction of new concepts like
  - **Joint Scientific Consultation** (JSC)
    - Exchange information with HTDs on development plans for a smooth preparation
  - **Joint Clinical Assessment** (JCA)
    - Description of relative effects
    - Degree of uncertainty
    - Considering strengths and weaknesses of the evidence

Objective

- To understand the **HTA Regulations' wide-reaching impact** on national HTA procedures, **influence** on price and reimbursement negotiations, and **strategic implications** for HTDs.

Methods

- **A scoping literature review** was conducted to develop the interview guide.
- **20 semi-structured interviews** with members of the Belgian government (n=4), European authorities (n=6), Health technology developers (n=6), academics (n=2), and sickness funds (n=2) were carried out from February to March 2023.
- Interviews were analysed using the thematic framework analysis.
- Three main topics: HTA, JCA, and ATMPs.

Results

Joint Scientific Consultation: a potential early dialogue

"The sooner you do that, I think, the better it is."

- **Parallel EMA scientific advice:** *"Creating best practices and whomever does those assessments should be formed in line with those recommendations."*
- **PICO**: an opportunity to align the heterogeneity in HTA criteria across Europe

"We must be careful that it does not become a many-headed monster."

Population	Intervention	Comparator	Outcomes

• Identify relevant populations based on the claimed indication
  • Full patient population applied for by the HTD
  • Subpopulations
	• Defined according to information about assessed intervention
	• Ex: Monotherapy, combination therapy, ...
		• Relevant comparators
		• Can be approved or not (off-label)
		• Can also be nondrug interventions
			• Choice of endpoints
			• Member States need to define their needs

- A framework is needed to include the patients' voice in JSC and JCA, e.g., through the use of patient-reported outcomes

"*This is also scientific advice, via patient perception.*"

Joint Clinical Assessment Report: the importance of fostering collaborations

- *"I think that's definitely a step forward to support innovation and consistency and similar access to all patients in Europe."*
- "*So, the challenges are really having this ability to work together and to learn to trust the work done by other Member States."*

Opportunities and challenges identified by the interviewees:

Opportunities / benefits

- **For patients**: More clarity and transparency, better assessments, broader access across Europe
- **For HTA bodies**: Gain in efficiency (no duplication), sharing of the workload (pooling expertise)
- **For HTDs**: Gain in efficiency due to a reduction in administrative burden, clearer and less scattered procedures (harmonisation)

Challenges

- **For patients**: impact on (national) timelines of reimbursement procedures
- **For HTA bodies**: Capacity building & training, teamwork/collaborating with other HTA bodies, adaptation of new methodologies, time pressure, remuneration for (co-)assessors
- **For HTDs**: Influence of conservative countries, internal teamwork

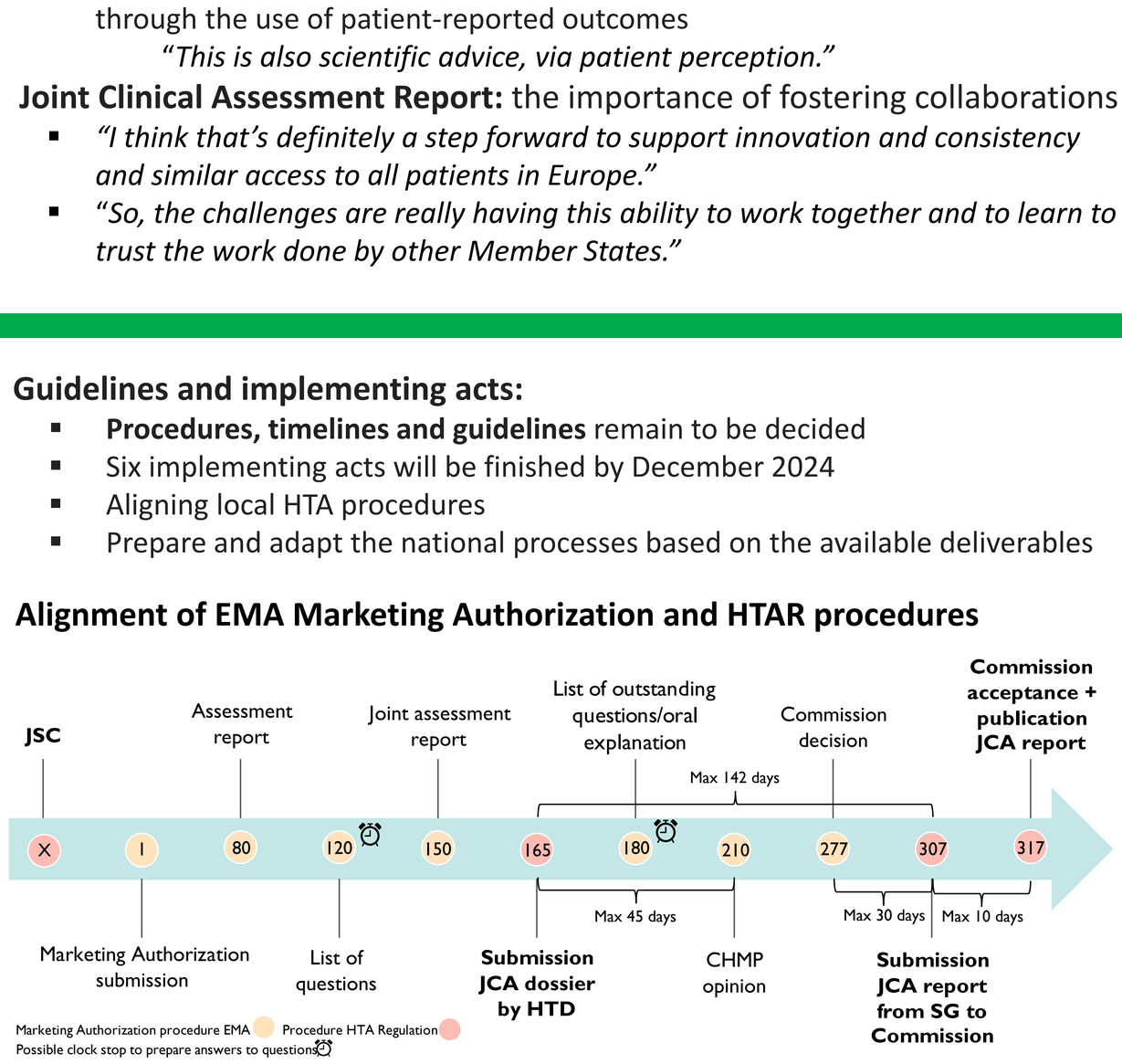
Increasing capacity to actively take part in the JSC and JCA is seen as a primary barrier by several stakeholders.
"*For me, that's the Achilles heel – finding writers, authors.*"

Adaptations of national timelines and procedures, such as the language used in the dossiers, play a significant role in enabling the HTAR.
"(...) *I think the language aspect is not a minor aspect.*"

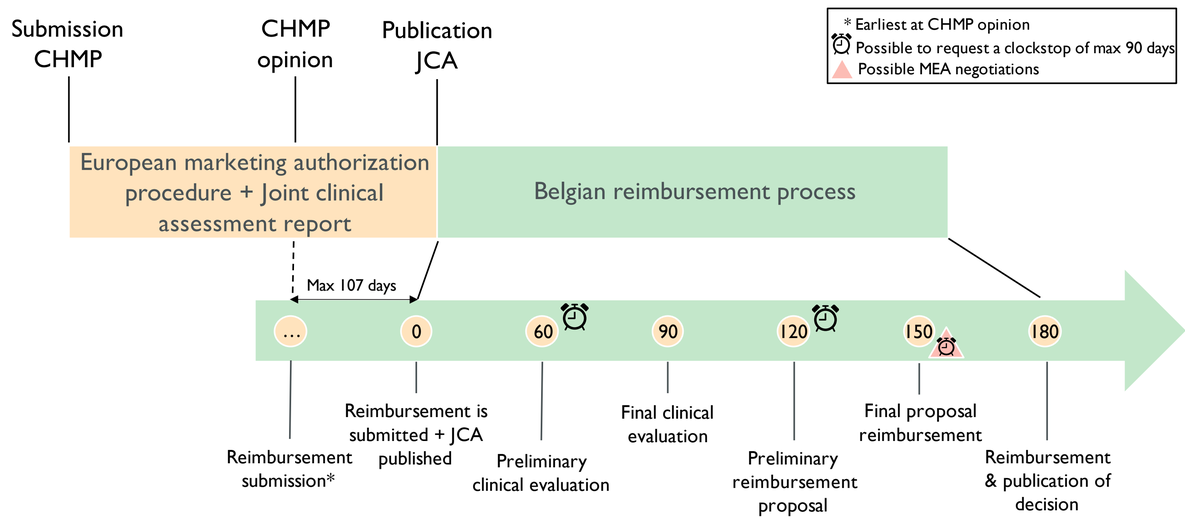
Guidelines and implementing acts:

- **Procedures, timelines and guidelines** remain to be decided
- Six implementing acts will be finished by December 2024
- Aligning local HTA procedures
- Prepare and adapt the national processes based on the available deliverables

Alignment of EMA Marketing Authorization and HTAR procedures



Timeline Belgian reimbursement procedure in relation to JCA report



The impact on the Beneluxa initiative:

Stakeholders perceive an overall positive future for the Beneluxa initiative in light of the HTAR, on the condition that there are (1) clear joint procedures, (2) national procedures are adapted accordingly, and (3) that Beneluxa could participate at EU-level as a kind of "joint member state".

List of abbreviations

JSC = Joint Scientific Consultation
JCA = Joint Clinical Assessment
HTA = Health Technology Assessment
HTD = Health Technology Developer
EMA = European Medicines Agency
PICO = **P**opulation, **I**ntervention, **C**omparator, and **O**utcome
SG = Subgroup
HTAR = Health Technology Assessment Regulation
MEA = Managed Entry Agreement

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Conclusions

- The introduction of Regulation 2021/2282 presents numerous opportunities, however, careful preparation and the collective commitment of member states is crucial to overcome the identified challenges for patients, HTA bodies, and HTDs.
- The implementing acts and procedural guidance are crucial as these will define the specific procedures, frameworks, and consequently the local implementation at member state level.