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HTA Regulation: procedure and impact on regulatory processes in Spain, France, Germany and Italy

HTA 273

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Objectives

The European HTA Regulation aims to standardize the assessment of medicines within the European Union to determine their safety and relative efficacy. This study explores the challenges and potential of the HTA regulation and JCA in the BIG4 countries: Spain, France, Germany, and Italy.

Methods

Documents published by the European HTA Coordination Group were reviewed and compared with national regulations on pricing and reimbursement procedures.

Results

Key challenges were identified in two specific phases of the JCA process: during the Assessment Scope phase and at the time of JCA report publication on the HTA digital platform.

Indirect Comparisons

Many responses to P.I.C.O. questions will come from indirect comparisons. According to literature data, these are often not accepted by HTA bodies.

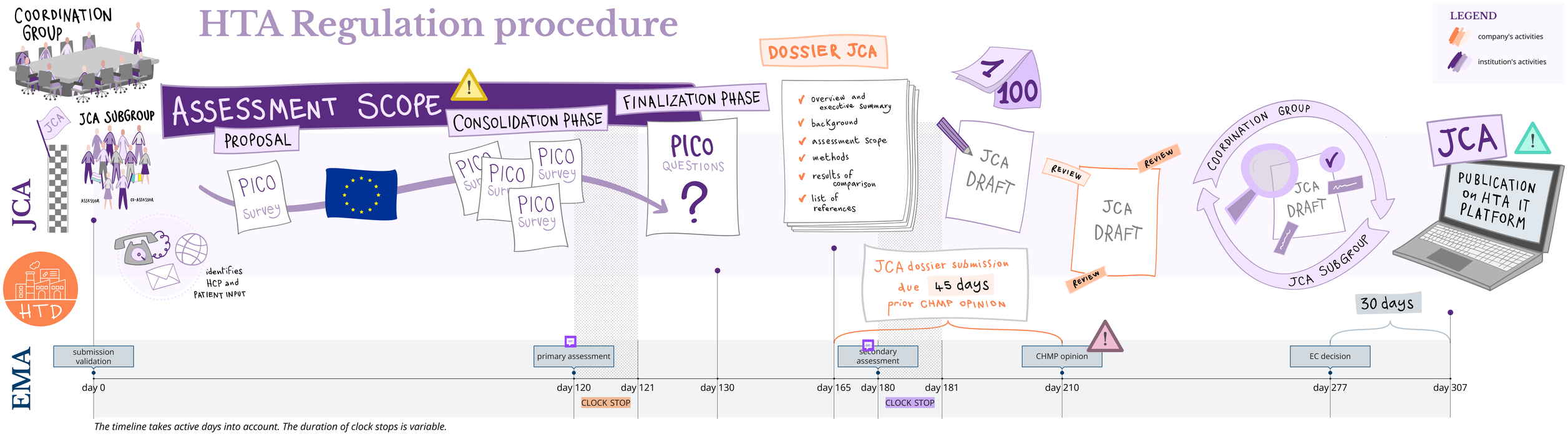
Assessment Scope

Italy: The shortage of specialized personnel hinders JCA efficiency. Off-label comparators may create misalignments with EU standards.
Germany: The simplified procedure for orphan drugs might be impacted, requiring full dossiers even for low-revenue orphan drugs.
France and Germany: Overlap between JCA and national assessments risks duplicating efforts.
Spain: The new Health Technology Positioning Group seeks to coordinate the regional needs of its 17 autonomous provinces. Regional fragmentation poses a challenge to JCA integration.

Publication of the JCA Report

Italy: There is a need to update P&R dossier guidelines to integrate JCA data.
Germany and France: Both countries already have an assessment system similar to JCA, which could lead to:
- delays in completing the process while awaiting the JCA report,
- risk of misalignment between JCA results and national evaluations.

HTA Regulation procedure



The timeline takes active days into account. The duration of clock stops is variable.

Impact on regulatory processes in Spain, France, Germany and Italy

Assessment Scope

ITALY

→ **Shortage of specialized personnel**
Italy faces a shortage of specialized personnel dedicated to the JCA process, which may negatively impact the assessment.

→ **Off-label comparator**
In Italy, a drug can be defined as a comparator even if it is prescribed off-label, provided it is part of already established therapeutic strategies. The P.I.C.O. using these comparators will influence the European context.

GERMANY

→ **Oprhan drugs**
In Germany, orphan drugs currently benefit from a simplified procedure within the AMNOG system, which does not require a full dossier submission for added benefit assessment, as long as the drug stays below a certain annual revenue threshold. However, with the introduction of the new European HTA Regulation, which establishes a centralized clinical assessment, there is a risk that this simplified procedure for orphan drugs may be revised or eliminated, requiring full dossiers even for low-revenue orphan drugs.

FRANCE AND GERMANY

→ **Risk of work duplication**
One of the goals of the new HTA Regulation is to avoid duplicating efforts between European and national assessments. Both countries perform evaluations within the P&R process that are similar to the JCA. This could lead to duplicated efforts, with the need to repeat or integrate the national assessment with the European one.

SPAIN

→ **Regional system fragmentation**
Spain is divided into 17 autonomous regions. Under the new Royal Decree, the Health Technology Positioning Group has been established, a committee that includes one representative from each autonomous region. The committee will manage the JCA at the national level, with each region presenting its own requirements. Consequently, this regional fragmentation could also influence the European context.

CHMP Opinion

ITALY

→ **100-day procedure**
In Italy, orphan drugs, hospital drugs or drugs of exceptional therapeutic and social importance have access to the accelerated '100 days' negotiation procedure. Submission is made after the CHMP opinion, but the JCA report will only be published 30 days after the EC decision (about 100 days after the potential national dossier submission), so it may not be available at the time of negotiation.

→ **The acceptance of indirect treatment comparison methods in oncology by health technology assessment agencies**
Many PICO questions will be addressed through indirect comparisons. According to literature data, these are often not accepted by HTA bodies, as indicated in the table.

	France	Germany	Italy	Spain	Total
Number of HTA evaluation reports	177	120	123	48	468
Number of HTA evaluation reports presenting at least one ITC	11	21	29	21	82
Proportion of HTA evaluation reports presenting at least one ITC	6%	18%	24%	44%	17%

Abbreviations: HTA health technology assessment, *ITC* indirect treatment comparison

Publication of the JCA report

GERMANY AND FRANCE

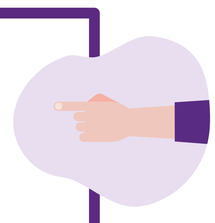
→ **Delays and conflicts with the HTA report**
Both countries already have an assessment system similar to the JCA. This could result in:
- delays in completing the process while awaiting the JCA report;
- risk of misalignment between JCA data and national assessments.

ITALY

→ **P&R dossier**
There is a need to revise the guidelines for compiling the P&R dossier to integrate the results of the JCA report.

Conclusions

Italy needs a revision of its drug evaluation procedures and national regulations, particularly for pricing and reimbursement processes. In Italy, the rules for early submission of dossiers for certain types of drugs should also be updated. In Spain, the fragmentation of the regional healthcare system presents a risk of increased workloads, as the standards of care across the 17 autonomous regions must be considered.
Germany and France, with methodologies similar to the JCA, must decide whether to fully integrate the JCA into their internal assessments to avoid duplication or participate in the JCA while maintaining separate national assessments. A coordinated and nationally adapted approach will be essential to optimize all political and operational efforts of the stakeholders involved.



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