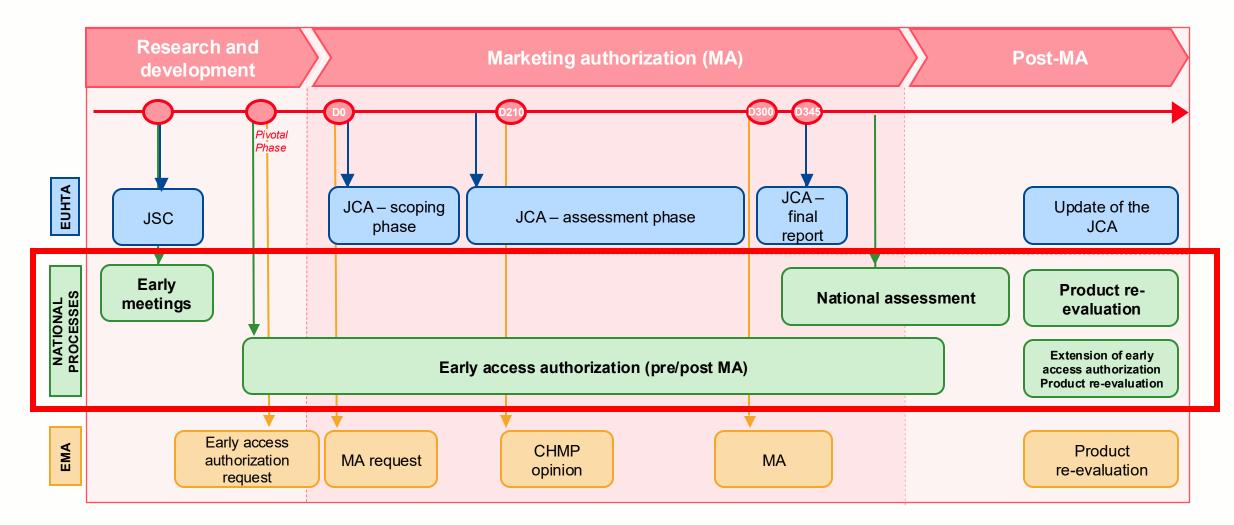
#### **European Access Academy**

# **EU HTAR: Status Review - National Perspective, France**

Pierre Cochat – Haute Autorité de santé (HAS), France



## Different procedures throughout the lifecycle of a medicinal product



JSC: Joint Scientific Consultation – JCA: Joint Clinical Assessment



### What are the principles and expectations of a JCA?

The French and European responsibilities in the development of a JCA are organized as follows:



#### Scientific assessment-

The clinical assessment of health products is centralized at the EU level, specifically:

- **Single dossier:** resubmitting data at the national level that has already been submitted at the European level is prohibited
- Defining the assessment scope (scoping phase PICO)
- Summary of comparative clinical evidence
- Analysis of the **certainty** of the available data



#### -National appraisal-

The assessment of the value of a health technology, pricing, and reimbursement remain the competence of the Member States:

- HTDs must still submit a reimbursement request
- HAS staff and Commission members will have access to the clinical data provided at the European level (JCA)
- Committees will continue to evaluate health technologies according to their doctrines
- Minstries continues to make reimbursement decisions



## Position of individual nations: 2 steps

1. Role of each individual nation in the HTAR assessment process

2. Impact of HTAR on each individual appraisal national process



## Position of individual nations: 2 steps

1. Role of France in the HTAR assessment process

2. Impact of HTAR on each individual appraisal national process



### **Preliminary measures**

- 1. Creation of an adequate committee within HAS (weekly meeting)
- 2. Information/training of HAS members
- 3. Information and training of Transparency Committee experts
- 4. Information/training of French representative of HTD
- 5. Online information at <a href="https://www.has-sante.fr">www.has-sante.fr</a>
- 6. Publication of a special issue in Quart Med Rev (French journal in English)



## Staff and experts: global HAS action

- 1. Involvement of a specific department, including methodologists
- 2. Involvement of the whole Medicinal Product Assessment Office

2 delegates for JSC + 2 delegates for JCA

Coordination, regulation and information

3. Involvement of the board of the Transparency Committee

Search for PICO experts

Opinion on PICO French label



## Position of individual nations: 2 steps

1. Role of each individual nation in the HTAR assessment process

2. Impact of HTAR on the French appraisal process



### **Evaluation of medicinal products in France**

1. Assessment Phase - Medicinal Product Assessment Office (SEM):

30 project leaders

Pharmacists and MD

2. Appraisal Phase - Transparency Committee (CT):

29 experts

MD, pharmacists, methodologists, patient representatives

No economic mission : different adequate committee



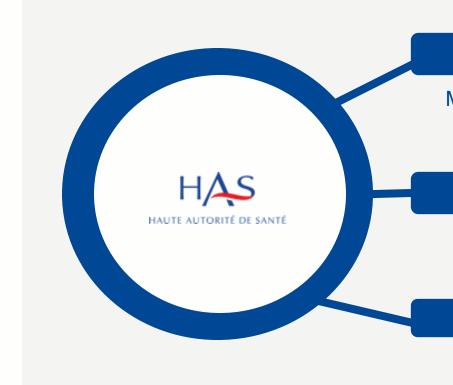
#### Which procedures are unchanged at the national level?

#### Early access pre-MA **Doctrines of the Committees** Early access requests submitted Transparency Committee (CT), Economic before obtaining MA must include all Committee for Health Products (CEESP), National Committee for the Evaluation of available data Medical Devices and Health Technologies (CNEDIMTS) → will continue to issue their opinions according to their evaluation principles Standard procedure for technologies not covered by JCAs

Health technologies not covered by JCAs will be assessed by the HAS in accordance with the current procedure.



## Which procedures are affected at the national level?



#### **National Early Dialogues**

Medicinal products/devices that have undergone or will undergo a JSC will not be eligible for an early national meeting

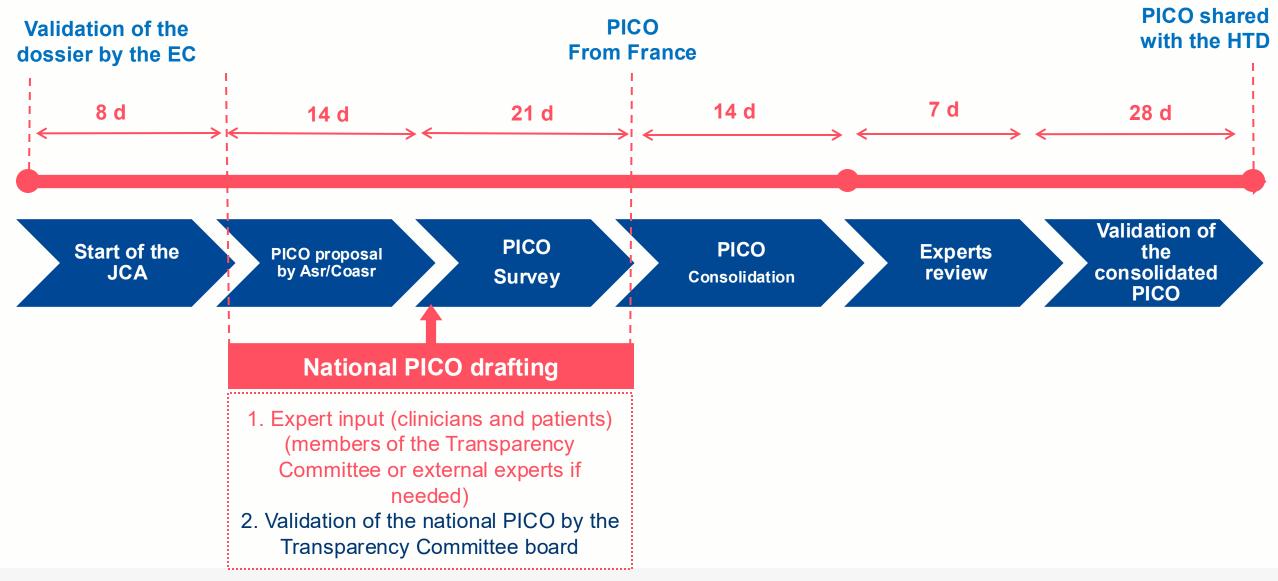
#### **Early Access Post-MA**

#### **Standard Evaluation Procedures**

The clinical data provided at the European level **will not be** requested again at the national level.



## SCOPING PHASE: National implementation





# Ongoing JCAs: new molecules in haematology/oncology + ATMP

Treatment of melanoma

Assessor: HAS, France

Co-assessor: AOTMiT, Poland

Treatment of paediatric low-grade glioma

Assessor: NCPE, Ireland

Co-assessor: IQWIG, Germany

**Treatment of bladder cancer** 

Assessor: ZIN, Netherlands Co-assessor: DMC, Denmark

Treatment of 5q spinal muscular atrophy

Assessor: NCPE, Ireland Co-assessor: HAS, France

Maintenance treatment of extensive-stage small cell lung cancer

Assessor: IQWIG, Germany

Co-assessor: INFARMED, Portugal

Treatment of locally advanced or metastatic breast cancer

Assessor: DVSV, Austria

Co-assessor: RIZIV- INAMI, Belgium

Treatment of extensive-stage small cell lung cancer

Assessor: IQWIG, Germany Co-assessor: NCPHP, Hungary

Treatment of synovial sarcoma or leiomyosarcoma

Assessor: TLV, Sweden

Co-assessor: NOMA, Norway

Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer

Assessor: IQWIG, Germany

Co-assessor: Slovenian Quality Health Care Agency, Slovenia

Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with nab-paclitaxel

Assessor: INFARMED, Portugal Co-assessor: SBU, Sweden



## Conclusion: feedback on early JCA experience

#### **Common challenges**

- Implementation of new processes that necessitate refinement and optimisation.
- Coordination and harmonisation between the first JCAs

#### Challenges as assessor

- Complex JCA: PICO requiring numerous sub-populations
- Complex PICO: consolidation across 27 Member States

#### Challenges as reviewer of other JCAs

- National procedures enabling to adequately address the national PICO:
  - Involvement of clinician and patient experts
  - Validation by the transparency committee board
- Implement this process and make it sustainable throughout the year



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## www.has-sante.fr









p.cochat@has-sante.fr

