



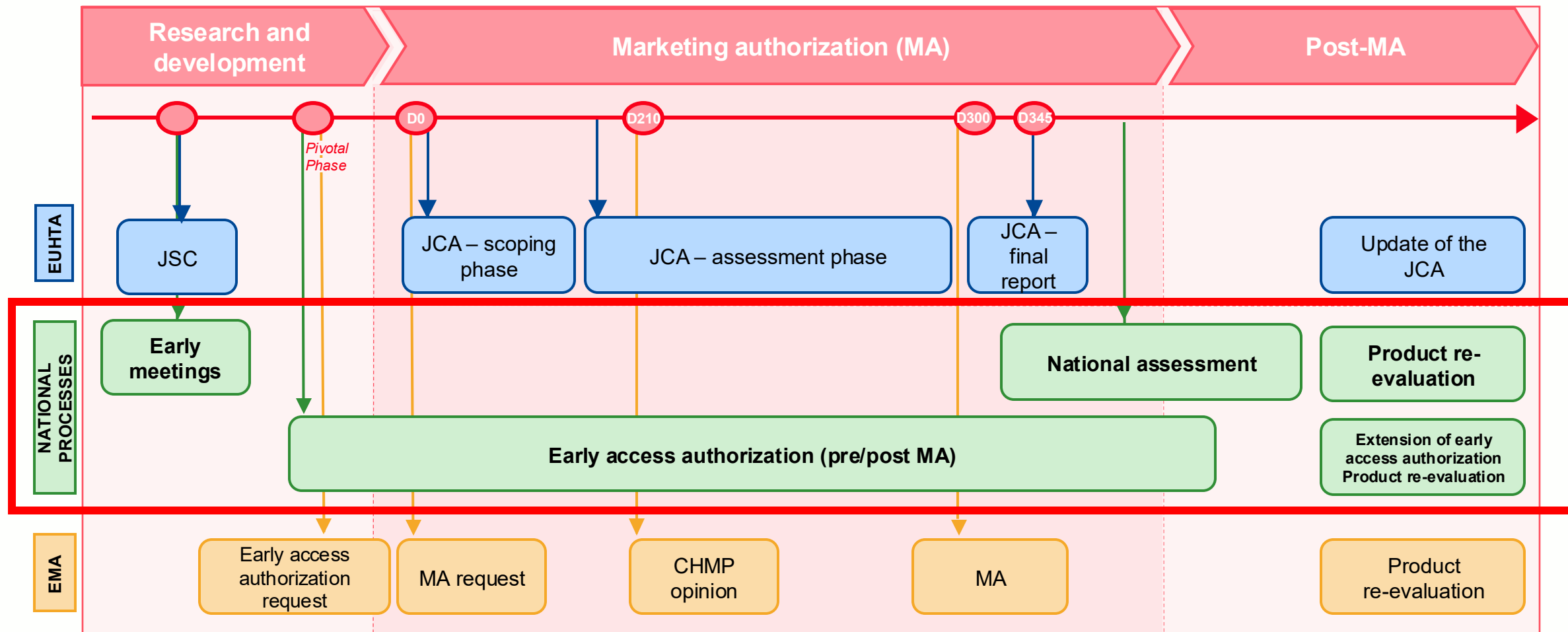
**European Access Academy**

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

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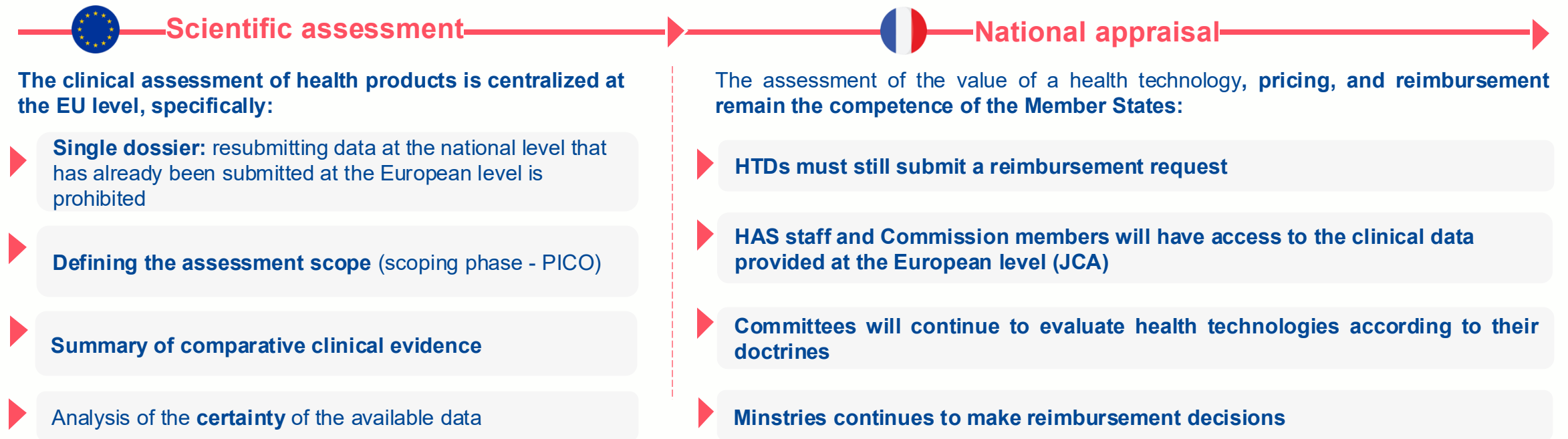
# Different procedures throughout the lifecycle of a medicinal product



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:



## 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 [www.has-sante.fr](http://www.has-sante.fr)
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

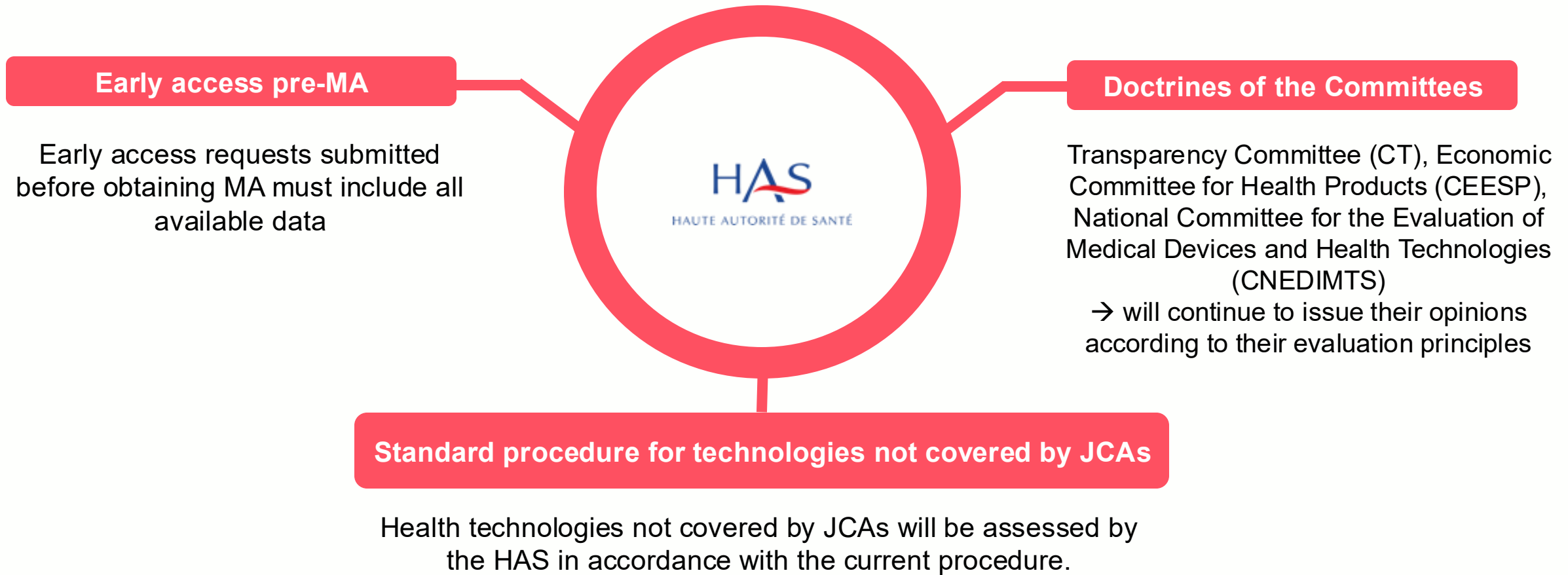
## 2. **Appraisal Phase** - Transparency Committee (CT):

29 experts

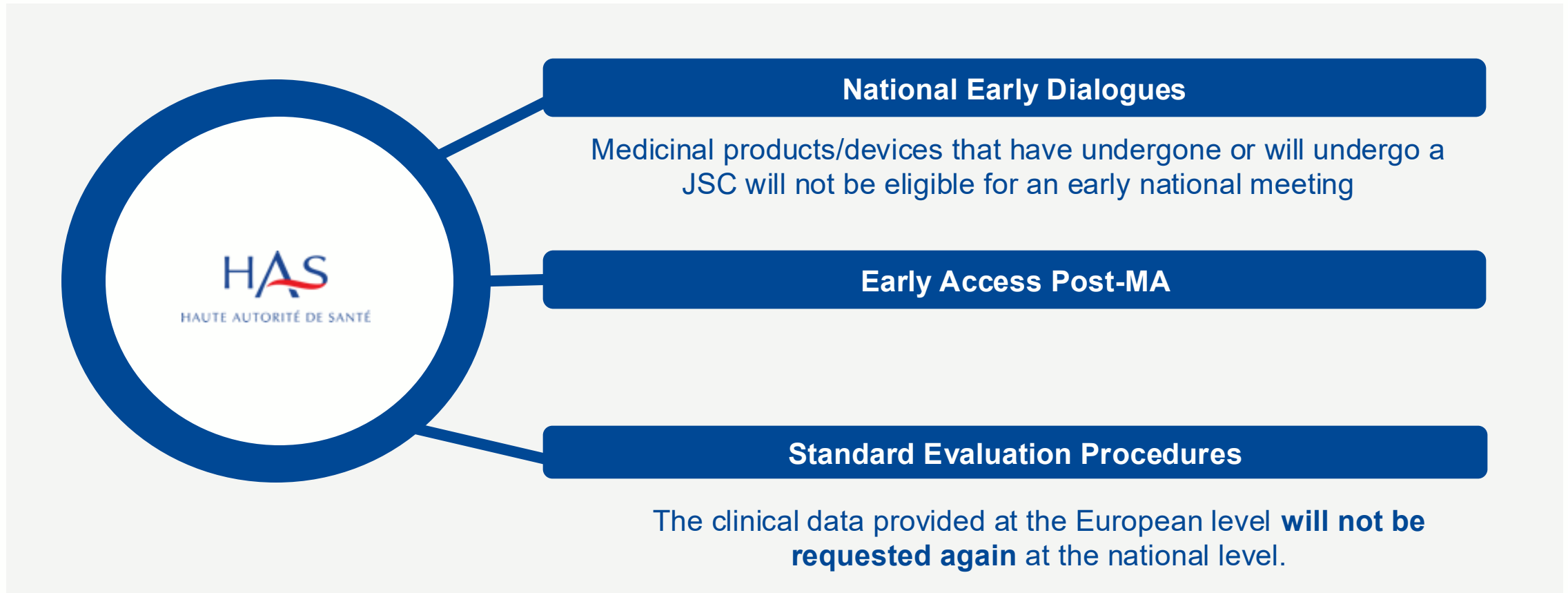
MD, pharmacists, methodologists, patient representatives

No economic mission : different adequate committee

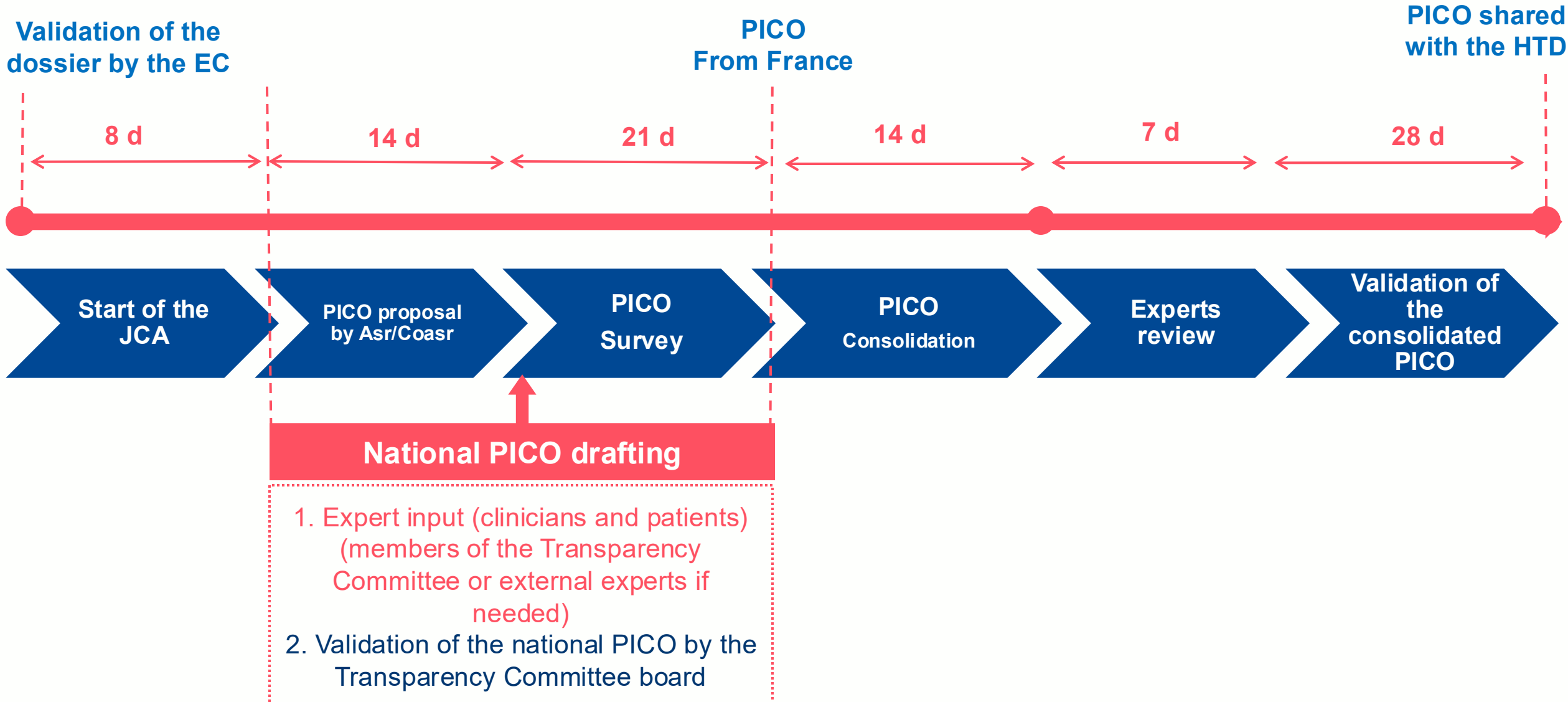
# Which procedures are unchanged at the national level?



# Which procedures are affected 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:* DSVV, **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

# Acknowledgements

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