European Access Academy

EAA Fall Convention

EU HTA – Procedural Insights & First Learnings

November 6/ 7th, 2025

Université Paris Cité & Virtual

Impulse Presentation

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Title of the Talk : Status Review National Perspective

Abstract

The HTAR relies on the introduction of two European assessment procedures: the joint scientific consultation (JSC) during the research and development phase, and the joint clinical assessment (JCA) during the marketing authorization (MA) phase. These two steps precede the national appraisal which may also include the early access process in France.

The French National Authority for Health (*Haute Autorité de santé*, HAS) -like other European HTA agencies- now combines an HTAR-based activity for certain drugs (new molecules in haematology/oncology and advanced therapy medicinal products, ATMP) in addition to its previous assessment/appraisal activity for all other medicinal products.

Indeed the appraisal of a health technology (HT) leading to reimbursement and pricing remains the competence of each individual Member State : HT developers (HTDs) must still submit a reimbursement request, HAS members will have access to the clinical data provided at the European level, the Transparency committee (TC) will continue to evaluate HTs according to its doctrine, and the Ministry will continue to make reimbursement decisions.

HAS has introduced preliminary measures: i) creation of an adequate committee within HAS (weekly meeting); ii) information/training of HAS members; iii) information/training of TC experts; iv) information/training of representative of HTD; v) online information www.has-sante.fr; vi) publication of a special issue of *Quart Med Rev* (French journal in English).

Then HAS had to set global actions for both staff and experts: i) involvement of the whole Medicinal Product Assessment Office (SEM), with 2 delegates for JSC and 2 delegates for JCA, in addition to coordination, regulation and information; ii) expert input (clinicians and

patients, members of the TC or external experts if needed) and validation of the national PICO by the TC board.

Which procedures are unchanged at the national level? i) early access requests submitted before obtaining MA must include all available data); ii) the TC as well as the Economic Committee for Health Products (CEESP) will continue to issue their opinions according to their evaluation principles); iii) standard procedure for 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? i) national early dialogues: medicinal products that have undergone or will undergo a JSC will not be eligible for an early national meeting; ii) early access post-MA; iii) standard evaluation procedures (the clinical data provided at the European level will not be requested again at the national level).

The current ongoing JCAs are: 8 drugs for cancer and 1 for ATMP; assessors/co-assessors are Austria 1, Belgium 1, Denmark 1, France 2, Germany 4, Hungary 1, Ireland 2, The Netherlands 1, Norway 1, Poland 1, Portugal 1, Slovenia 1, Sweden 1.

As a conclusion, following this first experience, some issues can be drawn. There are some commune challenges: i) implementation of new processes that necessitate refinement and optimisation; ii) coordination and harmonisation between the first JCAs. Some challenges are specific to the assessor: i) complex JCA: PICO requiring numerous sub-populations; ii) complex PICO consolidation across 27 Member States. And other challenges are related to the reviewer of other JCAs: i) national procedures enabling to adequately address the national PICO (involvement of clinician and patient experts, validation by the TC board; ii) implement this process and make it sustainable throughout time.