AGENCY
FOR HEALTH TECHNOLOGY ASSESSMENT
AND TARIFF SYSTEM

Poland’s footprint on the EU level regarding HTA

European Access Academy

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Engagement under EU HTA Regulation (2021/2282)

Coordination group Subgroups:

- Joint Clinical Assessments
- Joint Scientific Consultations
- Identification of Emerging Health Technologies
- The Development of Methodological and Procedural Guidance

Medicinal Products

Medical Devices
In Vitro Diagnostic Devices

The Committee on Heath Technology Assessment

Single Framework Contract for JCA/JSC Consortium

Ongoing engagement

In 2025 we were actively involved in:

- Tasks related to defining PICO at the national level (9 proposals)
- Preparation of Joint Clinical Assessment (JCA) report. **Currently we are involved in one process as co-assessor (with France)**:
  - INN: Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded
  - Indication: Treatment of melanoma
  - Class: ATMP
- Actively participate in Joint Scientific Consultations (JSC) subgroup tasks

Implementation of EU HTA Regulation in Poland

- Amendment to the Reimbursement Act (12 May 2011) – signed by the President in August 2025
- Draft Regulation of the Minister of Health on verification analysis

KEY FEATURES OF THE AMMENDMENT:

- **No need for a national clinical analysis** when EU-level data, analyses, and evidence are available for the same indication and target population.
- **Clinical analysis still required** if there is no full alignment with the EU assessment or if a Joint Clinical Assessment (JCA) is missing.
- **HTDs may supplement** the EU report with additional data where relevant.

Challenges and risks of the JCA

- Poor **quality of evidence** available at this stage of the lifecycle of the medicinal product
- Poor quality of the **HTD reports**
- Lack of **flexibility in deadlines**
- If **registration is not achieved**, all invested resources and work will fail to deliver the expected outcomes

Stakeholder engagement in PICO

Balancing stakeholder engagement and confidentiality (for national PICO):

- **Clinical expert inputs**: AOTMiT consults clinical experts under a signed confidentiality agreement (CA)
- **Challenge**: insufficient numer of clinicians willing to collaborate/sign the CA
- **HTD involvement**: HTDs can submit input anytime via **picojca@aotm.gov.pl**
- **Patient engagement:** At this moment there is no local patient involvement.

AOTMiT, in collaboration with NCAPR, has launched a new initiative called **CAPRICORD** aimed at enhancing public engagement in reimbursement processes. As part of AOTMiT's work package, pilot patient consultations will be conducted to inform the development of PICO.

Next Steps

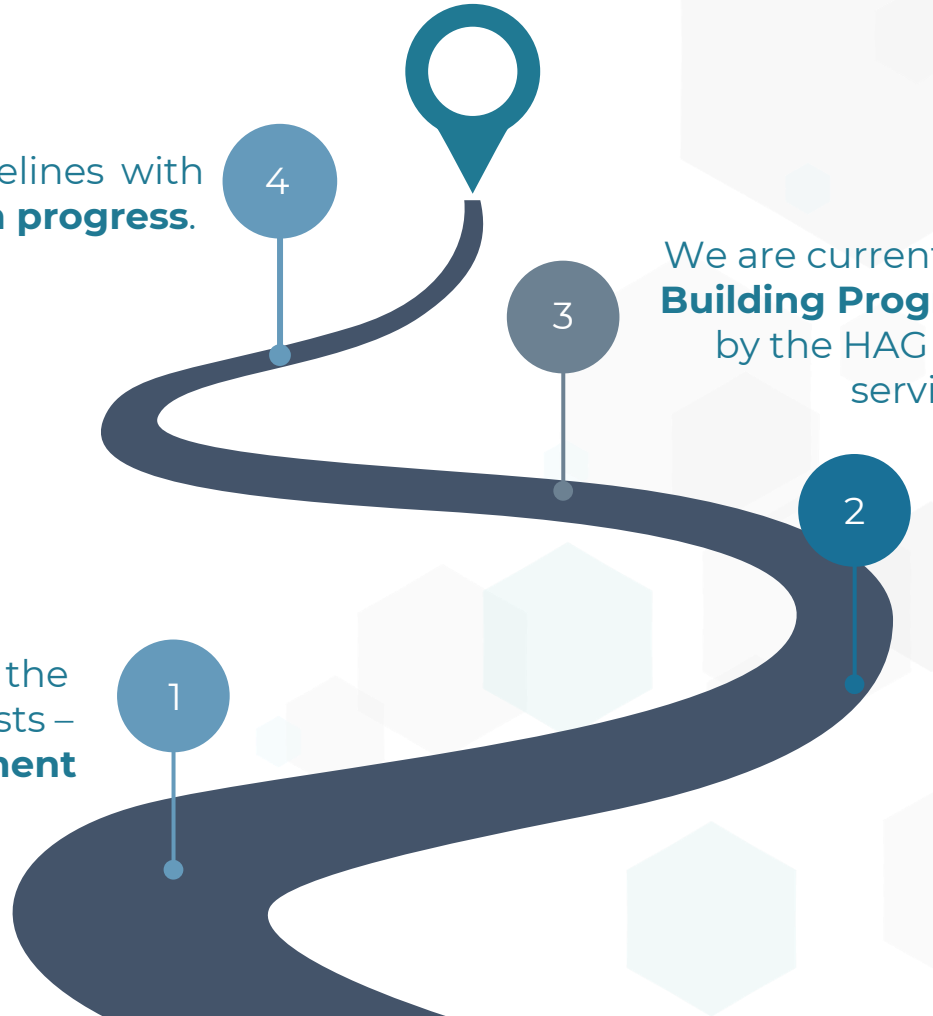
Capacity building

Further alignment of national guidelines with Cordination Group methodology **is in progress**.

We are currently participating in **HTAR Capacity Building Programme** training sessions delivered by the HAG INSIGHT Consortium under the service contract with HaDEA

Strenghten the team's capacity and expertise

From 2026, the Agency may expand the team – Capacity to hire 10 new analysts – November 2025: **Dedicated department** for JCA/JSC tasks established



Future Expectations at the national level

- JSC and JCA can improve the quality and relevance of clinical evidence from the very beginning of drug development
- Support for locally submitted dossiers – potentially replacing local clinical analyses
- Acceleration of the reimbursement process
- Incentives for HTD – reducing the costs of local procedures – provided the product is registered in the planned indication

Thank you for your attention

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