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Impulse Presentation

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Poland's footprint on the EU level regarding HTA

Abstract

This presentation outlines AOTMiT's (*pl. Agencja Oceny Technologii Medycznych i Taryfikacji, ang. Agency for Health Technology Assessment and Tariff System*) role and activities during the final stages of the preparations for the implementation of the Regulation (EU) 2021/2282, as well as its initial experiences following the Regulation's entry into force in January 2025.

AOTMiT is a designated member of the Coordination group. Although initially cautious of EU HTA processes, AOTMiT significantly intensified its involvement in the Coordination group starting June 2024. Despite joining the preparation relatively late, AOTMiT quickly caught up with other Members by establishing internal task force dedicated to supporting the implementation process. While aligning with the EU HTA processes, AOTMiT encountered both internal and external challenges, including resource limitations, need for the adaptation of the Polish law to the Regulation, and the necessity of strengthening stakeholder engagement while ensuring compliance with provisions for the protection of confidential information. Recognizing the pivotal role of the stakeholders, AOTMiT is committed to involving clinical experts in the scoping process to gather insights into real-world clinical practice and identify unmet clinical needs within the Poland's healthcare system.

The Agency faced with the increasing number of tasks related to the EU HTA, AOTMiT is planning to expand its workforce and invest in comprehensive training. These efforts aim to enable AOTMiT to take on more roles in Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC). To support capacity building opportunities and ensure full involvement in the processes AOTMiT joined the consortium for the single framework contract governing JCA and JSC in November 2024.

As of September 2025, AOTMiT continues to serve as a co-assessor in the JCA for the Autologous melanoma-derived tumor infiltrating lymphocytes and submitted 9 national PICO proposals and actively collaborates within all of the subgroups of the Coordination Group.

AOTMiT views its support for the EU HTA as a strategic investment in the future of the HTA. JCA are expected to harmonize HTA practices across the Member States, fostering greater consistency and efficiency. At the national level JCA, may support locally submitted dossiers, potentially replacing clinical analyses, thereby accelerating the reimbursement process. Moreover, they can offer incentives for applicants and help reduce the cost of local procedures.