authorized in Europe. Approval by the MHRA was 54 days earlier on average than for the European Medicines Agency. The results for various countries were as follows:

- England: 14 of 21 (67%) products assessed (9/14 [64%] recommended);
- Scotland: 14 of 21 (67%) products assessed (11/14 [79%] recommended);
- France: 14 of 21 (67%) products assessed (2/14 [14%] received Amélioration du Service Médical Rendu level I to III);
- Germany: 14 of 21 (67%) products assessed (5/14 [36%] achieved additional benefit);
- Italy: 10 of 21 (48%) products assessed (9/10 [90%] reimbursed); and
- Spain: 10 of 21 (48%) products assessed (7/10 [70%] reimbursed).

Days from regulatory approval to HTA were 306 (Scotland), 308 (France), 310 (UK), 330 (Germany), 398 (Spain), and 404 (Italy).
Conclusions: Compared with the EU4Health Programme, PO and the AC have enabled earlier marketing authorizations for medicines in the UK by an average of seven weeks. However, the proportion of therapies reimbursed and the delay from marketing authorization to reimbursement were comparable or more favorable for UK health technology assessment bodies. Thus, the UK may become a first-to-launch European market for certain therapies through PO and the AC.

PD200 Implications Of The European Artificial Intelligence Act For Health Technology Assessment

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Introduction: The European parliament is working on a proposal for an Artificial Intelligence (AI) Act. The goal is to guarantee that AI systems used in the European Union are "safe, transparent, traceable, non-discriminatory and environmentally friendly." The Act is not directly linked to health technology assessment (HTA), but implications for HTA are expected.
Methods: The final aim of the AI Act is the adoption of harmonized rules for AI foundation models. Foundation models are designed to produce a wide variety of outputs that are being adopted across various sectors. Therefore, their adaptation to specific (clinical) needs plays a key role and has implications on the required training data. The goal of our analysis was to critically investigate the potential implications of the Act's requirements for HTA. The analysis moves from the technology (foundation models in health care) to the requirements and adopted terminology.
Results: The definition of methods to assess the adaptation of foundation models has become a priority for HTA. The Act focuses on data quality, transparency, human oversight, and accountability. Available frameworks, such as the one developed by the AI MIND project, include them, but experience is required. HTA must define how to adapt its methods and frameworks as well as the risk levels addressed by the Act. In addition, the reference to energy efficiency standards confirms the need for HTA to clarify the role of and methods for environmental impact assessment. Finally, the patient perspective has great relevance in relation to the risk of discrimination.
Conclusions: The AI Act confirms the importance of topics already debated in HTA that still need resolution and testing. Harmonization of rules for AI and approaches for HTA is the main challenge. The AI Act, the HTA regulation, and ongoing European Union projects (i.e., AI-MIND and European Digital Health Technology Assessment) are showing the route to follow in the coming years.

PD201 Rare Disease Product Approvals: The Changing Regulatory And Health Technology Assessment Landscape Between 2013 And 2022

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Introduction: Globally, 7,000 rare diseases affect 300 million people, which poses challenges for developing treatments in these discrete patient populations. Developing medicines for rare diseases requires innovation, but despite regulatory incentives challenges persist for health technology assessment (HTA) and payers. Understanding the current regulatory and HTA decision-making landscape for orphan products is essential for all stakeholders.
Methods: Data on new active substances (NAS) approvals (2013 to 2022) by the European Medicines Agency, the United States Food and Drug Administration (FDA), the Pharmaceuticals and Medical Devices Agency (PMDA), Swissmedic, and the Therapeutic Goods Administration were collected to analyze the timing, approval pathways, and global rollout trends for orphan and non-orphan products. Data were collected from HTA agencies in Australia, England, France, Germany, the Netherlands, Poland, Scotland, and Sweden to explore synchronization in decision timing and first HTA decision. Comparative analysis encompassed decision frameworks and funding mechanisms for orphan products among HTA agencies.
Results: Orphan drug approvals increased in the past decade, with the FDA having the highest designation rate (55% for 2018 to 2022). Flexible pathways, mostly used by the FDA (92%) and the PMDA (100%), expedited orphan drug reviews. However, international submissions for orphan drugs experienced longer gaps than non-orphan drugs across the jurisdictions. Divergence in rollout timing to HTA and recommendation resulted from varied submission strategies and review processes. Only the Scottish Medicines Consortium had a dedicated orphan pathway. In England, the National Institute for Health and Care Excellence patient access and managed access agreements (84% of orphan recommendations) and cancer drug fund (45% of orphan recommendations) facilitated patient access.

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