#GetReadyForEUHTA

What Will Be Assessed at EU and at National Level?

- The EU Regulation 2021/2282 defines the legal requirements for a European Health Technology Assessment.
- Starting in 2025, oncology products and ATMP, for which a **marketing authorization application (MAA) is submitted to EMA** the same year or later, are subject to a European joint clinical assessment (JCA). Orphan drugs will follow in 2028, before all centrally authorized medicinal products will follow in 2030.
- Variations to an existing marketing authorization are only subject to EU HTA if a JCA report for the initial indication of the medicinal product has been published ("**once EU HTA, always EU HTA**" and vice versa "once national HTA, always national HTA").
- The JCA report will provide a neutral description of submitted evidence (no value statements, no conclusions on overall clinical added value) and must be considered in each subsequent national HTA procedure. Decisions on P&R remain a national decision.

What Is the Current Status of EU HTA Implementation?

- Implementation of the EU HTA Regulation is underway, with the first implementing act on JCA published and the implementation phase due to be completed in Q4 2024. Presumably, national authorities will only provide details on the impact and changes to national HTA procedures once the first implementing act on JCA has been adopted. It is clear, however, that EU HTA will impact national HTA. The extent of changes may differ per country.
- In preparation of a possible EU HTA, there is currently the opportunity to apply for an early advice on European level with the EMA and HTA authorities coordinated by the Federal Joint Committee (G-BA, Germany). European advice or **joint scientific consultations (JSC)**, which will be offered from 2025**,** should be established as crucial **milestone** in the **EU HTA strategy**!

What Is the Scope of the Dossier and What Is the Timetable?

- The scope of the EU dossier is defined by **PICOs** (Population, Intervention, Comparator, Outcomes): In a scoping process that starts with a PICO proposal, each Member State may submit a PICO corresponding to its healthcare setting. PICO requests are then consolidated, and the pharmaceutical company is informed about the consolidated PICO schemes that must be addressed in the EU dossier. It is expected that, depending on the label, several PICO schemes will have to be addressed to be able to meet the needs of all member states.
- Those consolidated PICO schemes will be determined only after marketing authorization application (MAA), meaning that preparation of the EU HTA dossier will be in parallel to regulatory processes under **extremely tight timelines**. Only 100 days are allocated for actual dossier preparation (based on standard procedure).
- Work should start about 12 months before the MAA with a PICO simulation. Once the PICO schemes have been consolidated, the development of the **EU HTA strategy** can begin.

Next steps to #GetReadyForEUHTA

Set the foundation

- Increase awareness in your comapny (also outside Europe: spillover effects?)
- Build a common knowledge base
- Support and prepare affiliates for EU HTA

Align organisational structure

- Prepare your organization, define responsibilities, plan capacities
- Strengthen the cooperation between market access and regulatory
- Streamline workflows for marketing authorization, EU HTA and national HTA
- Identify and engage with stakeholders
- Prepare to handle spilovers

Portfolio check

- Products that are subject to EU HTA?
- Consider and decide on the conduction of (parallel) scientific advice (JSC)
- (Re)assess your launch sequence and time

Mock-up EU HTA

- Identify PICOs
- Are affiliates prepared? PICO simulation is key!
- Simulate and practice EU dossier development

Stakeholder engagement and monitoring

- Engage with KOLs and medical societies on European level
- Engage with the stakeholder network
- Monitor publication of guidelines
- Comment on implementing acts
- Evaluate first assessments