#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 (EU HTA).
- 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?

- The implementation of the EU HTA Regulation is ongoing, and completion is planned for Q4/2024. Presumably, national authorities will only provide details on the impact and changes to national HTA procedures once the implementation phase is completed. 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 possibility to apply for an early advice on European level with the EMA and HTA authorities. **European advice/JSC** 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 PICO (Population, Intervention, Comparator, Outcomes) schemes: In a scoping process, each member state will be invited to submit a PICO corresponding to their healthcare setting. Individual PICO requests are then consolidated, and the pharmaceutical company is informed about the consolidated PICO schemes that have to 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 MAA, meaning that preparation of the EU HTA dossier will be in parallel to regulatory processes under extremely tight timelines. Based on a first draft on JCA timelines, only three months are allocated for actual dossier preparation (based on standard procedure).
- Work should start around 12 months prior MAA by identifying the potential national PICOs for all 27 EU countries. Upon consolidation of the PICO schemes the development of EU HTA strategy can start.

Next Steps to #GetReadyForEUHTA

Set the foundation

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

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 spillovers

Portfolio check

- Products that are subject to EU HTA?
- Consider and decide on (or against) the conduct of (parallel) scientific advice (JSC) as slots are limited
- (Re)assess your launch sequence and time (e.g., Do we want EU HTA from strategic perspectives?)

Mock-up EU HTA

- Identify PICO(s)
- Are affiliates prepared? (each member state will be invited to provide a PICO)

Monitor future developments

- Guidelines
- Timelines
- Implementing acts
- First assessments

As of November 28th, 2023

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