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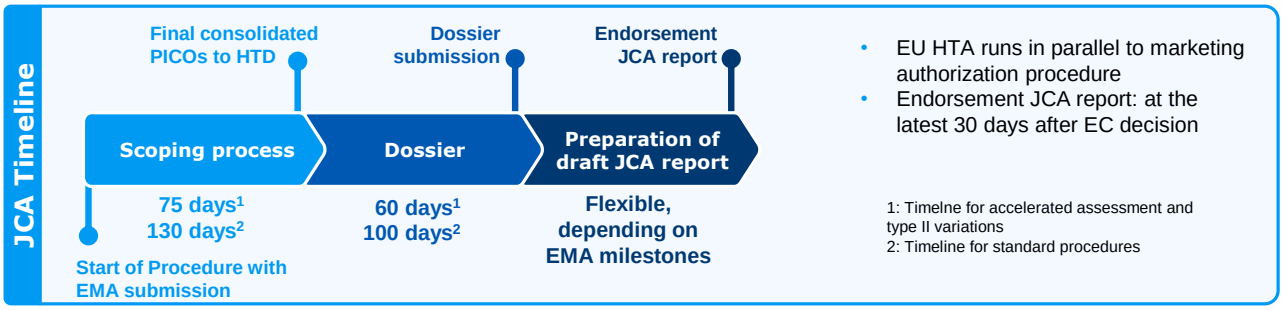
#GetReadyForEUHTA

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.
- Since 12 January 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 scientific analysis of clinical evidence on the relative effects of a medicinal product on health outcomes. The report will not contain any value statements nor conclusions on overall clinical added value, but a neutral description of submitted evidence. The JCA report must be considered in subsequent national HTA procedures. Decisions on P&R remain a national decision.
- EU HTA will impact national HTA to varying degrees – national implementation is still ongoing.

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 60-100 days are allocated for actual dossier preparation (depending on type of MA 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
- Prepare to handle spillovers

Portfolio check

- Products that are subject to EU HTA?
- Consideration and decision on the conduct of a Joint Scientific Consultation (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
- Evaluate first assessments

* Note that requirements as defined by the Implementing Regulation (EU) 2024/2745 on conflicts of interest management have to be followed strictly.

More Information: EU HTA: relevant documents