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HTA348

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How to Align EU HTA with National Market Access?

Objectives

EU Health Technology Assessment (HTA) is a new process, commencing in 2025. The intention is to facilitate national Market Access activities. For this, both workstreams (EU, national) have to be aligned. With EU HTA being applicable to 27 countries with the same number of reimbursement systems, a common conceptual understanding is precondition for alignment and potential synergies. What would be the characteristics of such an EU Market Access core model?

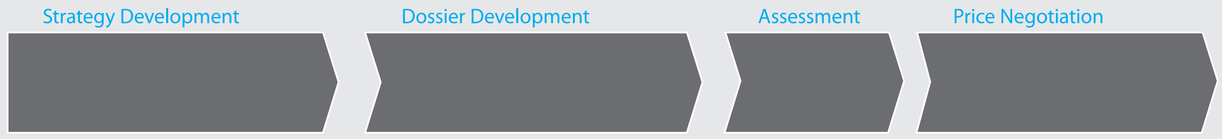
Methods

The analysis identifies common denominators for the various national Market Access activities from the perspective of the health technology developer and puts them into the context of EU HTA (as per Regulation 2021/2282 and Guidelines as per EUnetHTA 21 deliverables). Common denominator are work packages, which describe a certain activity from the perspective of the health technology developer. Based on these findings a draft core model is developed. Applicability is verified with the feedback from Market Access experts covering Germany, Italy, Spain, and France.

Results I

National Market Access

The national Market Access process includes both HTA and Pricing & Reimbursement (P&R) activities which can be described as 4 phases:



For these 4 phases a total of 33 distinct work packages can be differentiated, starting from clarification of the route of reimbursement up to price notification:

Not every work package is of relevance for the respective national Market Access, but most do exist in one way or another. For instance, only some HTA systems do offer a formal HTA advice, others use informal formats like advisory boards which serve as a surrogate to the formal procedure.

Taken together this allows for describing all Market Access activities at national level in 27 countries with 33 work packages, providing a common terminology for the respective activities.

EU HTA

The EU HTA process on the other hand consists of 3 phases, with no P&R activities for obvious reasons:

These 3 phases consist of 26 work packages in total, ranging from EU HTA obligation to review of JCA report and identification of lessons learned:

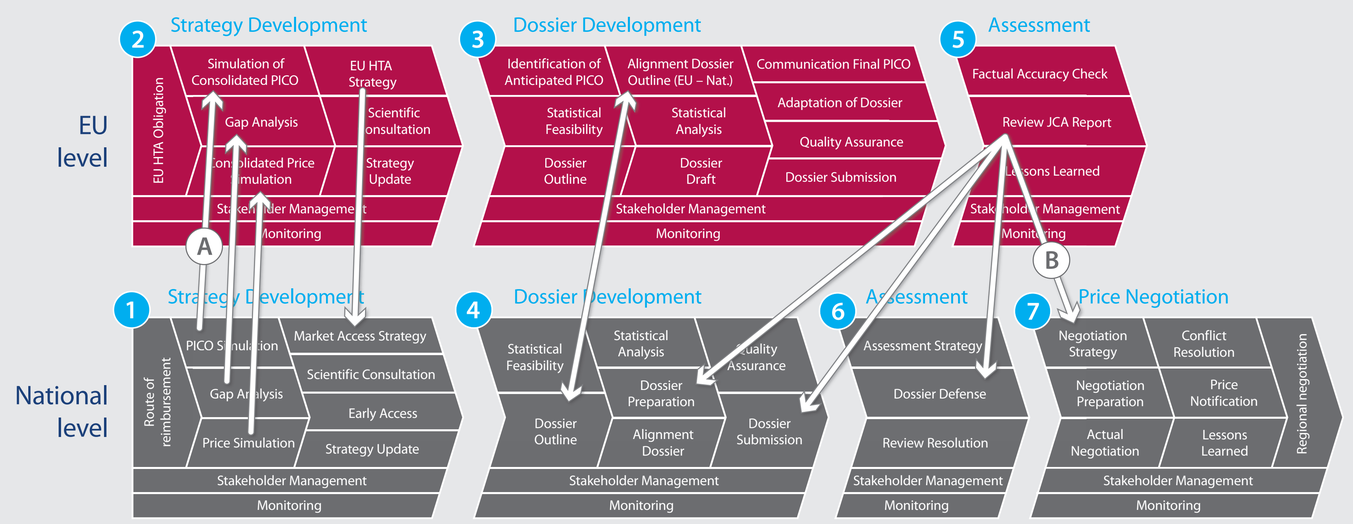
Work packages are defined following general understanding of HTA as well as requirements per EU HTA Regulation and corresponding guidelines. What is key is that this description can be done in a similar way as the national HTA process, using similar concepts.

Results II

EU Market Access Core Model

Both workstreams (national Market Access and EU HTA) run in parallel and can be described as such: This constitutes the EU Market Access Core Model.

As such the EU HTA Core Model allows to identify the links between work packages in national Market Access and EU HTA during all phases of both workstreams. For instance, the simulation of the consolidated PICO for EU HTA requires input regarding the national PICO simulation (A), and the JCA report will impact the national negotiation strategy (B).



Conclusion

- The complete national Market Access process can be described in a generic way from the perspective of the health technology developer.
- This provides a common conceptual framework to coordinate various national Market Access activities in different countries.
- In order to support national Market Access, EU HTA has to align with these national work packages (and vice versa).
- The EU Market Access Core Model described above can be applied for such coordination.

References

- REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282
- For EUnetHTA21 deliverables see: https://www.eunethta.eu/jointhtawork/
- Ecker T, EU HTA 101, 2023 (in press)

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