How fast will the EU HTA child grow? Estimation of the number of procedures in the first years of implementation

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ISPOR poster code: HTA300
Poster presented at ISPOR Europe 2023
12-15 November 2023 in Copenhagen, DK.

OBJECTIVES

According to Regulation (EU) 2021/2282, the joint clinical assessment (JCA) will initially be implemented for oncology drugs and ATMPs applying for EMA marketing authorization starting from January 2025. Orphan drugs will subsequently follow in January 2028, and in January 2030, all centrally approved drugs will be subject to the joint European clinical evaluation. Due to the staggered entry into the mandatory EU HTA process and the limited number of advice meetings during the gap years, the question arises as to how many procedures will be completed within the first years. EU HTA is expected to be a learning system. But how many procedures will we be able to learn from?

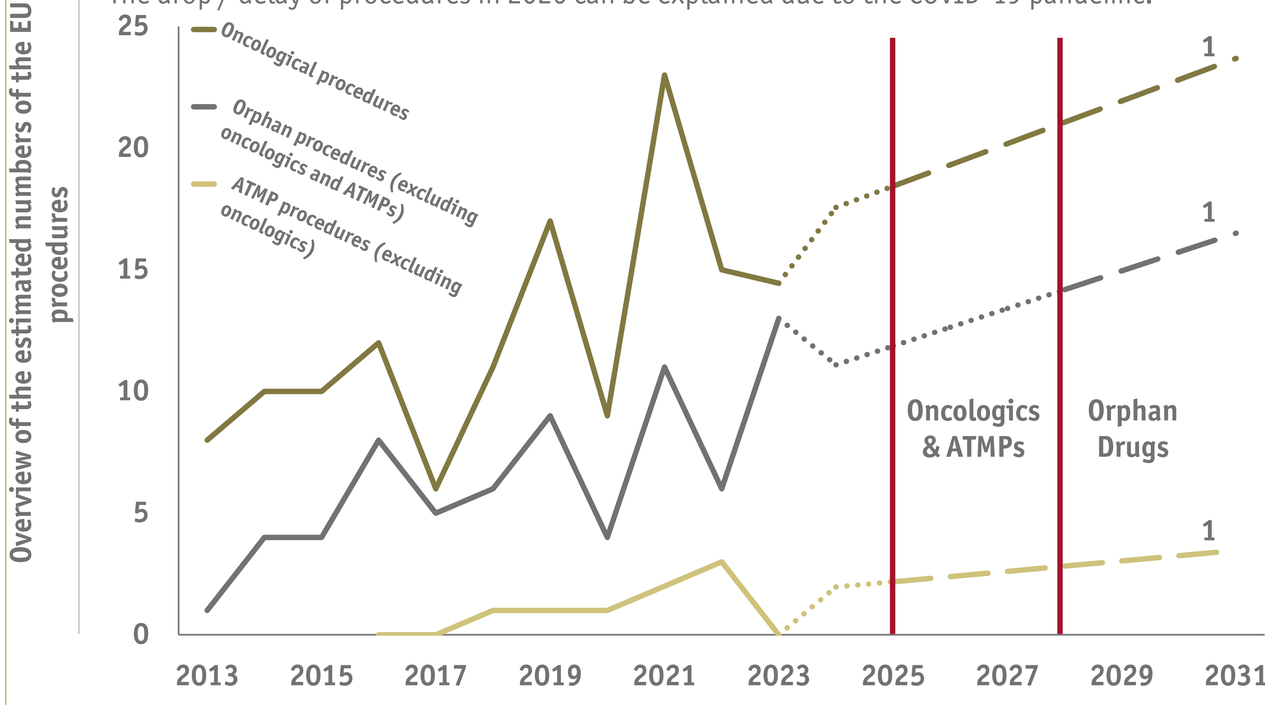
METHODS

The vast majority of EMA-approved medicines will eventually enter the German market and undergo the German benefit assessment "AMNOG". Thus, based on the total number of AMNOG procedures from the last ten years, we extrapolated the procedural volume for JCAs per area of indication in the first years of EU HTA implementation. Various aspects of EU HTA obligation must be taken into account, such as the specific conditions for indication extension procedures, which are only mandatory for EU HTA, if the initial assessment was already conducted under EU HTA.

RESULTS

The number of expected oncological, orphan and ATMP procedures was extrapolated based on the total number of AMNOG procedures over the last ten years.

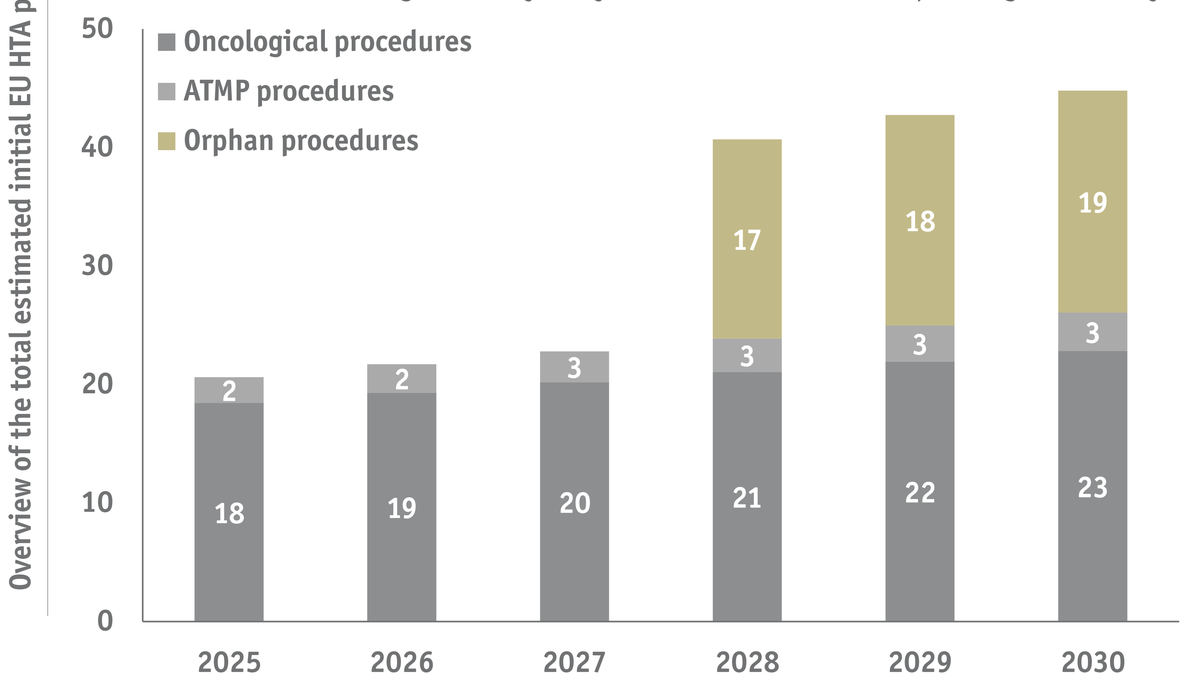
- The dotted lines represent the estimated procedures before, the dashed lines the estimated procedures after the start of EU HTA.
- The drop / delay of procedures in 2020 can be explained due to the COVID-19 pandemic.



[1]The estimation is based on a logarithmic model of initial submission procedures in the AMNOG-process between 2013 and 2023.

Summarized total number of expected EU-HTA procedures starting 2025

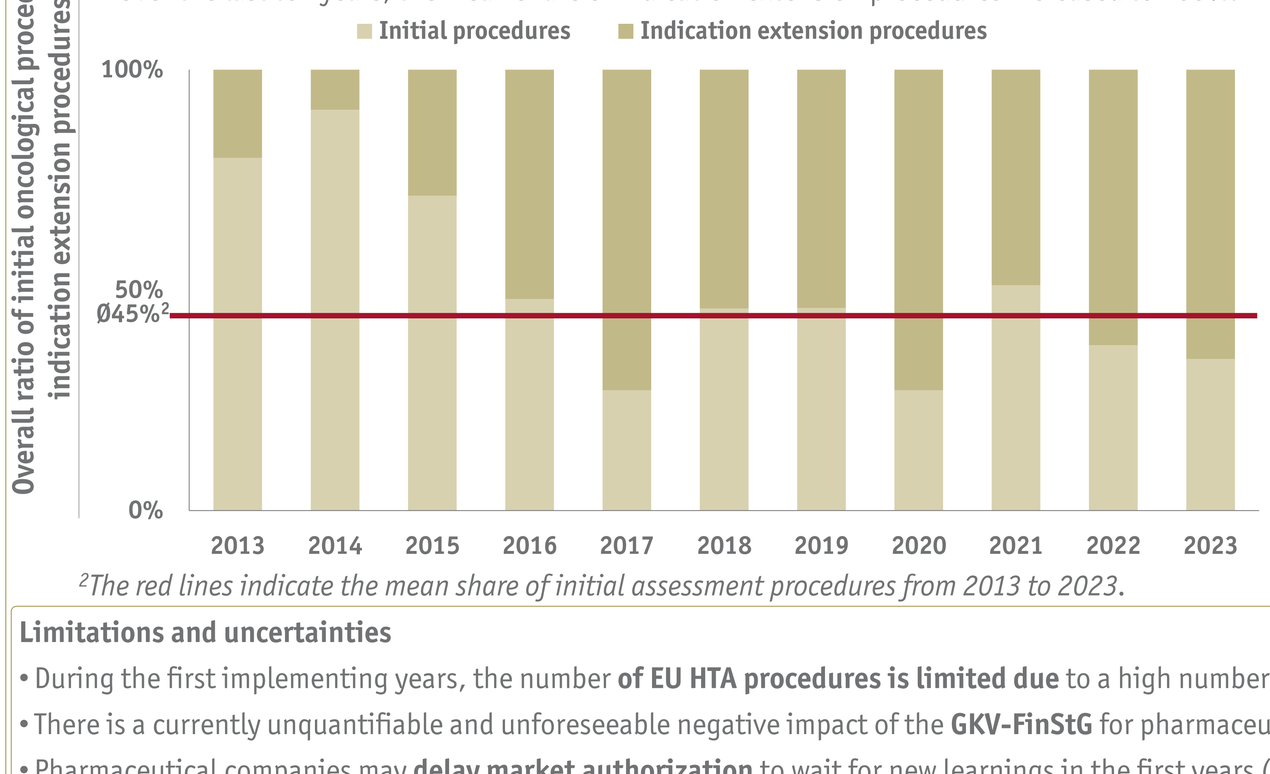
- We estimate around 20 procedures in the first year after the initial start of the EU HTA process.
- The number of total procedures is expected to double in size with the implementation of the EU HTA of orphan medicines.
- Unclear: manufacturers might actively delay their submission due to upcoming uncertainty.



Oncological and ATMP procedures start in 2025; orphan procedures start in 2028.

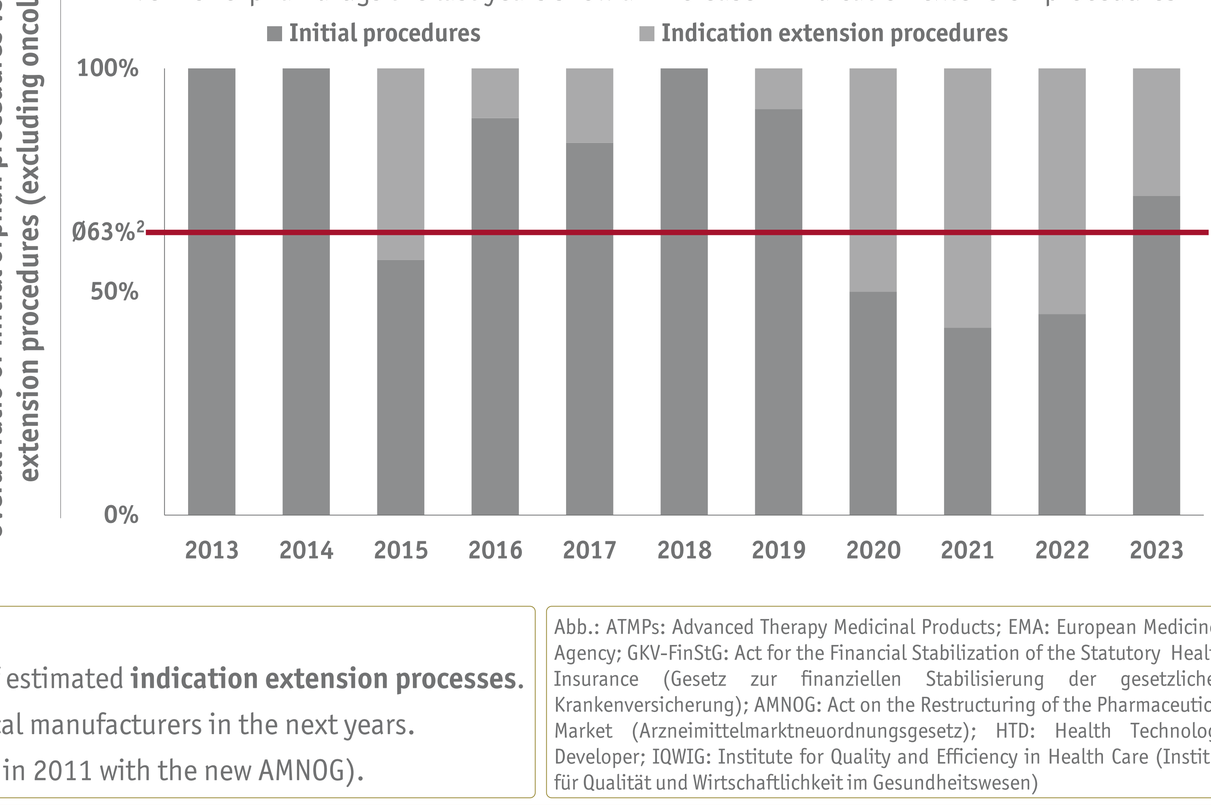
Initial vs. indication extension procedures – oncological procedures

- In the first years of the EU-HTA, only initial submissions need to undergo EU assessment, which will approximately be half of all submissions.
- Over the last ten years, the mean share of indication extension procedures increased to ~60%.



Initial vs. indication extension procedures – orphan procedures (excluding oncologics)

- In the last decade, two thirds of all orphan procedures (excluding oncologics) were initial assessment procedures.
- Even for orphan drugs the last years show an increase in indication extension procedures



[2]The red lines indicate the mean share of initial assessment procedures from 2013 to 2023.

Limitations and uncertainties

- During the first implementing years, the number **of EU HTA procedures is limited due** to a high number of estimated **indication extension processes**.
- There is a currently unquantifiable and unforeseeable negative impact of the **GKV-FinStG** for pharmaceutical manufacturers in the next years.
- Pharmaceutical companies may **delay market authorization** to wait for new learnings in the first years (as in 2011 with the new AMNOG).

Abb.: ATMPs: Advanced Therapy Medicinal Products; EMA: European Medicines Agency; GKV-FinStG: Act for the Financial Stabilization of the Statutory Health Insurance (Gesetz zur finanziellen Stabilisierung der gesetzlichen Krankenversicherung); AMNOG: Act on the Restructuring of the Pharmaceutical Market (Arzneimittelmarktneuordnungsgesetz); HTD: Health Technology Developer; IQWIG: Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)

CONCLUSION

There is a **high degree of uncertainty** in the EU HTA process as it is still taking shape. In the first years, there will be few orienting precedents that could be used as learning cases – for both the authorities and the manufacturers. In addition, during the gap years between late 2023 and early 2025, only 14 consultations are planned at the European level, which **could not prepare all eligible HTDs for the estimated EU HTA procedures**. Capacity bottlenecks are to be expected and should be addressed proactively.

- A new process means dealing with uncertainty, **a well-structured preparation on both an organizational and product level is key** for a successful launch during the early years of EU HTA.
- Based on our estimation, the **number of offered advice meetings in the gap years is not sufficient** to cover for the EU HTA procedures in the first few years.
- If pharmaceutical companies do not want to delay their market authorization, it is **crucial to secure a spot for an advice meeting** as early as possible.
- There will be a **learning curve for all involved parties** over the first years of the EU HTA process.

JCA 90 Mastering EU HTA

EU HTA is just around the corner and pharmaceutical companies will only have 90 days to produce the final JCA dossier. To perfectly orchestrate all workstreams into this tight timeline, one needs robust, convincing evidence and a comprehensive strategy that can anticipate and prioritize likely scenarios. Only through such an approach can one achieve the desired national price. That is why Numerus and SKC have combined their expertise in the collaborative solution - JCA90. With JCA90, we support our clients in mastering EU HTA. Visit our joint stand C2-043 at ISPOR Copenhagen.

All analyses have been generated by data from SKC's proprietary MAIS (Market Access Intelligence System = MAIS) database. This database contains and links information on completed and ongoing benefit assessments according to §35a SGB V of the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA). The MAIS-database records and evaluates relevant information from the dossier, the benefit assessment by IQWiG or the G-BA, the G-BA resolution as well as the Lauer-Taxe. It also contains an up-to-date overview of all procedures and their status.

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