EU Joint Clinical Assessment (JCA): Uncertain Impact on German AMNOG Timelines and Potential Delays

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Objectives

One of the main aims of the new EU Joint Clinical Assessment (JCA) process, which will come into force from January 2025, is to improve patient access to new medicines across the EU. Whilst the centralised EU procedure aims to reduce duplication and hasten the clinical assessment of local Health Technology Assessments (HTA) processes, it remains unclear what the implications for the local German HTA process (AMNOG) are. This research seeks to compare JCA timeline scenarios with those of AMNOG, focusing on scenarios that could impact local access.

Methods

JCA timelines were mapped using information provided in the EU HTA regulation[1], the implementing act on JCA[2] and EMA regulatory timelines[A],[3]. Milestones in the assessment timelines, including confirmation of final scope, dossier submission, publication of the draft and final assessors report, were compared to the current AMNOG timelines, which are outlined in the G-BA's rules of procedure[4] and Germany's Social Code 5 (SGB V)[5]

Results

Comparing the timelines revealed three critical milestones in the JCA process that potentially delay the start of AMNOG: **(1) JCA final scope** (approx. 10 days after D120 LoQ [A],[B]), **(2) JCA draft report**, and **(3) JCA final report** (not later than 30 days after EC decision / marketing authorization[A], see Figure 1. As a result of these key JCA milestones, health technology developers (HTD) may need to adapt their AMNOG dossiers resulting in potentially increased resource requirements at HTD side, and a potential postponement of their market launch and start of AMNOG:

- **Preparation time for the AMNOG dossier is likely to be reduced by at least two months.** Usually, HTDs start developing their AMNOG dossiers around 12 months prior to submission. Submission of an AMNOG dossier is due when a product is launched in Germany.[C] JCA final scope in form of the PICO scheme will be final only around 10 months prior to AMNOG dossier submission. While the HTD may of course start developing the AMNOG dossier – based on the German PICO scheme – 12 months prior to its submission, the delta requirements for the AMNOG dossier will not become final until the final scope of the JCA is decided.
- **HTDs might need to adapt the scopes of both their JCA and AMNOG dossiers and present additional evidence on short notice.** At any time during the development of the JCA, the assessors may request additional information, data, analyses or other evidence from the HTD, with a deadline of 7 or up to 30 days. As a consequence, HTDs might be required to adapt the scope of their AMNOG dossiers accordingly. Only with the JCA draft report, the HTD will have final clarity about the delta data requirements for the AMNOG dossier.
- **JCA might delay the start of AMNOG.** Assuming that the final JCA report is endorsed 30 days after EC decision and that the median time between EC decision and AMNOG dossier submission is 47 days[D],[6], HTDs would need to consider the JCA report for the AMNOG dossier within only 17 days. While this may be challenging but feasible for some products, it will be impossible for indication extensions. AMNOG dossiers for indication extensions need to be submitted 30 days after EC decision / marketing authorization making it thus impossible for HTDs to consider the final JCA report. At the same time, G-BA is currently (informally) discussing options to better align JCA and AMNOG. One option currently under discussion seems to be to continue to start the AMNOG assessment at the time of market launch, but to include the JCA report in the assessment only one month after the start of AMNOG, which would shorten the G-BA assessment period for AMNOG data (module 4) from six to five months.

Conclusion

It is currently suggested that JCA should not delay AMNOG timelines. However, after the critical JCA milestones there is a risk of delays due to increased internal coordination efforts on the part of the HTD. So far, no official guidance has been published by G-BA on the interaction between JCA report and AMNOG requirements or alignment of timelines. Until G-BA adapts its processes and rules of procedure there remains high uncertainty for HTDs seeking reimbursement in Germany. The main challenges for HTDs will be the increased time pressure, the coordination of multiple processes and requirements, the involvement of multiple stakeholders, and the consideration of all eventualities. In order to meet the original AMNOG timelines, HTDs must anticipate the potential impact of the JCA on the AMNOG dossier and prepare AMNOG dossiers in parallel to the JCA with the risk of short-term adaptations.

Notes: [A] This poster's analysis assumes EMA standard authorization procedures. Varying lengths of clock stops, accelerated procedures or procedures for type II variations are not considered. [B] Deadlines for the JCA final scope and draft report are to be set by the EC and should be aligned with the main steps of the EMA marketing authorization procedure. Timelines are based on theoretical assumptions and may vary in reality. [C] The median time between EC decision / marketing authorization and German market launch is 47 days.[D],[6] [D] Refers to new medicinal products; does not refer to indication extensions.

Sources: [1] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021, [2] Commission Implementing Regulation (EU) 2024/2699 of 18 October 2024, [3] EMA (2024) The evaluation of medicines, step-by-step, [4] G-BA (2024) Verfahrensordnung des Gemeinsamen Bundesausschusses, [5] Sozialgesetzbuch (SGB) Fünftes Buch (V) – Gesetzliche Krankenversicherung, [6] IQVIA/EFPIA (2024) EFPIA Patients W.A.I.T. Indicator 2023 Survey

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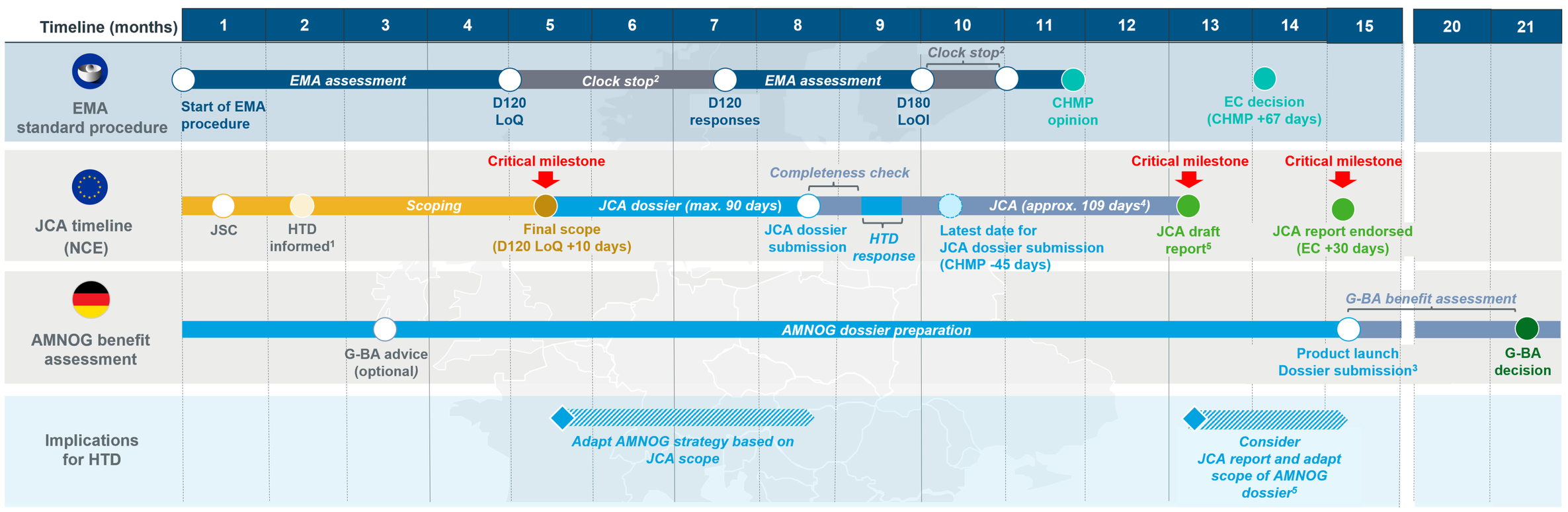
Figure 1: Comparison of EMA, JCA and AMNOG timelines



[1] Exact timing when HTD is informed not specified in JCA IA.
[2] D120 clock stop assumed to be 3 months on average (range 1-6 months). D180 clock stop assumed to be 1 month on average (range 0.5-2 months).
[3] Dossier submission is mandatory as soon as the product is launched with listing in the Lauer Taxe (either 1st or 15th of the month, depends on HTD decision, commonly conducted immediately after EC decision). In case of an indication extension, the dossier must be submitted within 30 days after EC decision.
[4] Time from receipt of HTD response to JCA report (assuming 21 days for completeness check and maximum duration of 15 days for HTD response).
[5] Together with the draft JCA report, the manufacturer may be required to submit additional data.

EMA activity | EMA clock stop² | HTD activity | Assessor activity | Scoping (member states complete the PICO survey; assessor and co-assessor will consolidate PICOs)

Abbreviations: AMNOG: Arzneimittelmarktneuordnungsgesetz (German Medicines Market Reorganization Act); CHMP: Committee for Medicinal Products for Human Use; D: Day; EC: European Commission; EMA: European Medicines Agency; EU: European Union; G-BA: Gemeinsamer Bundesausschuss (Joint Federal Committee); HTA: Health Technology Assessment; HTD: Health Technology Developer; JCA: Joint Clinical Assessment; JSC: Joint Scientific Consultation; LoOI: List of Open Issues; LoQ: List of Questions; NCE: New Chemical Entity; PICO: Population – Indication – Comparator – Outcome