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Analysis of Historical European Medicines Agency (EMA) Marketing Authorization (MA) Timelines: Will EU Joint Clinical Assessment (JCA) Timelines Be Longer Than Expected?

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Introduction and objectives

The new European Joint Clinical Assessment (JCA) process will run in parallel to the European Medicines Agency's (EMA) marketing authorization (MA) process, with both timelines being closely interlinked.

While the HTA Regulation (HTAR) sets the deadline for JCA dossier submission as no later than 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use (CHMP), the JCA Implementing Act and Procedural Guidance only allow 100 days after JCA scope finalisation in a standard EMA procedure – which is a moveable milestone depending on time required for JCA Subgroup's scoping exercise. Extension of the dossier submission deadline up to CHMP -45 days is only possible in justified cases, with the consent of the assessors.

This study aimed to **analyse the duration of EMA MA** processes and milestones for oncology products which were approved following a standard initial marketing authorisation applications and map the **impact of the regulatory timelines on JCA timelines**.

Methods

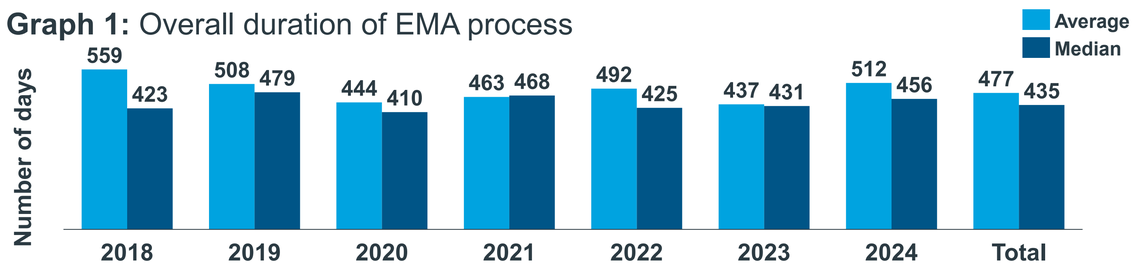
Using IQVIA's Market Access Insights database, we identified European Public Assessment Reports (EPARs) for oncology products in original indications, approved via standard EMA procedure from Jan 2018 to Nov 2024, and analysed:

- The timelines and number of clock-stops in each EMA MA process
- The impact of the calculated durations on key EU JCA milestones, testing two different scenarios
  - **Scenario a - standard timelines:** Scoping process of 87 days; JCA dossier submission 100 days after scope finalisation (**as per Procedural Guidance**)
  - **Scenario b - maximum timelines:** JCA scope shared no later than 10 days after CHMP adopts its list of questions (latest timepoint as per JCA Implementing Act), and JCA dossier submission no later than CHMP opinion - 45 days (**as per HTAR**)

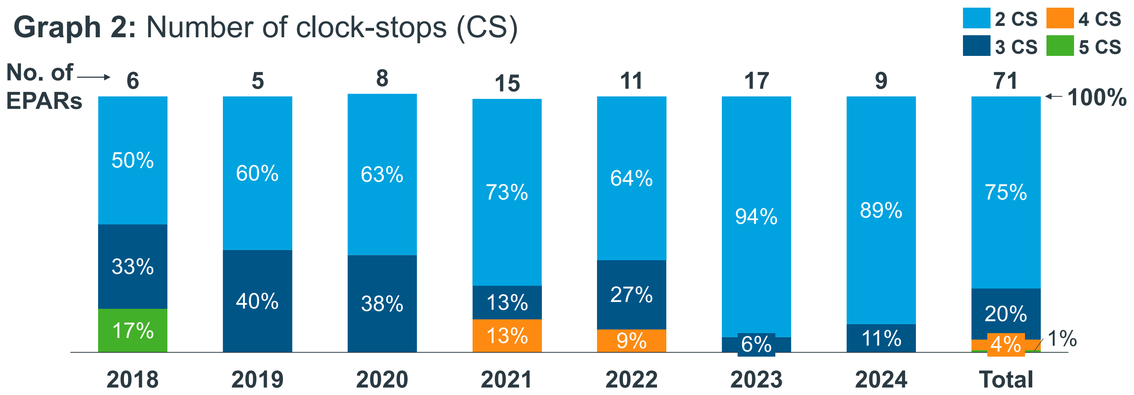
Results

- We identified 71 EPARs for oncology products in their original indications (excluding generics and biosimilars), approved following the standard EMA procedure, published between January 2018 and November 2024. The overall median duration of the EMA MA process (from submission to European Commission decision) was 435 days, the average was 477 days, ranging from 337 to 1,019 days **(Graph 1)**.
- The number of clock-stops varied from 2 to 5, while most (53) EPARs included 2 clock-stops. More than two clock-stops were needed in some cases due to unresolved issues flagged by the assessment committees. The occurrence of more than 2 clock-stops has declined since 2023, possibly reflecting EMA's initiative for more streamlined process (**Graph 2**).
- The average duration of all clock-stops was 158 days (median: 126 days), driven mostly by the duration of first clock-stop (average: 100 days, median: 83 days). Despite EMA's initiative for a more streamlined process, the average and median duration of the second clock-stop increased in 2024 compared to previous years. In 7 out of 9 (78%) EPARs from 2024, the duration of the second clock-stop was longer than the 30 days assumed in the Procedural Guidance **(Graph 3)**.
- When limiting the analysis to 24 EPARs having 2 clock-stops published in 2023 and 2024, the average duration of the first clock-stop was 90 days (range: 29 - 188 days), which is 30 days longer than the HTA Coordination Group's (CG) assumption in the Procedural Guidance. The average duration of the second clock-stop was 56 days (range: 3 – 292 days), 26 days longer than assumed in the Procedural Guidance **(Graph 4, scenario 1/2)**.
- When comparing these timelines to the EU JCA timelines, assessors could have 266 days on average to complete the JCA report, which is 75 days more than anticipated in the HTA CG Procedural Guidance (**Graph 4, scenarios 1a / 2a**).
- Although the time for JCA dossier submission is set up in the JCA Implementing Act as 100 days, the deadline can be expanded in justified cases to up to 45 days before CHMP opinion. However, a full extension would reduce the time for assessors to complete the JCA report – based on actual EMA duration in 2023-2024 down to 114 days (77 days after check for completeness and possible additional submission; **Graph 4, scenarios 2b**).

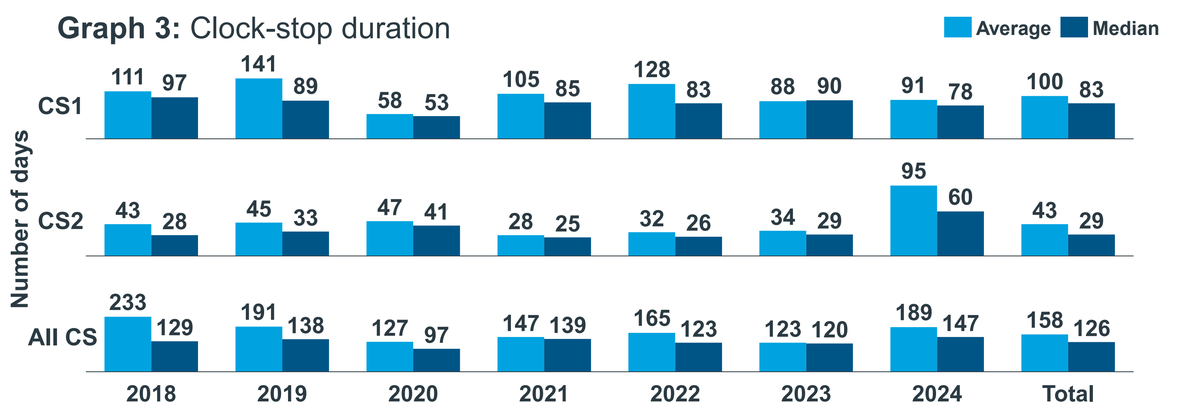
Graph 1: Overall duration of EMA process



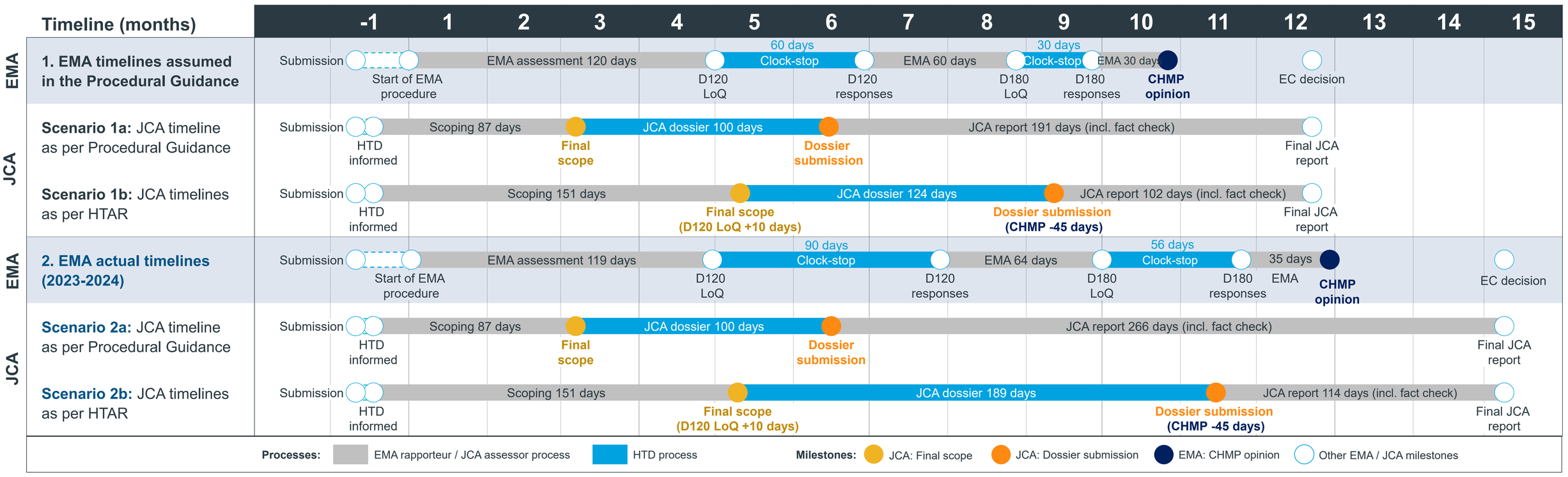
Graph 2: Number of clock-stops (CS)



Graph 3: Clock-stop duration



Graph 4: Comparison between EMA regulatory timelines and JCA timelines



Conclusions

- **The wide range of the EMA MA process duration indicates significant variability in regulatory timelines across products, which creates uncertainty around the timelines of JCA and its milestones**
- **Our analysis indicates that co-/assessors may have more time to develop the JCA report than anticipated in the HTA CG Procedural Guidance; HTDs should therefore consider proactively requesting an extension early in the JCA process, particularly if additional data is expected to be submitted to EMA during the first clock-stop**
- **However, the ongoing reform of the EU pharmaceutical legislation aimed at streamlining the MA process may reduce the overall regulatory timelines. Since the JCA timelines are directly linked with EMA regulatory timelines, it may potentially further reduce the already challenging timelines for assessing the JCA dossiers. The impact of the EU pharmaceutical legislation on synchronization with JCA processes remains to be seen**

References: 1) The Implementing Act of the EU Health Technology Assessment Regulation (HTAR) for Joint Clinical Assessments (JCA) of medicinal products; 2) HTA CG Procedural guidance for JCA medicinal products; 3) IQVIA's Market Access Insights; 4) Council of the European Union. (2025, June 4). *'Pharma package': Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector*. Consilium. **Abbreviations:** CHMP: Committee for Medicinal Products for Human Use; CG: Coordination group; CS: Clock-stop; D120: Day 120; D180: Day 180; EC: European Commission; EMA: European Medicines Agency; EPAR: European Public Assessment Report; EU: European Union; HTA: Health technology assessment; HTAR: Health technology assessment regulation; HTD: Health technology developers; JCA: Joint Clinical Assessment; LoQ: List of questions; MA: Marketing authorization

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