Potential Impact of Joint Clinical Assessment (JCA) on Health Technology Assessment Timelines in Ireland

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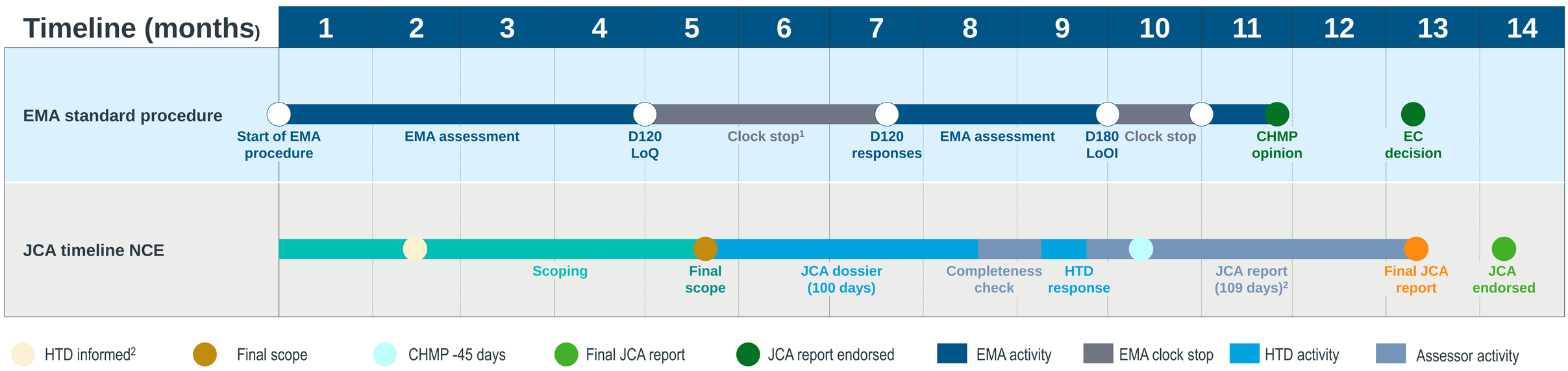
Introduction

Securing reimbursement for new medicines in Ireland can be a time-consuming process. In 2023, the average time from reimbursement application to availability of new drugs in Ireland was 729 days(1). One of the main aims of the European Joint Clinical Assessment (JCA) process is to reduce duplication of health technology assessment (HTA) processes and improve patient access to innovative technologies in Europe(2). However, uncertainty remains over how this process will impact national systems. The system for HTA in Ireland consists of an initial rapid review (RR) submission, followed by a more detailed full HTA if necessary.

Currently, health technology developers (HTDs) can initiate the assessment process with the submission of their rapid review (RR) dossier once they have received positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The adoption of a commission decision occurs several weeks after positive CHMP. The JCA report is to be endorsed no later than 30 days following the adoption of the commission decision. There are therefore potentially several weeks between positive CHMP and the availability of the JCA report. However, Article 13 of the HTA Regulation stipulates that Member States must give due consideration to the JCA report when carrying out a national HTA. A requirement to include the JCA report may therefore delay the start of the Irish HTA process. This research explores the potential impact JCA development timelines may have on the initiation of HTA processes in Ireland.

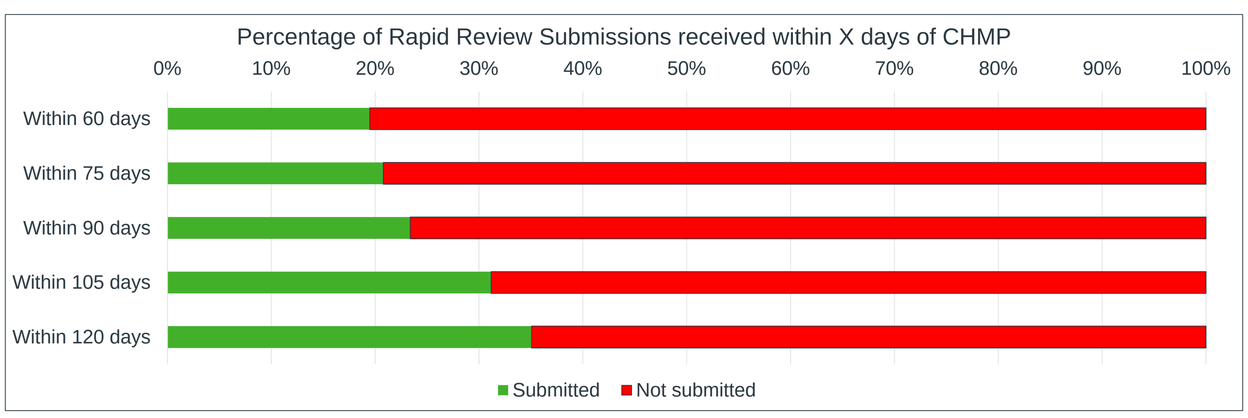


[1] D120 clock stop assumed to be 3 months on average (range 1-6 months). D180 clock stop assumed to be 1 month on average (range 0.5-2 months). [2] Exact timing when HTD is informed not specified in draft IA.

Abbreviations: CHMP - Committee for Medicinal Products for Human Use; D – Day, EC – European Commission, EMA - European Medicines Agency, HTD – Health Technology Developer, JCA – Joint Clinical Assessment, LoOI – List of Outstanding Issues, LoQ – List of Questions, NCE – New Chemical Entity

Methods

- A list of assessments published by the National Centre for Pharmacoeconomics (NCPE) in 2023 was collected
- For each published assessment, the date of RR submission and corresponding date of positive CHMP opinion and the date of the adoption of the commission decision (where available) were identified from publicly available sources
- The mean time between CHMP and adoption of the commission decision for the identified products was 60 days. Allowing 30 days for the development of the JCA report resulted in an illustrative time gap between CHMP opinion and the endorsement of the JCA report of 90 days
- The potential impact on the initiation of HTA processes in Ireland of a 90-day gap between positive CHMP and publication of the JCA report was explored based on the NCPE assessments published in 2023
- Given the uncertainty in the timings, alternative scenarios were explored to examine the sensitivity of the Irish HTA system to variations in JCA publication timelines.



Results

- The NCPE published the outcomes of 84 assessments in 2023. Of these, 7 products had acquired marketing authorisation through the national route and did not receive positive CHMP from the EMA
- For the remaining 77 eligible assessments, the average time between positive CHMP and RR submission was 427 days (median= 152 days)
- Fifteen submissions (19%) were made within 60 days of CHMP, increasing to 27 submissions (35%) being made within 120 days of CHMP
- If the gap between positive CHMP and the availability of the JCA report is 90 days, 18 RR submissions (23%) would have been delayed, awaiting the availability of the JCA report. The average delay for these 18 submissions would have been 51 days
- If the gap is reduced to 60 days, 15 submissions would have been affected with an average delay of 29 days
- At the other extreme if the gap is increased to 120 days, 27 submissions would have been affected with an average delay of 60 days.

Time from CHMP to JCA report	Submissions impacted	Average delay (days)	Longest delay (days)	Median delay (days)
60 days	19%	29	47	32
75 days	21%	42	62	45
90 days	23%	51	77	54
105 days	31%	51	92	61
120 days	35%	60	107	67

Discussion

Although the HTA process in Ireland allows for submission at positive CHMP, this option was not utilised by HTDs in the data analysed. There were no submissions made to the NCPE at CHMP. However, approximately 19% of submissions occurred within 60 days following CHMP and almost one in four submissions (23%) occurred within 90 days of CHMP. The exact timeframe from CHMP to the availability of the JCA report remains uncertain. However, the requirement to consider the JCA report at the rapid review stage has the potential to delay the start of the HTA process for a substantial percentage of reimbursement applications in Ireland. The current NCPE rapid review process has an assessment time of approximately 32 days(3). It remains to be seen whether the availability of a JCA report will reduce the assessment time of a rapid review. However, even in an optimistic scenario where time from CHMP to JCA report is only 60 days, the average delay that would have been experienced by impacted submissions in 2023 is 29 days. This delay would certainly outweigh any potential reduction in the rapid review assessment time.

Conclusion

Further clarification is needed on how the JCA report will be incorporated into the HTA process in Ireland and the potential impact it will have on patient access. It has the potential to delay the initiation of the assessment process for a substantial percentage of submissions (between 19% and 35%). Where a full HTA is required, the availability of the JCA report may reduce assessment time sufficient to overcome any delay. However, this is unlikely to be the case for assessments requiring only a rapid a review.

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