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What Was Heard Report

A Summary of Feedback from the Public Consultation on the Draft Pause the Clock Proposal for Pre-market Submissions/Applications

January 17, 2019

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WHO PROVIDED FEEDBACK?

After publishing the Pause the Clock policy proposal for a 60-day comment period ending October 9, 2018, Health Canada received 28 sets of comments (containing a total of 343 individual comments) from a variety of companies and associations representing different areas of the Canadian health products industry.

WHAT DID THE STAKEHOLDERS SAY?

Overall, there was no general consensus regarding the proposal as a whole. There were several comments acknowledging the potential usefulness of a pause the clock mechanism, and several comments suggesting that Health Canada focus on other mechanisms for ensuring timely review. Nearly all stakeholders had specific comments on the proposal, which were grouped into several different “themes” as detailed further below.

NO PAUSE WITHIN 15% OF THE PERFORMANCE STANDARD

While this principle was introduced to avoid delays late in the review period, many stakeholders voiced concerns about the inability to pause the clock in the last 15% of the performance standard, especially since a majority of clarification requests are issued in the last 2-3 months of the review. This inhibits the flexibility of stakeholders to utilize the pause the clock mechanism where it may be most useful and in certain situations could avoid Notices of Deficiency (NOD) and Notices of Noncompliance (NON).

REQUEST FOR AN EXTENSION TO RESPOND TO A REQUEST FOR CLARIFICATION (CLARIFAX) OR MINOR INFORMATION REQUEST TRIGGER

Many respondents felt that improved submission planning could accommodate extension requests within the usual review timeline. The following suggestions were given regarding this particular trigger:

- Extension should be applied once the 15-day standard response time has finished and resume upon receipt of the requested information;
- Health Canada should continue to grant short-term extensions without a pause (i.e. the minimum extension time to trigger a pause should be raised from a 5-day minimum in the proposal to 10 or 15 days);
- Additional details should be provided regarding the mechanism by which a sponsor should request an extension, how it is approved, timeframe for Health Canada approval, what the impact is on other review streams, etc.

EXPERT ADVISORY PANEL / COMMITTEE TRIGGER

Many sponsors felt that improved submission planning could accommodate the need for an expert advisory panel or committee within the usual review timeline, without any pause. Comments/questions revolved around the following issues:

- Additional details should be provided regarding the mechanism by which an expert advisory panel/committee will be deemed necessary, the timelines, and when in the review it can be used;
- Respondents agreed the use of an expert advisory panel/committee should be mutually agreed by the sponsor and Health Canada and that it should not occur near the end of review. It was also suggested that the need for an expert advisory panel/committee should be identified before or early in the review process and that the process should be transparent to the sponsor;
- While some sponsors felt there should be little need for an expert advisory panel/committee, if it is implemented it should not penalize the industry.

ACCEPTANCE OF ADDITIONAL DATA DURING THE REVIEW

It was suggested by stakeholders that the implementation of a pause the clock mechanism should be linked to the ability to submit new data to support a submission. A common opinion among stakeholders was that a pause the clock mechanism would be most useful for this purpose, as it could potentially avoid a NOD or NON.

SUBMISSION MANAGEMENT

Several concerns were raised that pauses would delay the approval of submissions. Stakeholders are concerned that the pause the clock mechanism would reduce predictability and instead Health Canada should focus on optimizing review processes. It was suggested that the current proposal for pause the clock should more closely align with international models instead, such as the European Medicines Agency's Stop Clock mechanism. There was also reference to adopting a more optimized review process under Health Canada's Organizational Review of the Regulatory Evaluation of Human Therapeutic Products initiative.

Stakeholders responded positively to the idea that a pause is not intended to pause all review streams and that Health Canada will continue with the review of all streams during a pause, where possible.

COLLABORATION

Several stakeholders raised questions about the possible impact of introducing a pause the clock mechanism on collaborative affairs, such as Health Technology Assessment-Health Canada alignment activities, joint reviews, and simultaneous global filings.

REPORTING

If a pause the clock mechanism were to be implemented, stakeholders asked that tracking of the pause the clock mechanism be consistent, transparent, and accurate, given that each use of a pause would alter projected approval dates. Reporting in this way would be useful as a means for sponsors to manage their time and expectations.

PENALTIES

Stakeholders suggested several changes to the penalty provision, either in eliminating it for missed performance standards or reverting back to the current penalty model. There were also

concerns that the pause the clock mechanism was designed with the intention of mitigating Health Canada penalties, and that instead there should be a focus on optimizing review processes and increasing predictability.

MEDICAL DEVICES

While respondents thought that the proposed triggers for medical devices were appropriate and would cover the most common reasons for a pause in a medical device application review, it was suggested that there be a change in wording to allow for case-by-case consideration and greater flexibility. Stakeholders suggested that each proposed trigger should have a performance standard to ensure that reviews and decisions are not delayed indefinitely and that there continues to be accountability for review periods. It was also suggested that other medical device categories be included in this pause the clock mechanism (e.g. standard medical device registrations, change to product, class III or IV medical device requests for additional information).

Multiple stakeholders also had concerns with the pause the clock provisions for combination products and the impact of the pause on accountability for overall review timelines and the possibility of prolonging the review timeline. Stakeholders are open to any additions to the policy that would increase transparency regarding this issue and increasing the performance standards specific to combination products.

OTHER SUGGESTIONS

As a part of the consultation, several stakeholders provided their input on additional triggers that they felt should be included in the proposal. These included concerns raised by other regulatory jurisdictions, Good Manufacturing Practices issues, Look-Alike Sound-Alike issues, administrative issues, new guidance under development that would affect submissions under review and when major re-analysis is required.

NEXT STEPS

Health Canada would like to thank all those who submitted their feedback on the policy proposal for the introduction of a pause the clock mechanism for pre-market submissions/applications. All comments have been taken into consideration and have helped inform the finalization of the pause the clock policy and associated guidance documents. Key changes that have been made based on internal and external consultations are outlined in the accompanying Notice to Stakeholders. Implementation of a final pause the clock policy will align with implementation of the new cost recovery framework by April 2020.