Frequently Asked Questions (FAQs):

Revision of timelines for variation applications of registered products [pharmaceutical products & natural and health supplement products (TMHS)] and a pilot study

1. **Do the revised timelines refer to the entire process's total timelines? What is the timeline for the first correspondence?**

   The revised timelines only account for cumulative NPRA assessment time, excluding PRH's response time.
   There is no breakdown for the first and subsequent correspondence, as this will be monitored internally. During the pilot study, these new timelines will be referred to in place of the timelines stated in the Malaysia Variation Guidelines (MVG, MVGB and MVG TMHS).

2. **It is noted that NPRA will not reject variation applications that exceed the maximum number of permitted variation types per registered product; however, the timeline may be extended. May I understand if the extended timeline will be even longer compared with the current timeline for bundle applications?**

   The extended timelines may vary based on how many variation types are grouped together. However, please note that the maximum timelines for variation applications that exceed the maximum number of permitted variation types will only be determined based on the outcome of the pilot study.

3. **May I clarify if a shorter timeline will apply if only one variation is submitted e.g. for MiV-PA?**

   The stated timelines are the maximum, e.g., for a maximum of five variations of the same category submitted. Depending on the number of variations in the same category submitted, the timeline may vary.

4. **Is participation in the pilot study voluntary? Alternatively, will PRH automatically be considered for inclusion in the pilot study as long as they submit variations after 1st June 2024, irrespective of the category of variation?**

   Starting on 1st June 2024, the pilot study will automatically include all variations submitted, irrespective of the variation category.

5. **It is mentioned that there is an inclusion of a new category under MiV-PA2* on safety-related changes: tell and do. What will be considered under this category?**

   To facilitate the implementation of safety-related changes for pharmaceutical products, this category is created for safety updates based on Directives issued by the Senior Director of Pharmaceutical Services as well as for safety changes initiated by the PRH that have been approved by DCA reference agencies only. However, for safety changes initiated by the

PRH without DCA reference agency approval, the variation application will still need to be submitted under MAV-2.

6. **Are there any maximum rounds of correspondence allowed by NPRA?**

   There will be 3 rounds of correspondence allowed.

7. **Is the revised variation timeline including correspondence timeline or there will be a stop clock for correspondence?**

   The proposed new timeline is excluding the PRH time and there will be a stop clock for correspondence.

8. **Is extension allowed for correspondence in the case where PRH is not able to provide a correspondence within a given timeline eg. 45 wd (MiV-PA) or 60 wd (MaV, Grouping/bundle applications)?**

   PRH may seek for extension of the timeline to respond to NPRA. Please note that the given timeline for PRH is for each correspondence and not a cumulative timeline.

9. **It is stated in the Grouping (bundle applications) maximum of 5 variation applications including a maximum of 3 MaV/MaVB applications*). What types of groupings fall under this category?**

   Some examples that may be submitted under this category include, but are not limited to, the following:
   MaV & MiV-PA, or MaV & MiV-N, or MiV-PA & MiV-N