1 March 2017
EMA/103586/2017
Human Medicines Evaluation

Type II variation and worksharing assessment timetables

Guide to selecting the appropriate timetable

The choice of the assessment timetable for a type II variation or worksharing procedure depends on the nature of the change(s) applied for and considerations regarding the **periodicity** of the timetable and **duration** of the assessment procedure.

Type II variation assessment timetables follow either a monthly or a weekly periodicity. Typical monthly timetables start once a month and conclude during the week of the CHMP plenary meeting. Alternative monthly timetables also start once a month, but conclude during the week of the PRAC plenary meeting. Weekly timetables start and conclude every week.

The use of **monthly timetables** is mandatory in the following cases:

- the opinion is followed by an amendment of the Commission decision granting the marketing authorisation that is to be issued within 2 months;
- the variation will/may require discussion at the CHMP plenary meeting.

In the remaining cases:

- **alternative monthly timetables** are to be used when the PRAC is involved in the assessment of the variation;
- **weekly timetables** can be used when the variation is assessed exclusively by the CHMP.

The procedure manager may advise on the appropriate time table to be followed, in view of the considerations above.

Because the use of alternative monthly or weekly timetables is by exclusion, a variation may occasionally need to be **switched** to a monthly timetable at the time of a Request for Supplementary Information (RSI), if the relevant criteria for the use of a monthly timetable apply. Switching in the opposite direction is not possible.

In terms of duration, type II variation assessments typically follow a **60-day timetable**. These include all standard type II variations to implement quality changes, changes to the Product Information or the conditions of the marketing authorisation, or submission of final (non-)clinical study results.

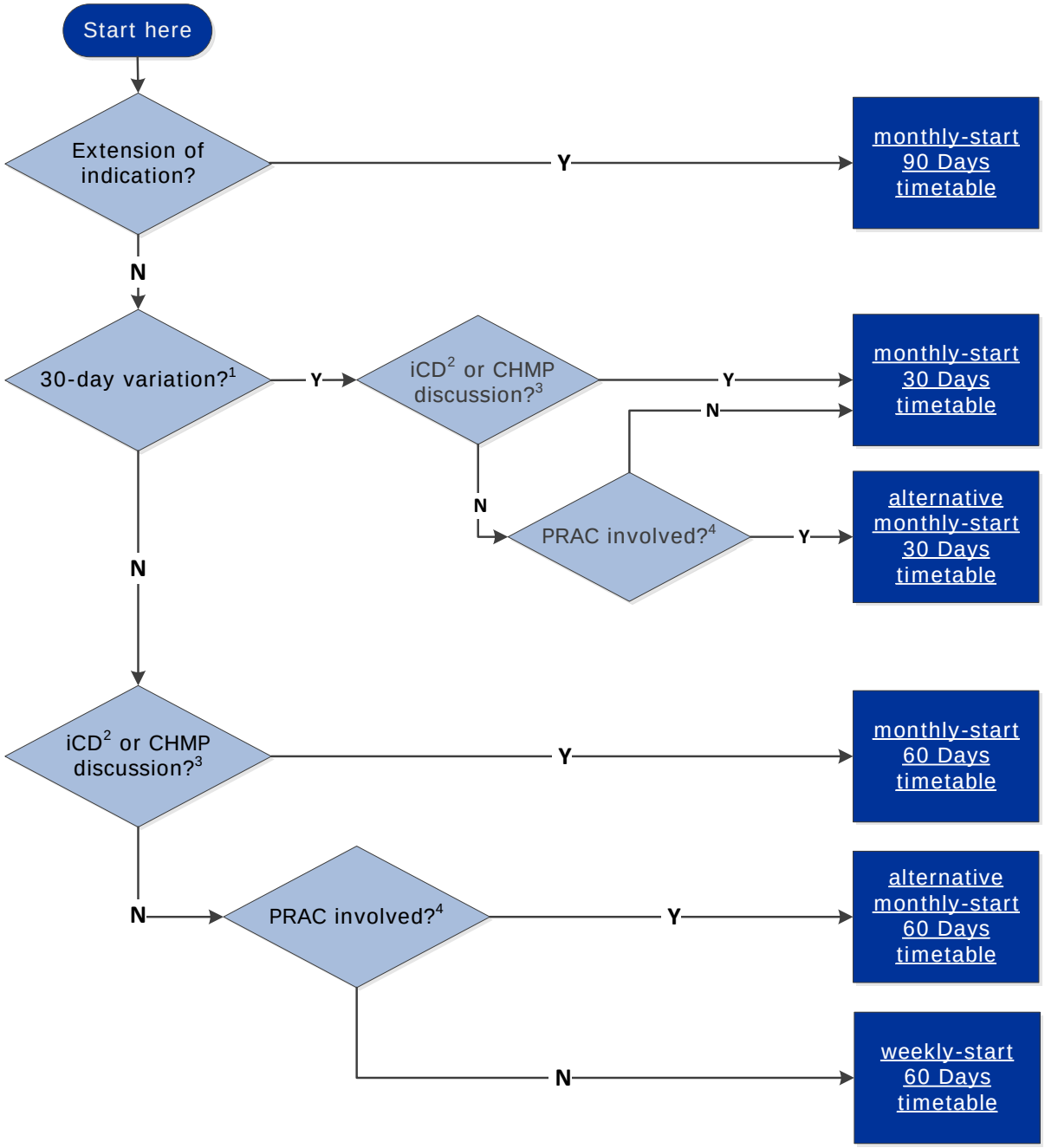
A shorter, **30-day timetable** may be exceptionally applied in agreement with the Agency, if the variation(s) concern(s) the implementation of safety-related changes that would benefit from a shortened assessment in view of the urgency of the matter.

A longer, **90-day timetable** applies to applications to extend the therapeutic indication.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Worksharing applications follow the same timetables as type II variations.

The appropriate timetable for any type II variation can be determined using the algorithm below. The algorithm is to be applied at the initial submission of the variation and the relevant timetable file can be opened using the links included therein. Each file contains timetables for the assessment of responses to RSI(s) and the initially selected timetable file should be used throughout the assessment, unless there is a switch (change in periodicity) as explained above.



[1] To be exceptionally agreed with the Agency ahead of the submission of a safety variation that would benefit from a shortened assessment in view of the urgency of the matter.

[2] iCD= immediate (European) Commission Decision: variations followed by 'immediate EC Decision' in line with article 23(1a)(a) of the variations Regulation (EC) No 1234/2008.

[3] A CHMP discussion is always applicable for extensions of indication. In other cases, the Procedure Manager will advise during the procedure, if a CHMP discussion may become necessary.

[4] PRAC involvement in type II variations typically occurs in case of RMP submission or submission of non-interventional PASS results without implications for the SmPC and Package Leaflet.