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EMA/103586/2017 Rev.1  
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.

Type II variation assessment timetables for non-ATMPs<sup>1</sup> follow either a monthly or a weekly periodicity start. 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 which is to be issued within 2 months (immediate Commission Decision-**iCD**<sup>2</sup>);
- the variation will/may require discussion at the CHMP plenary meeting;

In the remaining cases:

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

As the applicability of the above criteria may change during the assessment procedure, a variation timetable may occasionally need to be **switched** at the time of adoption of a Request for Supplementary Information (RSI, please refer to the decision tree for responses timetables below).

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 to the conditions of the marketing authorisation, or submission of final (non-)clinical study results.

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

A shorter, **30-day timetable** may be exceptionally applied after prior 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 level of urgency of the matter.

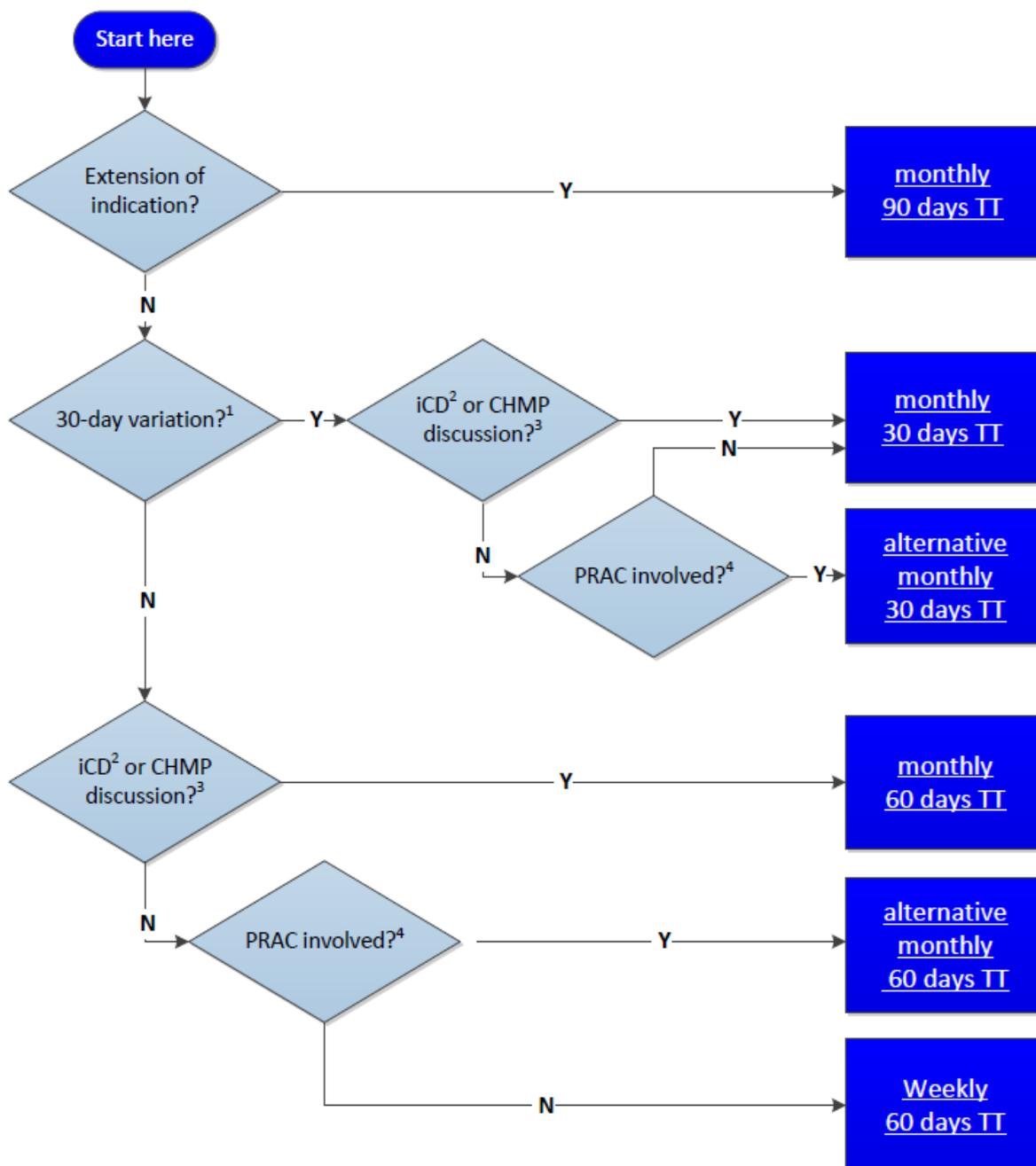
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<sup>1</sup> For ATMPs, please refer to [Type II and worksharing application assessment timetable-ATMP](#)

<sup>2</sup> Please refer to question 12 of the [post-authorisation guidance on type II variations](#)



The appropriate **initial** assessment timetable for any type II variation can be predicted using the algorithm below. The relevant timetable file opens when clicking on the corresponding link. The Agency will definitively determine the assessment timetable during validation of the variation application.



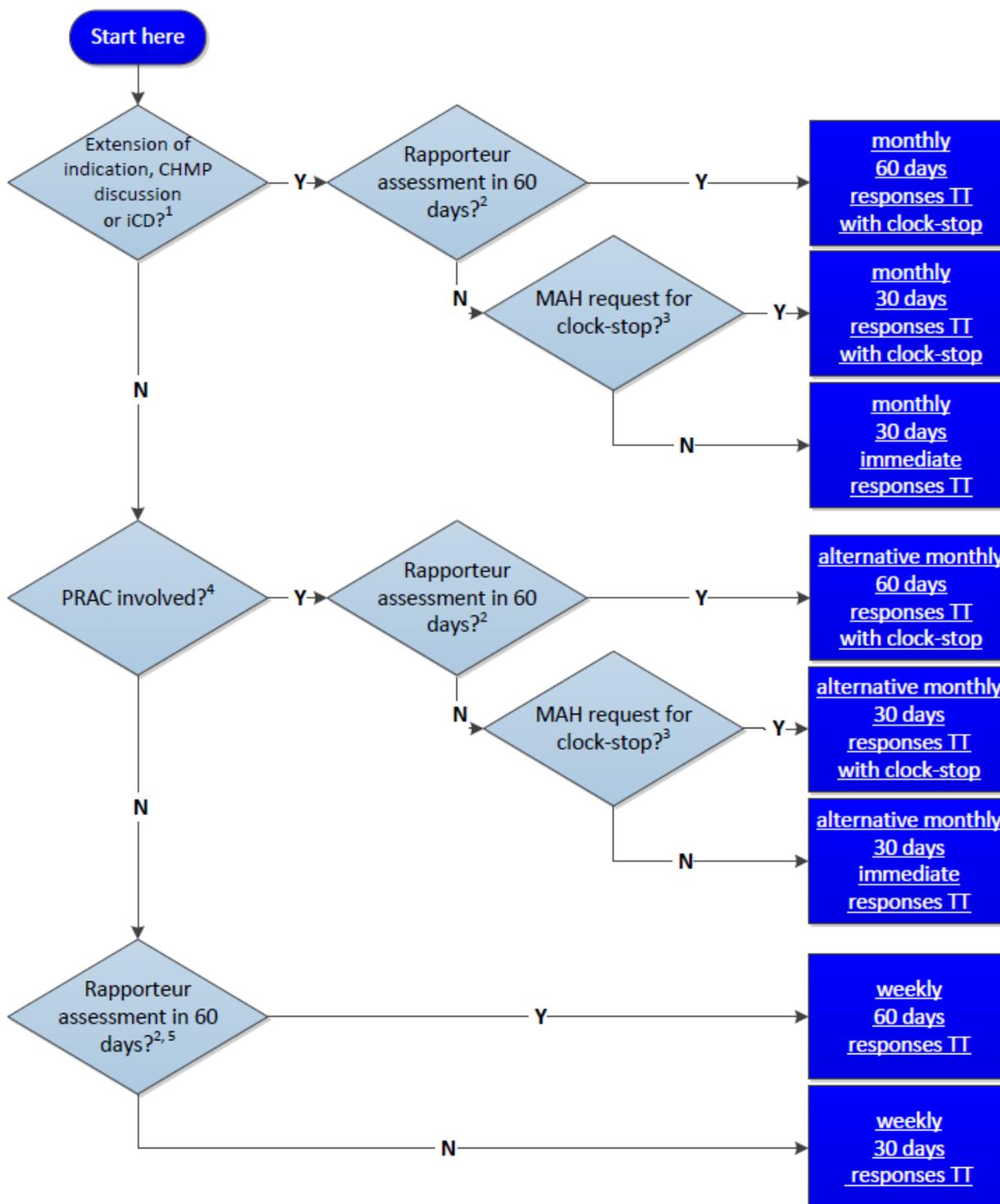
<sup>1</sup> To be exceptionally agreed with the Agency ahead of the submission of a safety variation that would benefit from a shortened assessment in view of the urgency of the matter.

<sup>2</sup> iCD= immediate (European) Commission Decision: this refers to variations followed by 'immediate EC Decision' in line with article 23(1a)(a) of the variations Regulation (EC) No 1234/2008.

<sup>3</sup> CHMP discussion is always applicable for extension of indication, posology change and switch of conditional Marketing Authorisation. In other cases, the Agency will advise during the procedure, if a CHMP discussion may become necessary.

<sup>4</sup> PRAC involvement in type II variations typically occurs in case of RMP submission, submission of non-interventional PASS results or when the variation follows a prior PRAC request from a PSUR or safety signal.

The nature (monthly, alternative monthly or weekly) of the timetable for assessment of **responses to a Request for Supplementary Information (RSI)** will most commonly be the same as that of the timetable used for the initial assessment. However, switches are possible, as explained above. Timetables used for the assessment of responses to RSI can be predicted using the algorithm below. The relevant timetable file opens when clicking on the corresponding link. The Agency will definitively determine the assessment timetable at the adoption of the RSI.



<sup>1</sup> iCD= immediate (European) Commission Decision: this refers to variations followed by 'immediate EC Decision' in line with article 23(1a)(a) of the variations Regulation (EC) No 1234/2008; CHMP discussion is always applicable for extension of indication, posology change and switch of conditional Marketing

Authorisation. In other cases, the Agency will advise during the procedure, if a CHMP discussion may become necessary.

<sup>2</sup> A 30-day assessment timetable is applied by default, unless the Rapporteur requests 60 days due to the number of questions and the associated volume of information to be assessed; the length of the assessment timetable for the responses is indicated by the Rapporteur in the assessment report.

<sup>3</sup> A 30-day clock-stop is applied by default when requested by the Marketing Authorisation Holder (MAH) in response to the receipt of the assessment report. Longer clock-stops are possible upon provision of a justified request to the Agency to be agreed by the Rapporteur/relevant Committee.

<sup>4</sup> PRAC involvement in type II variations typically occurs in case of RMP submission, submission of non-interventional PASS results or if the variation follows a prior PRAC request from a PSUR or safety signal.

<sup>5</sup> In a weekly timetable, submission of responses can occur at any weekly submission deadline leading to a clock-stop of up to 30 days. Longer clock-stops are possible upon provision of a justified request to the Agency to be agreed by the Rapporteur/relevant Committee.