

Procedure to follow for a MINOR CHANGE

Application of the petitioner simultaneously in all CMSs* via the R4BP3 specifying:
 - the RMS*¹ chosen
 - all of the CMSs

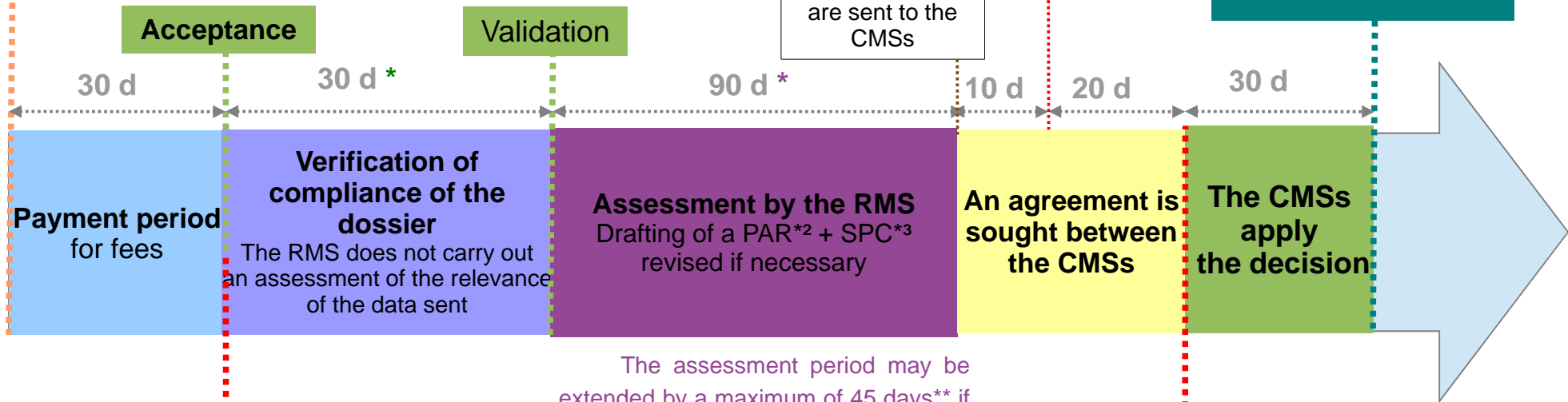
* If the application is incomplete, the applicant may be given an additional period of 45 d** to provide the necessary information (+ 30 d processing period)

If France is not the RMS

In application of the European Implementing Regulation (EU) No 354/2013

The applicant sends to France a translation of the SPC (RCP)

New SPC/RPC*³ recorded in the R4BP



If non-payment: Rejection of the application

The assessment period may be extended by a maximum of 45 days** if ANSES requests additional information needed for the product assessment

If disagreement between one or more CMSs and the RMS:

If the reason for the disagreement corresponds to those described in Art 37 of R 528/2012

If the reason for the disagreement does not correspond to those described in Art 37 of R 528/2012

An agreement is sought with the petitioner

See Diagram 5

**The deadline set by the Agency will be 90 days unless an extension to the deadline is justified by the nature of the data required or by exceptional circumstances

CMS* : Concerned Member States
 RMS*¹: Referent Member State
 PAR*²: Product Assessment Report (in English)
 SPC*³: Summary of Products Characteristics (in English)

DIAGRAM 5: IN CASE OF DISAGREEMENT WITH THE CMS on a change

In application of the
European Regulation
(EU) No 528/2012

