

# Procedure to follow for a MAJOR CHANGE

**Submission of the application simultaneously** in all CMSs\* via R4BP3/IUCLID specifying:  
 - the RMS\*<sup>1</sup> chosen  
 - all of the CMSs

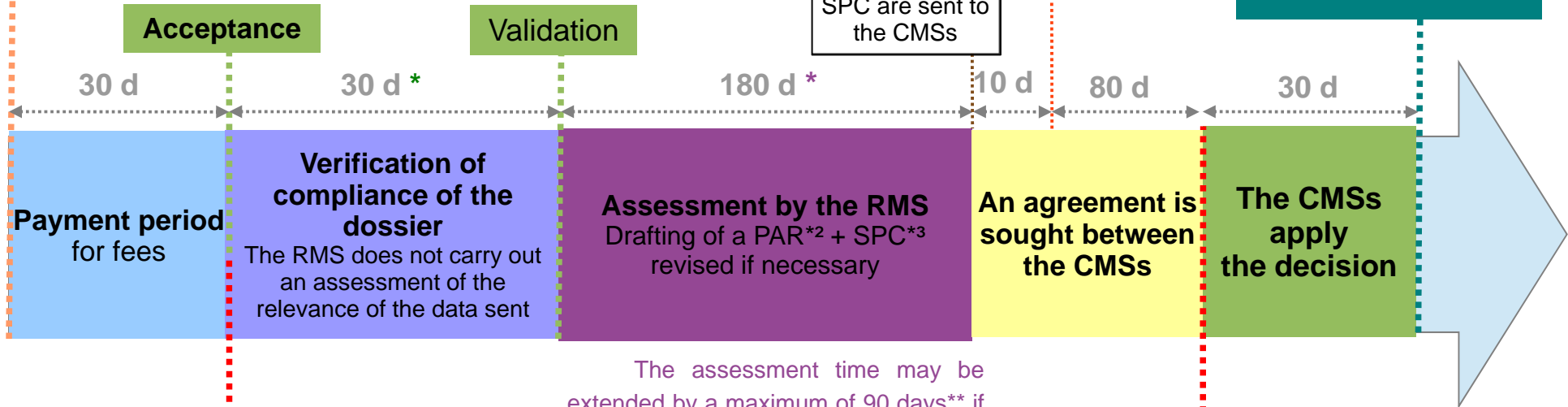
\* If the application is incomplete, the applicant may be given an additional period of 90 d\*\* to provide the necessary information (+ 30 d processing period)

**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 RCP/SPC\*<sup>3</sup> recorded in the R4BP**



**If non-payment: Rejection of the application**

The assessment time may be extended by a maximum of 90 days\*\* if ANSES requests additional information needed for the product assessment

**If disagreement between one or more CMSs and the RMS:**

\*\*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

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**

CMS\* : Concerned Member States  
 RMS\*<sup>1</sup> : Referent Member State  
 PAR/REP\*<sup>2</sup>: Product Assessment Report (in English) / Rapport d'Evaluation du Produit (in French)  
 SPC/RCP\*<sup>3</sup>: Summary of Product Characteristics (in English) / Résumé des Caractéristiques du Produit (in French)

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

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

