These are defined in Article 3-1-a-ac) of Regulation (EU) No 528/2012. They concern changes likely to have an impact on the marketing authorisation decision as regards compliance with the conditions laid down in Articles 19 and 25 of the BPR.

The authorisation must be granted before implementation of the change. See the major change explanatory document
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Regulations

- In cases where France is RMS: Chapter II, Article 8 of Regulation (EU) No 354/2013
- In cases where France is CMS: Chapter II, Articles 9 and 9a of Regulation (EU) No 354/2013

Timeframe

- In cases where France is RMS: 12 months with the possibility of a maximum of 7 further months if additional information is necessary.
- In cases where France is CMS: 5 months with the possibility of a maximum of 3 further months if additional information is necessary.

Validity of the MA

Expiry date identical to that of the reference MA.

Fees payable to ANSES

- To add a PT: 20,000 euros
- For all other major changes: 8000 euros
- In the case of mutual recognition of major change, to add a PT: 8000 euros
- In the case of mutual recognition of major change, for all other major changes: 3000 euros

- In the case of a simplified MA, to add a category of user: 2400 euros
- In the case of a simplified MA, to add a PT: 6000 euros

Composition of the dossier

Documents to be submitted on R4BP

Language

Draft SPC (xml format)

EN

Draft RCP (xml format)

FR

Completed IUCLID dossier including expected changes. In section 13:

- LoA and/or data on active substances
- Product MSDS in French
- Label / draft label in French (and instructions for use in French, if appropriate)
- Supporting documents to demonstrate that the proposed changes would not adversely affect the
- Opinion issued by ECHA regarding the classification of the application – if necessary
- ECHA decision concerning technical equivalence – if necessary
- Written confirmation from the evaluating RMS stating their agreement to evaluate the application

FR or EN

Supporting document (see ECHA website): “supporting document for the application for a major chang

FR or EN

Detailed composition form in Word format

FR or EN