

MA application with sequential mutual recognition procedure

In application of the European
Regulation (EU) No 528/2012 (Art. 33)

Submission of the application

Via R4BP3/IUCLID with
- the translation of the reference MA
- the RCP*² (translation of the SPC*²)

RCP*² recorded
in R4BP

Acceptance

Validation

30 days

30 days

90 days

30 days

Payment
period
for the fees

Verification of compliance
of the dossier
ANSES will not carry out an
assessment of the quality or
relevance of the data sent

Assessment by France
and search for an
agreement
with the CMSs

France applies
the decision

If non-payment:
Rejection of the application

If disagreement with the
RMS and/or the CMSs

Information from
the CMS that
sets the fees

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

*CMS : Concerned Member State
*²RCP/SPC: Résumé des Caractéristiques du Produits (in French) /
Summary of Product Characteristics (in English)

An agreement is sought
with the petitioner

See Diagram 4

MA Application

with mutual recognition procedure
if France is Concerned Member State

Diagram 4: In case of disagreement with the RMS

In application of the
European Regulation (EU)
No 528/2012 (Art. 35 and 36)

Drafting of a notification

- by ANSES if the disagreement concerns the assessment
- by the DGRP if the disagreement concerns the decision

Agreement sought by the Coordination Group (60 d)

DISAGREEMENT

AGREEMENT

Pending a decision:
The CMSs in
agreement with the
RMS may apply the
agreement

The Commission and
petitioner informed by the
RMS

Decision recorded by the
RMS in the R4PB

30 d

Application of
the decision
by the CMSs

120 d

OR

The Commission asks
ECHA for a scientific
and technical opinion

ECHA gives the petitioner
the opportunity to
respond within 30 d

The Commission gives the
petitioner the opportunity
to respond within 30 d

Commission decision
sent to the MS and the
petitioner