Flow chart for the Mutual Recognition (MRP) and Repeat use procedures (RUP)

| Approx. 90 days before submission to CMS | Applicant requests RMS to update Assessment Report (AR) and allocate procedure number |
| Day -14 | Applicant submits the dossier to CMS. RMS circulates the AR including SmPC, PL and labelling to CMSs. Validation of the application by CMSs |
| Day 0 | RMS starts the procedure |
| Day 30 | CMSs send their comments to the RMS, CMSs and applicant |
| Day 40 | Applicant sends the response document to CMSs and RMS |
| Until Day 48 | RMS evaluates and circulates a report on the applicant’s response document to CMSs. |
| Day 55 | CMSs send their remaining comments to RMS, CMS and applicant |
| Day 55-59 | The applicant and RMS are in close contact to clarify if the procedure can be closed at day 60 or if the applicant should submit a further response at day 60. |
| Day 60 | MRP: If CMS have no remaining comments at Day 55, the RMS closes the procedure.  
RUP: If no potential serious risk to public health (PSRPH) has been outlined by CMS at Day 55, the RMS closes the procedure.  
In case a CMS has remaining comments (MRP) or PSRPH (RUP) at Day 55, the applicant sends the response document to CMSs and RMS. |
### Day 60-90
The period 60-90 will only be used if a CMS has remaining comments (MRP) or PSRPH (RUP) at Day 55.

### Until day 68
RMS evaluates and circulates a report on the applicant’s response document to CMSs.

### Day 75
CMSs send their remaining comments to RMS, CMSs and applicant.

### Until Day 80
A break-out session (BOS) can be organised around Day 75 (but may take place between days 73-80)

### Day 85
CMSs send any remaining comments to RMS, CMS and applicant.

### Day 90
CMS notify RMS and applicant of final position (and in case of negative position also the CMDh secretariat of the EMA).

If consensus is reached, the RMS closes the procedure.

The Quality Assessor at the RMS should complete a product surveillance risk assessment, if applicable, when the product is transitioning from a national application to an MR application. This risk assessment is designed to provide information for post-marketing surveillance analysis by Official Medicines Control Laboratories.

Note that the risk assessment template does not need to be completed for repeat use MR procedures.

If consensus is not reached, the points for disagreement submitted by CMSs are referred to CMDh by the RMS within 7 days after day 90

### Day 150
Final position adopted by the CMDh:

If consensus is reached at the level of CMDh, the RMS closes the procedure. If consensus is not reached at the level of CMDh, the RMS refers immediately the matter to EMA for CHMP arbitration

### 7 days after close of procedure
Applicant sends high quality national translations of SmPC, PL and labelling to CMSs.

### 30 days after close of procedure
Granting of national marketing authorisations in the CMSs subject to submission of acceptable translations.

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*All days mentioned in this document should be regarded as calendar days. Whenever a response is received the RMS will send their position.*