1. Introduction

This document is produced by the CMDh in order to facilitate and harmonise the practical application of Article 28(3) of Directive 2001/83/EC as amended.

All timelines in this SOP are based on calendar days, i.e. days should be read as calendar days. The RMS and the applicant should be in close contact before and during the procedure in order to exchange information particularly on the timelines and how to proceed within the procedure.

1.1. Prerequisite: extracts from European legislation

- Article 28(1) of Directive 2001/83/EC as amended

"With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b,
The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as "reference Member State" and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3."

- Article 28(3-5) of Directive 2001/83/EC as amended

"3. In cases where the medicinal product has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The reference Member State shall prepare these draft documents within 120 days after receipt of a valid application and shall send them to the concerned Member States and to the applicant."

"4. Within 90 days of receipt of the documents referred to in paragraph 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly."

"5. Each Member State in which an application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement."

**Exclusions**

The decentralised procedure should not be used for applications for:

- products falling under the compulsory scope of the centralised procedure as set out in the Annex to Regulation (EC) 726/2004 i.e.:
  - i) products developed by certain biotechnological processes,
  - ii) products containing a new active substance not authorised in the Community at the time of entry into force of the Regulation and with therapeutic indication for treatment of certain diseases,
  - iii) products designated as orphan medicinal products pursuant to Regulation (EC) 141/2001;
- products where the company has selected to submit through the centralised procedure according to Article 3(2) and 3(3) of Regulation (EC) 726/2004, irrespective whether the marketing authorisation was granted, was rejected (negative opinion), or the applicant withdrew his application after an assessment by the EMEA of the submitted data;
- homeopathic products referred to under Article 16(2) of Directive 2001/83/EC according to Article 39(2) of that Directive;
- special, simplified registration of traditional herbal medicinal products which are not falling within the scope of Article 16d(1), cf. Article 16g(1) of Directive 2001/83/EC (unless agreed by Member States involved, reference is made to the CMDh Q&A on Traditional herbal medicinal products).

However, if the dossier for a withdrawn medicinal product or a medicinal product which has had a negative opinion in the centralised procedure is supplemented with new data based on new pre-clinical studies and tests and clinical trials, the application is considered to be based on a new dossier. For those applications, the applicant can apply again through centralised, mutual recognition or decentralised procedure where applicable, in those cases where a centralised procedure is not compulsory.
2. Outline of Decentralised Procedure

The Decentralised Procedure is divided in six steps:

- Pre-procedural steps,
- Validation phase
- Assessment step I
- Assessment step II
- Discussion at the CMDh, if needed
- National step

Reference is made to the Flow chart of the Decentralised Procedure (https://www.hma.eu/92.html).

2.1. Pre-procedural steps

2.1.1. Consultation with RMS

It is recommended that the applicant informs the Member State (MS) chosen as Reference Member State (RMS) that an application under the Decentralised Procedure is planned, as soon as the applicant has an estimation of the intended submission date of the application. See also Recommendations on submission dates of the DCP (https://www.hma.eu/92.html).

The applicant has to follow the rules adopted by the MS chosen as the RMS for allocating a timeslot. It is recommended to use the common request form in order to ask a MS to be the RMS in a decentralised procedure (https://www.hma.eu/92.html).

The applicant should seek regulatory advice or pre-discuss the application with the RMS either during a pre-submission meeting or via a teleconference/e-mail at least 2 months before submission of the dossier.

The RMS will inform the applicant when the marketing authorisation application could be submitted and will allocate a procedure number to this application (according to the CMDh guidance document on the numbering system for MRP and DCP).

In the case of possible different views among MSs on the legal basis of the application the matter can be discussed in the meeting of the Co-ordination group for Mutual Recognition and Decentralised Procedures (CMDh) prior to submission of the application but also during the validation phase. The discussion will be initiated by the RMS.

The RMS creates the procedure in the CTS database as soon as the applicant has informed the RMS that the dossier has been submitted to the RMS and all CMSs, so that CMS and RMS are able to communicate regarding the procedure through the CTS record immediately after receipt of the dossier.

2.1.2. Making the application

The applicant submits an application to the National Competent Authorities of each of the MS where a marketing authorisation is to be sought.

The applicant is required to give assurance, usually in the cover letter accompanying the application, that the dossier submitted is identical in all MSs concerned (RMS + CMSs). It is recommended to use the template for a cover letter as published on the CMDh website (http://www.hma.eu/219.html). The application should be made according to the legal basis applied for. Guidance on format, appropriate
number of copies of the dossier, languages requirements, fees etc. can be found in the document "Requirement on Electronic submissions (number and format) for New Marketing Authorisation Applications within MRP, DCP and National Procedures" as published on the CMDh website (https://www.hma.eu/277.html) and in the document "Additional Data requested for New Applications in the Mutual Recognition and Decentralised Procedures" as published on the CMDh website (http://www.hma.eu/91.html). Text proposals for SmPC, PL and labelling in English only are acceptable with the submission of the dossier. Sample mock-ups in an official language of the EU should be submitted for the application.

The applicant notifies the RMS of the dates of dispatch of the dossier, so that the RMS is able to update the CTS record and to complete the 'date of last dossier submission' in CTS. The validation period is 14 days and starts when the RMS and all CMSs have received a technically valid application. At the time of updating the CTS record, validation of the application does not have to be completed by the RMS.

### 2.2. Validation phase

The validation procedure described in 'Procedural Advice on Validation of MR/Repeat-use/DC Procedures' applies (see http://www.hma.eu/91.html).

The RMS finalizes the validation as soon as possible and circulates the 'RMS validation checklist for human medicinal products in DCP' (see http://www.hma.eu/91.html) to the CMSs and to the applicant.

If there are different views on the validity of the legal basis, the RMS may discuss this in the CMDh meeting.

CMS should not repeat the complete validation as done by the RMS, but limit their validation to the issues as mentioned in the 'CMS validation checklist for human medicinal products in DCP' (see http://www.hma.eu/91.html). Positive validation should only be indicated in CTS, not via e-mail.

If the application is withdrawn in a CMS during the validation period (i.e. before start of the procedure) the procedure should be regarded as finalised in that CMS. Consequently, this CMS should not receive any further communication/e-mails/documents related to this procedure. It is then considered that this CMS did not participate in the procedure.

It should be noted that successful passage through the initial validation phase does not preclude subsequent refusal, on grounds of non-compliance with the legislation or absence of satisfactory supporting data, at any other stage of the procedure, which become apparent on further consideration of the dossier according to Article 26.2 of the Directive 2001/83/EC as amended.

### 2.3. Assessment step I

The RMS confirms the start of the procedure and, if necessary, the updated timetable to CMS (via CTS) and applicant. The CMS retrieve the information from CTS only, there will be no additional e-mail.

In case the RMS needs to backdate the start of the procedure, this should be communicated to the CMSs and applicant via e-mail also. This should occur in exceptional cases only.

The assessment step I corresponds to the 120-day period for preparing Draft Assessment Report (DAR) and comments on draft SmPC, draft PL and draft labelling.

The RMS forwards the Preliminary Assessment Report (PrAR) (including comments on SmPC, PL and labelling) on the dossier to the CMSs and the applicant within 70 days after the start of the procedure. This PrAR will include a comment on whether 'user consultation' of the PL has been performed or is foreseen.
This PrAR (Overview) will also include a similarity assessment (Module 1.7.1). If necessary, a separate Similarity Assessment Report can be written. If applicable, an assessment of the claimed derogation(s) from orphan market exclusivity (Module 1.7.2) will be included in the PrAR or in a separate AR on the derogation(s).

The PrAR on the ASMF (both open and restricted part) will be sent to the ASMF holder by the RMS by day 70 also, with a statement that any additional comments sent by CMSs will be sent to the ASMF holder by the RMS between day 100 and day 105 (see also below).

The PrAR on the open part of the ASMF will also be sent to the applicant on day 70.

In case the ASMF worksharing procedure is followed, see https://www.hma.eu/306.html.

By Day 100 CMSs should communicate their comments to the RMS, other CMS and the applicant, using the template agreed upon, differentiating between potential serious risks to public health (PSRPH) and additional other concerns. Where a CMS is in agreement with the RMS, then a simple e-mail communication would suffice. It may also be sufficient for the CMS to indicate in CTS only in case there are no additional comments. The CMSs do not necessarily have to send an e-mail to the applicant in such cases.

The RMS should inform the applicant on all comments (also in case a CMS has no comments) raised.

Before sending comments, any issues should be carefully screened within national competent authorities. If a CMS raises a PSRPH it shall give a detailed exposition of the reasons of its position. CMSs should clearly differentiate between comments on the open and closed part of the ASMF.

When issues have been previously discussed and agreed upon by MSs either during DCPs or MRPs they should not be reopened for discussion during other DCPs or MRPs including the same MSs, unless new information has become available. The RMS should indicate in the assessment report which other products and procedures the SmPC, PL and labelling are based on, and the CMS should be listed. A reference to previous discussions in the CMDh should be included in the assessment report, if applicable. The CMS should also include reference to other agreed texts, when applicable. When reference is made to other products, MSs should refer to MRP or DCP numbers.

Between Day 100 and 105, the RMS may consult with the CMSs to discuss the comments raised.

Questions on the closed part of the ASMF will be sent to the ASMF holder by the RMS. The RMS should also inform the applicant in case questions on the closed part of the ASMF have been forwarded to the ASMF holder, indicating whether these are potential serious risks to public health and/or other concerns.

In order to achieve a common understanding of the comments and questions raised by the MSs concerned, it is recommended that the RMS and the applicant are in close contact.

If consensus is reached that the product is approvable, the RMS updates the Overview part of the PrAR to prepare the Final Assessment Report (FAR) including agreed SmPC, PL and labelling. At Day 105 the RMS may close the procedure, and the procedure continues with the national step.

If no consensus is reached that the product (including proposed SmPC, PL and labelling) is approvable, the RMS stops the clock at Day 105 and forwards the questions raised by the RMS and CMS, to the applicant as a Request for Supplementary Information (RSI).

Clock-stop period

During the clock-stop period, the applicant supplements the dossier by responding to the questions and providing updated SmPC, PL and labelling proposals, if necessary. The applicant is only allowed to submit new data in reply to the questions raised by the Member States during the procedure.
Within the clock-stop time, the applicant may undertake ‘user consultation’ of PL and in such a case the applicant should take into account MS comments received, if ‘user consultation’ had not yet been done. If MS have made comments on the PL it is not allowed to perform ‘user consultation’ during the clock-stop time with the PL submitted at the start of the procedure.

The applicant may submit a draft response to the Day 105 list of questions to the RMS, including updated SmPC, PL and labelling proposals, if agreed by the RMS.

It is the responsibility of the applicant to ensure that responses have been provided to all of the concerns raised by RMS and CMSs in the Day 105 list of questions (including those related to the ‘open’ and ‘restricted’ parts of the ASMF). All relevant supporting data should be included in the response. The RMS may be unable to restart the timetable if the response is incomplete or when an inspection (GMP, GVP or GCP) is necessary. The RMS will inform the applicant when to submit the response in the CMSs and propose a timetable for DCP assessment step II. The restart date will usually be within 6 weeks of the date of receipt of the draft response in the RMS.

Exceptionally, the RMS may require amendment to the response before its submission to CMSs and before restart of the timetable. An amendment will typically be requested when further clarification or analysis is required to address a concern that is critical to the benefit/risk evaluation of the product. The RMS will request amendment to the draft response once only and normally within 4 weeks of its receipt. The amended response should be submitted to RMS and the RMS will inform the applicant when to submit the amended response in the CMSs and propose a timetable for DCP step II. In any case, the RMS should agree the date of submission of the amended response with the applicant.

The RMS will inform the CMS’s and applicant as soon as possible if a delay in the restart is foreseen.

In case the applicant, in agreement with the RMS, does not submit a draft response to the RMS, he should give an advanced notice of 14 days on the proposed submission date of the final response document.

The applicant and the ASMF holder should submit the final response to the RMS and all CMSs within a period of 3 months, which can be extended by a further 3 months. In exceptional circumstances, a further extension of this period could be applied for and approved by the RMS. A request for an extension will only be considered by the RMS if the applicant provides appropriate scientific justification. Any request for an extension should be submitted to the RMS at the latest one month before the end of the 3 months period or one month before the earlier agreed date. If no request for an extension is received within this time, the RMS will automatically restart the procedure and distribute a Draft Assessment Report (DAR) on the basis of the information available at that time.

If it is not expected that the response will be submitted within an acceptable time (i.e. 6 months maximum), the RMS will request the applicant to withdraw the application in all MSs. If the applicant has not:

- submitted a response within 3 months, or
- submitted a response within the extended period requested and agreed by RMS, or
- withdrawn the application,

the RMS will continue the procedure, i.e. the RMS will restart the clock and distribute a Draft Assessment Report (DAR) on the basis of the information available at that time.

Applicants are reminded that data derived from new studies are not accepted during assessment step II, so it will not be possible to supplement a deficient dossier with new data once the clock has restarted.
During the clock-stop period, the applicant should monitor the potential similarity with authorised orphan medicinal product(s) under market exclusivity for the proposed indication(s). In case a marketing authorisation is granted, the applicant should submit or update the report on similarity (Module 1.7.1) and, if applicable, submit the data to support derogation from orphan market exclusivity (Module 1.7.2) with the Day 106 responses. Note: in case the market exclusivity of an orphan indication expires during the procedure it is not allowed to include this indication during the procedure, it has to be added via the appropriate variation once the procedure is completed.

After submission of the final response document and receipt of the list of despatch dates in all CMSs the RMS will finalise the timetable for Assessment Step II with the applicant and restarts the procedure at Day 106. The CMSs are informed of the restart via e-mail by the RMS, and the CTS is updated accordingly.

Between Day 106 and 120 the RMS updates the PrAR to prepare the Draft Assessment Report (DAR), draft SmPC, draft PL and draft labelling.

If the application is withdrawn before the Draft Assessment Report is distributed (i.e. before assessment step II) in a CMS which raised a PSRPH earlier in the procedure, then a CMDh referral won't be initiated on the basis of this PSRPH. The procedure should be regarded as finalised in that CMS, and consequently this CMS should not receive any further communication/e-mails/documents related to this procedure.

### 2.4. Assessment step II, including discussion at CMDh, if needed

The RMS starts the assessment step II on Day 120 at the latest by sending the Draft Assessment Report (DAR), (updated) similarity AR (if applicable), draft SmPC, draft PL and draft labelling to the CMS and applicant. The start of the assessment step II corresponds to Day 0 of the 90-day period mentioned in 28(4) of Dir. 2001/83/EC. During the assessment step II, new data/studies (or a delayed Day 106 response) cannot be submitted by the applicant or the ASMF holder. The RMS should clearly indicate in its conclusion if the product is approvable or not.

The RMS will update the CTS record with the date of sending of the DAR, draft SmPC, draft PL and draft labelling.

During the assessment step II period the procedure can be closed at any time-point before Day 210 if consensus is reached that the product is approvable. The RMS should circulate its conclusion that the product is approvable together with the final AR, final proposed SmPC/PL and labelling to the CMSs. The RMS should clearly indicate in this message that all remaining comments have been addressed satisfactorily and that the product(s) and SmPC/PL/labelling can now be approved. If necessary, a short assessment report can be added to the message. Each CMS sends its comments to the RMS, CMS and applicant, using the template agreed upon, differentiating between PSRPH and remaining additional other concerns no later than Day 145 of the procedure (i.e. Day 25 of 90-day period) and updates the CTS record. Where a CMS is in agreement with the RMS, then a simple e-mail communication would suffice. It may also be sufficient for the CMS to indicate in CTS only in case there are no additional comments. The CMS does not necessarily have to send an e-mail to the applicant in such case.

The RMS should inform the applicant on all comments (also in case a CMS has no comments) raised

However, in specific situations, the RMS can propose a shorter timetable for sending comments (within one week). If no comments have been received within one week, it is assumed that the CMSs agree with the proposed texts and that the procedure will then be concluded positively. However, in the
absence of agreement on this proposed shorter deadline for comments, the normal timetable will be followed (i.e. comments to be sent no later than Day 145)

Between Day 145 and 150, the RMS consults with the CMSs to discuss the comments raised.

If consensus is reached that the product is approvable, the RMS prepares the Final Assessment Report (FAR) and closes the procedure. The procedure continues with the national step.

The risk assessment template to identify risk factors and make recommendations for post-marketing surveillance analysis by Official Medicines Control Laboratories is available online and should be completed by the RMS by the end of the European phase of the procedure. The template does not need to be completed for products that are subject to Official Control Authority Batch Release (OCABR) testing.

If consensus is not reached by Day 150, the RMS communicates outstanding issues with the applicant.

During the entire procedure, the applicant should monitor the potential similarity with authorised orphan medicinal product(s) under market exclusivity to check if a marketing authorisation has been granted for an orphan medicinal product for the proposed indication(s). In case a marketing authorisation is granted, the applicant should submit or update their report on similarity (Module 1.7.1) and, if applicable, submit the data to support derogation from orphan market exclusivity (Module 1.7.2). In that case, the detailed RMS assessment of similarity should be updated accordingly. Note: in case the market exclusivity of an orphan indication expires during the procedure it is not allowed to include this indication during the procedure, it has to be added via the appropriate variation once the procedure is completed.

The applicant submits additional clarification by Day 160 or earlier, including any revised proposal for SmPC, PL and labelling if necessary. The RMS prepares a short report on the complete applicant’s response submitted at Day 160 and forwards it to the CMSs at the latest on Day 180 (i.e. Day 60 of the 90-day period). This report of the RMS will include proposals for an update of the Overview part of the DAR to derive the FAR.

The RMS should discuss with the CMS and applicant whether a Break-Out Session or Hearing would be suitable, and what would be the appropriate date.

At latest on day 195 (i.e. Day 75 of the 90-day period) a Break-Out Session (BOS) may be held with the involved MSs to reach consensus on the major outstanding issues. In order to facilitate the participation from MSs, the RMS may also decide to organise a BOS using virtual or telephone conference. The BOS will be held according to the principles outlined in the CMDh Best Practice Guide on Break-out sessions. If further discussion is needed in CMDh, the RMS will give an oral report of the BOS in CMDh. In all situations, the RMS will circulate the minutes of this meeting to the CMDh, the CMSs and the applicant.

After the BOS the applicant may submit amended SmPC, PL and labelling proposals in accordance with agreements made during the meeting.

During any time of the procedure, the RMS could also use the meeting of the CMDh as an opportunity to discuss major issues that are raised during the procedure and seek assistance in solving the issues. Scientific discussion in the CMDh is recommended to discuss potential problems in the assessment of complex formulations, different interpretations of the Bioequivalence Guideline, quality issues or risk minimisation measures early in a procedure. Especially in situations where several parallel procedures of the same active moiety are ongoing it will help the MSs to agree on a consistent approach in the assessment.
It is advised to introduce any major amendments to the SmPC, PL and labelling during an early stage of the procedure in order to allow full discussion in each MS. The CMS should make every effort to send their comments before Day 195 and resolve outstanding issues before Day 205 (i.e. Day 85 of the 90-day period).

Only in exceptional cases should changes to the SmPC, PL and labelling be introduced after Day 205. In such cases the RMS should actively inform the CMSs about this. The RMS and CMS have the responsibility to ensure full transparency during the procedure.

On occasion it may be desirable to have a virtual or telephone conference between the MSs around day 195-205 (i.e. Day 75-85 of the 90-day period) to reach agreement.

Between Day 195 and Day 210, the RMS consults with the CMSs and the applicant to discuss the remaining comments raised.

At Day 210 (i.e. Day 90 of the 90-day period) the RMS closes the procedure if consensus was reached with all MS on the outstanding issues, or if the RMS concludes that the product is not approvable.

- If consensus is reached that the product is approvable, the RMS includes information in the FAR on how major outstanding issues were solved by discussions e.g. via written procedures and/or by discussion in the CMDh (if applicable). The RMS sends to the CMSs and the applicant, the final agreed SmPC, labelling and PL, and the final AR (including approved finished product specifications at release and end of shelf-life). It is recommended to upload the clean final SmPC, labelling and PL to CTS for transfer to the MRI product index. The procedure continues with the national step.

- If the RMS concludes that the product is not approvable, the RMS includes information in the FAR on the remaining outstanding issues at the end of the procedure. No referral to CMDh will follow. The procedure continues with the national step.

If CMS(s) by Day 210 cannot approve the positive RMS assessment report, SmPC, PL and labelling on the grounds of PSRPH, the CMS(s) shall notify the RMS, CMS(s), the CMDh secretariat at the European Medicines Agency and the applicant at Day 210 at the latest, preferably before 16.00 CET, by using the agreed template for a referral request (http://www.hma.eu/262.html). The notification shall include a detailed exposition of the reasons for the negative position. This also applies in case the applicant has withdrawn the application after distribution of the DAR in a CMS based on PSRPH raised by this CMS.

Even if CMSs earlier in the procedure have informed that they are of the opinion that there are potential serious risks to public health with the application, they need to confirm their final position on Day 210, so that it is clear to all parties involved, whether the issues have been resolved or not by the applicant’s response. It is encouraged to finalise a DCP on Day 210 at 16.00 CET. It is recommended that the CMSs give their final position according to the timelines given above so that the procedure can be closed on Day 210. It is not advisable to have Day 210 on a Saturday or a Sunday.

In exceptional cases, if the RMS changes its recommendation in the assessment report from negative after Day 205 the RMS will send this final positive position to the CMSs. The RMS will then mention in the cover e-mail that the RMS will refer the issue (which is now considered resolved by the RMS) to the CMDh for referral unless ALL CMSs have confirmed by e-mail on day 210 at the latest that they no longer maintain their concerns on potential serious risk to public health and agree with the RMS’s positive position.

If a CMS maintains a PSRPH at Day 210, the RMS will refer the matter to the CMDh by circulation of the assessment report, proposed SmPC, PL and labelling and the explanation of the grounds for referral from the disagreeing CMS(s) to all CMDh members, CMDh chair, the CMDh secretariat at the European Medicines Agency and the applicant, within 7 days after Day 210, by using the agreed
template for a referral notification (http://www.hma.eu/262.html). The 60-day procedure in CMDh is described in the CMDh SOP 'Disagreement in procedures-Referral to CMDh'.

According to Article 29 (1-6) of Dir. 2001/83/EC as amended, all MSs concerned shall use their best endeavours to reach agreement on the action to be taken within 60 days of the communication of the points of disagreement, at the level of the CMDh.

- If consensus is reached, the RMS records the agreement, closes the procedure at Day 270 (at the latest) after the CMS have approved the Final Assessment Report, SmPC, PL and labelling, and informs the applicant accordingly. The procedure continues with the national step.

- If no consensus is reached at the level of CMDh, the RMS informs the European Medicines Agency immediately after Day 60 of the CMDh discussion period, with a view to the application of the procedure under Articles 32, 33 and 34 of Dir. 2001/83/EC as amended. The RMS provides the European Medicines Agency with a detailed statement of the matters on which the MSs have been unable to reach agreement and the reasons for their disagreement. A copy shall be forwarded to the applicant and CMSs by the RMS. The procedure described in Chapter 3 of the Notice to Applicants should be followed using the appropriate form to notify the European Medicines Agency. MSs that have approved the Final AR, the SmPC, PL and labelling may, at the request of the applicant, authorise the medicinal product (i.e. continue with the national step) without waiting for the outcome of the procedure laid down in Article 32 of Dir. 2001/83/EC as amended. In that event, the authorisation granted shall be without prejudice to the outcome of that procedure.

2.5. National step

The National Competent Authority of each involved MS shall adopt a national decision within 30 days after the RMS closes the procedure.

- Also during the national step, i.e. until the national decision has been issued, the applicant (and national competent authority) should monitor potential similarity with authorised orphan medicinal product(s) under market exclusivity for the proposed indication(s) to check if a marketing authorisation has been granted. In case a marketing authorisation is granted for an orphan medicinal product for the proposed indication(s), the applicant should submit or update the report on similarity (Module 1.7.1) and, if applicable, submit the data to support derogation from orphan market exclusivity (Module 1.7.2). In that case, the RMS will circulate their (updated) assessment of similarity or (updated) separate similarity report to the CMSs. Note: in case the market exclusivity of an orphan indication expires during the procedure it is not allowed to include this indication during the procedure, it has to be added via the appropriate variation once the procedure is completed.

- In case the procedure ended with a decision that the product is approvable, the applicant submits high quality national translations of the SmPC, PL, labelling and mock-ups (if required) no later than 7 calendar days after the procedure is closed. MSs may introduce linguistic changes only to the SmPC, PL and labelling and must ensure their national version of product information is a faithful translation of the final harmonised position. The ‘blue box concept’ for adequate national information on the label and PL will be permissible.

- In case the procedure ended with a decision that the product is not approvable, all MSs need to take a final decision at national level, unless the applicant withdraws the application.