CMDh ends the pilot for splitting of procedures

Sometimes the MAs of MRPs or DCPs are sold to different MAHs for specific member states and the new MAHs are planning different development routes for these products. In these cases, splitting of the MRP/DCP into several smaller lines seems to be reasonable for preventing MAHs from unnecessary variation procedures for their products, and for keeping the dossiers clear. The CMDh started a pilot procedure in January 2016 for 10 procedures which was finalised in November 2016. Due to the low number of procedures the CMDh decided to extend the pilot phase several times until June 30, 2019 without restriction to the number of procedures involved in the pilot, in order to learn more about this procedure, and to have sufficient time for evaluating the legal possibility for a permanent procedure. In order to be suitable for such a splitting of procedures, the following conditions had to be fulfilled:

- The initial MRP/DCP should be finalised;
- Different MAHs in the different MS were a prerequisite for the splitting. Splitting into several lines was only possible per different MAHs.
- The new RMS(s) had to be an existing CMS in the MRP/DCP procedure. They had to agree to act as the new RMS in the split procedure;
- Splitting was allowed only once in the lifecycle of a product; splitting into several lines (i.e. more than two RMS) was allowed.
- All regulatory procedures had to be completed before the splitting could take place;
- It was not acceptable to split single strengths of a procedure to a new RMS.

Example:

XX/H/9999/001/DC: CMS = MS1, MS2, MS3, MS4
XX/H/9999/002/DC: CMS = MS1, MS2, MS3, MS4, MS5

A split of the procedure 002 alone would only be possible for splitting MS5 off and MS5 becoming the new RMS.

The splitting has been performed as follows during the pilot procedure:

The proposed procedure for splitting was sent by the MAH via email to the current RMS and proposed new RMS with a request for splitting and contained the following information:
In case of agreement of old and new RMSs, the old RMS introduced the splitting in CTS by using the splitting function. The new RMS(s) issued new procedure number(s) and informed the old RMS, who included it in CTS and informed the MAH and the new CMS(s) accordingly (see below for timetable for this procedure). The RMS of the initial procedure kept the procedure number but the CMS(s) that were switched to the new procedure were no longer involved in the initial procedure from the CTS product sheet. Both procedures remained as active procedures in CTS.

The initial RMS provided the new RMS with the PAR in word format, if applicable.

The package leaflet was updated at the time of the next variation/notification affecting the package leaflet to update the list of product names in section 6.

Variations of the newly created lines with new RMS and new procedure number were submitted starting with the sequential number XX/H/nnnn/vvv /001.

In case of eCTD submissions, each procedure was afterwards handled in its own dossier lifecycle. The existing eCTD lifecycle continued for the existing (old) procedure number with the existing dossier UUID. A new eCTD lifecycle was created for each new procedure number, by

- either copying the existing eCTD dossier with all sequences to a new eCTD dossier and assign a new dossier UUID (preferred option);
- or generating a new baseline (0000) from the existing eCTD lifecycle and assigning a new dossier UUID for this new dossier;

No regulatory activities were allowed during the splitting of the procedures. In case all conditions as mentioned above were considered by the applicant the splitting procedure as such was finalised by the old and new RMS within 30 days after the application. Fees for this procedure were a national issue.

**Pilot outcome:**

After nearly 3,5 years of experience with the splitting procedures the CMDh took the final decision in its meeting in June 2019 not to extend the pilot further and to stop the splitting procedure immediately. The decision has been taken on the basis of the experience gained during the pilot procedure and is substantiated by the following reasons:

- Many of the procedures were split in the past not only in two lines with two RMS but in a way that all CMS had different MAHs so that it was split completely with each former CMS ending up as new RMS without any CMS in the procedure.

- In the follow-up of these splittings the SmPC was amended differently in the new RMS procedures which led to a disharmonisation of the formerly common product information, which is contrary to the intention of the EU network. Additionally, the assessment of these amendments by the different RMS led to a perceptible increase in the work of the single NCAs being the new RMS due to multiple assessments which should be avoided in order to save resources. It was furthermore noted that all upcoming variations were submitted as single

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1 Agreement is only needed from those MAHs that are split off to the new line with a new RMS
variations in one member state only. No worksharing procedure was used, even in cases of identical changes.

- In many cases, the different MAHs proposed for the split procedures could be interpreted as ‘the same MAH’ according to the definition in the Commission Communication 98/C 229/03.

All aspects taken into account, the CMDh considered the disadvantages of the procedure outweighed the advantages. It was therefore decided not to prolong the pilot and to stop it immediately starting from July 1, 2019. Open requests for splitting will be finalised by the responsible NCAs.

In exceptional cases were a splitting is legally necessary, e.g. divestment cases or triggering of Article 50 by a member state (e.g. Brexit), the CMDh reserves the right to accept these subject to CMDh endorsement.
### Timetable

<table>
<thead>
<tr>
<th>Day 0</th>
<th>The current RMS and the new RMS(s) receive an application for splitting from the MAH(s).</th>
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</thead>
<tbody>
<tr>
<td>Day 10</td>
<td>Current RMS informs the new RMS(s) if the split is acceptable (in accordance with the limitations set down by this procedural advice).</td>
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<tr>
<td>Day 20</td>
<td>New RMS(s) inform(s) if they accept the RMS-ship for the new, split, procedure. The new RMS(s) issue(s) new procedure number(s) and informs the CMS accordingly. At the latest by Day 30, the old RMS(s) create(s) the new CTS product sheet for the new procedure by using the CTS splitting function.</td>
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<tr>
<td>Day 30</td>
<td>When the CTS product sheet for the new procedure has been created and updated, the CMS, the old RMS and the MAH are notified by the new RMS that the splitting is complete.</td>
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</table>
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