Cesp update of list of “regulatory activities” accepted by the famhp & update on practical information

The allowed regulatory activities or in other words, the allowed dossier types for CESP submissions to the famhp are:

Which regulatory activity can I tick in CESP?	**To which division the submission will be send?**
Initial Marketing Authorisation Application	- Human:VHBPRE (medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
Repeat use procedure (RUP)	- Human:VHBPRE (medicinal products for human use)
Variation Type IA	- VHBPOST(medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
Variation Type IB	- VHBPOST(medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
Variation Type II	- VHBPOST(medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
Extension	- VHBPRE (medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
Periodic Safety Update Report (PSUR)	- Vigilance
Renewal	- VHBPOST(medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)

Active Substance Master File	- VHBPRE (VHBPRE centralises ASMF for both medicinal products for human and veterinary use)
Notification 61 (3)	- VHBPOST (only for MRP and DCP dossiers, concerning medicinal products for human use)
National notification	- VHBPOST (art. 34§4 national notifications, only applicable for medicinal products for human use)
Transfer of a marketing authorisation	- VHBPOST(medicinal products for human use) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
National variations	- VHBPOST (these are the administrative national variations such as change language role, change distributor except for the transfer of MAH – see above) - Veterinary: Division for medicinal products for veterinary use (medicinal products for veterinary use)
PASS	- VIG: for submission of PASS for medicinal products for human use under PRAC surveillance - VET: for submission of PASS for medicinal products for veterinary use
Homeopathic MP application	- For homeopathic MP (for human or veterinary use), always tick that “regulatory activity”. The details concerning the dossier type (new application, variation, renewal,…) is to be clarified within the CESP “comment” field.
Herbal MP application	- For herbal MP, always tick that “regulatory activity”. The details concerning the dossier type (new application, variation, renewal,…) is to be clarified within the CESP “comment” field.
Authorisation for temporary use	- Division medicinal products for veterinary use

Good to know:

1. Central procedures concerning medicinal products (MP) for hulman use or for MP for veterinary use, can be submitted via CESP. However the EMA foresees to make the use of the "central repositories" mandatory from 1 march 2014 on. From that moment on, the famhp will no longer allow CP submissions via CESP. It is always usefull to consult the training material available on the CESP website (video, ...).

2. Starting from 11th october 2013 the new CESP system will go live. The way to use it by the applicant, is slightly modified. All necessary training material is available on the CESP site.

3. If you ticked a "regulatory activity" which does not appear in the list here above, the CESP submission will not be accepted by the famhp. In that case you will receive a mail (via a "noreply" address) explaining that you need to re-submit the concerned dossier. Depending on the dossier concerned, you will need to choose another way of submission (CD-ROM, eudralink,…) or you will need to resubmit the dossier via CESP selecting the correct "regulatory activity".

4. CESP is only supported by the famhp as far as the initial submission is concerned. Additional information concerning an already submitted dossier (such as for example answers to questions) are not accepted via CESP. As soon as the dossier manager is assigned for the dossier, the further follow-up of the dossier is assured by direct mail traffic between you and the concerned dossier manager.

5. In order to guarantee a correct and efficient transfer of your dossier, the famhp advices you to limit the size of the dossier to 2 GB. If this seems not possible, please contact the concerned division.

6. Be sure your dossier is zipped before submitting it via CESP. Check that the "delivery form (xml)" is outside the zip folder. Avoid the use of special characters (ä, Ä, é, ö, Ö, ü, Ü,ç, &, etc.) when naming the zip file. Do not use folders above the procedure folder within the zip. It is recommended to use for example: ***MRPBE-H-xxxx-WS-04/0000/m1/eu/10-cover/common/common-cover.pdf.*** Be sure that the sum of the pathlength of the documents, the folders up to the folder on top of the root folder is maximum 180 characters.

7. Be sure that the submission is transferred first, followed by the "delivery form (xml)", and not the other way around! You always need to transfer one dossier at a time followed by it's delivery file (xml), before starting the transfer of the second submission. NEVER use twice the same xml file, the xml file should be unique for each submitted dossier. Never rename the delivery file.

8. Within two hours after loading your dossier via CESP, you will receive a first mail (CESP Submission Upload Notification). Afterwards you will receive a second mail (CESP Agency Delivery Notification) for each concerned member

state, which assures that the dossier was transferred to the concerned member state. The second mail is send within 24 hours after the CESP submission. If not, the CESP helpdesk is to be contacted (cesp@hma.eu). Note that these mails do not replace the acknowledgement of receipt sent by the famhp. Only the latter can be used as proof for the implementation of some variations.

9. By using CESP the applicant declares to agree with the conditions as mentioned here http://cesp.hma.eu/TermsConditions

Questions
CESP:
Questions concerning the registration, the technical set-up and the connection can be handled via cesp@hma.eu.

If you need advice concerning a specific submission, please contact the concerned division:

VHBPRE: els.verschaeren@fagg.be , katelijne.vankeymeulen@fagg.be
VHBPOST: iris.geussens@fagg.be; roselien.poppe@fagg.be
VIGILANCE: katrien.bernaert@fagg.be; lesley.verley@fagg.be
VET: dries.minne@fagg.be, valerie.vanmerris@fagg.be
HOMEO-PHYTO: wim.vervaet@fagg.be