ELECTRONIC SUBMISSIONS OF APPLICATIONS FOR MARKETING AUTHORISATIONS FOR HUMAN MEDICINAL USE THROUGH CESP.

What is CESP?

The Common European Submission Platform (CESP) is an initiative of a group of EU member states and industry representatives, managed by the Heads of Medicines Agencies (HMA). The aim of the CESP is to examine whether it is possible to establish an electronic platform to which applications and deviations in the national procedure, MRP and DCP for both human and veterinary medicinal products can be sent.

In October 2011 a Proof of Concept (PoC) was set up to test this. Given the success of this PoC, the next steps were approved by the HMA in November 2011. Two subgroups were established to create a structure for the 'governance' and financing of the CESP as well as to further develop the technical platform. The technical group is responsible for the further development and establishment of an 'extended PoC'. This 'extended PoC', to which 'real-life' applications and deviations could be sent, was also successful. The 'extended PoC' will now be transformed into a 'pre-production pilot' in October. In the coming months the pilot will be moulded further into a complete production environment for the CESP.

New Pilotphase 29/10/2012

Starting on 29 October 2012 it will be possible to submit applications for marketing authorisations and deviations in the national, MRP or DCP procedures through the improved Common European Submission Platform (CESP).

<u>Participation of the FAMHP to CESP</u>
The FAMHP has decided only to accept submissions for new applications for marketing authorisations, human in the national, MRP and DCP-procedure through CESP.
For the time being the FAMHP does not accept submissions of variations, clinical studies, PSUR's or applications for veterinary use.

When submitting through the CESP, the parallel sending of CDs or DVDs to the FAMHP is no longer necessary. This makes submission fast, safe and easy.

The CESP is available for all EU member states and authorisation applicants and holders.

The FAMHP advises all companies to start using the CESP.

Website and registration

The improved CESP can be accessed via http://cesp1.hma.eu. This website contains much information (e.g. FAQs, training videos), and you can register through it for an online training session.

Registration for the improved CESP can be done starting now through this new website. It was decided to employ a "self-service model for user management". This means that every company must appoint its own "company administrator", who establishes and maintains the access to CESP for employees of that company. To initiate the registration of the "company administrator", a form must be completed using the Registration link on the new website.

NB: you can only start submitting applications through the improved CESP on October 29.

Transition from old CESP to improved CESP

Perhaps you have already been using the earlier version of CESP, via http://cesp.hma.eu. This version of CESP will remain operational until October 26. After this date the old CESP environment will be inactive.

NB: even if you are already using the old version of CESP, you must re-register for the improved version in connection with the new "self-service model".

Questions

Please address questions about registration, technical details of setting up the connections or the transfer from the old CESP to the improved version to: cesp@hma.eu.

National contactperson: cesp@fagg.be