



Ministero della Salute

DIREZIONE GENERALE DELLA SANITÀ ANIMALE
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Trasmissione elettronica
N° prot. DGSAF in DOCSPA/PEC

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SUBJECT: Activation of European portal - CESP – for submitting applications for authorization for veterinary medicinal products, including technical documentation/dossiers.

Start of the second phase.

As you know, on September 4th, 2017, the Directorate General for Animal Health and Veterinary Medicinal Products (Office 4) started implementing **CESP (Central European Submission Portal** - www.cesp.hma.eu) for the submission of applications, beginning with the Centralized procedures.

In respect to this, the addressees are informed that as of **April 16th, 2018**, this Office **will only accept the submission of applications** for authorization for veterinary medicinal products, including part 1, **through the CESP** rather than in electronic form (CD-ROM), **also for Mutual Recognition and Decentralised procedures, including any variations.**

The applicant, MAH, shall submit the application, MAA (eAF + dossier), concerning all the aforementioned procedures, through the CESP platform only. The technical documentation (dossier) shall be submitted in VNeS format.

Please note that for ongoing MR e DC procedures, including variations, any further documentation, required to complete the assessment, must be sent via the previous channel (CD-ROM).

We wish to reaffirm that the marketing authorization applications, variation applications, MAH transfers submitted through **purely national procedures, will still have to be submitted through standard channels only** (CD-ROM), until the start of the third phase of implementation.

Details on procedures are available on the Ministry of Health website:
http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=veterinari&menu=immissione

Further specific requests for clarifications/information can be sent to cesp@sanita.it.

This note will be published on the Ministry of Health website.

The Head of the Office
(*Angelica Maggio)

** "handwritten signature replaced by electronic signature under art. 3, par. 2 of Legislative Decree No. 39/1993"*