



Ministero della Salute

DIREZIONE GENERALE DELLA SANITÀ ANIMALE E
DEI FARMACI VETERINARI
Ufficio 4- medicinali veterinari
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<Spazio riservato per l'apposizione
dell'etichetta di protocollo>

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SUBJECT: submission of applications for the authorization of veterinary medicinal products under the national procedure through CESP. **Beginning of phase three.**

As it is known, on 4 September 2017 the Directorate General for Animal Health and Veterinary Medicines - Office 4 – started to use **CESP (Central European Submission Portal - www.cesp.hma.eu)** for the submission of applications for the authorization of veterinary medicinal products, starting from the centralized procedures.

On 16 April 2018, the submission of applications through CESP was also activated for both the mutual recognition and the decentralized procedures.

Considering the serious health situation due to the current COVID-19 epidemic, this Administration has implemented smart working, allowing the staff to access the Ministry only in emergency situations. Consequently, at this moment I cannot access the documents sent in paper form or as a CD-ROM.

Even trade associations claimed they are having trouble preparing and sending documents in paper form and questions have been raised on how to operate.

Given the above, all recipients and MA holders are informed that

starting from 15 April 2020

Office 4 will accept applications for the authorization of veterinary medicinal products, including part I, submitted **through CESP**, instead of the electronic (CD-ROM) or paper format. This will also apply to **national procedures, including variations, renewals and Active Substance Master File (ASMF) deposit.**

The MAH shall submit the application (eAF + dossier), which can refer to any of the procedures above, through CESP. The technical documentation (dossier) shall be submitted in VNeS format. The “*marca da bollo*” to be affixed on the cover letter will be self-certified indicating the serial number of the *marca da bollo* used, which will be kept with the original documentation of the dossier at the company, for this period of emergency due to COVID-19.

Together with the application submitted through CESP, the applicant shall send the contact points below a notification e-mail, specifying the appropriate code referred to in the attached table.

1. Authorizations through the national procedure: a.montinaro@sanita.it;
2. National renewals: l.bindi@sanita.it;
3. ASMF deposit: d.marcoccia-esterno@sanita.it.

In the case the application cannot be submitted through CESP, the applicant shall inform Office 4 by e-mail so as to arrange an alternative solution.

As for the ongoing national procedures, it should be noted that any further documents necessary to complete the procedures can be submitted by the certified mailbox dgsa@postacert.sanita.it up to a maximum size of 50 MB, or through CESP in case of a greater file size.

For any further information on the procedures, please consult the website of the Ministry of Health: http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=veterinari&menu=immissione and the relevant sections.

Further specific requests for clarifications /information can be sent to the e-mail address cesp@sanita.it.

The recipients are kindly requested to disseminate this circular as widely as possible, which will also be published on the website of Ministry of Health.

The Head of Office 4
(*Dr. Angelica Maggio)

**"handwritten signature replaced by printed signature pursuant to article 3, paragraph 2 of Legislative Decree No.39/1993"*

Contact points:
Dr. Stefania Dalfrà
e-mail: s.dalfra@sanita.it
Dr. Anna Soriero
e-mail: a.soriero@sanita.it

Instructions on the data to be provided when submitting the application through CESP

- This message was sent to you automatically by CESP.HMA.EU

A Submission CESP_Submission_679101.xml has been uploaded to your Agency.

Details of your Submission:

First Name :

Surname :

Email :

Contact Number :

Company Name :

Procedure Number : **Insert the national procedure code as indicated in the table below**

- Comments : **Name of product**
- Department Type: Veterinary Medicines
- Regulatory Activity Type : **New MA/ Type-IA variation/ ASMF etc.**
- Sub Activity ID:
- Sub Activity Detail:
- Procedure Type : **National**
- etc.

**Codes to be indicated both when submitting the application through CESP
and in the notification e-mail to contact points**

Type of procedure	Code	
New MA	NA_Name VMP_Nuova AIC	
New MA – Repeat USE	NA_Name VMP_RUP	
New MA – Line Extension	NA_Name VMP_LE	
Type-IA Variations	NA_ n° AIC_ IA	For grouping please add: _G
Type-IB Variations	NA_ n° AIC_ IB	For grouping please add: _G
Type-II Variations	NA_ n° AIC_ II	For grouping please add: _G
Renewals	NA_ n° AIC_ R	
New MA Replies + Line Extension + Repeat USE + Variations + Renewals	To be submitted by certified e-mail To be submitted through CESP only if greater than 50 MB	
ASMF	NA_Name active substance_ASMF	
PSUR	NA_AIC number_PSUR	