



**HELLENIC/GREEK DEMOCRACY
MINISTRY OF HEALTH
NATIONAL ORGANIZATION FOR MEDICINES
284, Messogion Avenue, 155 62 Holargos**

INTERNET UPLOAD

Cholargos, 135785
Protocol number.: 23.12.2020

Division: Product Assessment
Section: Assessment of Veterinary
pharmaceutical products and Animal Feed
Address: 284, Messogion Avenue, 15562
Cholargos
Site: www.eof.gr
Information: Malemis Ioannis
Telephone: 213-2040213
e-mail: vet@eof.gr

DECISION

**Subject: SUBMISSION/REPORTING OF SALES OF VETERINARY MEDICINAL PRODUCTS
BY THE MARKETING AUTHORIZATION HOLDERS & LOCAL REPRESENTATIVES FROM YEAR 2021 ONWARDS**

ENTRY INTO FORCE: From/By the date of signature

Taking into consideration:

- Provisions of Law 1316/1983 (National Gazette 11 A/13-1-1983), as amended and it is in force.
- The obligation for the market to be continuously and adequately supplied with pharmaceuticals to meet/cover market needs in the Greek territory.
- Addressing the use problems of Veterinary Medicinal Products Sales Submission System

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WE DECIDE

In the context of improving the monitoring of the adequacy of medicines in the domestic market, and in conjunction with the modernization of the reporting system for sales of veterinary medicinal products, a new web-based application has been installed on the EOF with the title/name "Veterinary Medicinal Products Sales Submission System". The application became operational on Monday 29/07/2019.

The submission of Veterinary Medicinal Products sales should be carried out according to the following timetable.

Entry/Submission of 1st quarter of each year, until 20/04 of the same year.
Entry/Submission of 2nd quarter of each year, until 20/07 of the same year.
Entry/Submission of 3rd quarter of each year, up to 20/10 of the same year.
Entry/Submission of 4th quarter of each year, until 20/01 of next year

Therefore, the closing date/deadline for the submission of sales data for Veterinary Medicinal Products for each quarter is the 20th day of the following month after quarter expiry/finalization/end

We point out that after the end of the 20th day of the month following the end of the quarter, the Veterinary Medicinal Products Sales Submission System will not allow the submission of the quarter data which have been finalized within the deadline. Any data submitted electronically out of the deadline will be automatically classified as data for the next quarter. That means that, if the data

of the first quarter of 2021 are submitted electronically on April 21, 2021, they are automatically registered in the second quarter of 2021.

We kindly remind that each Marketing Authorization Holder (MAH) or on his behalf the Local Representative (LR) in Greece are required/obliged to register/report/submit the sales **of the whole/sum of the veterinary medicinal products** in the online Veterinary Medicinal Product Sales Submission System. This obligation derives from the provisions of Law 1316/1983 (Government Gazette 11A / 13-01-1983), as amended and in force.

The application is located on the EOF Portal, www.eof.gr, at: on-line Services, "Veterinary Medicinal Products Sales Submission System". Accredited/Authorised users will be logged in using the passwords they already have/acquire and used to submit data to the previous system. New users can request passwords through the application.

According to the Sales Submission System operational principle, each user (company) after logging in to his account using his credential has the ability to submit only the sales of the products that the company name appears in the Marketing Authorization as a Marketing Authorization Holder or as a Local Representative. If a company appears in the Marketing Authorizations of different Veterinary Medicinal Products as MAH or LR with two different EOF codes or names, in order to submit the sales of all products, the creation of two different accounts (and two different credentials) is required. Provided, of course that these two different codes or names correspond to the two different legal entities. Otherwise (in case that these two differed codes or names correspond to the same legal entity) , a national variation should be submitted through the CESP platform in order to change the name of MAH or LR for the Marketing Authorizations that have the incorrect code and / or name of MAH or LR (in order to harmonize the marketing authorizations).

After the user enters the system, to the right of the screen, activating the question mark icon (?) Provided pdf files with detailed instructions for using the application.

To facilitate the sales submission process via the Sales Submission System, two alternative submission methods are available for users:

1. Recoding of each registration individually by typing
2. Ability to load an Excel data file (csv) on the Organization server (Attention! The separator between the columns of the CSV file must be semicolon (;). If the CSV generated by excel has a comma (,) as separator then the following actions should be done: Windows Start menu-> Control Panel-> Region and Language-> Additional settings-> List separator, there type << ; >>)

Due to the problems that arose both in the submission and in the export and processing of the Sales Submission System's data, from year 2021 and afterwards, should be submitting the sales of all the veterinary medicinal products. This also applies to products or packaging that have no sales. The number "0" (zero) will be entered/registered on these products. In order not to be increased the administrative burden on the part of companies regarding the submission of sales, we suggest that the submission be made through data files (Excel-CSV).

After the finalization of each quarter sales data submission, a Signed (Scanned) Responsible Statement/Declaration of Law 1599/1986 should be sent to the EOF only electronically, at: vet@eof.gr in which should be stated that the submission of sales data has been completed and the data are accurate and true.

For any problems that may arise when using the new application, please contact vet@eof.gr or phone 213-2040213.

The President of Board of Directors of EOF

Dimitrios Filippou

INTERNAL DISTRIBUTION

- EOF President of Board of Directors/EOF
- Division of Product Assessment
- Section of Assessment of Veterinary Pharmaceutical Products and Feed
- Information technology Division
- Division of Information and Public Relations