# CYPRUS MEDICINES VERIFICATION ORGANIZATION (Κ.Ο.Ε.Φ)

**Ref. No.** ΚΟΕΦ-002/2017

Nicosia, 20th October 2017

**To:** Wholesalers (Representing Market Authorization Holders), KEFEA PASYPAGEF, ΣFEK, KRINERA

**Copy to:** Registrar Drugs Council (Mrs. Emilia Mavrokordatou)

Dear Collaborators,

**Subject:** Enrollment of Market Authorization Holders (MAHs) to the European Medicines Verification Organization (EMVO) European Hub for the uploading of data to the European Medicines Verification System (EMVS)

With reference the above subject and to the obligation of the Republic of Cyprus to implement Directive 2011/62 / EU (FMD) and Regulation 2016/61 (DR), applicable on 9 February 2019 you are kindly requested to inform the Marketing Authorization Holders (MAH's) you represent, to proceed, as soon as possible, with their enrollment to the EMVO (European Medicines Verification Organization) repository.

Upon completion of their enrollment, they will be enabled to upload data for prescription medicinal products for which they hold a Market Authorization License, as provided for, in the aforementioned Regulation. For the best possible co-ordination, any action by the MAH's should be performed, following consultation / cooperation with the pharmaceutical companies they represent.

The data to be uploaded to the EMVO repository under the provisions of Article 4 of the Regulation include the following:

(i) a code identifying at least, the name, common name, pharmaceutical form, dosage, pack size and package type of the medicinal product bearing the unique identification code ("product code"),

(ii) an arithmetic or alphanumeric sequence of up to 20 characters, generated by a determinant or non-specific randomization algorithm ("serial number");

(iii) batch number;

(iv) expiry date.

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The uploading of prescription medicine's data in the EMVS repository will allow for the authentication and decommissioning of the unique serial code of the medicinal products, before they are dispensed to patients, in all markets of the European Economic Area, where they are exported and sold.

The enrollment process of the MAHs as OBP's (On Boarding Partners) which will enable them to upload data to the EMVS (European Medicines Verification System) should begin as soon as possible because, for security reasons, the system will perform a multi stage verification procedure of the data entered and the whole process will need some time to be fully completed. A presentation demonstrating the whole process step by step is hereby attached.

It should be noted that MAH's who will need to generate their own product codes (item (i) above) should be registered members, of GS1, Cyprus (Chamber Building, Andreas Andreou, tel. 22889737) enabling them to obtain GTIN (Global Trade Item Numbers).

We are hoping for your cooperation and immediate response on the above issue because, any delay in fulfilling our obligation to implement the aforementioned Regulation before the 9th February 2019 will directly impact sales of medicinal products in Cyprus as well as, in other markets of the European Economic Zone having implemented the verification and decommissioning system.

We remain at your disposal for any assistance you, or the MAHs you represent, may require.

Yours faithfully,

Arthur Isseyegh
Director ΚΟΕΦ

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