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Pharmaceutical Services,
Ministry of Health,
1475 Nicosia,
CYPRUS

Act. Director
Pharmaceutical Services,
for the att. of Mrs Emily Mavrokordadou,

Date 12th December 2017

We are writing to you in the spirit of a joint initiative of the European Medicines Verification Organisation (EMVO) and ΚΟΕΦ to raise awareness at national level.

With regard to the high risk that represents falsified medicines entering the legal pharmaceutical supply chain in Europe, the European Commission published on the 1st of July 2011 the Falsified Medicines Directive (Directive 2011/62/EU) introducing tougher rules to improve the protection of public health with new harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled. The Directive is supplemented by a Delegated Regulation (2016/161 DR), as published on the 9th of February 2016, that details the characteristics of the safety features, how medicine authenticity should be verified, and by whom within the pharmaceutical supply chain.

Together with EMVO we undertake all actions necessary to set up the European Medicines Verification System in time and to ensure that the system will be compliant with the FMD provisions. Our common goal is to reach out and connect more than 2000 pharmaceutical corporations to the EU Hub. **So far, only 300 of them started the on-boarding process**. The challenges ahead of us are colossal and we can no longer progress without your support.

Indeed, the system architecture requires that pharmaceutical corporations are connected to the EU Hub, while end-users (i.e mainly private (community) pharmacies, wholesalers, private hospitals and public hospital pharmacists) have to be connected to the National Medicine Verification System. However, as you may imagine, the CyMVO and EMVO's ability to reach the national pharmaceutical corporations and national end-users is limited in force and scope. Consequently, we believe that thanks to your network, access to data and expertise, your entity has a major role to play in making sure that all parties involved are aware of their duties and have all information in hand to ensure their compliance with the legislative provisions in due time.

Within this frame, please allow us to detail each party's responsibilities.

On the one hand, pharmaceutical corporations have to proceed with an on-boarding process to the EMVO and become therefore On-boarding Partners (OBPs). The on-boarding is an online based process which is composed of several steps in which the OBP is asked to provide company information, to sign a Participation Agreement with EMVO, and to go through a Legitimacy Check before accessing the technical related part of the development of its connection to the Hub. The OBP is the legal entity that have to conduct the on-boarding on behalf of all its affiliated Marketing Authorisation Holders (MAHs) and develop the connection to upload their data to the EU Hub. In order to cover these on-boarding costs and share the burden of the Hub development costs, the OBP will be requested to pay a onetime on-boarding fee. The amount of the fee depends on the total number of MAHs affiliated to the OBP and the latest fee enforced at the time of the on-boarding.

On the other hand, end-users have to on-board to each NMVO of the national territories they are active in. The whole verification process will take place at national level, while the EU Hub will act as a data router and allow for inter-market operability. In order to share the burden of the development of the National Medicines Verification System (NMVS) and the maintenance of the whole European Medicines Verification System (NMVS and EU Hub), the MAHs will be requested to have a contract in place and pay an annual flat fee to each NMVO of the national territories they are active in.

Those two requirements combined are a prerequisite to allow companies to offer medicinal products on the European market from February 2019 onwards.

It is now urgently required for those companies to on-board to the relevant organizations as this process may take some time. Pharmaceutical corporations have now to take appropriate actions in order to be compliant in February 2019. In order to raise awareness on national level, EMVO and our national organization need your support in your capacity as national competent authority in that field.

Therefore, in order to be as helpful as possible towards the on-boarding processes to come, we would be thankful if you could share the following sources of information:

- The EMVO Website (in English), including documentations, detailed information and videos regarding the initial on-boarding www.emvo-medicines.eu
- The EMVO On-boarding Portal
- The EMVO Helpdesk, reachable by mail at helpdesk@emvo-medicines.eu or by phone +372 611 90 44 from Monday to Friday.
- Director of ΚΟΕΦ Mr. Arthur Isseyegh by email at artouros@ldlaw.com.cy or by phone 99650285

In addition, please allow us to highlight that the hospital sector isn't standing in an advanced stage of the process, at the moment. While the European Association of Hospital Pharmacists (eahp) and the European Hospital and Healthcare Federation (HOPE) recently joined the EMVO affiliated membership, it seems that there remains an important lack of awareness, knowledge and commitment within the sector. As an important majority of the European hospitals are publicly financed, an awareness campaign addressed to all hospitals and, when the context suggests it, to the relevant payers and decision makers at national, regional or local level (s) is more relevant than ever. It should be ensured by

National Competent Authorities that public hospitals benefit from a sufficient allocation of resources, the setting-up of an implementation plan and a robust change management scheme, the efficient adaptation of their processing and the development best-practices sharing.

The countdown is running quickly and we are hopeful we can count on your support in order to ensure that we would all be ready on time. In addition, any proactive communication campaign would of course be highly appreciated.

In the meantime, please do not hesitate to contact us in case of any questions or if any element remains unclear.

We thank you very much in advance for your consideration and the actions you would take in that field.

Yours sincerely,

Arthur Isseyegh
Director ΚΟΕΦ