Subject: Joint call of the National Institute of Pharmacy and Nutrition and the Hungarian Medicines Verification Organization Non-profit Plc. (HUMVO) to the Marketing Authorization Holders active on the Hungarian market regarding the registration/on-boarding process to the HUMVO

Dear Marketing Authorization Holder!

As you are probably informed, the Article 54(a) of DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Community code relating to medicinal products for human use requires the mandatory placement of the safety features on the packaging of certain prescription medicines.


Marketing Authorization Holders will be responsible for providing all products that are covered by the legislation after 9 February 2019 with appropriate safety features (a unique identifier and antitampering device).

Under the Regulation, interconnected databases operated by non-profit legal entities at EU and Member State level should be established to ensure the end-to-end verification of the medicines bearing the safety features.

The European central repository was developed and is improved continuously by the European Medicines Verification Organization ("EMVO"). HUMVO, as national medicines verification organisation is responsible for creation and operation of the Hungarian National Medicines Verification System (HUMVS).

The HUMVO Board of Directors has been negotiating with EMVO’s pre-qualified service providers regarding the setting up of the HUMVS. As a result of these negotiations HUMVO
has signed the contract with Arvato Systems GmbH for elaborating the HUMVS. Annex 1. contains the preliminary timeline of the system implementation.

According to the Article 54(a) of Directive 2001/83/EC the costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.

The key steps to be undertaken by Marketing Authorization Holders to comply with the new requirements include:

- Identifying the products in scope of the new requirements and require safety features (as defined in Article 2 of the Commission Delegated Regulation (EU) 2016/161).
- Changing packaging to include safety features and having it approved by the regulatory authority.
- Upgrading production lines to apply the unique identifiers and anti-tamper device.
- Onboarding to the EU Hub which is managed by EMVO – see EMVO website for details of onboarding process which has both contractual and technical elements.
- Registering with HUMVO and paying the relevant fees.

Steps of registration to HUMVO:

1. Complete the registration form so we have all your details, including invoicing requirements. The aim of the registration is the identification of all parties having valid Marketing Authorization in Hungary for products covered by the DA and therefore will have payment obligation for HUMVO. One form will be required per MA holder, but this may be completed by the local affiliate based on a written agreement.

2. Signing the HUMVO MAH Agreement: Each Marketing Authorization Holder will be required to sign a separate agreement, which will be sent by HUMVO, who is currently working on the elaboration of this contract.

Please send your response including the filled in registration form (attached as Annex 2. to this mail) to HUMVO’s address info@humvo.hu until 20 March 2018. In case of any questions concerning this mail please feel free to contact HUMVO on the same address.

Determination of the payable fees is in process; the exact fee will be communicated before sending the final agreement.

We would like to emphasize that until 9 February 2019 the whole Hungarian pharma supply chain should be connected to the European Hub through the National Repository to comply to the requirements set out by the regulation. To do this, both the setup of an organizational background and the right infrastructure is necessary.
We kindly ask for your constructive support and cooperation concerning the above to successfully setting up the Repository System in Hungary until the required deadline and with all the necessary services defined by the regulations.

Budapest, 5 March 2018

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