Latvijas Zāļu verifikācijas organizācija, biedrība
Reģistrācijas Nr. 40008259320, PVN Nr. LV40008259320
Kr. Barona iela 13/15-50, Rīga, LV-1011

Letter No.: LETT- 0054/1

Date: 15-01-2019

To: Marketing Authorization Holders (MAH)

Regarding: MAH contacts for alert handling process

According to our responsibilities Latvian Medicines Verification Organization (LZVO) is currently working on establishing the Alert management process in Latvia in close cooperation with Latvian National Competent Authorities (NCA).

Based on the legal acts of the Republic of Latvia: Cabinet Regulation No. 416, adopted 26 June 2007, "Procedures Regarding the Distribution and Quality Control of Medicinal Products", the Health Inspectorate (*Veselības Inspekcija*) is the Competent Authority in Latvia who will examine each potential falsification case individually.

Therefore, in Latvia the short guideline to all end users regarding the alert handling procedure:

- Currently there are 10 error codes that cause alert in the system.
- If medicine receives alert ID, it must be placed in quarantine after 9 February 2019.
- Each end user (pharmacy, wholesaler, hospital or other healthcare institution) has to report to Health Inspectorate about the alert affected medicine and to inform also MAH. Hospitals and other healthcare institutions must inform only Health Inspectorate.
- MAHs have to inform Health Inspectorate about potential falsification cases too.
- All involved parties (MAH, end user, LZVO) directly have to inform Health Inspectorate about the results of investigation done.
- If MAH has found technical issue/reason of alert, he is obliged to inform the end user and the Health Inspectorate. Based on the provided information/prove, the end user can release the product from the quarantine.
- If no reason is found, Health Inspectorate takes further decision on investigation and handling of the product.

In order to quickly solve technical issues and investigate alerts in LZVO system after 9 February 2019 we kindly ask you to provide us with the following information:

MAH name	
e-mail address	
phone number	

We inform you that LZVO will share these contact details with end users and NCAs via e-mail or on website www.lzvo.lv in order to facilitate to investigate and handle alert issues. Please note that if the above listed contact details include personal data (e.g. the e-mail address contains name and surname

of a MAH employee) you are responsible for obtaining the data subject's consent for publishing of this data on the website www.lzvo.lv. Such consent is not required if the respective contact details do not include any personal data.

Please, indicate in your response if you would prefer that the contact details are not published on the website www.lzvo.lv but only shared with the end users and NCAs trough e-mail.

If any of the contact details above include personal data then please forward to the respective person, whose data is concerned the following information as per Article 14 of the GDPR:

1) the data controller is Latvijas Zāļu verifikācijas organizācija, reg. No. 40008259320 (**LZVO**), e-mail: info@lzvo.lv;
2) the data controller's data protection officer can be reached via e-mail: info@lzvo.lv;
3) the purpose of processing is outlined above (investigation and handling of alert issues); the legal basis of overall processing is to ensure LZVOs compliance with its legal obligations under Commission Delegated Regulation (EU) 2016/161 and Directive 2011/62/EU as well as protection of the vital interests of natural persons through ensuring that falsified medicines are not distributed on EU market (GDPR, Article 6 1.(c) and 1.(d)); the legal basis for publishing your contact details on the www.lzvo.lv website is your consent that you have provided to the MAH (GDPR Article 6 1.(a));
4) categories of personal data processed – name and contact details of the MAH contact person;
5) the personal data may be shared with end users of LZVO system and NCAs through e-mail and/or published on www.lzvo.lv website; you may at any point withdraw your consent for your contact details being published on www.lzvo.lv website;
6) the personal data will be stored for as long as is necessary for the purpose of data processing described above;
7) data subject has the right to request access to and rectification or erasure of personal data or restriction of processing concerning the data subject and to object to processing as well as the right to data portability;
8) the data subject has the right to lodge a complaint with a supervisory authority - Data State Inspectorate.

We kindly ask you to submit the information mentioned above to info@lzvo.lv until 18 January 2019.

Considering experience from other countries as well as receiving first feedback reports from our end users, LZVO has several cases when serialized products are physically on the Latvian market, but product and batch data are not uploaded in the European HUB.

Therefore, we kindly ask you to confirm that MAH you represent will do the retrospective upload in EU-HUB of all serialized products for Latvian market until end of January 2019!

Sincerely

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Chairman of the Board