THE REPUBLIC OF LATVIA
STATE AGENCY OF MEDICINES

INFORMATION FOR MARKETING AUTHORISATION HOLDERS AND SPONSORS OF CLINICAL TRIALS CONCERNING E2B IMPLEMENTATION STATUS IN LATVIA

Electronic reporting of Individual Case Safety Reports (ICSRs)

In accordance with Commission Implementing regulation (EU) No 520/2012 adopted 19 June 2012 on the performance of pharmacovigilance activities provided in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (herenafter – Implementing regulation) and the Cabinet Regulation of Latvia No 47 adopted 22 January 2013 'Procedure for Pharmacovigilance' marketing authorisation holders (MAHs) shall ensure the availability of the adverse drug reaction reports in the European Union database (hereinafter - Eudravigilance database).

The State Agency of Medicines of Republic of Latvia (SAM) has implemented the European Union (EU) electronic data exchange system of adverse reactions through the web trader component of EVWEB and the following rules apply for spontaneous reports and reports from non interventional studies:

- the SAM Pharmacovigilance Department message receiver identifier for the post-authorisation module in the ***production environment*** is ***LRZBP2005***
- the SAM Pharmacovigilance Department message receiver identifier for the

post-authorisation module in the ***test environment*** is ***LRZBP2005T.*** As the SAM is using Eudravigilance web trader it is not requested for marketing authorisation holders to perform the testing.

The marketing authorisation holders (MAHs) are obligated to report to the SAM:

All serious suspected adverse reactions ocurring in Latvia which are brought to attention by report from a healthcare professional, pharmacist or patient or during a post-authorisation study immediately, but no later than 15 days after receiving the information.

The following adverse drug reactions shall be transmited electronically to message receiver identifier ***LRZBP2005***.

The SAM will send an acknowledgement for the received report. The SAM is responsible for forwarding information regarding all serious adverse drug reactions occurring in Latvia to the European Medicines Agency (EMA). Therefore, the MAHs should not send serious reports

originating from Latvia directly to the EMA, as this will result in duplicates in the European pharmacovigilance database (EudraVigilance).

- When reporting a Latvian literature case, a copy of the article, should be

sent by post, fax +371 67078428 or e-mail Kristine.Plensnere@zva.gov.lv to the Adverse Drug Reactions Monitoring Department of SAM.

- Non-serious suspected adverse drug reactions ocurring in Latvia are collected by MAH. The submission of non-serious cases to SAM is not required. Reporting requirements of serious and non-serious adverse reactions **during the interim period** are available on the Eudravigilance website: Reporting requirements of Individual Case Safety Reports (ICSRs) applicable to marketing authorisation holders during the interim period.
- Serious adverse reactions occurring in third countries
  All suspected serious adverse reactions occurring in the territory of a third country should be transmitted electronically directly to the EudraVigilance database by the MAH. The MAH should indicate as message receiver identifier **EVHUMAN**. It is not necessary to report cases from the third countries to the SAM, as they are available to the SAM via the EudraVigilance database.

The reporting responsibilitys should be fulfilled in accordance with:

- EMA/873138/2011 Guideline on good pharmacovigilance practices (GVP), 22 June 2012 Module VI – Management and reporting of adverse reactions to medicinal products
- The Extended Eudravigilance Medicinal Product Report Message (XEVPRM), which is the format for the electronic submission of information on all medicinal products for human use authorised in the Union in accordance with the second subparagraph of Article 57(2) of Regulation (EC) No 726/2004, as published by the Agency
- ICH E2B(R2)‘Maintenance of the ICH guideline on clinical safety data management: data elements for transmission of Individual Case Safety Reports’

ICH M2 standard ‘Electronic Transmission of Individual Case Safety Reports Message Specification’

Electronic reporting of Serious Unexpected Suspected Adverse Reactions (SUSARs)

In accordance with the Directive 2001/20/EC and the Cabinet Regulation No 289 'Regulations on Conducting Clinical Trials and Observational Studies and Labelling of Investigational Medicinal Products, and Procedure for Conducting Inspections on Compliance with the Requirements of Good Clinical Practice' of 23 March 2010, **the sponsors of clinical trials conducted in Latvia shall transmit electronically all serious unexpected suspected adverse reactions (SUSARs) to the Eudravigilance**

Clinical Trials Module. SUSARs that occur in the trial sites in the territory of Latvia should also be submitted electronically to the SAM-Latvia clinical trial module.

The above responsibility should be fulfilled in accordance with the 'Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (`CT-3´) (2011/C 172/01). The SAM-Latvia has implemented the EU electronic data exchange system of adverse reactions through the web trader component of EVWEB. For interventional clinical trials, the following rules apply:

Sponsors of the clinical trials conducted in Latvia should report SUSARs occurring in the territory of Latvia electronically to

- The SAM-Latvia clinical trial module with the message receiver identifier **LRKPN2005** and to
- The EudraVigilance Clinical Trial Module with the message receiver identified **EVCTMPROD**

Sponsors of the clinical trials conducted in Latvia should report SUSARs occurring outside the territory of Latvia directly to the Eudravigilance Clinical Trials Module with the message receiver identifier **EVCTMPROD**.

CONTACT INFORMATION

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