Translation from Latvian

April 26th, 2019

JSC "OLAINFARM" PHARMACOVIGILANCE DATA PROTECTION POLICY

JSC "Olainfarm" (Olainfarm) is marketing authorization holder (MAH) both in and outside European Union (EU).

MAH has to ***set up and maintain pharmacovigilance system designed to monitor the safety of authorised medicinal products and find any changes in their risk-benefit balance*** (the Objectives) in accordance with EU and Republic of Latvia legislation in force. Processing of personal data, including special categories of personal data (**Personal data**) of natural persons is performed to achieve the Objectives. Realisation of the Objectives and processing of Personal data by the controller as public health protection measures are necessary for compliance with a legal obligation and in the public interests; measures correspond to lawfulness criteria of Personal data processing set in Article 6 (1c) and Article 6 (1e) of GDPR[1] and Commission implementing regulation[2] establishing that the Objective of public health protection is essential public interest.

Personal data privacy requirements should apply to any information that itself or together with other information allow to identify natural person (Data subject). Olainfarm respects privacy and strictly defines and controls Personal data which are collected and processed. Olainfarm ensures proper Personal data protection according to approved data protection regulations.

Olainfarm processes Personal data fairly, ensuring maximal transparency in relation to Data subjects (patients) by providing them concise, transparent information in an intelligible and easily accessible form, using clear and plain language.

Olainfarm does not process personal data without a legal basis and specified, explicit and legitimate purposes: processing of personal data is based on MAH competence, ensuring the Company's obligations in the collection, processing, analysis and reporting of Individual Case Safety Reports (ICSRs) established in Article 24 of Regulation[3] (EC) No 726/2004, Articles 107 and 107a of Directive[4] 2001/83/EC, as well as in Modules of Good pharmacovigilance practices delegated by Article 108a of Directive 2001/83/EC, particularly ensuring the obligation of GVP ADR Module[5]. These Obligations correspond with information set in Article 9 (2i) of GDPR with regard to processing of special categories of personal data for reasons of public interest in the area of public health.

Olainfarm does not process Personal data in a way incompatible with the Objectives. Olainfarm by default processes Personal data which:

- are necessary for the achievement of the specific purposes;
- are accurate and, where necessary, kept up to date; Data subjects are co-responsible for accuracy and timely updating of their Personal data.

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[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

[2] Commission implementing regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for 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

[3] Regulation (EC) no 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[5] Guideline on good pharmacovigilance practices (GVP)
Module VI – Management and reporting of adverse reactions to medicinal products

Within the context it is important to understand that natural person, who reports on ADR (Reporter) and patient (about whom information is provided) should be identifiable for validation and processing of ICSR by Olainfarm to ensure the Company's obligations established by EU regulations.

Personal data which allow to identify Reporter and patient are as follows:

1. Identifiable reporter (Data subject) characterized by parameters established in EU Pharmacovigilance regulations and guidelines:
- Possible category of Data subjects (e.g. physician, pharmacist, other healthcare professional, lawyer, consumer or other non-healthcare professional),
- Possible types of processing of Personal data: name, initials, or address (e.g. reporter's organisation, department, street, city, state or province, postcode, country, email, phone number)

2. Identifiable patient as Data subject characterized by at least one of the following qualifying descriptors established in EU Pharmacovigilance regulations and guidelines:
Possible types of processing of Personal data: name, surname, initials, medical record number (from general practitioner, specialist, hospital, or investigation), date of birth, age, age group, gestation period, gender.

The term 'identifiable' refers to the possibility of verification of the existence of a patient based on the available information.

In a scope of Pharmacovigilance activities information on patients is collected, processed, stored and revised according to the requirements established by regulations on ADRs' circulation. In a scope of ICSRs, received pharmacovigilance data may include special categories of personal data which are related to patients or their authorized representatives (e.g. family member).

Within the context following information for effective safety analysis should be taken into consideration: patient age and / or age group, sex, weight, height, ethnic group, relevant medical history (including disease anamnesis), initials or assigned ID number and / or birthdate. Patient initials or assigned ID number and / or birthdate are important for identification in cases when the same ICSR was reported repeatedly (duplication of ICSR); name and contact details of the reporter are important for collection of follow-up information in order to ensure completeness and accuracy of ICSR data.

ICSRs and all related information are electronically entered in validated ADR database which is located in JSC "Olainfarm" information system server. Any information which can allow to identify patient or reporter Personal data is masked (anonymized) by usage of nullflavor flags "Masked". Received ICSRs and all related additional information is uploaded in PHG ADR database which is protected with encrypted password.

All identifiers which allow to identify the patient are anonymized (masked) when information on ADR is transmitted to Pharmacovigilance Regulatory Authorities (e.g. European Medicines Agency).

According to EU Individual Case Safety Report (ICSR) Implementation Guide[6] for undermentioned categories of data the "MSK" flag is not considered valid: HP qualification, literature reference, clinical trial / clinical study EU registration number, patient sex, patient last menstrual period date, medical history start date, medical history continuing, medical history end date, text for relevant medical history and concurrent conditions (not including reaction / event), relevant past drug history start date, relevant past drug history end date, date of death, last menstrual period date of parent, sex of parent, relevant medical history and concurrent conditions of parent start date/ continuing / end date, relevant past drug history of parent start date, relevant past drug history of parent end date, date of start / date of end of reaction / event, date and time of start of drug and date and time of last administration.

[6] EU Individual Case Safety Report (ICSR) Implementation Guide EMA/51938/2013 Rev 1 (or a valid updated version of the document)

Olainfarm understands the responsibility of healthcare professionals (HP; e.g. physician, pharmacist) as Reporters and Data controllers to report on the observed suspected adverse drug reactions to the appropriate Regulatory Authority or to the respective marketing authorisation holder and ensures safety of Data subject's (patient's) Personal data[7].

Personal data are submitted to JSC "Olainfarm", Rupnicu street 5, Olaine, LV-2114 and are located and stored in JSC "Olainfarm" information system server for as long as the product is authorised and for at least 10 years after the marketing authorisation has ceased to exist according to Commission implementing regulation. Personal data are deleted or anonymized immediately after achieving relevant purposes; JSC "Olainfarm" has rights to continue the processing of Personal data for purposes other than those for which the personal data were initially collected only where the processing is compatible with the purposes for which the personal data were initially collected. Olainfarm fulfils organisational and technical measures to ensure appropriate security of Personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage in compliance with risk degree of processing of Personal data.

Set of documents and measures, including regular employees' education, is established and continually developed at the Company in order to achieve the Objectives.

If you have any questions regarding this policy, please contact:

JSC "Olainfarm"
Rupnicu street 5, Olaine, LV-2114
by email: dataprotection@olainfarm.lv
or phone: +37128327856 (mobile phone)

If you have question regarding pharmacovigilance, please e-mail adr@olainfarm.lv or phone +371 67013724 (on working hours); +371 26137761 (24-hour mobile phone).

JSC „Olainfarm" Chairman of the Board (*signature*) L.Macijevskis

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TRANSLATION APPROVED:

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[7] Republic of Latvia Cabinet Regulation No. 47 adopted 22 January 2013 Pharmacovigilance Procedures