TABLE OF CONTENTS

Personal data processing – any operation or any set of operations concerning personal data, including in any case the collection, recording, organization, storage, updating or modification, retrieval, consultation, use, dissemination by means of transmission, distribution or making available in any other form, merging, linking, as well as blocking, erasure or destruction of data.

Special categories of personal data – data related to racial or ethnic origin, political opinions, religious belief, trade union, membership, physical, physiological, genetic, mental and other features.

Distribution of personal data – actions related to making the data available to indefinite range of persons.

Provision of personal data – actions related to making data available to a definite person or a definite range of persons.

Random number generator – is a sequence of numbers or symbols, what means the particular outcome sequence will contain some patterns detectable in hindsight but impossible to foresee.

For other terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

V. PROCEDURE

A. General Specification

The patient/reporter must provide their informed consent to allow the collection of personal data, which includes any information that can directly or indirectly identify an individual, such as names, email addresses, IP addresses, and more.

Processing and/or collection (where required) of Personal data at Pharmex conducts by Responsible person appointed by Director. Data confidentiality requirements should be adhered by Responsible person according to local legislation of the countries of activity.

Only the data needed for any individual subtask can be handled.

Personal Data shall be stored for the current period of time for the particular Data Processing purpose.

B. Process

1. Pseudonymization and anonymization

Pseudonymization uses a form of encryption to translate identifiable parts of personal data to unique artificial identifiers, so-called pseudonyms. By using pseudonymization you are applying a security measure to the personal data you have. Pseudonymization means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific person without the use of additional information. Such additional information must be kept carefully separate from personal data.

Pseudonymization and encryption of received Personal Data happens in accordance with ENISA recommendation. Counter and Random Number Generator are used in pseudonymization with the use of mapping table (using a multi-digit combination of letters and numbers). It is always considered that the pseudonymization process is performed by a Responsible Person as part of the operation/provision of a service.