

I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure of lawful handling of Personal Data of staff and personnel, also patients and clients in relationship with pharmacovigilance activities in accordance with local legislation at PharmExpert LLC (Pharmex).

II. SCOPE

This procedure shall apply to requirements of management the processing of Personal Data in a manner that recognizes the right of individuals to protect their Personal Data in Pharmex.

III. RESPONSIBILITIES

Role	Responsibility
All employees of Pharmex	<ul style="list-style-type: none">Fully adhere to this SOP
Responsible Person	<ul style="list-style-type: none">Ensure the confidentiality, security and retention period of Personal Data
Director	<ul style="list-style-type: none">Oversight and implementation of this procedure

IV. DEFINITIONS

Abbreviations used in the text are spelled out on its first mention.

Data anonymization – the process of protecting private information by erasing or encrypting identifiers that connect an individual to stored data.

Pseudonymization – is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Pseudonym – also known as cryptonym or just nym, is a piece of information associated to an identifier of an individual or any other kind of personal data (e.g. location data). Pseudonyms may have different degrees of linkability (to the original identifiers).

Data subject – any natural person, whose personal data is being processed, e.g. employee, research subject, investigator, representative of the sponsor or any other natural person.

Personal data – is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Anonymization is the process of removing personal identifiers, both direct and indirect, that may lead to an individual being identified. Also, this process is about protecting private or sensitive information by erasing or encrypting identifiers that connect an individual to stored data. The purpose of anonymization is to prevent individuals in a dataset from being identified.

2. Personal Data in pharmacovigilance

Pharmex may receive Personal Data directly from patients or other sources (health care professionals, medical representatives, social network, literature search) during the pharmacovigilance services performance.

Significant Personal Data that might be collected during Pharmacovigilance activities are: patient initials, ID number, (demographic information (age, year or date of birth, gender), state of health and medical history, such as information about adverse reaction details of the product suspected of having caused an adverse reaction, including information about the dose taken and/or prescribed, contact details of patient or reporter for follow-up process.

a) If information was received via phone by patient/reporter:

- Introduce the general notice below regarding privacy of Personal Data.
- If the patient does not want his or her contact details recorded as part of the AE report, the patient must be informed that the company is legally required to record an anonymized form of the AE report and that the patient will not be able to get a copy of the report if their contact details are redacted.
- Only essential information for further case investigation shall be collected.

b) If information was sent via e-mail:

Assure the patient/reporter about confidentiality of his/her Personal Data using the following notice statement regarding personal information collection.

Notice (regarding Personal Data protection):

"All the information and personal data you will share with PharmExpert LLC will be protected and kept confidential in accordance with local regulations. The information will be used only for the purpose of drug safety surveillance and it may be shared with health authorities and made available in their regulatory databases".

Note. An electronic mail (e-mail) address constitutes a typical identifier of an individual. An e-mail address has the form local@domain, where the local part corresponds to the user that owns the address and the domain corresponds to the mail service provider. Users tend to use the same e-mail address for different applications, sharing it with various organizations, due to these special characteristics, when e-mail addresses are used as identifiers, their protection is essential. Both counter and RNG can be used for the pseudonymization of emails.