Data protection notice for pharmacovigilance declarations

Pharmacovigilance covers all activities aimed at monitoring, evaluating, understanding and preventing adverse drug reactions (ADRs) resulting from the use of medicinal products in humans.

The aim of this system is to collect information on the risks posed by medicines to patients' health and to public health in general. It ensures the safety and proper use of medicines, best informs patients and healthcare professionals, and continuously ensures a positive benefit-risk balance for patients.

The monitoring of pharmacovigilance declarations made under this system is based on the collection and processing of personal data.

In this context, the personal data of the persons reporting adverse drug reactions, as well as those of the patients concerned, are collected and processed by the Division of Pharmacy and Medicines of theDirectorate of Health in order to continuously ensure the safety of medicines on the market, in accordance with Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter "the Regulation").

The processing of personal data in the context of pharmacovigilance reports is carried out in order to (I) be able to contact reporters again when additional information on reported ADRs and their evolution is required, (II) avoid multiple registration of the same adverse reaction report in the European pharmacovigilance database, (III) monitor the safety of the medicine(s) or vaccine(s) and its/their quality, in order to ensure a positive benefit-risk balance for patients.

The legal basis for this processing is to be found in:

- Loi du 24 novembre 2015 modifiant la loi modifiée du 21 novembre 1980 portant organisation de la Direction de la santé et la loi modifiée du 16 aout 1968 portant création d'un Centre de logopédie et de services audiométrique et orthophonique ;
- Loi du 4 juillet 2000 relative à la responsabilité de l'État en matière de vaccinations ;
- Règlement grand-ducal modifié du 15 décembre 1992 relatif à la mise sur le marché des médicaments.

The categories of personal data processed by the Division of Pharmacy and Medicines are as follows: they depend on the spontaneous reporting of adverse reactions by citizens or health professionals to the Directorate of Health:

1. For the person reporting the adverse reaction to the Division of Pharmacy and Medicines:

- Identification data (surname, first names, qualification and doctor code for health professionals);
- Contact details (telephone number and/or e-mail address);

in order to be able to contact the reporter again if additional information is required.

2. For the patient concerned by the declaration:

- Identification data (initials, date of birth, gender, weight, height) to avoid multiple registration of the same adverse reaction report;

- Relevant data on the patient's state of health (known allergies, addictions, current diseases, medical history, ongoing drug treatments).

The provision of such data is necessary to enable pharmacovigilance declarations to be properly monitored and recorded.

Personal data are transferred by the Division of Pharmacy and Medicines to the following recipients:

- The *Centre Régional de Pharmacovigilance de Nancy* (CRPV) to which the Pharmacy and Medicinal Products Division has entrusted the analysis of dossiers relating to pharmacovigilance declarations. The *Centre Régional de Pharmacovigilance de Nancy* may contact reporters if necessary, analyses the potential link between the reported adverse reaction and the medicine or vaccine, and register all previously pseudonymised reports in the European Pharmacovigilance Database.

- The European Medicines Agency (EMA), in pseudonymised format, via the European pharmacovigilance database, EudraVigilance. Personal data concerning the person reporting the reaction is not transferred. The data in EudraVigilance are accessible to the other National Competent Authorities of the Member States of the European Union, and for the firm holding the marketing authorization for the medicine suspected of causing the adverse reaction. The purpose of this sharing is to enable the entities responsible to ensure the safety of the medicinal products for which they are responsible. For more information on data processing and how EudraVigilance works, please refer to the EMA's Data Protection Notice on this subject[1].

Personal data is kept by the Division of Pharmacy and Medicines (DPM) for a period not exceeding that necessary for the purposes pursued, in accordance with its legal obligations. This period is 10 (ten) years after the end of the marketing of the medicines concerned by the declaration, as defined by Article 16 of Implementing Regulation (EU) 520/2012 of the European Commission.
After twenty (20) years of storage at the DPM, pharmacovigilance data and documents are transferred to the Luxembourg National Archives for historical storage. While the DPM will still be able to access it as part of its tasks, given the sensitivity of the data concerned, pharmacovigilance cases will be protected by a period of communication to the public.

Any person whose data are processed has the right to request access to his personal data and to obtain a copy of it and, if the personal data are incomplete or incorrect, to have it corrected. They also have the right to limit the processing of their personal data, the right to object to their use and the right to have them erased, under the conditions and within the limits provided for by the General Data Protection Regulation.

It is possible to exercise the rights listed above by submitting a written request and proving his identity to the Directorate of Health, by email to info_donnees@ms.etat.lu or by post to Directorate of Health, Data Protection, 13a, rue de Bitbourg, L-1273 Luxembourg.

[1] https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-eudravigilance-human-ev_en.pdf

It is also possible to submit a complaint with the National Commission for Data Protection by post to the following address: 15, boulevard du Jazz, L - 4370 Belvaux or by completing the online form which is available on the CNPD website in the Individuals section “Particuliers Faire valoir vos droits” (“Enforcing your rights”).