

Data protection notice concerning declarations of quality defects of medicinal products for human and/or veterinary use

As part of the quality defect declaration form for medicinal products for human and/or veterinary use, the personal data of the persons reporting quality defects, as well as those of the patients concerned, if applicable, are collected and processed by the Division of Pharmacy and Medicines – Health Directorate, in order to continuously ensure the quality and safety of medicinal products on the market.

The processing of personal data is carried out in order to be able to contact the reporter of the alert if any additional information on the declared quality defect(s) is required. In particular, in cases where the pharmaceutical company would need to collect the affected medicine to carry out in-depth analyses and determine the causes, consequences and decisions to be made regarding the medicinal product.

The personal data collected are as follows:

1. Using the declaration form for quality defects of medicinal products intended for patients:

The personal data collected from the patient or reporting person (if the reporting person is not the patient) are: first name, surname, telephone, email address, postal address.

This data will not be transferred by the DPM.

2. Using the declaration form for quality defects of medicinal products intended for healthcare professional, wholesaler-distributor and marketing authorisation holder:

The personal data collected from the issuer of the report are: first name, surname, profession or name of the wholesale distributor or name of the marketing authorisation holder, telephone, email address, postal address.

The processing of these personal data is carried out in order to be able to contact the issuer of the report if additional information on the declared quality defect(s) is required.

Failure to provide personal data would prevent the DPM from obtaining all the details necessary for a proper understanding of the quality defect.

Processing of personal data has their legal basis in:

- Loi du 24 novembre 2015 modifiant la loi modifiée du 21 novembre 1980 portant organisation de la Direction de la santé
- Règlement grand-ducal modifié du 15 décembre 1992 relatif à la mise sur le marché des médicaments
- Loi du 25 novembre 1975 concernant la délivrance au public des médicaments, (Mém. A - 77 du 29 novembre 1975, p. 1540; doc. parl. 1875). Art 4, art 20

Declarations of quality defects are kept for a period of 10 years by the DPM after the notification of the quality defect. Beyond this period, the data are transferred to the Luxembourg National Archives.

Each person whose data are processed has a right to request access to his personal data and to obtain a copy thereof as well as, in the event that such personal data are incomplete or incorrect, their rectification. They also have the right to restrict 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 Health Directorate, by email to info_donnees@ms.etat.lu or by post to Health Directorate, Data Protection, 13a, rue de Bitbourg, L-1273 Luxembourg.

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 - Enforcing your rights section ("Particuliers Faire valoir vos droits").