Privacy Policy

This Privacy Policy sets out the manner in which the adverse drug reaction (ADR) reporting system and Med Safety app processes personal data gathered from users. It outlines the importance of the data and explains your rights under the RA Law "On personal data protection".

Please note that we do not accept responsibility or liability for any external websites that you may access via a link from this website. External websites will have their own privacy policies, which you should read.

Who we are

Scientific center of drug and medical technology expertise (SCDMTE) is a medicine regulatory agency under the Ministry of health (MoH) with the right to manage and process personal data.

Why do we need your information?

The SCDMTE acts on behalf of the MoH to protect and promote public health and patient safety by ensuring that medicines are used safely and meet appropriate standards of safety, quality, performance and effectiveness.

The ADR reporting system enables the SCDMTE to monitor the safety of medicines in Armenia to ensure they are acceptably safe for patients and those that use them. You contribute to this by informing us of suspected side effects of medicinal products.

To submit information on ADR we require certain personal information. We ask for the reporter's name and contact details so that we can get in touch if we need more information. We also require health and demographic details (such as age, sex, ethnicity etc) of the person affected by the incident to understand the impact on different populations.

The information you provide will be kept safely, securely and confidentially. We will not share personal identifiers with any person outside the SCDMTE without your explicit consent, unless we are required to do so by law. You can also ask someone else to send a report in about a suspected side effect if you do not wish to give us your name.

What personal data do we collect?

<u>When you register for an account</u>

You may register with the Med Safety app by providing your name and contact details, but registering is not essential. This information is requested for your convenience as registering will enable multiple report

submissions without requiring multiple entry of your details. Once registered, you can also view previously submitted reports.

The SCDMTE may contact registered users about the ADR reporting, or the services you have used. We will not pass your personal data to other organizations for commercial or any other use except as identified in this policy.

When you report an ADR

We encourage reports from the individual affected, their friends and relatives, healthcare professionals and manufacturers – anyone may submit an ADR report on their own or someone else's behalf.

We collect information on the reporter and the individual affected; this will be the same person if you are reporting about yourself.

We collect the following personal information about the reporter:

- First name, last name
- Contact details; email address, telephone number
- Job title and organization details if the reporter is a healthcare professional or manufacturer representative
- IP address

We collect the following personal information and special category information about the individual affected:

- We require at least one of the following characteristics: initials, age, sex, weight, height Ethnicity (optional)
- Information about the suspected product and a description of the adverse incident
- Health data, including medical history and medications

Legal basis

Our legal basis in processing your personal data is Article 6 (point 8) and Article 17 of the RA Law "On medicine" where the SCDMTE has obligation to ensure professional examination of drugs and expertise of drug side effects and development of appropriate recommendations. It's necessary for protecting and promoting public health and patient safety. Personal data processing is carried out according to the RA Law "On personal data protection".

Retention and disposal

We only keep your personal information for as long as necessary to fulfill the purpose we collect it for, including reporting or legal requirements.

Sharing your information

Reports related to side effects to medicines

This information will also be made available to the World Health Organisation's Uppsala Monitoring Centre and pharmaceutical companies with identifiable details removed. We will also provide a copy of your report to your healthcare provider where you have requested this.

Disclosing your information

ADR report data may be requested under the legislation of RA, while we are legally obliged to provide the requested information.

Changes in our policy

SCDMTE have the right to update and improve this privacy policy in accordance with the new data protection laws. We will inform you of any changes to this privacy policy if we believe the changes would impact on your rights or introduce a new purpose in processing your information.

Contacting Us

If you have any questions about this Privacy Policy, the practices of this system or your dealings with this system please contact us at vigilance@pharm.am.