**Med Safety App Privacy Policy**

This Privacy Policy sets out how the National Directorate of Health Surveillance through its Department of Pharmacovigilance and the Med Safety application process personal data collected from users.

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

Note: Please understand that if you experience an adverse reaction to a drug, you should seek medical assistance, because you will not receive any help by this means.

**Who are we?**

The National Directorate of Health Surveillance (DNVS) under the Ministry of Public Health and Social Welfare (MSPBS), is the Regulatory Authority for Medicinal Products for Human Use with the aim of ensuring the quality, safety and effectiveness of them.

The DNVS will exercise the functions of protection of personal data in accordance with the Law regulating Private Information, the Law on Access to Public Information and other regulations applicable to the subject matter.

For more information about DNVS, [please](https://www.mspbs.gov.py/dnvs) https://www.mspbs.gov.py/dnvs

**Why do we need your information?**

DNVS is the executing agency of Law 1.119/97, whose role is to assure the population of medicines that meet quality and efficacy safety requirements.

One way to meet this goal is to publicize the adverse reactions of medications.

The drug adverse reaction reporting system that you are now using allows monitoring of drug safety in Paraguay. You contribute to this system by reporting suspected adverse drug reactions.

The reporting system administered by the Department of Pharmacovigilance of DNVS requires certain information, including some personal data.

We request the name and contact details of the notifier so that we can contact you if we need more information. We require demographic and health details (such as age, sex, ethnicity, etc.) of the person affected by the adverse reaction to understand the impact on the different populations, the medications they are receiving, the adverse reaction they produced and additional information they can provide.

The information you provide will be kept secure, protected and confidential. We will not share personal data with anyone outside the Pharmacovigilance Department without your explicit consent, unless we are required to do so by law. You can also ask someone else to submit a report of suspected adverse reaction if you do not wish to give us your name.

**What personal information do we collect?**

When you sign up for an account

You can register for the Med Safety app by providing your name and contact details, but registering is not essential. This information is requested for your convenience, as registration will allow you to make multiple reports of suspected Adverse Drug Reactions (RAM) without requiring multiple entry of your data. Once registered, you can also view previously submitted reports.

The Department of Pharmacovigilance may contact registered users about RAM reports or services you have used. We will not transfer your personal data to other organizations for commercial or other use, except as identified in this policy.

When you report a RAM

We encourage the reports of the affected person, their friends and family, health professionals and manufacturers; anyone can submit a RAM report on their behalf or someone else's.

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

We collect the following personal information about the notifier:

* First and Last Name
* Contact details; email address, phone number
* Profession and workplace if the notifier is a health care professional or a representative of the manufacturer/health registry holder
* IP address

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

* We require at least one of the following characteristics: initials, age, sex, weight, height, ethnicity (optional)
* Information about the suspicious drug and a description of the adverse reaction
* Health data, including medical history and medications

**Base Legal**

The legal basis for processing your personal data is Law 1.682, which in Article 3 establishes as lawful the collection, storage, processing and publication of personal data or characteristics, which are carried out for scientific, statistical, surveys and surveys of public opinion or market study, provided that publications do not individualize the persons or entities investigated.

Reports made using the Med Safety app require some information about the affected person. If you submit a report about yourself, the information will relate to you and include some special category personal data, such as information about your health or ethnicity.

When we share data from the Med Safety App this will only be done for scientific or public health research purposes and without individualization of the persons or entities investigated in accordance with the current Law.

**Retention and disposal**

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

**Sharing your information**

We will not share your information with third parties for direct marketing purposes.

We do not share your identity with anyone outside the DNVS without your explicit consent, unless we are required or permitted to do so by law. Examples include whether we receive a court order to do so.

We may receive requests for adverse reaction reporting data under the Access to Public Information Act. While we are legally required to provide some of the requested information, we only provide summary information with all identifiable data of excluded persons.

We may provide data from the Adverse Reactions Reporting Database for scientific or public health research purposes. See Section 2 for more information.

Reports related to adverse drug reactions

This information will also be made available to the Uppsala Monitoring Centre – UMC, a collaborating centre of the World Health Organization for international monitoring of drug safety, eliminating identifiable details.

**Disclosure of your information**

Adverse drug reaction report data may be requested in accordance with Health Authority law, while we are legally required to provide the requested information.

**Changes in our policy**

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

**Contact 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 farmacovigilancia.dnvs@mspbs.gov.py](mailto:farmacovigilancia.dnvs@mspbs.gov.py)

**Version History**

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| --- | --- | --- |
| Version number | Update date | Update summary |
| 1.0 | 09/11/2020 | Creating the privacy policy of the Med Safety app |
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