



# Med Safety App Privacy Policy

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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.

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 are we?**

The National Agency for Medicines and Health Products (ANMPS), established by the law of July 12, 2023, is a public agency responsible for ensuring the safety, efficacy, and quality of medicines and health products throughout their lifecycle. It develops the necessary scientific and technical expertise and collaborates with various entities (CNPV and other pharmacovigilance departments) to promote human and veterinary health and prevent risks that could compromise patient safety.

You will find further information about ANMPS on the transitional site of the ANMPS : [www.dpm.tn](http://www.dpm.tn) and about the CNPV at [www.pharmacovigilance.rns.tn](http://www.pharmacovigilance.rns.tn)

## **Why do we need your information?**

Our goal is to protect and promote public health and patient safety by ensuring that medicines are safely used and meet appropriate standards of safety, quality, performance and effectiveness.

The ADR reporting system enables to monitor the safety of medicines in Tunisia to ensure they are acceptably safe for patients. 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, 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.

## **What personal data do we collect?**

When you visit the website or app not applicable we didn't set cookies



### When you register for an account

To register with the Med Safety app, you may provide your name and contact details. Once registered, you can submit multiple reports and also view previously submitted reports.

The ANMPS or the Chalbi Belkahlia National Pharmacovigilance Center (CNPV) 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, healthcare professionals and manufacturers.

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

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

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

### **Legal basis**

The legal basis for the processing of your personal data in Tunisia is a primarily Organic Law No. 2004-63 of 27 July 2004 on the protection of personal data. This law guarantees the right of every individual to the protection of their personal data as a fundamental right protected by the Tunisian constitution.

The key points of this law include:



The processing of personal data must be carried out in accordance with the principles of transparency, fairness, security and respect for human dignity.

Any processing operation is subject to prior notification to the National Authority for the Protection of Personal Data (INPDP).

Processing without the prior consent of the data subject is prohibited, except in cases provided for by law.

Specific rules apply to the processing of data relating to minors or incapacitated persons, requiring the authorisation of their legal guardian or a judge.

The data controller must inform the data subject of the existence of the processing, its purposes, the consequences, and their rights of access, rectification, and opposition.

The data controller, the data processor and their agents are bound by data confidentiality, even after the processing has ended.

This law establishes a clear legal framework for protecting the personal data of Tunisian citizens and strictly regulates its processing by any public or private entity in Tunisia.

### **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**

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

We do not share your identity with any person outside the ANMPS and the other entities responsible of pharmacovigilance without your explicit consent, unless we are required or permitted to do so by law.

If the situation arises, we would only share confidential patient information if we were satisfied that the disclosure is essential for the purpose described above and we would ensure that:

We share the minimum information required to achieve the purpose.

### **Reports related to side effects to medicines**

This information will also be made available to the World Health Organization's Uppsala Monitoring Centre and pharmaceutical companies with identifiable details removed.



If you would like to receive a medical report and have further investigations, please contact the Pharmacovigilance department related to your region: [see annexe 8](#)

### **Disclosing your information**

ADR report data may be requested under Tunisian law, in which case we are legally required to provide the requested information.

### **Changes in our policy**

The ANMPS 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 <anmps@rns.tn >.

### **Version history**

Version number	Date of update	Summary of update
1.0	27/08/2025	Creation of privacy policy for Med Safety App