



## **Privacy Policy**

### **VigiMedCA App**

#### **VigiMedCA App Privacy Policy**

This Privacy Policy sets out how the Adverse Drug Reaction Reporting System (ADR) and the VigiMedCA app process personal data collected from users.

Please note that we accept no responsibility or liability for any external website that you may access via a link provided from this website. External websites will have their own privacy policies, which you should read.

#### **Who are we?**

We are the Health Regulation Agency (ARSA), created by Presidential mandate by Decree PCM-032-2017 dated April 28, 2017, ratified by Decree No. 7-2021 Law of the Regulation Agency Health. We are responsible for the supervision, review, verification, control, surveillance and supervision of compliance with the legal, technical and administrative regulations of the establishments, suppliers, products and services of health interest and those who carry out activities or practice behaviors that have or may have an impact on the Health of the Population, and regulation, granting, renewal, modification, suspension or cancellation of Registrations, permits, licenses, certifications and other sanitary authorizations.

More information about ARSA can be found in [www.arsa.gob.hn](http://www.arsa.gob.hn)

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

The National Pharmacovigilance Centre (CNFV) acts on behalf of the Health Regulation Agency, 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 efficacy.

The AMR notification system allows the CNFV to monitor the safety of drugs in Honduras to ensure they are acceptably safe for patients and those who use them. You contribute to this by informing us of the possible side effects of medicines.



To send information about RAM, we need certain personal information. We request the name and contact details of the notifier so that we can get in touch if we need more information. We also require demographic and health details (such as age, gender, ethnicity, etc.) of the person affected by the incident to understand the impact on different populations.

The information you provide will be kept secure, secure and confidential. We will not share personal identifiers with anyone outside the CNFV without your explicit consent, unless required to do so by law. You can also ask another person to submit a report about a possible side effect if you do not wish to provide us with your personal data.

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

#### When you register for an account

You can register in the VigiMedCA app by providing your name and contact details, but registering is not essential. This information is requested for your convenience, as registration will allow for multiple reporting without requiring multiple input of your data. Once registered, you can also view the reports submitted earlier.

The CNFV may contact registered users about RAM reports or services it has 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 a RAM

We encourage reports from the affected person, their friends and family, healthcare professionals and manufacturers; anyone can file a RAM report on their own behalf or on behalf of another person.

We collect information about the notifier and patient; this will be the same person if you report for yourself.

We collect the following personal information about the notifier:

- First name, Surname



- Contact details; e-mail address, telephone number
- Position and details of the organization if the informant is a healthcare professional or a representative of the manufacturer.
- IP address

We collect the following personal information and special category information about the patient:

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

### **Legal basis**

Our legal basis for the use of data in the country is governed by the Law on Transparency and Access to Public Information, this law dictates in Article 16 the Restriction of access to information and in Article 17 mentions Classification of information as confidential.

No person may oblige another to provide personal data that may cause discrimination or cause damage or economic or moral risks to the persons referred to in Article 25, Prohibition of delivery of information.

### **Retention and disposal**

We only retain your personal information for as long as necessary to fulfill the purpose for which we collected it, including legal or reporting 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 of the ARSA without your explicit consent, unless we are required or permitted to do so by law. Examples include if we receive a court order to do so or if you are a healthcare professional reporting an adverse drug-related incident, the details of which can be found below. Exceptionally, we may share this where we have established a basis for sharing personal data and can demonstrate that it is necessary and proportionate to do so.



The law allows agencies like us to share sensitive patient information for specific purposes including recognizing trends in communicable diseases, such as COVID-19, and the monitoring and management of outbreaks of these.

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

- We share the minimum information required to achieve the purpose
- Access to information is limited to healthcare professionals or those who have an equivalent duty of confidentiality to a healthcare professional.
- Those who would have access to the confidential information are involved in the proposed relevant processing and are fully aware of the purpose.
- Appropriate technical and organizational measures were taken to prevent unauthorized processing of information.

#### **Reports relating to the side effects of medications.**

This information will also be made available to the World Health Organization's (WHO) Uppsala Monitoring Center (UMC) and pharmaceutical companies, removing identifiable details. We will also provide a copy of your report to your health care provider when you have requested it.

#### **Disclosure of Your Information**

RAM report data may be requested under ARSA legislation, as long as we are legally required to provide the requested information.

#### **Changes to our policy**

The CNFV has 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 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@arsa.gob.hn](mailto:farmacovigilancia@arsa.gob.hn)

## Version History

Version number	Update date	Update Summary
1.0	11/10/2021	Creation of privacy policy for the VigiMedCA application