



## **Med Safety App 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.

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 Medicines and Healthcare products Regulatory Agency (the MHRA) is an Executive Agency of the Department of Health and Social Care (DHSC). The DHSC, together with its Executive Agencies is a single legal entity (or 'controller') for the purposes of data protection law. The Agency has three centers, MHRA, NIBSC and CPRD; and carries out controller functions for the personal data for which it is responsible. These responsibilities include determining the purposes and means of processing the personal data.

You will find further information about the MHRA and DHSC on [www.gov.uk](http://www.gov.uk).

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

The Quality Assurance of Pharmaceutical Products Program (QAPPP) at the Ministry of Public Health aims 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 QAPPP to monitor the safety of medicines in Lebanon 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 QAPPP 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?**

### When you visit the website or app

Our cookies capture certain online identifiers and information when you visit our Yellow Card website or use the Yellow Card app. For more information about this or how to manage your preferences, please read our [cookie policy](#).

### When you register for an account

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 QAPPP 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 lawful basis for processing your personal data is GDPR Article 6(1)(e), which allows us to process personal data when this is necessary to perform our public tasks as a regulator.

Yellow Card reports require some information about the individual affected. If you are submitting 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. The lawful bases we rely on to process special category personal data are Article 9(2)(i) of the GDPR and Schedule 1 part 1(3) of the DPA, both of which enable us to process such information when it is necessary for reasons of the public interest in the area of public health.

Where we share Yellow Card data for scientific or public health research purposes, we rely on GDPR Article 9(2)(j) as our lawful basis for processing special category personal data and Schedule 1 part 1(4) of the DPA. These bases permit us to process personal data for these purposes where it is in the public interest, subject to appropriate safeguards to protect your rights and freedoms.

### **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 MHRA 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 incident relating to a medical device, further details of which can be found below.. Exceptionally, we may share this where we have established a lawful basis for sharing personal data and can demonstrate that it is both necessary and proportionate to do so.

We may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded.

We sometimes provide Yellow Card data for scientific or public health research purposes. Please see Section 2 for further information about this.

Regulation 3(3) of the Health Service Control of Patient Information Regulations 2002 does permit bodies such as ourselves to share confidential patient information for specific purposes that include recognising trends in communicable diseases, such as COVID-19, and monitoring and managing outbreaks of these.

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

- Access to the information is limited to healthcare professionals or those who owe 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 organisational measures were in place to prevent unauthorised processing of the information.

#### 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. 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 Regulatory Authority, while we are legally obliged to provide the requested information.

## **Changes in our policy**

QAPPP 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 that the changes would impact 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 <pv@moph.gov.lb>.

## **Version history**

Version number	Date of update	Summary of update
1.0	<enter date>	Creation of privacy policy for Med Safety App