Annexure-3

Med Safety 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 we are

The DRAP has established the Pakistan National Pharmacovigilance Centre (PNPC), under the Division of Pharmacy Services, DRAP, Islamabad, to monitor therapeutic goods‟ safety across the country. To this end, the Centre has started National and International coordination for the development and promotion of pharmacovigilance in Pakistan.

Why do we need your information?

PNPC under the Division of Pharmacy Services, Drug Regulatory Authority of Pakistan (DRAP) acts to monitor, protect and promote public health and patient safety by ensuring that therapeutic goods are used safely and meet appropriate standards of safety, quality, performance and effectiveness.

Pakistan National Pharmacovigilance Centre (PNPC) is responsible for collection, validation, assessment and monitoring of adverse drug reactions in the country. The centre collects adverse drug reactions from patients, healthcare professionals, provincial pharmacovigilance centres, provincial health departments, public health programmes and market authorization holders.

Your contribution, by informing us of suspected side effects of medicinal products is important.

Some personal information is required to submit ADRs which contains reporter's name and contact details to be contacted by us if more information is needed. 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.

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.

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 on someone else's behalf.

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

Retention and disposal

We only keep your personal information for as long as necessary to fulfil 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 with identifiable details removed.

Changes in our policy

The Drug Regulatory Authority of Pakistan has the right to update and improve this privacy policy in accordance with the new data protection laws. Any changes to this privacy policy will be inform, 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 npc@dra.gov.pk.

* By accepting the terms you agree to provide the above mentioned personal information and in this way authorizing Pakistan National Pharmacovigilance Centre and Uppsala Monitoring Centre to use this data for assessment of ADRs and signal detection in order to prevent harm to other patient and promoting safe use of therapeutic goods.