Privacy Policy

This Privacy Policy sets out the type of information the Food and Drugs Authority ("FDA" or "we" or "us") receives from you when you report adverse reactions via the Med Safety App or the Safety Watch System and the manner in which such information is used and/or processed. It also outlines the importance of the information and your privacy rights in line with the Data Protection Act, 2012 (Act 843).

1. Who are we?

The Food and Drugs Authority (FDA) is the national regulatory body responsible for the regulation of food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials. The FDA's legal mandate is found in Part 6 (Tobacco Control Measures), Part 7 (Organisation and Responsibilities of the FDA), and Part 8 (Clinical Trials) of the Public Health Act, 2012 (Act 851).

2. Why do we need your information?

The FDA acts to protect and promote public health and safety by ensuring that food, medicines (including vaccines, blood and blood products and herbal medicines), medical devices, cosmetics and household chemical substances are safe and meet prescribed standards of safety, quality, performance and effectiveness.

The requirement of a safety monitoring system of regulated products is provided under Section 125 of the Public Health Act. Reporting of adverse reactions resulting from the use of regulated products is mandatory for marketing authorization holders but voluntary for healthcare professionals, consumers and patients.

The objective of the FDA's safety monitoring system is to provide an early warning that the safety of a product may require further investigation.

The FDA requires certain personal information and demographic details in order to contact the reporter of the adverse reaction, where necessary, and to understand the impact of the product on different populations and to conduct research to improve systems and knowledge of medicinal products.

3. Who do we collect data from?

The FDA collects information from anyone who reports an adverse reaction through the FDA online platform, i.e. the SafetyWatch System, or the Med Safety Mobile app.

The FDA receives reports from the individual affected, their friends and relatives, healthcare professionals and market authorization holders.

4. What personal data do we collect?

The FDA collects information provided by the reporter of the adverse reaction on both the reporter and the individual affected by the regulated product. We may collect the following personal information:

- **Personal Details**: Name, job title and organization of the reporter (if a healthcare professional or qualified person for pharmacovigilance), telephone number, postal address and email address. Others are demographic details (such as gender, date of birth or age, weight or height) of the person affected by the adverse rection.
- **Details of the Suspected Medicine(s) or Product(s)**: The name of the suspected medicine(s), manufacturer, batch number, etc..
- **Reason(s) for taking the Medicine**: What the medicine is being used for and the dosage.
- **Adverse Reaction:** Description of the adverse reaction, when it started and ended and the outcome.
- **Medical History:** Short medical history of the affected person, including medications.

[The FDA also automatically and temporarily stores information such as your computer's Internet Protocol (IP) address, the domain from which you accessed the SafetyWatch System or the Med Safety Mobile app, the website address from which you came to the SafetyWatch System, the date and time you arrived at our site and how long you spent there, the name and version of your computer's operating system and browser, the pages you visited, etc.

We use this information to improve the SafetyWatch System and the Med Safety Mobile app and provide a better experience for our users. The information is available only to our web managers and staff who require this information to perform their duties. It is retained only for as long as needed for analysis purposes.]

5. Retention and disposal

The FDA will only keep your personal information for as long as necessary to fulfill the purpose for which the information is collected, including reporting or legal requirements.

6. Sharing your information

The information you provide is kept safe, secure and confidential. The FDA will not share personal identifiers with third parties.

Reports related to adverse reactions to health products will be made available to the World Health Organization’s database (VigiBase) and also shared with the UK Medicines and Healthcare products Regulatory Agency to help in the automated detection of new safety information. Please, note that personal details (including name, job title and organization of

the reporter (if a healthcare professional or qualified person for pharmacovigilance), telephone number, postal address and email address) are not shared in these reports.

The FDA will not disclose, give, sell, or transfer your personal information unless it is required by law or regulation or for law enforcement reasons.

7. Links to other sites

Please, note that we do not accept responsibility or liability for any external websites that you may access via a link from the Med Safety App or the SafetyWatch System. External websites will have their own privacy policies, which you should read.

8. Your rights

You have the right to request:

- information about how your personal data is processed
- a copy of that personal data
- that anything inaccurate in your personal data is corrected immediately

You can also:

- raise an objection about how your personal information is processed
- request that your personal information is erased if there is no longer a justification for it
- ask that the processing of your personal information is restricted in certain circumstances

For a more comprehensive understanding of your privacy rights and how your information may be used by the FDA, please refer to the Data Protection Act, 2012 (Act 843).

9. Changes in our policy

The FDA has the right to update and improve this privacy policy. In that case, the 'last updated' date at the bottom of this page will change. We will also inform you of any changes to this privacy policy if the changes will affect how your personal information is processed. Any changes to this privacy policy will apply to you and your data immediately.

10. Contacting us

If you have any questions about this Privacy Policy, the SafetyWatch system or the Med Safety App, please contact the FDA at drug.safety@fda.gov.gh

Alternatively, you can write to:

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT2783
Cantonments, Accra

Version Number	Date	Summary of updates
Version 2	24th August 2020	None