

## Pharmacovigilance Privacy Notice

As a pharmaceutical company, Jazz Pharmaceuticals plc and its corporate subsidiaries and affiliates including GW Pharmaceuticals companies (hereafter collectively “Jazz”, “we”, “us”) are legally required to monitor the safety of all Jazz products worldwide (also known as our pharmacovigilance obligations). To comply with our pharmacovigilance obligations and in the interest of protecting patient safety, we are obliged to collect and process personal information (i.e. information that directly or indirectly identifies a natural person) from individuals who experience and/or report an adverse event (meaning an unfavourable, untoward or unintended event following the use of our products, whether or not considered associated with the treatment).

This Pharmacovigilance Privacy Notice is intended to provide you with important information regarding how we collect, share and use your personal information for pharmacovigilance purposes and how you can exercise your privacy rights under applicable data privacy laws.

### 1. How do we collect your personal information?

Any personal information which we process is provided to us either by you directly, from a health care professional reporting an adverse event on behalf of a patient or via a third party (e.g. pharmacy, regulatory agency, distributor, market research agencies, etc).

### 2. What personal information do we collect about you?

We will only collect the minimum information required for the purposes of fulfilling our pharmacovigilance obligations.

#### **(a) About the patient**

Personal information includes, but is not limited to:

- Patient ID/Initials
- Contact Details (if patient is the Reporter)
- Social Media Handle
- Date of Birth
- Gender
- Age/Age Group at Onset
- Ethnic Origin
- AE information including:
  - Symptoms
  - Duration
  - Outcome
  - Suspect Drug
  - Concomitant Medications
  - Hospitalisation details relevant to the AE
  - Medical History

#### **(b) About the reporter**

- Reporter Name
- Contact Details
- Social Media Handle
- Profession
- Professional qualifications

### 3. **Why do we collect your personal information?**

Pharmacovigilance regulations were put in place to protect Public Health. It requires pharmaceutical companies to collect safety information related to their products and investigate any reports of adverse events that they receive.

As part of meeting our pharmacovigilance obligations, we may process personal information to:

- investigate the adverse event;
- contact reporters for further information about the adverse event reported;
- collate the information about the adverse event with information about other adverse events received by Jazz to support safety monitoring of the product; and
- provide mandatory reports to national and/or regional competent regulatory authorities.

We will only use personal information collected for pharmacovigilance for this purpose.

### 4. **Legal basis for processing your personal information**

Jazz process personal information collected for pharmacovigilance to comply with its legal obligations to monitor and report adverse events and for reasons of public interest and public health.

### 5. **Who do we share your personal information with?**

Personal information provided as part of an adverse event report are shared within Jazz on a worldwide basis through the Jazz Global Safety Database. The Jazz Global Safety Database is validated and tested periodically to ensure appropriate security and access to the system is restricted to authorised personnel only.

Jazz is also obliged to transfer adverse event data to regulatory authorities such as Health Canada, the European Medicines Agency, the US Food and Drug Administration, and any other national regulatory authorities for their databases including the European Medicine Agency's EudraVigilance database. Any names and contact details of patients are hidden, meaning that only information on age/age group, date of birth and gender is transferred in addition to the information concerning the reaction and the health of the patient.

Jazz may also disclose your personal information:

- (i) to pharmacovigilance service providers (e.g. safety database providers, call centre operators);

- (ii) to any third party that acquires, or is interested in acquiring, all or part of Jazz's assets or shares, or that succeeds Jazz in carrying on all or a part of its business, whether by merger, acquisition, reorganization or otherwise; or
- (iii) as required or permitted by law, including to comply with a subpoena or similar legal process or government request, or when Jazz believes in good faith that disclosure is legally required or Jazz has a legitimate interest in making a disclosure, such as where necessary to protect Jazz's rights and property.

Adverse event information may also be published in case studies. In such situations any identifying information will be removed from the publication to ensure complete anonymity.

## **6. International transfers of personal information**

Jazz may disclose your personal information to recipients (as described above) located outside of Canada in a country which may not have data privacy laws equivalent to those of Canada. Once outside of Canada, your personal information will be subject to applicable foreign legal requirements, which may include lawful requirements to disclose personal information to government authorities in certain circumstances that differ from laws of Canada.

Certain international recipients of your personal information may have signed special contracts with Jazz Pharmaceuticals to provide legal protection for your transferred personal information.

You can request further information using the contact details below.

## **7. How long will we keep your personal information?**

Adverse event and safety information for Jazz's products, which may include personal information and related correspondences, are retained at least for the duration of the product life-cycle and for an additional twenty-five years after the product has been removed from the market in accordance with our Records Management Policy.

## **8. Your Rights**

You have certain rights under applicable privacy laws, which may be subject to limitations and/or restrictions. These include the right to:

- request access to and correct your personal information held by Jazz Pharmaceuticals; and
- the right to lodge a complaint about the processing of your personal information with the applicable federal or provincial privacy commissioner.

Please be aware that there may be limitations to your rights if they interfere with our legal pharmacovigilance obligations. For security reasons you may be required to provide adequate identification before we are able to action any of your rights.

In order to exercise any of your rights please contact us using the contact details provided below.

## **9. Contact Us**

All your requests, inquiries or complaints regarding this Privacy Notice or relating to the processing of your personal information including all requests as detailed in the Section, 'Your Rights' above, should be sent in writing to Jazz's Privacy Office at the following address: Jazz Pharmaceuticals, Privacy Office, 3170 Porter Drive, Palo Alto, CA 94303, U.S. or by email at: [privacy@jazzpharma.com](mailto:privacy@jazzpharma.com) .