Pharmacovigilance Privacy Notice:

As a pharmaceutical company, Mundipharma and its corporate subsidiaries, affiliates, and Independent Associated Companies, (hereafter collectively "Mundipharma", "we", "us" or "our") are legally required to monitor the safety of all our products worldwide (also known as our pharmacovigilance obligations).

To comply with our pharmacovigilance obligations in in the interest of protecting patient safety and public health, we are obliged to collect and process information which may directly or indirectly identify a natural person ("Personal Data") from individuals who experience and/or report an unfavourable, untoward or unintended event following the use of our products ("Adverse Event"), whether the Adverse Event is considered to be associated with the treatment or not.

This Pharmacovigilance Privacy Notice is intended to provide you with important information regarding Personal Data we collect, share and use, for pharmacovigilance purposes and how you can exercise your privacy rights under applicable privacy and data protection laws (including the EU General Data Protection Regulation ((EU) 2016/679) or "GDPR"). For the purposes of data protection laws, we are the controller of the Personal Data.

How do we collect Personal Data?

Personal Data which we process for pharmacovigilance purposes is provided to us either by a patient directly or a reporter such as a healthcare professional or third party (e.g. pharmacy, regulatory agency, distributor, market research agency, etc.) reporting an adverse event on behalf of a patient.

What Personal Data do we collect for pharmacovigilance?

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

(a) Personal Data about the patient includes, but is not limited to:
   a. Patient ID/Initials
   b. Contact Details (if patient is the Reporter)
   c. Date of Birth
   d. Gender
   e. Age/Age Group at Onset
   f. Ethnic Origin
   g. Adverse Event information
      i. Symptoms
      ii. Duration
      iii. Outcome
      iv. Suspect product
      v. Concomitant Medications
      vi. Hospitalisation details (if any) relevant to the Adverse Event
      vii. Patient Medical History

(b) Personal Data about a Reporter, includes but is not limited to:
   a. Reporter Name
   b. Contact Details
   c. Profession

d. Professional Qualifications (if the person is a healthcare professional)

Why do we collect Personal Data?

Pharmacovigilance regulations were put in place to protect Public Health. The regulations require pharmaceutical companies to collect safety information related to their products and investigate any reports of Adverse Events received. As part of meeting our pharmacovigilance obligations, we may process Personal Data 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 reported to Mundipharma to support safety monitoring of the product;
- provide mandatory reports to national and/or regional competent regulatory authorities.

We only use Personal Data collected for pharmacovigilance for this purpose.

Legal basis for processing your Personal Data

Mundipharma processes Personal Data collected for pharmacovigilance to comply with legal and regulatory obligations to monitor and report Adverse Events and for reasons of public interest and public health.

Who do we share your personal data with?

Personal data reported as part of an Adverse Event are shared within Mundipharma on a worldwide basis through our Global Safety Database. The Mundipharma Global Safety Database is validated and tested periodically to ensure appropriate security. Access to the Global Safety Database is restricted to authorised personnel only for whom access is necessary.

Mundipharma is also obliged to transfer Adverse Event data to national regulatory authorities databases, including the European Medicine Agency's EudraVigilance database. Information transferred is limited to age/age group, date of birth, gender information concerning the reaction, and the health of the patient.

Mundipharma may also disclose your Personal Data:

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

Adverse Event information may also be published in case studies and shared with distributors and licensors. In such situations any identifying information is removed prior sharing the data to ensure complete anonymity.

International transfers of Personal Data

Where we transfer your personal data we will use suitable measures, such as standard contractual clauses and (where appropriate) supplementary measures, to protect your personal data being shared outside of your country to countries that do not offer a suitable level of protection. We may need to share your personal data with a government authority, regulator or to otherwise comply with our legal obligations.

How long will we keep pharmacovigilance Personal Data?

Adverse Event and safety information for Mundipharma products, which may include personal data and related correspondence, is 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.

Your Rights

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

- Request access to your Personal Data, and request a copy of the data we hold;
- Rectify any information we hold if it is incorrect;
- Request the restriction of processing your personal information in the event of data inaccuracy;

Our processing of your personal data is in pursuit of a public interest objective in public health. This means that you do not have a right to object, a right to erasure, or a right to data portability. These limitations to your rights are due to 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.

Contact Us

All your requests, inquiries or complaints regarding this Privacy Notice or relating to the processing of your personal data including all requests as detailed in the Section, 'Your Rights' above, should be sent in writing to us at the following address: data.privacy@mundipharma.com. You can contact our data protection officer here. To help us efficiently deal with your request, it would be helpful if you could state in your communication your relationship and/or interactions with us, as well as the specifics of your query or request when contacting us.

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