PRIVACY NOTICE FOR PHARMACOVIGILANCE, PRODUCT COMPLAINTS AND MEDICAL INQUIRIES

1. WHO WE ARE

Immedica Pharma AB, with registration number 556835-6322 ("**Immedica**"), is a Swedish pharmaceutical company commercializing medicinal products for rare diseases primarily in Europe and the Middle East. We are responsible for the processing of your personal data since we decide why and how the personal data is processed and are therefore the data controller under this Notice. Immedica may exercise this responsibility alone or jointly with other company(-ies) in the Immedica group. In this Notice, the terms "Immedica", "we" or "us" refer to Immedica and its group companies.

2. ABOUT THIS PRIVACY NOTICE

As a pharmaceutical company, Immedica is required by law to respond to, collect and evaluate reports of product complaints, adverse drug reactions and other safety information concerning our medicinal products as well as medical information inquiries while also protecting the personal data we process. The detection, collection, monitoring and prevention of adverse reactions from the use of medicinal products is called pharmacovigilance ("**PV**"). This Privacy Notice for PV, Product Complaints and Medical Inquiries (the "**Notice**") explains how we process your personal data in connection with product complaints, medical inquiries and reports of adverse drug reactions or other safety related information about our medicinal products. We may receive such reports for instance directly from patients or healthcare professionals or through other pharmaceutical companies with whom we cooperate.

Immedica will process personal data about you in accordance with this Notice and applicable laws. At Immedica, we collect information about adverse reactions and other safety related information, including lack of efficacy, exposure during pregnancy and breastfeeding, off label use, overdose, misuse and medication errors relating to our medicinal products into a safety database. Product complaints are

registered into a complaints database. We analyse the personal data on a regular basis to determine if there are any new information about our medicinal products that we need to share with authorities, business partners or healthcare professionals and patients. Any personal data related to medical information inquiries may be used to answer the inquiry, follow up on such requests and maintain the information in a medical information database for reference. Where required by law (such as for PV and product complaints purposes), we may also be required to report the personal data to regulatory authorities. These procedures are conducted to ensure safety and benefit of our medicinal products, protect patients from unjustified harm and ensure the quality of our products.

3. CATEGORIES OF PERSONAL DATA WE COLLECT ABOUT YOU

Depending on how you interact with us and for what purpose, we collect and process different types of personal data about you. In order for you to more easily understand what type of personal data we may process about you, we have categorized the personal data into the following categories, including data elements:

Personal data that we may collect about you for the purposes contemplated in this Notice	
Category	**Description and examples of personal data**
Contact Details	• First and/or last name, or initials • Residential address • E-mail • Telephone number • Profession/Title

Personal data that we may collect about you for the purposes contemplated in this Notice	
Demographic Information	• Age • Gender • Weight • Height
Health Data	• The nature of the product complaint and/or adverse reaction • Disease history • Medical condition • Medical treatment and examination results
Genetic Data	• Data about gene deficiency

4. CATEGORIES OF RECIPIENTS WHO WE SHARE YOUR PERSONAL DATA WITH

We may share or transfer your personal data to third parties. The table below describes the categories of such third-party recipients. Please see Section 7 where we specify in further detail in which instances we may share your personal data to third parties.

Category of third-party recipients	Description
Staff	Refers to employees or in-house consultants at Immedica
Healthcare Professionals	Refers to individuals involved in the decision-making relating to the purchase, procurement, provision or prescription of medicinal products, for instance nurses, physicians or pharmacists

Category of third-party recipients	Description
Regulatory Authorities	Refers to any national or multinational authority responsible for granting regulatory approvals for medicinal products and supervising the safety and quality of medicinal products, for instance the European Medicines Agency and local/national medicine agencies
External Service Providers	Refers to third-party party service providers appointed by Immedica for the provision of services which we cannot perform ourselves. Examples of external service providers are IT and software providers and business service consultants
Business Partners	Refers to companies supporting Immedica in commercializing our products. Examples of business partners are contract manufacturers, wholesale and transport companies and distribution partners

5. HOW WE COLLECT YOUR PERSONAL DATA

Immedica collects personal data under this Notice in various ways, including:

- directly from you, for instance if you submit a report of an adverse drug reaction or make a medical information inquiry;
- from Healthcare Professionals;
- via Immedica's Business Partners; and/or
- from Regulatory Authorities.

6. FOR WHAT PURPOSES DO WE USE YOUR PERSONAL DATA AND WHAT LEGAL BASIS DO WE RELY ON

6.1 PHARMACOVIGILANCE

The table below explains the categories of personal data and the purposes for which Immedica processes your personal data in connection with reports of adverse events and other product safety-related matters. We have also described the legal basis we rely on and for how long we will store your personal data.

Purpose of the processing	Categories of personal data used for the purpose	Legal basis for the processing	Retention period
To register, track, document and store adverse reactions and other product safety information in our global safety database, which is regularly analyzed for potential new safety signals.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
Tracking of case safety reports.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.

Purpose of the processing	Categories of personal data used for the purpose	Legal basis for the processing	Retention period
To perform a scientific evaluation and investigation of any collected adverse reactions or other safety information potentially related to Immedica pharmaceutical products.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To take the necessary actions in response to new safety signals, including update of the product information as required.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To, if necessary, contact you for further information about the adverse reaction.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To provide mandatory reports to national and/or regional competent regulatory authorities and collaboration partners so that they can analyse the quality and safety of the medicinal product.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.

6.2 PRODUCT COMPLAINTS

The table below explains the categories of personal data and the purposes for which Immedica processes your personal data in connection with product complaints. We have also described the legal basis we rely on and for how long we will store your personal data.

Purpose of the processing	Categories of personal data used for the purpose	Legal basis for the processing	Retention period
To register, evaluate, classify, assess and respond to product complaints, to follow up on such requests and to maintain the information in a product complaints database for reference.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To assess trends or potential quality issues associated with the collected product complaints.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To take the necessary actions in response to quality issues, including update of the product information as required.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.

Purpose of the processing	Categories of personal data used for the purpose	Legal basis for the processing	Retention period
To, if necessary, contact you for further information about the product complaint you reported.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To provide mandatory reports to national and/or regional competent regulatory authorities and collaboration partners so that they can analyse the quality and safety of the medicinal product.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.

6.3 MEDICAL INQUIRIES

The table below explains the categories of personal data and the purposes for which Immedica processes your personal data in connection with medical inquiries. We have also described the legal basis we rely on and for how long we will store your personal data.

Purpose of the processing	Categories of personal data used for the purpose	Legal basis for the processing	Retention period
To answer a medical information inquiry, follow up on such inquiry and maintain the information in a medical information database for reference.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.
To, if necessary, contact you for further information about the medical information inquiry from you.	Contact Details, Demographic Information, Health Data, Genetic Data	Comply with legal obligations	At least for the duration of the product life cycle and for an additional ten (10) years after the medicinal product in question has been taken from the market.

7. WHO WE SHARE YOUR PERSONAL DATA WITH

Immedica will not share or transfer your personal data to third parties other than those indicated in this Notice. In connection with the activities and for the same purposes as those listed in this Notice, your personal data can be accessed by, or disclosed to, the following recipients with a justified need to access the information in accordance with applicable legislation:

Category of recipient	Categories of personal data
Staff	Contact Details, Demographic Information, Health Data, Genetic Data
Healthcare Professionals	Contact Details, Demographic Information, Health Data, Genetic Data
Regulatory Authorities	Contact Details, Demographic Information, Health Data, Genetic Data
External Service Providers	Contact Details, Demographic Information, Health Data, Genetic Data
Business Partners	Contact Details, Demographic Information, Health Data, Genetic Data

8. TRANSFER OF PERSONAL DATA TO OTHER COUNTRIES

We strive to process your personal data within the EU/EEA. However, due to the global nature of Immedica's operations, Immedica shares personal data to companies in the Immedica group, healthcare professionals, business partners, external service providers and authorities when we perform the activities described in this Notice. Some of the recipients of your personal data as stated above may reside outside the EU/EEA. The level of legal protection for personal data is not the same in all countries and may not provide the same level of protection as the data protection laws in the EU/EEA or of the country in which you live.

In case of a transfer of your personal data to recipients based in countries outside the EU/EEA, Immedica will take reasonable efforts and adopt adequate safeguards to keep your personal data processed in line with applicable requirements under the GDPR. These safeguards consist of one of the following legal mechanisms:

(a) **Standard Contractual Clauses**. According to these clauses, the recipient of your personal data needs to protect your personal data and provide you with rights and protection that are on the same level as EU-standards. These clauses have been adopted by the European Commission.

(b) **Adequacy Decision by the European Commission**. This means that we transfer personal data to countries outside the EU/EEA which have adequate level of data protection, according to a decision adopted by the European Commission. Follow this link to see which countries that have received an adequacy decision by the European Commission.

9. YOUR RIGHTS

You have several rights in accordance with applicable data protection legislation, including the GDPR. You have the right to:

- **request information** about your personal data processed by Immedica;
- **request correction** of your personal data if incorrect or incomplete;
- **request transfer** of your personal data to you or another person in a commonly utilizable format;
- **file a complaint** to a data protection authority;
- **object to processing** of your personal data as far as such processing is only based on Immedica's legitimate interest;
- **request the deletion** of your personal data if they are no longer necessary for the purposes of processing or there is no legal ground for their further processing.

Please note, however, that these rights may be limited in order to fulfil PV and product complaints obligations. Your rights are limited where there is a legal ground for processing your personal data, for example we cannot delete information that has been collected as part of an adverse reaction report unless it is inaccurate. Immedica may require you to provide proper identification before we comply with any request to access or correct your personal data.

10. HOW TO CONTACT US

The company responsible for the processing of personal data and that acts as the data controller under this Notice is:

Immedica Pharma AB
Solnavägen 3H
113 63 Stockholm
Sweden

If you want to reach any of us, have questions or want to exercise your rights explained above, you are welcome to contact us. Please do so by sending an e-mail to privacy@immedica.com.

11. CHANGES TO THIS NOTICE

We work continuously with improving our products and services and may update this Notice from time to time. We encourage you to periodically review this page for the latest information on our privacy practices and you can see when this Notice was last updated by checking the date below.