



## Pharmacovigilance and Medical Information Inquiries Privacy Notice

### 1. General Statement

Celltrion, Inc. (“we”, “us”, “our” or “Celltrion”) acknowledge the importance of detecting, monitoring and reporting of adverse medical events (pharmacovigilance) in terms of public health. At the same time, we are committed to protecting and respecting your personal data. In the event that your medical report is obtained, we are committed to collecting, maintaining, and securing personal data about you in accordance with our internal data protection policies and local laws including the EU General Data Protection Regulation (“GDPR”).

This Pharmacovigilance and Medical Information Inquiries Privacy Notice (“Privacy Notice”) outlines the types of personal data we collect and how we process your information for the purposes of pharmacovigilance related activities. We advise you to carefully read this Privacy Notice so that you are aware of how, where and why we are using your personal data.

The scope of this Privacy Notice is limited to the collection and processing of your personal data for pharmacovigilance and/or medical information inquiries.

If you have any queries regarding this Privacy Notice, please contact us using the following email address:

- [DPO\\_KR@celltrion.com](mailto:DPO_KR@celltrion.com) if you live in Republic of Korea;
- [DPO\\_EU@celltrion.com](mailto:DPO_EU@celltrion.com) if you live in Europe (EU/EEA); or
- [DPO@celltrion.com](mailto:DPO@celltrion.com) (Rest of the world except Korea and Europe)

This Privacy Notice is updated from time to time. If we update the terms, we will provide notice through our website, or by other means, so you can to review the changes. Please check back regularly if you continue to use this website or interact with Celltrion.

For purposes of this Privacy Notice, “personal data” is any information by which you can be individually identified both directly and indirectly, including, but not limited to, your name, an identifiable number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

### 2. Why we collect and use

*For Pharmacovigilance activities.* Each of marketing authorization holders of Celltrion’s medicinal products is obliged to report pharmacovigilance related information to health authorities worldwide. Celltrion is performing such pharmacovigilance activities on behalf of the marketing authorization holders pursuant to a specific delegation agreement. Each of marketing authorization holders is therefore a Data Controller and Celltrion is a Joint Controller under the GDPR.

*For Medical Information Inquiries.* Celltrion, as a manufacturer of pharmaceutical products, may receive inquiries from various people such as healthcare professionals or care givers with respect to the products. Any medical information inquiry received by Celltrion may contain inquirer’s as well as patients’ personal data. Any personal data



provided to Celltrion related to a medical inquiry 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 pharmacovigilance), we may also be required to report the data to regulatory authorities. Celltrion will be a Data Controller under the GDPR.

### **3. Type of information we have**

We may obtain and process limited personal data for the purpose of pharmacovigilance and/or responding medical inquiries as follows:

#### About the patients:

- patient names and/or initials;
- date of birth, age group, gender, weight, height; and  
*special categories of information*
- information about health, racial, or ethnic origin and sexual life; and
- medical history and status.

#### About the reporter of adverse events/medical information inquirer

- name, contact details; and
- profession, and relationship with the patient subject to the report.

### **4. How We Share Your Personal Data; the Legal Basis for Processing.**

#### ***For The Purpose Of Pharmacovigilance Activities***

Your personal data may be shared with the following entities in order to comply with our legal obligations regarding pharmacovigilance activities:

- Primarily the adverse event report containing your personal data will be submitted to the applicable health authorities. We may also respond to requests from public and government authorities.
- We may share your personal data with a member of Celltrion Group around the world, including Celltrion Global Safety Data Center, a Philippines company which is operating our global pharmacovigilance database, and Celltrion Healthcare Hungary Kft., the Marketing Authorisation Holder of our medicinal products within the EU. Our group companies will use your personal data for the same purposes as we do.
- We may also share your personal data with outside third parties, including our distribution partners, marketing authorization holders of our medicinal products, pharmacovigilance data processors, certain software or IT systems services provider in order to enable us to comply with applicable pharmacovigilance laws and regulations.

The basis for processing your personal data is to comply with our legal obligation with



respect to pharmacovigilance. Any personal data provided to us related to reporting adverse events or other activities related to pharmacovigilance will be used solely for these purposes. Where no legal obligations are imposed, we may share the information based on the legitimate interest or upon your express consent.

### ***For The Purpose Of Responding To Medical Inquiries***

Your personal data related to adverse events is very important for public health and will be used for, among others, prevention of adverse effects or any other medicine-related problem. Therefore, we may share your personal data in order to respond to medical inquiries from healthcare professionals based on the legitimate interest and where applicable, your consent.

Before sharing your personal data with third parties for purposes stated in this Privacy Notice, personal data will be pseudonymized where appropriate or required by applicable law.

## **5. The Rights of Individuals**

If you would like to request to review, correct, update, suppress, restrict or delete personal data that you have provided to us through the Site, or if you would like to request to receive an electronic copy of such personal data for purposes of transmitting it to another company, you may contact us at [DPO@celltrion.com](mailto:DPO@celltrion.com) or [DPO\\_EU@celltrion.com](mailto:DPO_EU@celltrion.com), if you live in Europe (EU/EEA). We will respond to your request consistent with applicable law.

In your request, please tell us what personal data you would like to have changed, whether you would like to have it suppressed from our database, or otherwise let us know what limitations you would like to put on our use of it. For your protection, we may need to verify your identity before implementing your request. We will try to comply with your request as soon as reasonably practicable, but in any case less than one month.

If you live in Europe, you have the following rights with respect to our use and processing of your personal data:

- a) The right to access
- b) The right to correction
- c) The right to restrict processing
- d) The right to erasure
- e) The right to object to processing

Please be noted that these rights may be limited by applicable law and may be denied to comply with a legal obligation.

At any time, you have the right to complain to Celltrion's DPO or a relevant supervisory authority. This will usually be the Data Protection Authority located in the country where you are normally resident. A list is available here: [https://edpb.europa.eu/about-edpb/board/members\\_en](https://edpb.europa.eu/about-edpb/board/members_en)

## **6. International Transfers**



Your personal information may be transferred to, and processed in, countries other than the country in which you are resident. These countries may have data protection laws that are different to the laws of your country.

Specifically, our servers are located in South Korea and our group companies and third party service providers and partners operate around the world. This means that when we collect your personal information we may process it in any of these countries.

However, we have taken appropriate safeguards to require that your personal information will remain protected in accordance with this Privacy Notice. These include implementing the European Commission's Standard Contractual Clauses for transfers of personal information between our group companies, which require all group companies to protect personal information they process from the EEA in accordance with the GDPR.

Our Standard Contractual Clauses can be provided on request. We have implemented similar appropriate safeguards with our third party service providers and partners and further details can be provided upon request.

On 17 December 2021, the European Commission (the Commission) adopted an adequacy decision for South Korea. This means that free transfers of personal data from the European Economic Area (EEA) to private and public entities in South Korea will be permitted from that date onwards (including remote access from South Korea).

In exceptional cases, we may use explicit informed consent as the lawful basis for international transfer of data.

## **7. Security Measures**

We seek to use reasonable organizational, technical and administrative measures to protect your personal data. Specific measures we use include encrypting your personal information in transit and at rest.

- Our organizational measures include establishment and implementation of internal management plans, regular employee training, etc.
- Our technical measures include installation of security programs, encryption of matters such as unique identifier, installation of access control system, and management of access authority.
- Our physical measures include access control such as to the data processing room or data storage room.

## **8. Data Retention**

As information related to pharmacovigilance are important for public health reasons, reports for adverse events are kept for minimum of ten (10) years after the withdrawal of our medicinal product in the last country where the product is marketed.

Personal data retained as part of a medical information enquiry which are not subject to pharmacovigilance obligation (such as names and contact details of inquirer of general medical information inquiry) are kept for five (5) years after receipt unless retention for a longer period is necessary.



When we have no ongoing legitimate business need to process your personal data, we will either delete or anonymise it or, if this is not possible (for example, because your personal information has been stored in backup archives), then we will securely store your personal information and isolate it from any further processing until deletion is possible.

## **9. How to complain**

In the first instance, please contact our data protection officer via [DPO@celltrion.com](mailto:DPO@celltrion.com) or [DPO\\_EU@celltrion.com](mailto:DPO_EU@celltrion.com) (if you live in Europe). You may contact our data protection officer at the following address:

Data Protection Officer  
Dong Ik (Richard) Shin  
20F, IBS Building, 263, Central-ro, Yeonsu-gu  
Incheon, 22006, Republic of Korea  
Tel.: +82 32 850 9010  
Email: [DPO@celltrion.com](mailto:DPO@celltrion.com) / [DPO\\_EU@celltrion.com](mailto:DPO_EU@celltrion.com)

We appointed GDPR-Rep.eu as representative according to Art 27 GDPR. If you want to make use of your GDPR data privacy rights, please visit: <https://gdpr-rep.eu/q/15163507>  
You may contact our representative at the following address:

GDPR-Rep.eu  
Maetzler Rechtsanwalts GmbH & Co KG  
Attorneys at Law  
c/o Celltrion, Inc.  
Schellinggasse 3/10, 1010 Vienna, Austria  
(Please add the following subject to all correspondence: GDPR-REP ID: 15163507)

You can also complain to your local Data Protection Authority if you are unhappy with how we have used your data. Our Data Protection Representative is located in Vienna, Austria and the contact details of Austrian Data Protection Authority (DPA) is as follows:

Österreichische Datenschutzbehörde  
Barichgasse 40-42,  
1030 Vienna  
Austria / Europe  
Telephone: +43 1 52 152-0  
E-Mail: [dsb@dsb.gv.at](mailto:dsb@dsb.gv.at)

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