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Human Medicines Division

# European Medicines Agency's Data Protection Notice concerning the processing of patient and product traceability data for Zynteglo following the withdrawal of the marketing authorisation

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the transfer of product and patient traceability data for the medicinal product Zynteglo from the former marketing authorisation holder to the Agency following withdrawal of the marketing authorisation.

This includes:

- The secure transfer of the data in electronic format to the Agency;
- The storage and recordkeeping of the data in a secure electronic system by the Agency;
- The access of data by authorised person(s) of the Agency.

## 1. Who is responsible for processing your data?

### *1.1. Who is the data controller?*

The Agency is ultimately responsible to comply with your data protection rights and freedoms. On behalf of the Agency, the Head of Division for Human Medicines is appointed as 'Internal Data Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Data Controller via the following email address: datacontroller.humanmedicines@ema.europa.eu

## 2. Purpose of this data processing

The purpose of this data processing activity is to comply with the provisions set out in Article 15(5) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products i.e., in case of bankruptcy or liquidation of the marketing authorisation holder, and in the event that the marketing authorisation is not transferred to another legal entity, the product and patient traceability data shall be transferred to the Agency.

Following the withdrawal of the marketing authorisation of the medicinal product Zynteglo and the transfer of the responsibilities from the former marketing authorisation holder to the Agency, this includes the following responsibilities:

- The establishment and maintenance of a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the cells it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product was used.
- To ensure that the traceability systems established in accordance with the above continue to be complementary to, and compatible with the legal requirements, including the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC as regards human cells and tissues other than blood cells.
- Secure storage of the data referred to above for a minimum of 30 years after the expiry date of the product.

### *2.1. Personal data concerned*

In this processing operation, we process personal data which were collected from data subjects by the hospital, institution or private practice during cell donation. Such data may include the following:

- Name, date of birth, Patient identifier (ID), Chain of Identity (COI), HPC-A DIN/ID, Drug Product Bag ID

### *2.2. Legal basis of the processing*

The processing operations of the medicinal product and patient traceability data for Zynteglo by the Agency are necessary for compliance with a legal obligation and may be justified under Article 5(1)(c) of the European Union Data Protection Regulation[1] (EUDPR). The legal obligations to which the Agency is subject to is expressly provided by Article 15(5) of Regulation (EC) No 1394/2007 as explained above.

## 3. How long do we keep your data?

30 years after the expiry date of the medicinal product.

## 4. Who has access to your information and to whom is it disclosed?

The data collected will be processed internally by staff within the EMA Division responsible for Human Medicines. However, considering the confidential nature of the data, data will be kept as confidential and access to the data will be restricted on a need-to-know basis to the internal controller and selected H-Division members.

[1] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

## 5. Your data protection rights

As data subject (i.e., the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

## 6. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Data Controller** at datacontroller.humanmedicines@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en