polpharma	ADVERSE EVENT REPORTING FORM FOR HEALTHCARE PROFESSIONAL	3rd EDITION 21/08/2024

REPORT: ☐ INITIAL ☐ FOLLOW-UP

I. PATIENT DETAILS

PATIENT INITIALS	COUNTRY OF OCCURRENCE OF THE ADVERSE EVENT	DATE OF BIRTH OF THE PATIENT DD/MM/YYYY	PATIENT AGE at the time of the adverse event	PATIENT GENDER	PATIENT WEIGHT	PATIENT HEIGHT
				☐ **FEMALE** **Is the patient pregnant?** ☐ YES ☐ NO ☐ UNKNOWN ☐ **MALE**		

II. SUSPECTED MEDICINE

NAME OF THE MEDICINE (with dosage)	BATCH NUMBER/ EXPIRATION DATE	DOSAGE (total per day)	SINGLE DOSE	ROUTE OF ADMINISTRATION (e.g. oral, sublingual, intravenous)	WHAT DATE DID YOU START TAKING THE MEDICINE? DD/MM/YYYY	WHAT DATE DID YOU STOP TAKING THE MEDICINE? DD/MM/YYYY	REASON FOR TAKING

ACTION TAKEN WITH DRUG AS A RESULTS OF THE EVENT:
(if several medicines are suspected to cause the adverse event(s) please reply to each one)

☐ DOSE INCREASED ☐ DOSE REDUCED ☐ WITHDRAWN ☐ DOSE NOT CHANGE ☐ UNKNOWN

ANY OTHER MEDICINES BEING TAKEN AND ADDITIONAL DETAILS (excluding medicines used in the treatment of adverse event(s)).

NAME OF THE MEDICINE	SINGLE DOSE	DOSAGE (total per day)	ROUTE OF ADMINISTRATION	WHAT DATE DID YOU START TAKING THE MEDICINE? DD/MM/YYYY	WHAT DATE DID YOU STOP TAKING THE MEDICINE? DD/MM/YYYY	DRUG INDICATION

ADDITIONAL RELEVANT INFORMATION

e.g. medical history, test results, allergies, pregnancy with the last menstrual period date

ADDITIONAL DETAILS:

III. ADVERSE EVENT(S)

SUSPECTED EVENT	START DATE DD/MM/YYYY	END DATE DD/MM/YYYY

TYPE OF EVENT:

☐ **SERIOUS**
(CHECK THE APPROPRIATE FIELD/FIELDS)

- ☐ **CAUSED DEATH**
  cause of death:.....
- ☐ **HOSPITALIZATION (MORE THAN 2 DAYS) OR PROLONGED HOSPITALIZATION**
- ☐ **INCAPACITY OR DISABILITY**
- ☐ **LIFE THREATENING**
- ☐ **CONGENITAL ANOMALY/BIRTH DEFECT**
- ☐ **OTHER MEDICALLY IMPORTANT CONDITION**

☐ **NON-SERIOUS (DOES NOT MEET THE ABOVE CRITERIA)**

DESCRIPTION OF THE ADVERSE EVENT(S)	

PLEASE SELECT AN OUTCOME FOR SUSPECTED EVENT

☐ RECOVERED ☐ RECOVERED WITH ABNORMALITY ☐ RECOVERING (DURING TREATMENT)
☐ NOT RECOVERED ☐ CAUSED DEATH ☐ UNKNOWN

WAS THE EVENT ABATED AFTER DISCONTINUED USE OF MEDICINE/REDUCED DOSE?	**MEDICINE:** ☐ YES ☐ NO ☐ UNKNOWN
DID THE EVENT REOCCUR AFTER REUSE OF THE MEDICINE?	**MEDICINE:** ☐ YES ☐ NO ☐ UNKNOWN

Please complete this form and send it to the address as soon as possible:

Pharmacovigilance Area of Medical Department of Zakłady Farmaceutyczne Polpharma S.A.
Bobrowiecka 6, 00-728 Warszawa, e-mail: phv@polpharma.com

DO YOU THINK THERE IS A CONNECTION BETWEEN THE ADVERSE EVENT AND THE MEDICINE USED?	☐ YES* ☐ NO ☐ UNKNOWN *If so please explain why?

IV. REPORTER DETAILS

First name and surname	**Profession/Specialization**	**Stamp**
Adress	**Telephone number**	
Email address	**Date** **DD/MM/YYYY**	
Do you agree to further contact us in order to supplement the information you have provided?	☐ YES* ☐ NO * Preferred way of contact: ☐ Email address _____ ☐ Telephone number _____	

PERSONAL DATA CONTROLLER - GENERAL INFORMATION

On the basis of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter referred to as: "**GDPR**"), we hereby inform that:

[Controller, data protection officer, contact details]

1. The Controller of your personal data is the Marketing Authorization Holder of the medicinal product which is the subject of the notification, i.e.:
   a. Zakłady Farmaceutyczne Polpharma S.A. with its registered office in Starogard Gdański (83-200) at ul. Pelplińska 19

(hereinafter referred to as the "**Controller**").

2. You can contact the Controller in writing to the above addresses. The Controller has appointed a Data Protection Officer, whom you may contact in all matters relating to the personal data protection, by writing to Zakłady Farmaceutyczne POLPHARMA S.A. (office in Warsaw) Bobrowiecka 6, 00-728 Warszawa, by sending an e-mail to: dpo@polpharma.com or by telephone on: 22 364 63 11.
3. Where an adverse event has occurred following the use of a medicinal product, the adverse event may be reported to Medical Department, adress: Zakłady Farmaceutyczne POLPHARMA S.A. (office in Warsaw), ul. Bobrowiecka 6, 00 -728 Warszawa, tel.: 22 364 61 00, email: phv@polpharma.com.

[Purpose and legal basis for personal data processing]

4. Your personal data will be processed:
   a. for the purpose necessary for the Controller's ensuring high standards of quality and safety of medicinal products and, in particular, monitoring the safety of medicinal products, including the keeping of records of individual adverse events to medicinal products and the reporting of individual adverse events to medicinal products to the competent authorities– on the basis of:
      - personal data, including the name and surname and address of the medical profession of the person reporting the adverse event of a medicinal product pursuant to Article 6(1)(c) of the GDPR, i.e. processing is necessary to fulfil the legal obligation imposed on the Controller pursuant to Article 36e(1) (2) and (3) of the Polish Pharmaceutical Law, also pursuant to Article 9 (2) (i) GDPR;
   b. determination, investigation or defence of potential claims between you and the Controller - basis of Article 6(1)(f) of the GDPR, i.e. on the basis of the legitimate interest pursued by the Controller, which is the possibility to pursue claims.
5. You will not be subject to automated decision-making, including decisions based on profiling.
6. Provision of Your personal data is obligatory.

[Categories of personal data recipients]

7. Your personal data may be disclosed to the following entities: employees, IT service providers, providers of consulting and legal services.
8. Your personal data may be made available to entities and bodies authorized to process such data under the law, in particular to the President of the Office of Medicinal Products, Medical Devices and Biocidal Products, the European Medicines Agency and other competent authorities of the Member States of the European Union, in which the Controller has obtained a marketing authorisation for a medicinal product.
9. The Controller does not intend to transfer your personal data outside the European Economic Area or to an international organisation.

[Personal data storage period]

10. Your personal data shall be processed for the period necessary to achieve the purposes for which the data are processed or until an objection is raised (if the processing is based on the legitimate interest of the Controller) or until the withdrawal of consent (if the processing is based on the given consent) - depending on which of the events occurs earlier.
11. After the expiry of the aforementioned period, personal data shall be stored for 10 years from the expiry date of the medicinal product series to which the application referred or until the claims expiry or until you have objected to the processing (if the processing is based on legitimate interest of the Controller) or have withdrawn your consent (if the processing is based on consent) – whichever occurs first.

[Rights]

12. You have the right to:
    a. access to data concerning you, the right of rectification, erasure, restriction of processing, the right to object to the processing of data;
    b. transfer personal data, i.e. to receive from the controller personal data in a structured, commonly used machine-readable format;
    c. to the extent that the processing of your personal data is based on consent, the right to withdraw consent to the processing of your personal data at any time. The withdrawal of consent shall not affect the lawfulness of the processing carried out on the basis of consent prior to its withdrawal.
13. In order to exercise the above rights, you need to contact the Controller or the Data Protection Officer, using the aforementioned contact details (contact details provided above).
14. You also have the right to lodge a complaint with a personal data protection supervisory authority (President of the Personal Data Protection Office), if you believe that the data processing violates the GDPR.