SUSPECT ADVERSE REACTION REPORT	

I REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTANCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
7+13 DESCRIBE REACTION(S) (including relevant tests/lab date)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20 DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTERER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOW UP	

Personal data processing notice for persons reporting adverse drug reactions

In performance of the obligation under Article 13(1) and (2) and Article 14(1) and (2) 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 would like to inform you that:

1. **Tarchomińskie Zakłady Farmaceutyczne "Polfa" Spółka Akcyjna with its registered office in Warsaw**, address: ul. A. Fleminga 2, 03-176 Warszawa (KRS [National Court Register] number: 27741, hereinafter referred to as "**Data Controller**" or "**TZF Polfa S.A.**") is the controller of your personal data.
2. The Data Controller has appointed a Data Protection Officer, who can be contacted by writing to: **iod@tzf.pl.**
3. Your personal data will be processed by the Data Controller for the following purposes and on the following legal bases:

Legal basis	Purposes of processing
GDPR Article 6(1)(f) in order to pursue the Data Controller's legitimate interests	1. Answering inquiries submitted using the contact form; 2. Identifying Client needs; 3. Administration and management processes, mainly concerning our website;
Article 6(1)(c) of GDPR in order to comply with legal requirements to which the controller is subject as regards ensuring the safety of use of medicinal products, medical devices and cosmetics.	1. Monitoring of adverse reactions to medicinal products and archiving pursuant to Article 12 of Commission Implementing Regulation (EU) No. 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No. 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council; 2. Handling adverse drug reaction reports (legal basis: Article 36e(1) of the Pharmaceutical Law Act of 6 September 2001), with the exception of healthcare professionals for whom relevant laws governing the rules of professional practice provide for the obligation to report adverse reactions to medicinal products.

4. If we receive personal data in the report, they will be anonymized, which means that none of the employees of Polfa Tarchomin S.A. will be able to identify you and therefore the information submitted to supervisory authorities and national agencies will be anonymous. You have the right to access the content of your data and the right to rectify, erase your data and restrict their processing, as well as the right to data portability and the right to object.

5. Your personal data will not be transferred to third parties except to the following recipients:
   - entities authorized by law, e.g. supervisory authorities, law enforcement agencies or courts. In the case of a tax scheme, the personal data will be transferred to the Head of the National Revenue Administration,
   - other recipients of the data may also include entities performing tasks for the Data Controller on the basis of a signed agreement, and in particular those providing IT system support and maintenance services and auditing the Data Controller's operations, as well as suppliers of external systems supporting the Data Controller's operations, consultants, advisors and other entities cooperating with the Data Controller.
6. The personal data may be transferred to a third country, i.e. a country that is not part of the European Economic Area (EEA) on the basis of:
   - GDPR Article 45(1) – a decision of the European Commission concluding that there is an adequate level of protection (for countries for which such a decision has been issued);
   - GDPR Article 46(2)(c) – standard contractual clauses approved by the European Commission (for other countries).
7. Personal data related to reporting an adverse reaction to a medicinal product shall be processed throughout the validity period of the marketing authorisation for the medicinal product covered by the report and for 10 years after the expiry of the authorisation.
8. You have the right to lodge a complaint with the supervisory authority competent for personal data protection if you consider that the processing of your data violates the provisions of the General Data Protection Regulation of 27 April 2016.

This document was last updated on 15 October 2025.