Personal data processing notice for persons filing complaints

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, 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. If the complaint concerns, for example, quality of service, packaging or logistics issues, the data may be processed for the purpose of: • handling customer claims, • defense against potential claims, • improving the quality of products and internal processes. 2. Accepting and handling a complaint concerning a pharmaceutical, medical or dietary supplement. 3. Contacting the person who filed the complaint in order to obtain additional information necessary to analyse the complaint. 4. Analysis of the causes of the incident and taking corrective or preventive actions.
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. Documentation and reporting to competent authorities (e.g. Office for Registration of Medicinal Products or EMA) regarding product safety. 2. The data are processed for the purpose of complying with the obligations arising from legal regulations, in particular: • **Pharmaceutical Law Act** of 6 September 2001, • **Act on Medical Devices** of 20 May 2010, • **pharmacovigilance** or product quality regulations.

4. Your personal data will not be transferred to third parties except to the following recipients:

4.1. 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,

4.2. 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.

5. 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:

5.1. 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);

5.2. GDPR Article 46(2)(c) – standard contractual clauses approved by the European Commission (for other countries).

6. Personal data related to reporting an adverse reaction to a medicinal product shall be processed for the period of:

6.1. Medical devices:

- Pursuant to Article 10(8) of Regulation (EU) 2017/745 (MDR), documentation concerning safety, incidents and complaints must be retained for at least 10 years after the last copy of the device has been placed on the market (or for 15 years – for implants).

6.2. Medicinal products (drugs):

- Personal data related to complaints or adverse drug reaction reports – for the period of validity of the marketing authorisation and at least 10 years after the expiry of the marketing authorisation and the withdrawal of the product from the market.

6.3 Food supplements and cosmetics

- Pursuant to general provisions of civil law, supplements and cosmetics are not subject to pharmacovigilance regulations (statute of limitations on consumer claims – 6 years),
- quality and complaint requirements – 5-6 years from the end of the complaint handling process – defence against claims.

7. You have the right of access to the content of your data, the right to rectification, erasure and restriction of processing, as well as the right to file an objection to the processing of your personal data on the basis of our legitimate interest. If you consider that the processing of your personal data violates the provisions of the GDPR, you also have the right to lodge a complaint with the President of the Data Protection Authority (ul. Stawki 2, 00-193 Warsaw).

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