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DRUG EXPOSURE DURING PREGNANCY – PREGNANCY AND POSTPARTUM FORM

v 1. 22.07.2020

PART A Pregnant women

REPORT ☐ PRELIMINARY ☐ SUPPLEMENTARY

Report completion date DD/MM/YY	

Source of information:

☐ Pregnant patient ☐ Primary Care Physician ☐ Gynecologist/Obstetrician

☐ Pediatrician ☐ Other (please specify)

I. DATA OF PATIENT EXPOSED TO DRUG DURING PREGNANCY

Patient initials	Country where drug exposure in pregnancy occurred	Patient's DOB DD/MM/YY	Patient's age at the time of drug exposure in pregnancy	Weight	Height

1. Number of previous pregnancies

2. Did any complications occur during previous pregnancies? ☐ YES* ☐ NO

**If yes, please provide detailed information on irregularities during pregnancy, including the stage of pregnancy when complications occurred:*

3. Patient's medical history

Please enter the past or current diseases such as hypertension, diabetes mellitus, epilepsy, heart diseases, asthma, allergies, depression or other mental disorders, sexually transmitted diseases, hepatitis (type), viral infections (specify), AIDS.

Pharmacovigilance and Medical Information Department, Zakłady Farmaceutyczne POLPHARMA S.A.
6 Bobrowiecka Street, 00-728 Warsaw, Poland, **email:** phv@polpharma.com, **fax:** +48 22 364 61 66

II. INFORMATION ABOUT THE CURRENT PREGNANCY (OR FETUS IN CASE OF PLANNED TERMINATION OR MISCARRIAGE – PLEASE COMPLETE PART III)

1. Date of last menstruation	
2. Current gestational age	
3. Gestational age at the time of patient exposure to drug	

4. Course of pregnancy ☐ normal ☐ complicated *(e.g. GTD)*, please describe with dates:

5. Estimated delivery date

6. Please specify the multiplicity of pregnancy *(e.g. single pregnancy, twin pregnancy)*

7. If infertility was treated, please describe the treatment

III. INFORMATION ABOUT THE FETUS (IN CASES OF PLANNED TERMINATION OF PREGNANCY OR MISCARRIAGE)

1. Reason for termination	
2. Gestational age at termination	

3. Results of physical examination of the child (sex, detected fetal malformations)

IV. INFORMATION ON EXPOSURE DURING PREGNANCY

Please provide details about the medicinal products, herbal products and dietary supplements (e.g. vitamin supplements) used during pregnancy.

Full product name (with dose)	Batch number/ Expiry date	Dosage regimen	Single dose	Route of administration *(e.g. oral, sublingual, intravenous, etc)*	Treatment start date dd|mm|yy	Treatment end date dd|mm|yy	Therapeutic indication

1. Did you experience any adverse reactions after taking the above-described **drugs**? ☐ YES* ☐ NO

***If yes, please provide the following information:**

Drug name	Adverse reaction	Types of reactions Serious/Non-serious ***(**If serious, specify the cause out of those given below)***	Start date dd|mm|yy	End date dd|mm|yy

****Type of reaction: Serious (please select the cause and enter it in the table):**
● death *(please specify the cause of death)*, ● hospitalization *(more than 2 days)* or extended hospitalization, ● persistent or significant disability or incapacity, ● life-threatening reaction, ● fetal malformations/congenital malformations, ● other medically significant reactions

Description of adverse reaction:

Description of adverse reaction – continued:

2. Did the patient smoke cigarettes, consume alcohol or use any other stimulants during pregnancy? ☐ YES* ☐ NO

**If yes, specify the type of stimulants, amount and frequency of use:*

3. Past illnesses that occurred during pregnancy *(e.g. flu)*

4. Serological test results *(e.g. rubella, toxoplasmosis)*

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5. **Test results during pregnancy** *(please specify whether the result was normal if the information is available):*

Test name	Test date	Test result
ULTRASOUND		
Doppler ultrasound		
Maternal blood pressure		
CBC		
Liver tests (AST, ALT)		
Urinalysis *(e.g. creatinine, urea)*		
Uterine artery flows		
Cervical length		
Serum markers (AFP and others)		
Chorionic villus sampling (CVS)		
Amniocentesis		
Other		
Other		

6. **Family medical history**
Family history of congenital malformations *(determination of relationship – with the mother/father, determination of kinship between the parent and the person with the defect)*

V. INFORMATION ABOUT THE CHILD'S FATHER

1. DOB

2. Medical history

Please describe the past or current diseases, e.g. hypertension, diabetes mellitus, epilepsy, heart diseases, asthma, allergies, depression or other mental disorders, sexually transmitted diseases, hepatitis *(type)*, viral infections *(specify)*, AIDS.

3. Chronically used drugs at the time of conception

Please specify all drugs taken *(name, dose, dosage form, dosage regimen, duration of treatment, indications)*.

VI. REPORTING PERSON'S DETAILS

1. Full name

2. Correspondence address

3. Contact phone number

4. Email

5. Medical specialty *(if the reporting person is a medical practitioner)* Stamp

6. Do you agree to be contacted again to obtain supplementary information, if needed? ☐ YES* ☐ NO

*If yes, please indicate the preferred route of contact:

☐ phone ☐ e-mail

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

PATIENT INFORMATION REGARDING THE GDPR IS BELOW. If you are a healthcare professional, go to page 8 and read the information regarding the GDPR.

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. Warszawskie Zakłady Farmaceutyczne Polfa S.A. with its registered office in Warsaw (01-207), ul. Karolkowa 22/24, OR
   b. Zakłady Farmaceutyczne POLPHARMA S.A. with its registered office in Starogard Gdański (83-200) at ul. Pelplińska 19.
   (hereinafter each separately 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 reaction has occurred following the use of a medicinal product, the adverse reaction may be reported to the Pharmacovigilance Risk Assessment Unit, address: 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 ensuring high standards of quality and safety of medicinal products by Controller and, in particular, monitoring the safety of medicinal products, including the keeping of records of individual adverse reactions to medicinal products and the reporting of individual adverse reactions to medicinal products to the competent authorities– on the basis of:
      - data concerning health will be processed pursuant to Article 9(2)(i) of the GDPR, i.e. processing is necessary for reasons related to the public interest in the field of public health in the form of ensuring high standards of quality and safety of medicinal products pursuant to the provisions of law, i.e. pursuant to Article 36e(1) of the Polish Pharmaceutical Law Act;
      - other personal data will be processed 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) of the Pharmaceutical Law Act;
   b. contacting the attending physician and obtaining additional information from the attending physician in connection with adverse reactions to the 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) of the Pharmaceutical Law Act;
   c. determination, investigation or defence of possible claims between you and the Administrator with regard to health data pursuant to Article 9(2)(b) of the GDPR, i.e. processing is necessary for the determination, investigation or defence of claims; in the case of other personal pursuant to Article 6(1)(f) of the GDPR, i.e. on the basis of the legitimate interest pursued by the Administrator, 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 voluntary.

[Categories of personal data recipients]

7. Your personal data may be disclosed to the following entities: attending physician (if consent is granted to contact with the attending physician), 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.

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

HEALTHCARE PROFESSIONAL INFORMATION REGARDING THE GDPR IS BELOW. If you are a Patient, go to page 7 and read the information regarding the GDPR.

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:

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   (hereinafter each separately 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**.
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[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 reactions to medicinal products and the reporting of individual adverse reactions 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 reaction 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]

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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.

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    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.

PART B Postpartum women

REPORT ☐ PRELIMINARY ☐ SUPPLEMENTARY

Report completion date DD/MM/YY	

Source of information:

☐ Pregnant patient ☐ Primary Care Physician ☐ Gynecologist/Obstetrician

☐ Pediatrician ☐ Other (please specify)

If PART A of the report has been completed in the previous submission, please complete ONLY sections IV to VI. Please enter additional information, if needed, supplementing the previous report in sections I to III.

I. DATA OF PATIENT EXPOSED TO DRUG DURING PREGNANCY

Patient initials	Country where drug exposure in pregnancy occurred	Patient's DOB DD/MM/YY	Patient's age at the time of drug exposure in pregnancy	Weight	Height

1. Number of previous pregnancies	
2. Did any complications occur during previous pregnancies?	☐ YES* ☐ NO

** If yes, please provide detailed information on irregularities during pregnancy, including the stage of pregnancy when complications occurred:*

3. Patient's medical history

Please enter the past or current diseases such as hypertension, diabetes mellitus, epilepsy, heart diseases, asthma, allergies, depression or other mental disorders, sexually transmitted diseases, hepatitis (type), viral infections (specify), AIDS.

II. INFORMATION ON EXPOSURE DURING PREGNANCY

Please provide details about the medicinal products, herbal products and dietary supplements (e.g. vitamin supplements) used during pregnancy.

Full product name (with dose)	Batch number/ Expiry date	Dosage regimen	Single dose	Route of administration *(e.g. oral, sublingual, intravenous, etc)*	Treatment start date dd|mm|yy	Treatment end date dd|mm|yy	Therapeutic indication

1. Did you experience any adverse reactions after taking the above-described **drugs**? ☐ YES* ☐ NO

**If yes, please complete the information below:*

Drug name	Adverse reaction	Types of reactions Serious/Non-serious ***(**If serious, specify the cause out of those given below)***	Start date dd|mm|yy	End date dd|mm|yy

****Type of reaction: Serious (please select the cause and enter it in the table):**
● death *(please specify the cause of death)*, ● hospitalization *(more than 2 days)* or extended hospitalization, ● persistent or significant disability or incapacity, ● life-threatening reaction, ● fetal malformations/congenital malformations, ● other medically significant reactions

Description of adverse reaction:

Description of adverse reaction – continued:

III. INFORMATION ABOUT THE CHILD'S FATHER

1. DOB

2. Medical history
Please describe the past or current diseases, e.g. hypertension, diabetes mellitus, epilepsy, heart diseases, asthma, allergies, depression or other mental disorders, sexually transmitted diseases, hepatitis (type), viral infections (specify), AIDS.

3. Chronically used drugs at the time of conception
Please specify all drugs taken *(name, dose, dosage form, dosage regimen, duration of treatment, indications)*.

IV. INFORMATION ABOUT DELIVERY

1. Delivery date

2. Delivery method ☐ natural ☐ cesarean section

3. Course of pregnancy ☐ normal ☐ complicated *(e.g. GTD)*, please describe:

4. Course of delivery ☐ normal delivery, scheduled delivery ☐ * complicated delivery *(e.g. preterm delivery, delayed delivery)*

**If any complications occurred during delivery, please provide detailed information:*

V. INFORMATION ABOUT THE NEWBORN

1. Gestational age at delivery

2. DOB

3. Initials

4. Child's gender ☐ female ☐ male

5. Results of the child's physical examination on the day of birth:

WEIGHT	LENGTH	HEAD CIRCUMFERENCE	APGAR SCORE

6. Were malformations diagnosed at birth? ☐ YES* ☐ NO

**If yes, please provide detailed information*

7. Does the child have a chronic disease? ☐ YES* ☐ NO

**If yes, please provide detailed information (type of disease, treatment used):*

8. Did or does your child take any medications? ☐ YES* ☐ NO
(name, dose, dosage form, dosage regimen, duration of treatment, indications):

**If yes, please provide detailed information (type of disease, treatment used):*

VI. REPORTING PERSON'S DETAILS

1. Full name

2. Correspondence address

3. Contact phone number

4. Email

5. Medical specialty *(if the reporting person is a medical practitioner)* Stamp

6. Do you agree to be contacted again to obtain supplementary information, if needed? ☐ YES* ☐ NO

*If yes, please indicate the preferred route of contact:

☐ phone ☐ e-mail

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

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[Purpose and legal basis for personal data processing]

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      - data concerning health will be processed pursuant to Article 9(2)(i) of the GDPR, i.e. processing is necessary for reasons related to the public interest in the field of public health in the form of ensuring high standards of quality and safety of medicinal products pursuant to the provisions of law, i.e. pursuant to Article 36e(1) of the Polish Pharmaceutical Law Act;
      - other personal data will be processed 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) of the Pharmaceutical Law Act;
   b. contacting the attending physician and obtaining additional information from the attending physician in connection with adverse reactions to the 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) of the Pharmaceutical Law Act;
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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.
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[Personal data storage period]

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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.

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

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   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.
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SUPPLEMENTARY INFORMATION TO PARTS A and B OF THE REPORT (WHEN THE PREGNANCY IS COMPLICATED)

Completion date DD/MM/YY	

Source of information:

☐ Pregnant patient ☐ Primary Care Physician ☐ Gynecologist/Obstetrician

☐ Pediatrician ☐ Other (please specify)

1. Malformations or any irregularities detected since the last contact with the Marketing Authorization Holder

2. Assessment of child development

past/current diseases	
past hospitalizations	
used drugs	
breast-feeding	☐ YES ☐ NO

3. Other important information

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

PATIENT INFORMATION REGARDING THE GDPR IS BELOW. If you are a healthcare professional, go to page 18 and read the information regarding the GDPR.

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. Warszawskie Zakłady Farmaceutyczne Polfa S.A. with its registered office in Warsaw (01-207), ul. Karolkowa 22/24, OR
   b. Zakłady Farmaceutyczne POLPHARMA S.A. with its registered office in Starogard Gdański (83-200) at ul. Pelplińska 19.
   (hereinafter each separately 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 reaction has occurred following the use of a medicinal product, the adverse reaction may be reported to the Pharmacovigilance Risk Assessment Unit, address: 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 ensuring high standards of quality and safety of medicinal products by Controller and, in particular, monitoring the safety of medicinal products, including the keeping of records of individual adverse reactions to medicinal products and the reporting of individual adverse reactions to medicinal products to the competent authorities– on the basis of:
      - data concerning health will be processed pursuant to Article 9(2)(i) of the GDPR, i.e. processing is necessary for reasons related to the public interest in the field of public health in the form of ensuring high standards of quality and safety of medicinal products pursuant to the provisions of law, i.e. pursuant to Article 36e(1) of the Polish Pharmaceutical Law Act;
      - other personal data will be processed 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) of the Pharmaceutical Law Act;
   b. contacting the attending physician and obtaining additional information from the attending physician in connection with adverse reactions to the 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) of the Pharmaceutical Law Act;
   c. determination, investigation or defence of possible claims between you and the Administrator with regard to health data pursuant to Article 9(2)(b) of the GDPR, i.e. processing is necessary for the determination, investigation or defence of claims; in the case of other personal pursuant to Article 6(1)(f) of the GDPR, i.e. on the basis of the legitimate interest pursued by the Administrator, 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 voluntary.

[Categories of personal data recipients]

7. Your personal data may be disclosed to the following entities: attending physician (if consent is granted to contact with the attending physician), 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.

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

HEALTHCARE PROFESSIONAL INFORMATION REGARDING THE GDPR IS BELOW. If you are a Patient, go to page 17 and read the information regarding the GDPR.

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:

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   (hereinafter each separately referred to as the "**Controller**").
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[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 reactions to medicinal products and the reporting of individual adverse reactions 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 reaction 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]

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    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).
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