SIDE EFFECTS REPORT FORM FOR PATIENTS

Complete all the lines marked with and give as much other information as you can

1. About the suspected side effect

What were the symptoms of the suspected side effect and how did it happen?

How bad was the suspected side effect?/ Please tick the box that best describes how bad the symptoms were/

□ Mild □ Unpleasant but did not affect everyday activities □ Bad enough to affect everyday activities □ Bad enough to see a doctor

□ Bad enough to be admitted to hospital □ Caused very serious illness □ Caused death □ Other

When did the side effect start?

How is the person feeling now ? / Please tick the box that best describes his/her condition/

□ Better (no more symptoms) □ Getting better □ Still has symptoms □ More seriously ill

□ Other…….

If possible, please give more details.

/for example.: did the person receive any treatment for the symptoms? did he/she stop taking the medicine as a result of side effect?, did the symptoms disappeared after stopping the drug?/

2. Person who had the suspected side effect

Who had the suspected side effect?

□ You □ Your child □ Someone else

Date of the person who had the suspected side effect /Supply as much information as you can/

Initials □ Male □ Female

Age Weight Height

Other relevant information / for example does the person have any medical conditions or allergies**?/**

Make sure you have completed all the fields marked

3. About the medicine(s) which might have caused side effect

Give details of the medicine you suspect of causing the side effect.

Name of the medicine □ prescription □without prescription

Dosage (for ex ample: one 250 mg tablet, twice a day)

What was it taken for?

Therapy start date: Therapy end date

Did you stop the drug because of side effects □ Yes □ No

If you were taking any other medicine at the same time (which might have caused an interaction) give details of it.

Name(s) of other medicine(s) (if applicable) □ prescription □without prescription

Dosage (for example: one 250 mg tablet, twice a day)

What was it taken for?

Therapy start date: Therapy end date:

Do you think this medicine might also have caused the side effect □ Yes □ No □ Possibly

If yes, please give the name of this medicine:

Did you stop the medicine because of side effects □ Yes □ No

Have you taken other medicines or herbal remedies lately? □ Yes □ No

If yes please list them

Name(s) of the medicine

4. About your doctor (optional)

Would you like a copy of this report be sent to your doctor ? □ Yes □ No

If yes, please give the doctor's name and address

Doctor's first name and family name:

Address:

Postcode:

5. About the person making the report *

Contact details – please supply a full postal address, phone number and e-mail address

Mr/Mrs

First name: **Family name:**

Address: **Postcode:**

Telephone number: **E-mail:**

Date:

*Please make sure that all fields marked are filled. Filled form please send immediately to the fax number:**+48 22 344 74 10.** Original of the form please send by mail to: USP Zdrowie Sp. z o.o., ul. Poleczki 35, 02-822 Warszawa or give it to the company representative.*

Personal data processing notice

Pursuant to Article 13(1) and 13(2) of Regulation 2016/679 of the European Parliament and of the Council (EU) of 27 April 2016 the 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 ("GDPR"), please be informed that:

1. USP Pharmacia Sp. z o.o. in Warsaw, ul. Ziębicka 40, zip code 50-507, is the controller of your personal data.

2. Your personal data will be processed for purposes related to compliance with the pharmacovigilance obligation arising from the Polish Pharmaceutical Law of 6 September 2001 (Article 6(1)(c) of the GDPR). For special categories of personal data, e.g. health-related data, USP Pharmacia processes your data on the ground of necessity in connection with public interest in the area of public health, such as assurance of high quality standards and safety of cosmetics (Article 9(2)(i) of the GDPR).

3. The individuals obligated to report adverse effects of medicinal products are required to give their personal data under applicable provisions of the Polish Pharmaceutical Law of 6 September 2001 and other legislation.

4. Other individuals give their data voluntarily but they must do this for their report to be accepted.

5. Your personal data will be provided to government bodies authorised under applicable laws (e.g. drug registration offices).

6. Your personal data shall be retained for a period as required under applicable laws.

7. You have a right to access your data, a right to data rectification, a right to restriction of processing and a right to object.

8. You have a right to lodge a complaint to a competent supervisory authority whenever you believe that the processing of your personal data is in breach of the GDPR.