**Questions and answers: Adverse Drug Reactions reporting**

As a patient, you could report noxious and unwanted effects of medicines directly to the authority. You can also report them on behalf of someone in your care, such as a child or relative.

All medicinal products can theoretically cause adverse drug reactions (ADRs). For this reason, patients should be informed accordingly. If you suspect that you are suffering of an adverse effect related to your medicine, please speak to your doctor or pharmacist for advice.

**What is an adverse drug reaction / undesirable effect?**

An adverse drug reaction (ADR) or undesirable effect, are synonymous, and correspond to a noxious and unintended response to one or more medicinal product.

**Why should I report an adverse drug reaction?**

Although medicines are studied extensively in clinical trials before they are authorised, still some their side effects can be unknown and can only appear after extensive been over time. By reporting undesirable effects, you can help to provide more information about medicines, allowing the detection of potential unknown adverse drug reactions, the quantification and/or better characterization, which will ultimately help to make them safer.

**How do I report an adverse drug reaction?**

If you think a medicinal product has caused an undesirable effect, please check the package leaflet included inside the package for information on how to report it. For more details, please check INFARMED – National Authority of Medicines and Health Products, I.P.’s website (use these link to ensure you are reporting to the appropriate website (PORTAL RAM): https://www.infarmed.pt/web/infarmed/submissaoram).

To report it, just access the link, select User or Healthcare Professional and fill in the fields with all possible information, taking into account that the information marked with \* is mandatory and at the end press the button "Submit".

**What information should I report?**

If possible, you should provide the following information when making your report:

* information on the person who has had the undesirable effect (such as age and sex);
* the description of the undesirable effect;
* the dose and the name of the medicinal product suspected to have caused the undesirable effect (brand name as well as active ingredient);
* the batch number/reference of the product (found on the packaging);
* any other medicines being taken around the same time (including non-prescription medicines, herbal remedies and contraceptives);
* any other health conditions that the person who experienced the side effect may have
* your contacts, as the reporter, in order to allow to validate/complete the information provided.

**When should I report an adverse drug reaction?**

To report an adverse drug reaction, it is enough to have a suspicion of its occurrence and the available information should be sent to the authority as soon as possible.

You cannot always be certain that what you are experiencing is caused by the medicine, but by reporting suspected adverse drug reactions you can help the authorities in their investigations, which will lead to safer medicines.

**What happens to my report after I've sent it?**

Once submitted, you will receive a confirmation email with the submission number, which will be used in future contacts related with this submission.

After the analysis has been completed you will receive information on the outcome of the assessment, if the case is classified as serious.

Your report, along with others, will be reviewed by pharmacovigilant experts to ascertain if there is any new information (known as a 'safety signal'). After evaluating the safety signal and all other relevant data, medicines authorities may issue new warnings or advice on how the product should be used, and can even stop its use.

**What are the criteria for considering a case of suspected adverse reaction as serious?**

* be fatal,
* be life-threatening,
* motivate or prolong hospitalization,
* result in temporary or permanent disability
* be clinically important, means an adverse event that may not be immediately life-threatening or result in death or hospitalisation but may require an intervention by a healthcare professional or specific treatment,
* cause congenital anomaly or malformation.

**Can I get help with reporting an adverse drug reaction?**

Yes. Your doctor or pharmacist can help you complete your report, and you can also request that they send the report on your behalf.

**I submitted an adverse reaction notification through Portal RAM and have not received feedback. Does this mean that my notification was not received?**

If you have submitted a notification and have not received feedback, the most likely reason is that you have provided an incorrect or non-existent email address. For clarification, we ask you to contact Infarmed at the email address cimi@infarmed.pt, or by phone at +351 217987373.**The medicine has a black triangle symbol in its package leaflet. What does this mean?**

The inverted black triangle symbol '▼' serves as a reminder to report any suspected undesirable effects, either because the medicine is new or because there is a particular need to find out more about its long-term safety. The symbol does not mean that your medicine is unsafe.

**Are my personal data protected?**

Personal data are requested in order to be able to contact the reporter if any further clarification is required regarding the notification. Your report is used solely for the scientific evaluation of the medicine. The information is kept secure and confidential and is not shared with entities outside the National Pharmacovigilance System (SNF) in accordance with the National Commission for Data Protection (CNPD)/ EU data protection legislation.

The notification submitted do not include patient’s direct personal data that would allow their identification *per se*. However, information on patient's age and gender is important to perform a proper analysis of the factors that may impact on patients’ susceptibility in developing certain adverse reactions.

**Where can I find information on side effects that have already been reported with the medicine?**

You can check the package leaflet inserted inside the medicines package. You can also check the publicly available European database (www.adrreports.eu) or contact INFARMED – National Authority of Medicines and Health Products, I.P. for further information.

**Are there alternative means to the ADR Portal for reporting an adverse reaction?**

Yes, the information can be sent to the National Pharmacovigilance System (Infarmed or any Regional Pharmacovigilance Unit - see Pharmacovigilance System - Contacts) by any means: email, mail or even by telephone.

**What is the Portuguese National Pharmacovigilance System?**

The Portuguese National Pharmacovigilance System (PNPS) was created in 1992 and includes the Directorate of Medicines Risk Management of INFARMED, I.P., which is the coordinator, and also several Regional Pharmacovigilance Units (URF). Each Regional Pharmacovigilance Unit promotes training sessions for reporters and assesses the notifications of adverse drug reactions (ADR) occurring in their acting geographical areas. The PNPS monitors the safety of medicines which have been launched in Portugal, assessing any problems related to adverse drug reactions and implementing safety measures whenever necessary

**Portuguese National Pharmacovigilance System (contacts):**

**INFARMED - National Authority of Medicines and Health Products, I.P.**

Direção de Gestão do Risco de Medicamentos

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1749-004 Lisboa - Portugal

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E-mail: farmacovigilancia@infarmed.pt

**Pharmacovigilance Unit of Braga** (includes: all the municipalities of the District of Braga, District of Viana do Castelo, District of Vila Real and of District of Bragança).

Hospital de Braga

Sete Fontes – São Victor

4710-243 Braga

Tel: 253 027 611

E-mail: farmacovigilancia.braga@hb.min-saude.pt

**Pharmacovigilance Unit of Oporto** (includes: all municipalities belonging to the District of Porto)

Faculdade de Medicina da Universidade de Porto

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E-mail: ufporto@med.up.pt

Site: www.ufporto.med.up.pt

**Pharmacovigilance Unit of Beira Interior** (includes: all municipalities belonging to the Districts of Guarda, Viseu and Castelo Branco)

Faculdade de Ciências da Saúde - Universidade da Beira Interior

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**Pharmacovigilance Unit of Coimbra** (includes: all the municipalities belonging to the Districts of Aveiro, Coimbra and Leiria)

AIBILI

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**Pharmacovigilance Unit of Lisbon, Setúbal e Santarém** (includes: all municipalities belonging to the districts of Lisbon, Setúbal and Santarém)

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**Pharmacovigilance Unit of Central and Northern Alentejo** (includes: all municipalities belonging to the districts of Évora and Portalegre)

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**Pharmacovigilance Unit of Algarve and Baixo Alentejo** (includes: all municipalities belonging to the Districts of Beja and Faro

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**Pharmacovigilance Unit of Azores** (includes: all municipalities belonging to the Azores archipelago)

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**Pharmacovigilance Unit of Madeira** (includes: all municipalities belonging to the Autonomous Region of Madeira)

Instituto de Administração da Saúde, IP-RAM.

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