YOUR GUIDE TO REPORTING ADVERSE DRUG REACTIONS

Source: Egészségvonal (Health Helpline)
https://www.egeszsegvonal.gov.hu/ellatorendszer/gyogyszerellatas/32-mellekhatas-figyeles.html#a_mellkhats_bejelentsnek_mdja)

"How to report adverse drug reactions ('side effects')?

ADR (Adverse Drug Reactions) reporting is an important source of information for NNGYK, our national pharmaceuticals regulator, when it comes to learning about potential new and hitherto unknown risks of medicinal products. It allows the authority to take measures as necessary (including making any recalls, changing application instructions or amending information supplied to patients, etcetera).

Anyone who has discovered a 'side effect', i.e. a potential adverse reaction to a medicinal substance, or learnt about an adverse event potentially associated with the use of a medicinal product (healthcare professionals, patients and/or their family members, etc.) can make a report.

You can report a suspected adverse reaction (side effect) in any of the following ways:

1. By making a report online
Link to Online ADR reporting information for patients

Please fill in the report electronically and send it to NNGYK with just one click.
You are kindly requested to opt for this method of reporting in all cases where you have the opportunity to do so.

2. By making a report offline
Should you wish to make a report offline, please download the ADR Report Form. The downloaded form can be completed electronically, or manually after being printed out. Please choose the corresponding contact details as indicated below to send the completed form by e-mail, facsimile or post:

E-mail address: adr.box@ogyei.gov.hu
Fax No.: +36-1-886-9472
Postal address: 1372 Budapest, Pf. 450

3. By making a free-text report (without filling in a form)
Alternatively, you may also inform the authorities by means of a free-text report (i.e. without filling in a form). If you decide to use this method, please select the appropriate contact details from the above to send your report.

Your report should include at least the following information:

- The patient's initials and/or age,
- A description of the symptoms and/or complaints,
- The name of the suspected product(s),
- The name and contact details (e-mail address, telephone number) of the person making the report.

In addition to such necessary basic information as above, please make sure that you provide as much detail as possible: the more accurate and detailed your report is, the easier it will be for recipients to evaluate the situation. Please bear in mind that it is also advisable to seek advice from your physician or pharmacist prior to making a report about how exactly to formulate what you have got to say. Should you be able to enclose a medical evaluation or final hospital assessment, that will be very helpful. At the same time, you can rest assured that NNGYK will process your report in any case, whether or not it is supported by a medical opinion. Please note that you can access the European Medicines Agency (EMA)'s guidelines on reporting adverse drug reactions here."

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