



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working Party with Patients' and Consumers' Organisations (PCWP): Reporting of adverse drug reactions by patients and consumers





Adverse Reaction reporting by Patients and Consumers

- New Pharmacovigilance Legislation
 - Takes account of the fact that patients are well placed to report suspected adverse reactions to medicinal products
 - Facilitates the reporting of suspected adverse reactions to medicinal products by both healthcare professionals and patients
 - Ensures that methods for reporting by patients and consumers are available
 - A standardised text shall be included in the patient information leaflet, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system
 - Requires to specify the different ways of reporting available (electronic reporting, postal address and/or others)



Adverse Reaction reporting by Patients and Consumers

- New Pharmacovigilance Legislation
 - The Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients



Web-forms and ADR reporting by Patients/Consumers

- Contact details of reporter
 - Patient, consumer, carer, friend, relative
 - (for follow up and obtaining further information if necessary)
- Contact details of healthcare professional
 - (for follow up and obtaining further information if necessary)
- Personal information
 - Age/Age group/gender
- Information on side effect
 - Description of reaction, dates, outcome, impact on quality of life
- Information on medicine/s
 - Name of medicine, start and end dates, dosing, route of administration, indication(s), co-medication
- Medical history and information on previous use of the medicine



Health Care Professionals



National Competent Authority

Reporting by patients, consumers and health care professionals to National Competent Authority



Patients Consumers





Reporting to the National Competent Authority (NCA)

Agency conducted survey on patient reporting currently established in Member States

- 16 Member States already implemented direct patient reporting
 - Paper forms
 - Web-reporting
- Based on the experience gained so far at the level of Member States the following questions are raised:



Questions to PCWP

- Would a separate form for patients and healthcare professionals be preferable?
 - Simplified and user friendly forms
 - Possibility to use lay language rather than medical terminology such as MedDRA (Medical Dictionary for Regulatory Activities)



Example: MHRA Patient Reporting Form

welcome to the online reporting site for the Yellow Card Scheme

This site can be used to report suspected side effects to any medication including vaccines.

Not Registered?

If you are a new visitor to the site or have not registered previously, please select one of the options below before entering the main site. This will allow us to provide you with the best possible information to help you while using the site.

I'm a member of the public

I'm a health care professional

Already Registered, Login Here

If you have already registered with this site, please login.

Fields marked with a * are required

Email Address *

Password *

Login

[I have forgotten my password](#)

Information in other languages:

English	Arabic	Burmese	Chinese	Danish
Dutch	Portuguese	Urdu	Estonian	Slovenian



Example: MedDRA use MHRA Patient Reporting Form

Fields marked with a * are required

As you type in the box, the website will suggest terms from our dictionary which are possible matches for the word entering. If one of these terms is appropriate for the side effect, then please select this. If none of these is suitable whatever you type in this box will be added. More than one side effect can be entered if needed, simply click on 'a effect'.

Side effects added:

Suspected Side Effect *

Please select an outcome for

☐ Recovered

☐ Recovered with some lasting effect

☐ Getting better

☐ Side effect continuing

☐ Caused death

☐ Unknown

☐ Other (Please give details in the text box)

Add another Side Effect

Please describe how the experience was (select all that apply).

☐ Mild or slightly uncomfortable

☐ Uncomfortable, a nuisance or irritation, but able to carry on with everyday activities

Search for side effects

rash

- rash
- rash (nonspecific)
- rash acneiform
- rash all over
- rash at site of injection
- rash both legs
- rash bullous
- rash desquamating
- rash ecchymotic
- rash erythematous
- rash face
- rash follicular
- rash generalised

by selecting from the options



Example reaction section at TGA

State:

Medicine Details (Minimum of one entry required)

Drug Name: Batch # (if known): Date Administered Form:

Reaction Details

Reaction Onset Date:

Adverse Reaction Description:

Severity:

Treatment of Reaction:

Outcome:

If outcome is 'Death' or 'Recovered' enter Date of Outcome:



Question to PCWP

- What is the most preferable way to enter information on the medicine?
 - Choice from a standardised medicines list
 - Authorised/registered medicinal products marketed in the country of the reporter
 - Simplified drop down lists for dose/route of administration
 - Dose form for administration e.g. solution for injection instead of powder and solvent for solution for injection



Example: DKMA Reporting Form

Hvad er navnet på medicinen? * ?

Dosis pr. døgn? Fx 1 tablet 3 gange dagligt

Form?

Vælg venligst

Vælg venligst

Tablet

Inhalator

S Kapsel

Mikstur

Stikpille

Creme

Gel

Salve

H Øjendråber

Næsespray

F Plaster

Indsprøjtning



Example: TGA Reporting Form

TGA eBusiness Services Australian Adverse Drug Rea

[Save](#)[Save & Close](#)[Close](#)

All dates must be entered in DD/MM/YYYY Format.

★ Medicine:

Please use tradenames, asterisk if medicine is suspected and include AUSTL or AUSTR

Dose:

Frequency:

Form:

Route:

Date Started:

Date Stopped:

Reason for Use:

Batch Number:

[Save](#)[Save & Close](#)[Close](#)

Last updated: 9 September 2011

URL: <https://www.ebs.tga.gov.au/ebs/adrs/ADRSLodg.nsf/f4e33c7fa8b407454a2569d1000516e3>



Example: MEB Reporting Form

Bijwerking [1]

Vermoedelijke bijwerking*

Begindatum bijwerking* -- dag -- -- maand -- -- jaar --
(dag en maand zijn niet verplicht, maar graag zo precies mogelijk invullen)

Hoe lang gebruikte uw patient het geneesmiddel voordat de klachten optraden? selecteer eenheid

Afloop* selecteer afloop...

Waren er nog andere bijwerkingen? [Andere bijwerking +](#)

Geneesmiddel [1]

Verdacht geneesmiddel* metop

Specificeer geneesmiddel METOPIRON
 METOPROLOL
 METOPROLOL MET THIAZIDEN

RVG code

Mogelijke interactie

Startdatum*
(dag en maand zijn niet verplicht, maar graag zo precies mogelijk invullen)

Dosering

Toedieningsweg selecteer...

Look up for medicines



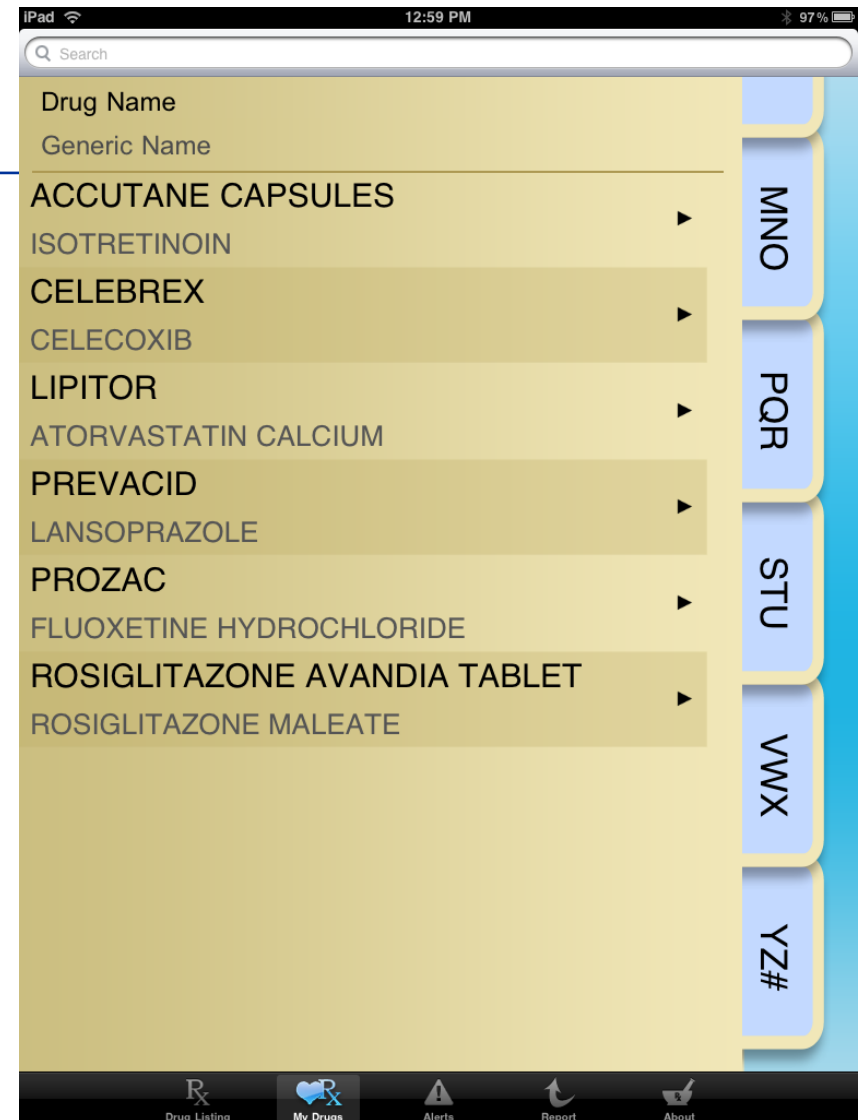
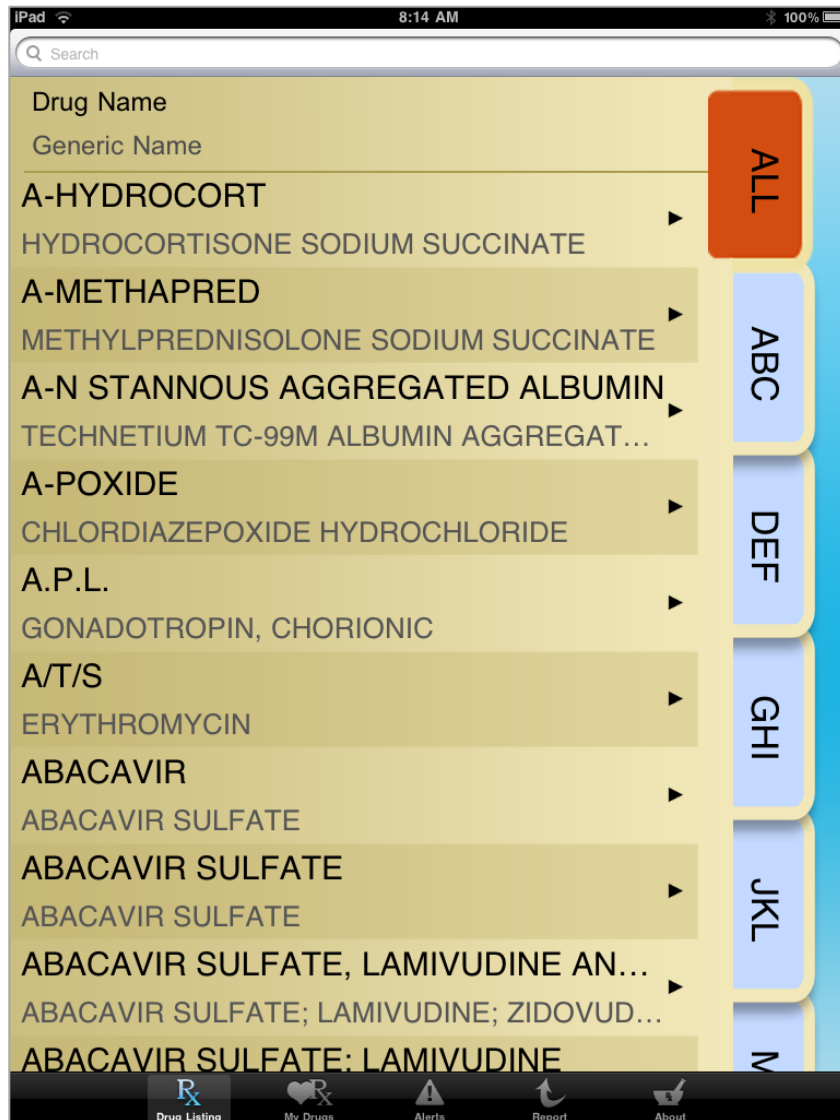
Question to PCWP

- Conditional questions
 - Would it be considered helpful to add targeted questions depending on patient groups (e.g. pregnancy)
- Feedback to patients/consumers
 - What feedback would you like to receive following your submission of an adverse reaction report
 - Would a link to the product information be helpful?



Question to the PCWP

- What kind of technologies do you consider useful to encourage patient and consumer reporting
 - Web forms, smart phone or tablet apps
- Example: MedWatcher app recently launched in United States
 - Facilitates reporting directly to FDA
 - Can communicate FDA drug alerts



17 >10k medications

Stores personal medication list



Example: MedWatcher, US

12:38 PM 100%

Certain personal information is required if you are a healthcare provider so that FDA can respond appropriately to the report. If you are a patient/caregiver, no personal information will be displayed.

I am a:

- ☐ Healthcare Professional
- ☒ Patient/Caregiver

If you would like to submit a report to FDA, choose healthcare provider. If you would like to post to user reviews, choose patient/caregiver.

Step 1 Step 2 Step 3 Step 4 Step 5

Rx My Rx Alerts Report About

9:23 AM 100%

Drug & Patient Details

ACCUTANE CAPSULES

Dose or Frequency (Optional)

acne

Describe what happened when the medication was taken:

Rectal bleeding

Continue to Step 3

Step 1 Step 2 Step 3 Step 4 Step 5 Submit

Rx My Rx Alerts Report About

1:03 PM 95%

Reporter Information

Patient Gender

☒ Male ☐ Female

Patient Age

Patient City

Patient State

Patient ZIP

Continue to Step 4

Step 1 Step 2 Step 3 Step 4 Step 5 Submit

Rx My Rx Alerts Report About



Example: MedWatcher, US

Complications

Did the event result in a ... death?

☐ Yes ☐ No

Please provide a date

Date of Death

birth defect?

☐ Yes ☐ No

hospitalization or medical attention?

☐ Yes ☐ No

Continue to Step 5

Step 4

Step 5

Submit

Report

Additional information:

Continue to Submit

Step 5

Submit

Submit

Press Submit Event to post your report to user reviews.

Personal and identifying information is kept confidential.

If you would like to submit your report directly to FDA, please call 1-800-FDA-1088 (1-800-332-1088), or submit a report using the Healthcare Provider option in Step 1.

Submit Event

Cancel and Clear

Submit



iPad 8:14 AM 100%

FDA Drug Alerts

MedWatch Archive, 2010

- Intravenous Medications Manufactured by Claris: Recall due to contamination of products**
Originally Posted 05/29/2010 ▶
- PediaCare Children's Products [Blacksmith Brand]: Recall of four products**
Originally Posted 05/29/2010 ▶
- Arrow Brand Medicated Oil and Embrocation: Consumer Warning, Product Considered Toxic**
Originally Posted 05/28/2010 ▶
- Hylanex recombinant (hyaluronidase human injection): Recall**
Originally Posted 05/26/2010 ▶
- Orlistat (marketed as Alli and Xenical): Labeling Change**
Originally Posted 05/26/2010 ▶
- Proton Pump Inhibitors (PPI): Class Labeling Change**
Originally Posted 05/25/2010 ▶

Drug Listing My Drugs Alerts Report About

iPad 8:50 AM 96%

Proton Pump Inhibitors (PPI): Class Labeling Change
www.fda.gov/Safety/MedWatch/SafetyInfo... Google

U.S. Department of Health & Human Services
www.hhs.gov

FDA U.S. Food and Drug Administration A-Z Index Search go

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MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

- 2010 Safety Alerts for Human Medical Products
- 2009 Safety Alerts for Human Medical Products
- 2008 Safety Alerts for Human Medical Products
- 2007 Safety Alerts for Human Medical Products
- 2006 Safety Alerts for Human Medical Products
- 2005 Safety Alerts for Human Medical Products
- 2004 Safety Alerts for Human Medical Products
- 2003 Safety Alerts for Human Medical Products
- 2002 Safety Alerts for Human Medical Products
- 2001 Safety Alerts for Human Medical Products
- 2000 Safety Alerts for Human Medical Products

Proton Pump Inhibitors (PPI): Class Labeling Change

Including Nexium, Dexilant, Prilosec, Zegerid, Prevacid, Protonix, Aciphex, Vimovo, Prilosec OTC, Zegerid OTC, and Prevacid 24HR

Audience: Family Practice, consumers

[Posted 05/25/2010] FDA notified healthcare professionals and patients of revisions to the prescription and over-the-counter [OTC] labels for proton pump inhibitors, which work by reducing the amount of acid in the stomach, to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications.

The new safety information is based on FDA's review of several epidemiological studies that found those at greatest risk for these fractures received high doses of proton pump inhibitors or used them for one year or more. The majority of the studies evaluated individuals 50 years of age or older and the increased risk of fracture primarily was observed in this age group. While the greatest increased risk for fractures in these studies involved people who had been taking prescription proton pump inhibitors for at least one year or who had been taking high doses of the prescription medications (not available over-the-counter), as a precaution, the "Drug Facts" label on the OTC proton pump inhibitors (indicated for 14 days of continuous use) also is being revised to include information about this risk. FDA recommends healthcare professionals, when prescribing proton pump inhibitors, should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition.

The safety communication includes a data summary with a table and references which support the epidemiological studies reviewed for this communication.

[05/25/2010 - Drug Safety Communication - FDA]
[05/25/2010 - Possible Increased Risk of Bone Fractures With Certain Antacid Drugs - FDA Consumer Health Update]

Page Last Updated: 05/25/2010
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players.](#)

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Summary of Questions to PCWP

- Is a separate form for patients/consumers preferred?
- Is lay language preferred to medical/scientific terminology?
- Is a list of medicines helpful when entering the suspect/interacting/concomitant medication?
- Are simplified drop down lists helpful for example for route of administration?
- What feedback and further information would be useful to you?
- What additional technology such as apps would be useful?



Further information slides



Websites

- *Australia:*
<https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf/LoginScreen?OpenForm>
- *Netherlands:* <http://www.lareb.nl/meldformulier/patient/melden.asp>
- *Denmark:* <http://laegemiddelstyrelsen.dk/en/topics/side-effects-and-trials/side-effects/report-a-side-effect-or-incident/humans/report-a-side-effect-from-human-medicine--ves-e-form.aspx>
- *UK:* <http://yellowcard.mhra.gov.uk/>
- *Ireland:* <http://www.imb.ie/EN/Safety--Quality/Online-Forms/Human-Medicine-Adverse-Drug-Reaction.aspx>



Legislative provision

- ***Directive 2010/84/EU Article 107(a):*** *Each Member State shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 102(c) and (e).*

Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web- portals or by other means.



Legislative provision

- ***Regulation (EU) No 1235/2010 Article 25:*** *The Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients in accordance with the provisions referred to in Article 107a of Directive 2001/83/EC.*
- ***Regulation (EU) No 1235/2010 Article 26(f) :*** *The Agency shall, in collaboration with the member states and the Commission, make public information about how to report to national competent authorities suspected adverse reactions to medicinal products and the standard structured forms referred to in Article 25 for their web-based reporting by patients and healthcare professionals, including links to national websites.*



MedDRA

- The Medical Dictionary for Regulatory Activities (MedDRA) is a dictionary of medical terms, organised at the highest level by System Organ Class (SOC) down to the lowest, most specific term (Lowest Level Term: LLT). It is the internationally agreed terminology for coding and analysing of Adverse Drug Reactions (ADRs). MedDRA also supports encoding of medical and social history, indications, investigations and physical examination findings.
- MedDRA coding is mandatory for the adverse drug reaction when reporting electronically via ICH E2B. Normally performed by the National Competent Authority (NCA) when adverse reaction reports are received on paper. Highly medical terminology and can be complex to apply correctly.