EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Healthcare Professionals Working Group (HCPWG): Reporting of adverse drug reactions by web-based forms

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Adverse Reaction reporting by healthcare professionals

- New Pharmacovigilance Legislation
  - Facilitates the reporting of suspected adverse reactions to medicinal products by both healthcare professionals and patients
  - 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

Adverse reaction reporting

- New Pharmacovigilance Legislation

  Adverse reactions include reports on noxious and unintended effects from the authorised use of a medicinal product and also:

  – Use outside the terms of the marketing authorisation including misuse and abuse
  – Medication error
  – Overdose
  – Occupational exposure

Health Care Professionals

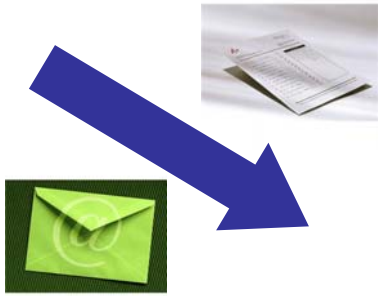
National Competent Authority

Patients Consumers

New reporting rules:
Reporting by patients, consumers and health care professionals to National Competent Authority

EudraVigilance Human

Health Care Professionals



National Competent Authority

Marketing Authorisation Holder

EudraVigilance Human

Patients Consumers

<u>New reporting rules:</u>
Re-routing of adverse reactions to the national Competent Authority of the country where the adverse reaction occurred

Web-forms and ADR reporting

- Contact details of healthcare professional
  - (for follow up and obtaining further information if necessary)
- Personal information on patient
  - Age/Age group/gender
- Information on adverse drug reaction
  - Description of reaction, dates, outcome, seriousness, rechallenge, test results, cause of death
- Information on medicine/s
  - Name of medicine, start and end dates, dosing, route of administration, indication(s), co-medication
- Medical and drug history
- Supporting documentation

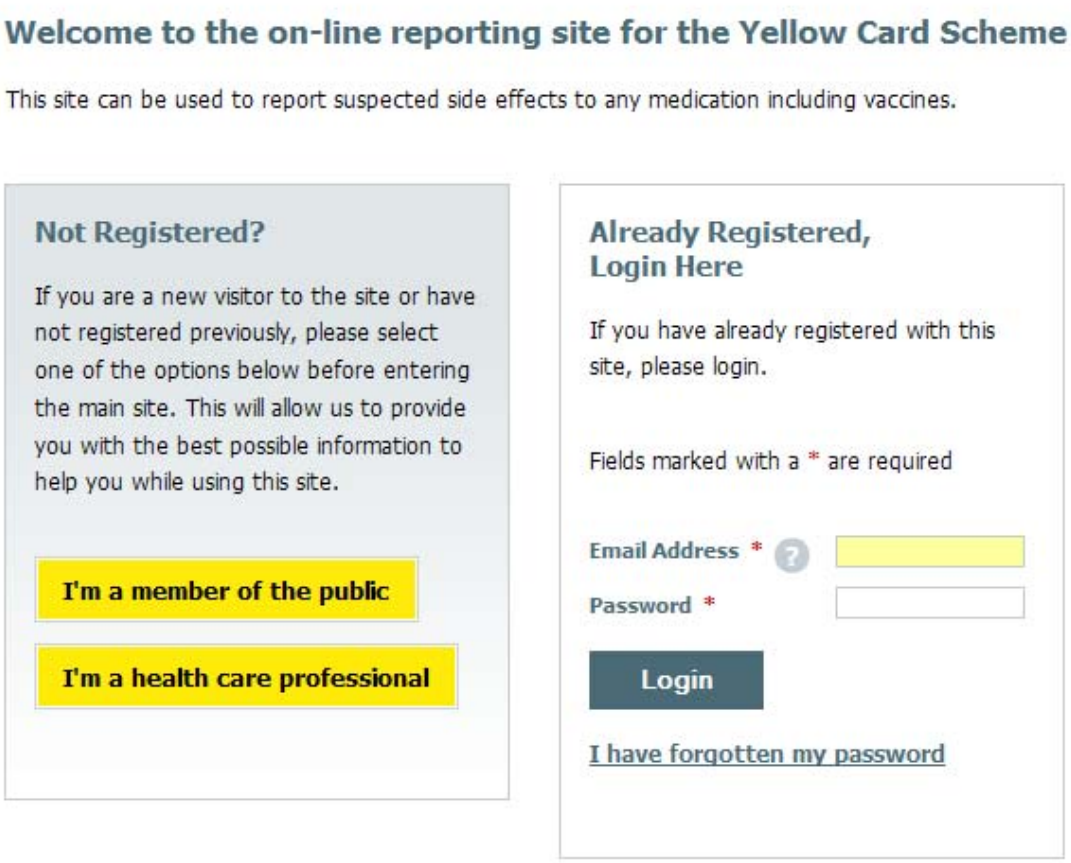
Questions to HCPWG

- Would a user registration system be considered useful?
  - Stores your contact details for future use
  - Allows retrieval of previously submitted reports e.g. for follow-up on new information on an individual case

Questions to HCPWG

- Would a separate form for healthcare professionals and patients be preferable?
  - Possibility to use medical terminology such as MedDRA (Medical Dictionary for Regulatory Activities) as well as lay language
- Would a separate form be preferable for certain classes of drugs?
  - For example: vaccines (eg: PEI, FDA VAERS)

Example: MHRA HCP Reporting Form



Example: MHRA HCP Reporting Form

Step 3 - Suspect Reactions

Fields marked with a * are required

As you type in the box, the website will suggesting possible terms from our dictior
are entering. If one of these terms is an appropriate term for the reaction, then p
entered if needed, simply click on 'add another Suspect Reaction'.

Suspect Reactions added:

Suspect Reaction *

Please select an outcome for each suspect reaction

- Recovered
- Recovering with some lasting effects
- Recovering
- Not recovered
- Caused Death
- Unknown
- Other (Please give details below)

Add another Suspect Reaction

Do you consider the reaction to be serious? *

Yes No

Example reaction section at TGA

Medicine Details (Minimum of one entry required)

*

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

Add Additional Medicine Details

Reaction Details

Reaction Onset Date:

*** Adverse Reaction Description:** Acute pancreatitis

Severity: Caused or prolonged inpatient hospitalisation

Treatment of Reaction:

Outcome: Not yet recovered

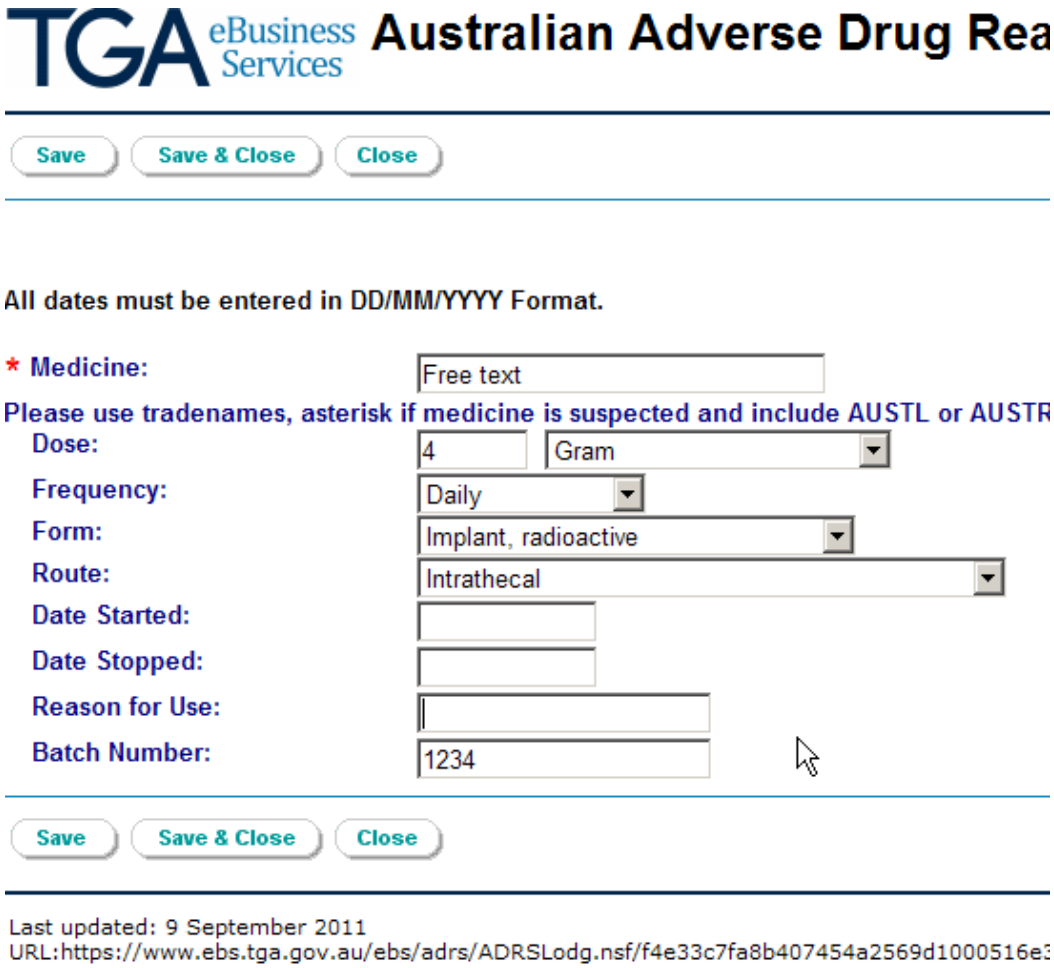
If outcome is 'Death' or 'Recovered' enter Date of Outcome:

Sequelae of Reaction: (•) No ( ) Yes

Question to HCPWG

- 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
  - Drop down lists for dose/route of administration
    - Full European Pharmacopoeia
    - Shortened list

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:** Free text

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

Dose: 4 Gram

Frequency: Daily

Form: Implant, radioactive

Route: Intrathecal

Date Started:

Date Stopped:

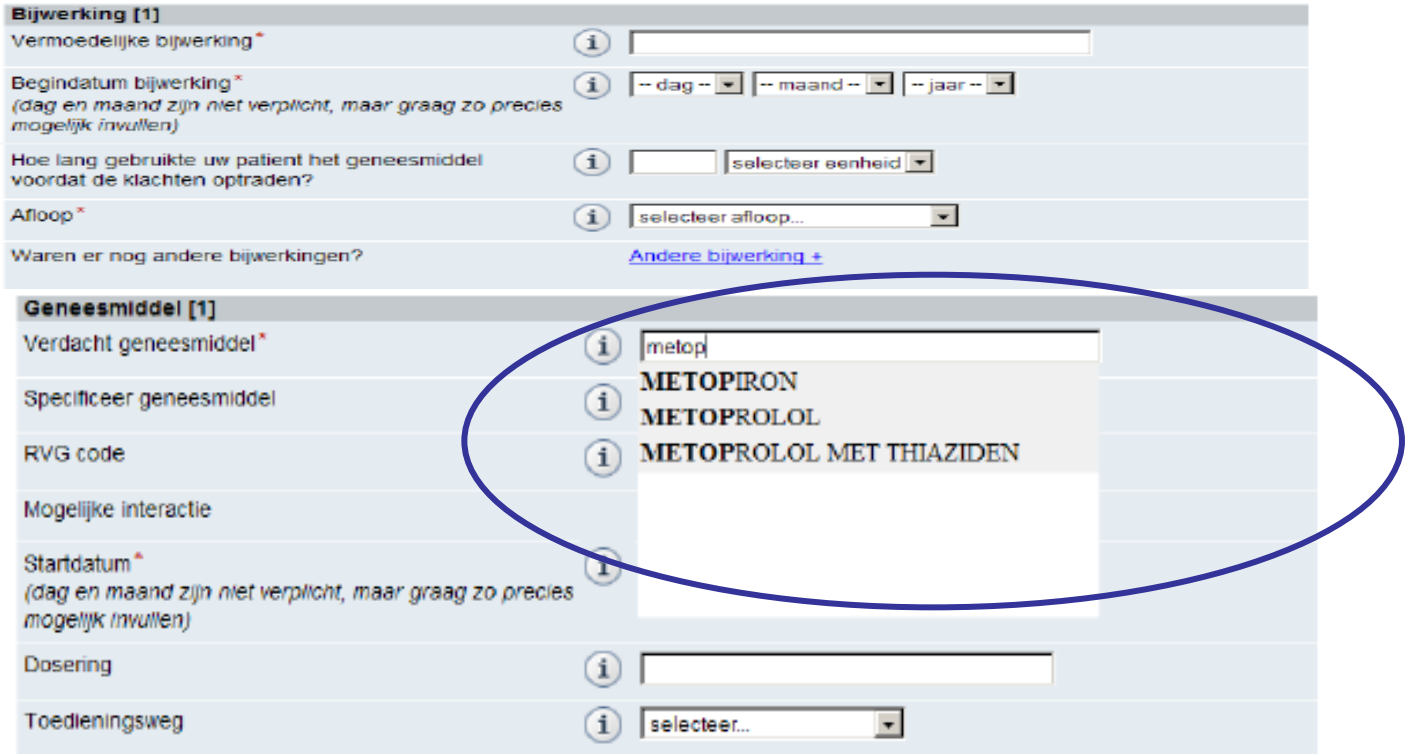
Reason for Use:

Batch Number: 1234

Save | Save & Close | Close

Last updated: 9 September 2011
URL:https://www.ebs.tga.gov.au/ebs/adrs/ADRSLodg.nsf/f4e33c7fa8b407454a2569d1000516e3

Example: Lareb Reporting Form



Look up for medicines

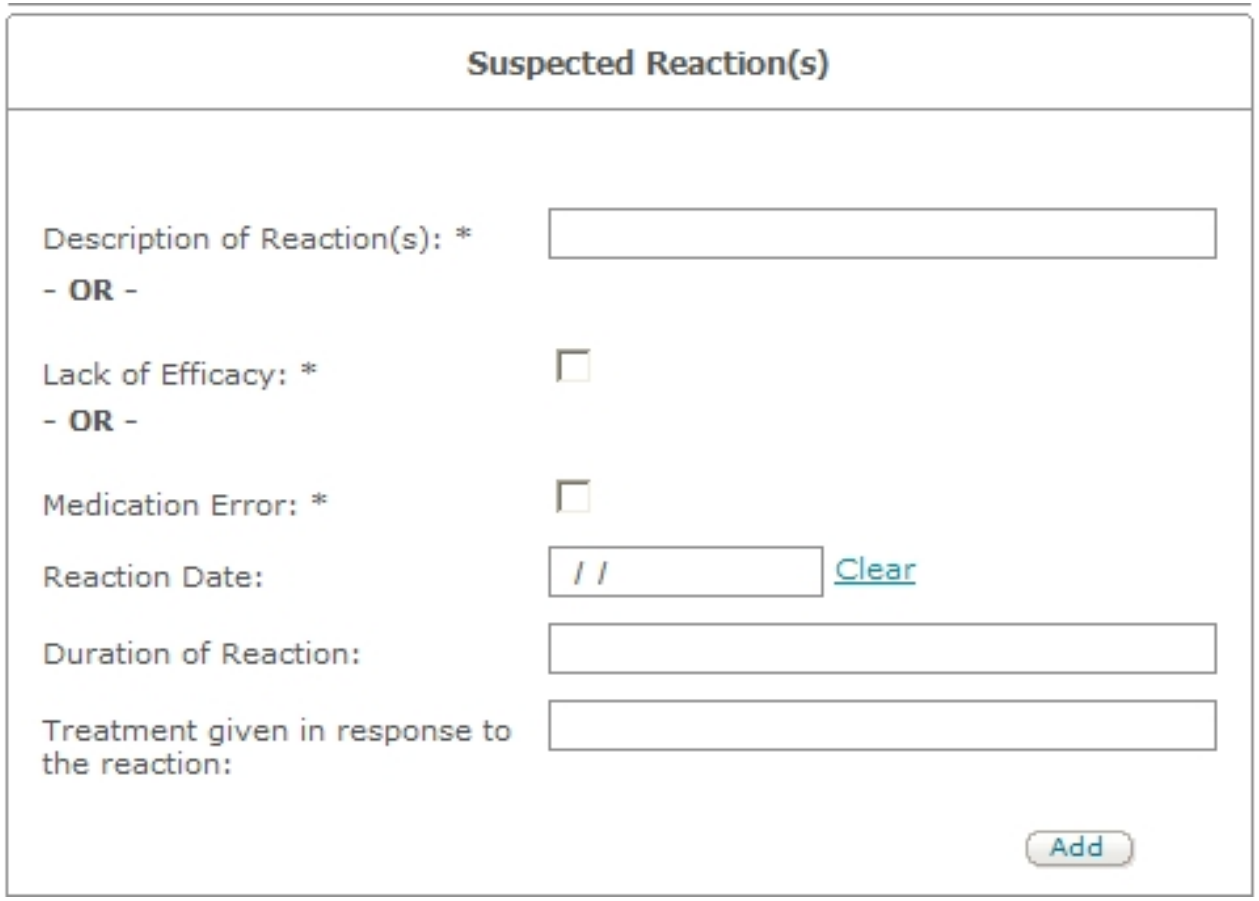
Question to HCPWG

- Interactive questions
  - Would it be considered helpful to formulate questions on interactive basis e.g.: what is the gender of your patient? What is the suspect drug?
- Upload facility
  - Would it be useful to be able to upload e.g.: the discharge summary

Question to HCPWG

- Reports of ADRs resulting from medication error, use outside terms of marketing authorisation (off-label), misuse and abuse, overdose and occupational exposure
  - Would radio buttons/check boxes/drop down lists be useful as a prompt?

Example from IMB



Suspected Reaction(s)

Description of Reaction(s): *

- OR -

Lack of Efficacy: *

- OR -

Medication Error: *

Reaction Date: / / Clear

Duration of Reaction:

Treatment given in response to the reaction:

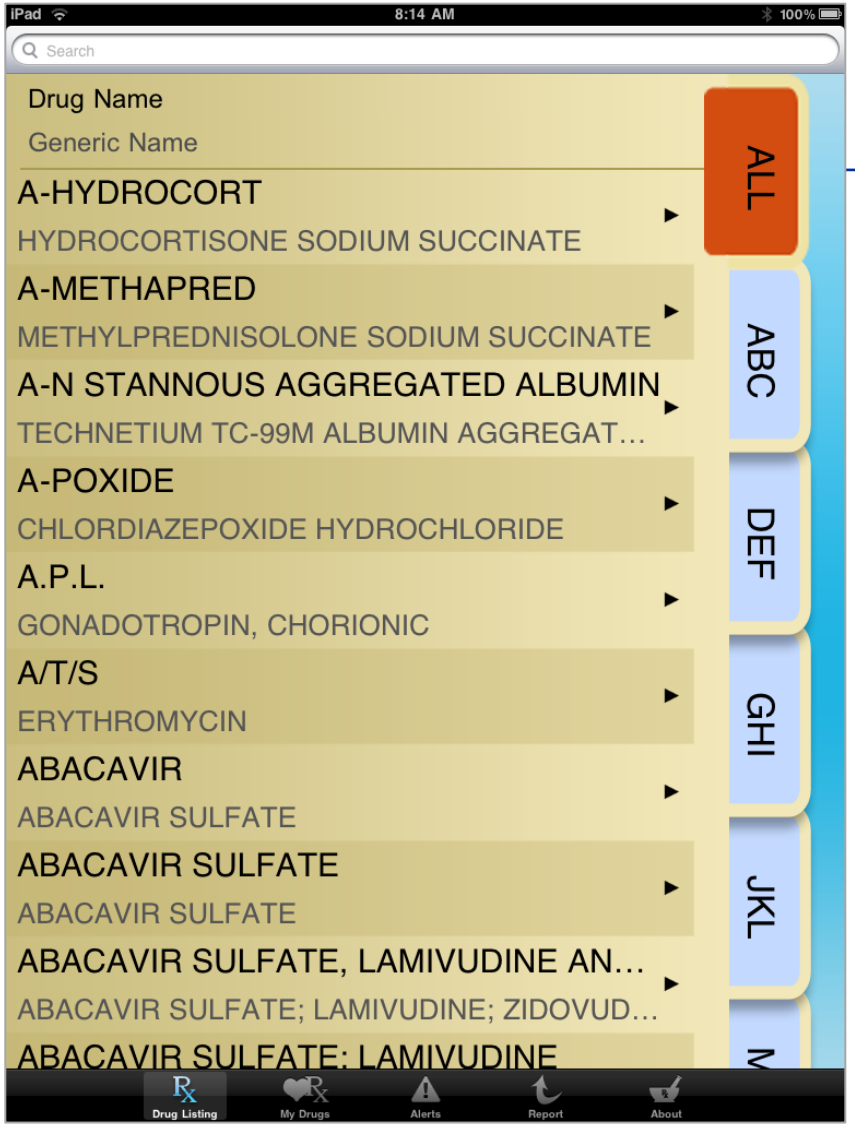
Add

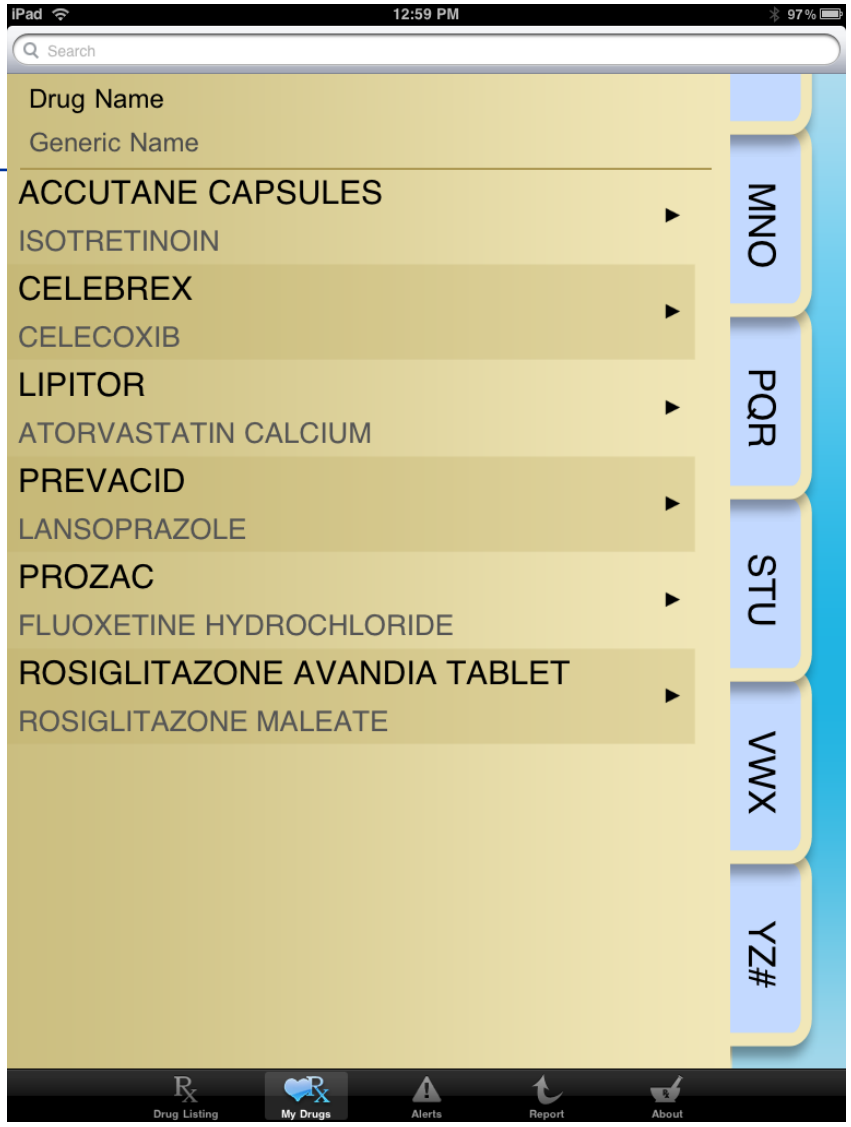
Question to HCPWG

- Conditional questions
  - Would it be considered helpful to add targeted questions depending on patient groups (e.g. pregnancy/paediatrics/breast feeding/elderly)
- Feedback
  - 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 HCPWG

- What kind of technologies do you consider useful to support 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
    - Integrate with existing clinical workflows

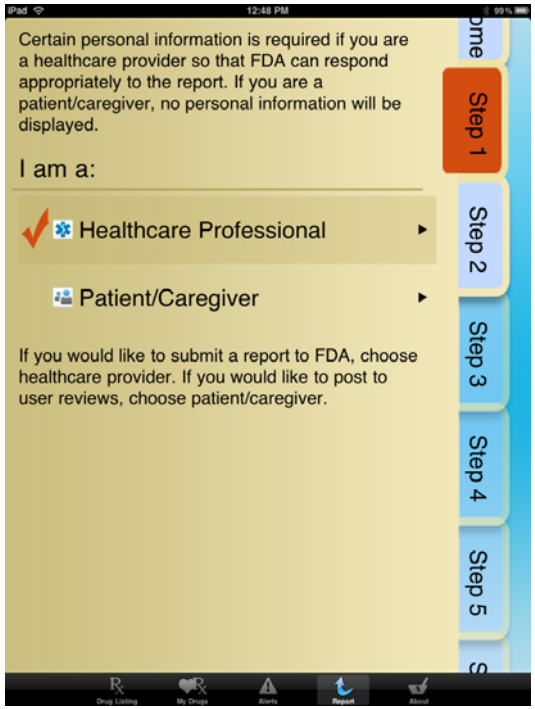


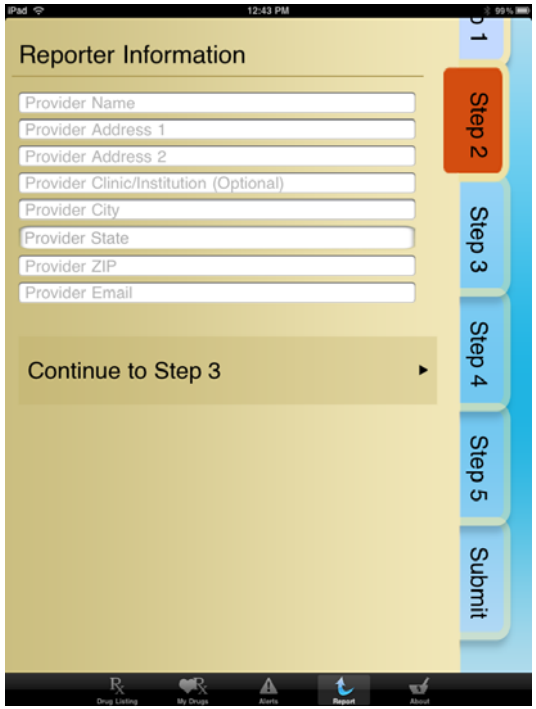


>10k medications

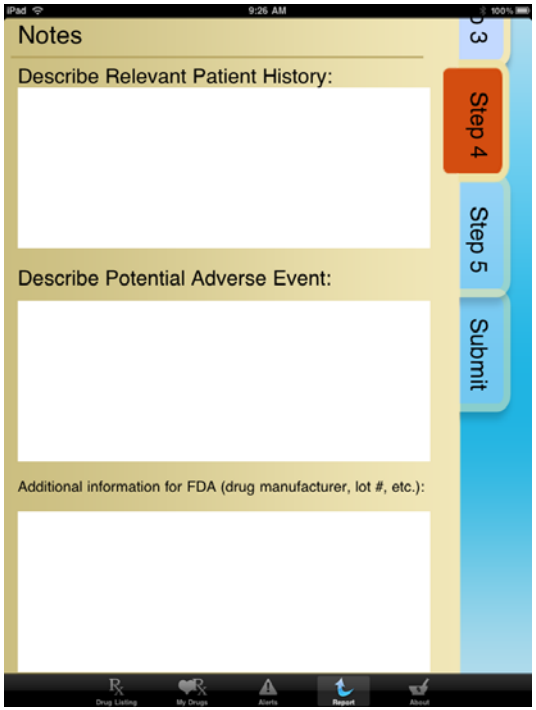
Stores medication list

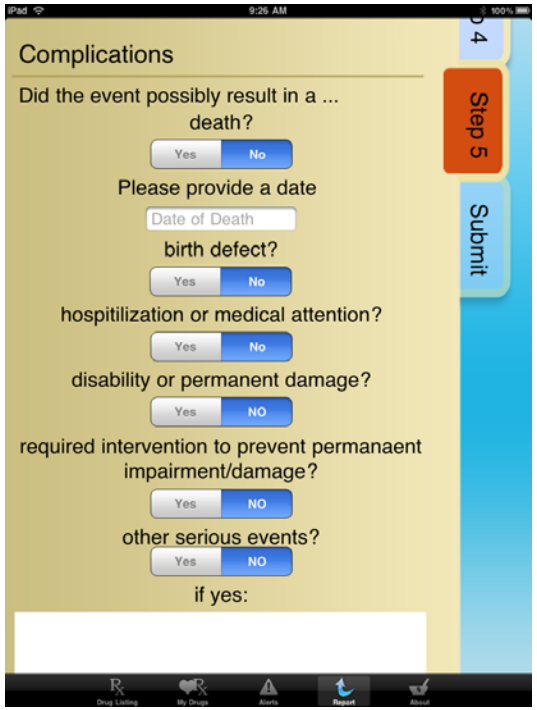
Example: MedWatcher, US

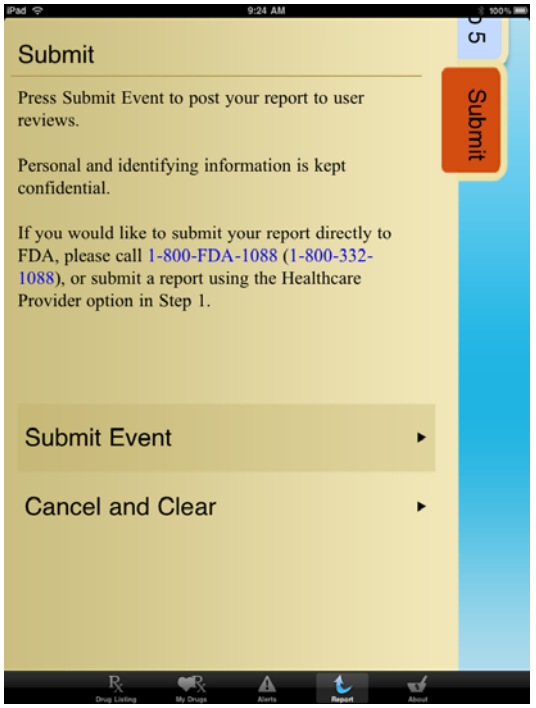




Example: MedWatcher, US





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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
Hylenex 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
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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 HCPWG

- Is a separate form for patients/consumers preferred?
- Is medical/scientific terminology preferred to lay language?
- 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?
- Are interactive questions helpful?
- What feedback and further information would be useful to you? How would you wish to be contacted on follow-up information by NCAs?
- What additional technology such as apps would be useful?

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.