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

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

National Competent Authority

Patients Consumers

Reporting to the National Competent Authority (NCA)

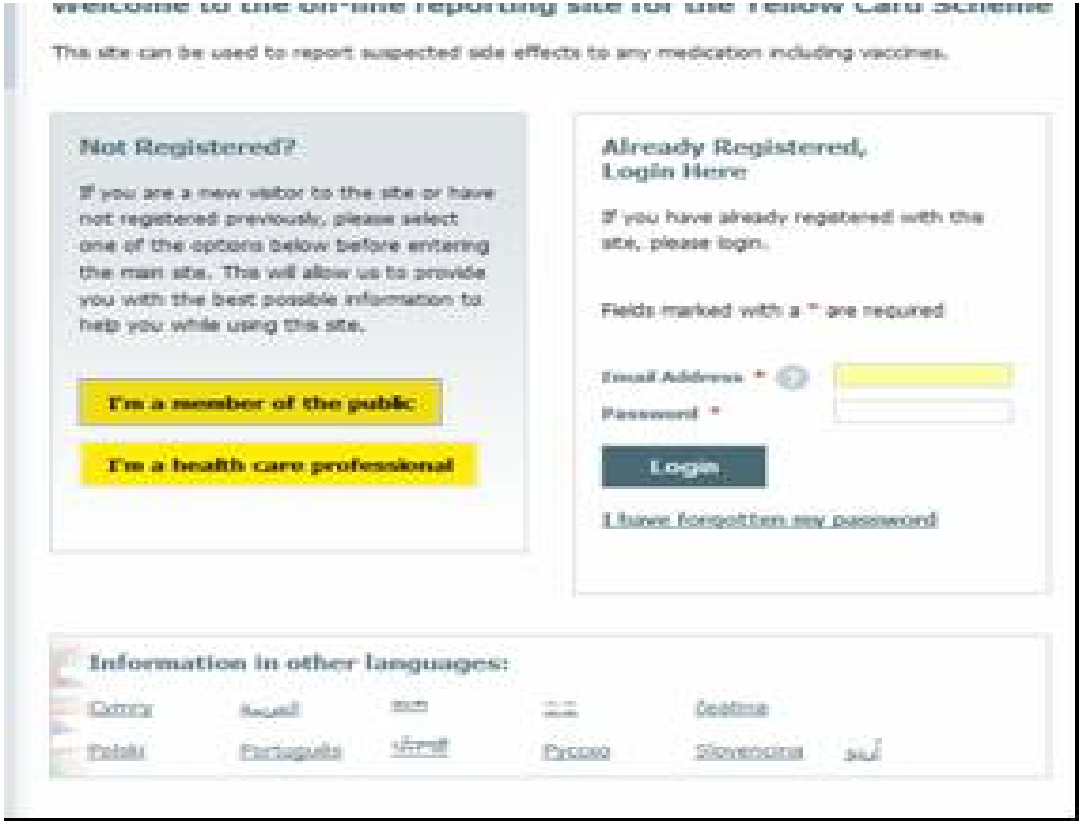
Agency conducted survey on patient reporting currently established in Member States

- 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:

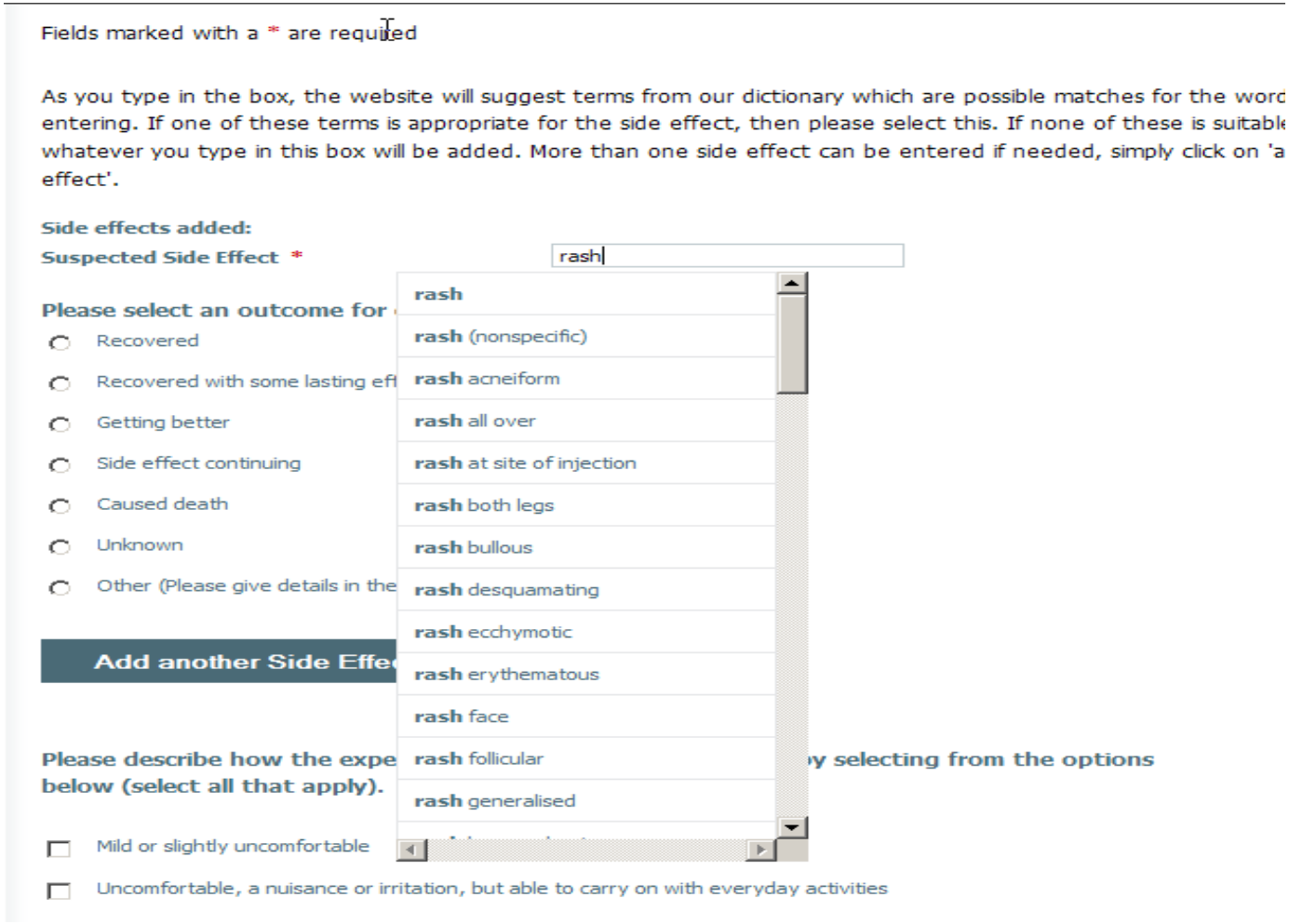
Questions to PCWP

- 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)

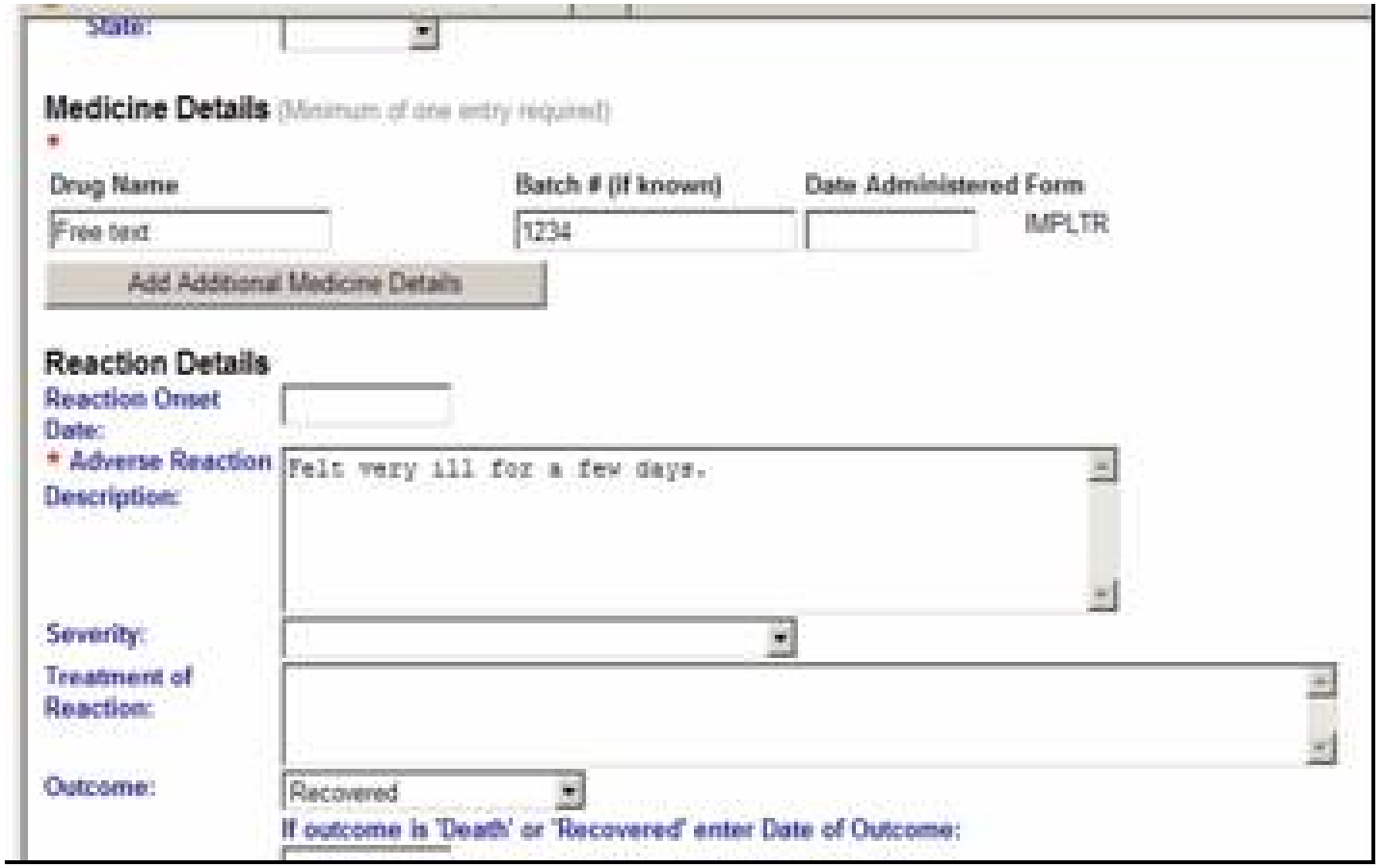
Example: MHRA Patient Reporting Form



Example: MedDRA use MHRA Patient Reporting Form



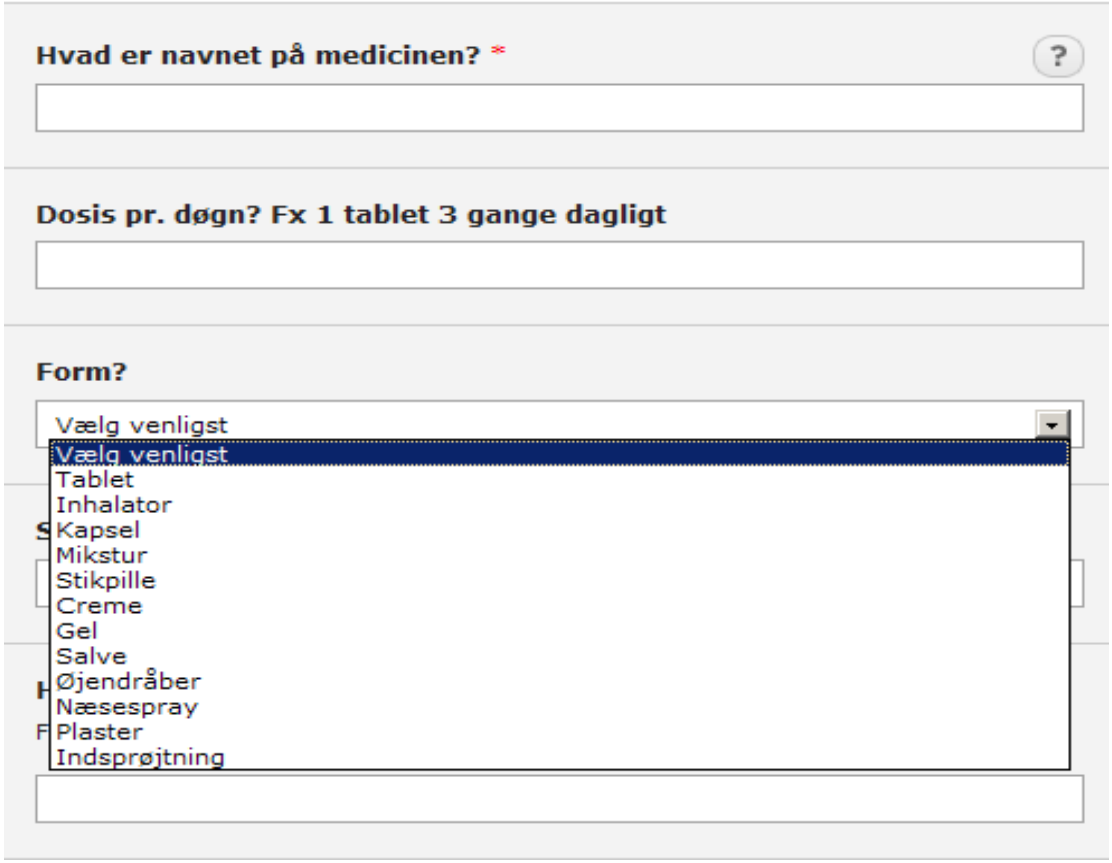
Example reaction section at TGA



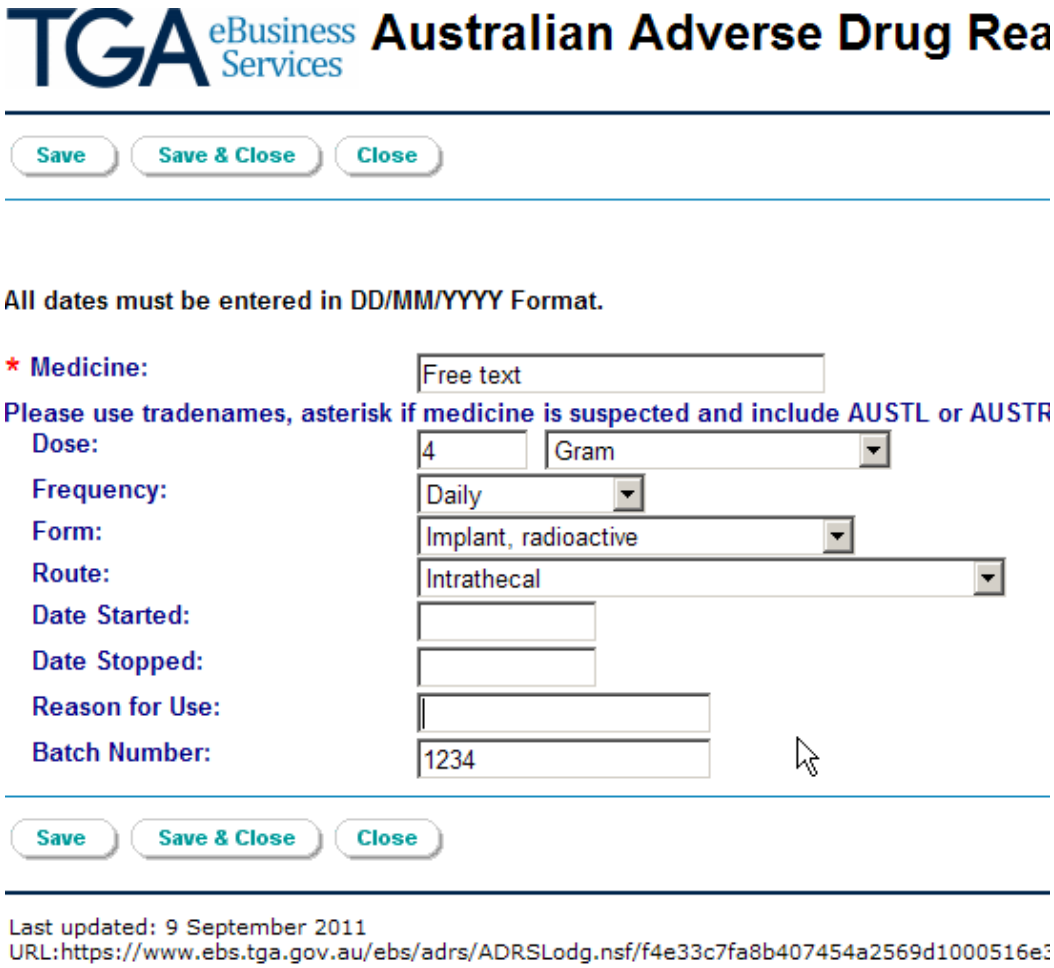
Question to PCWP

- 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



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:

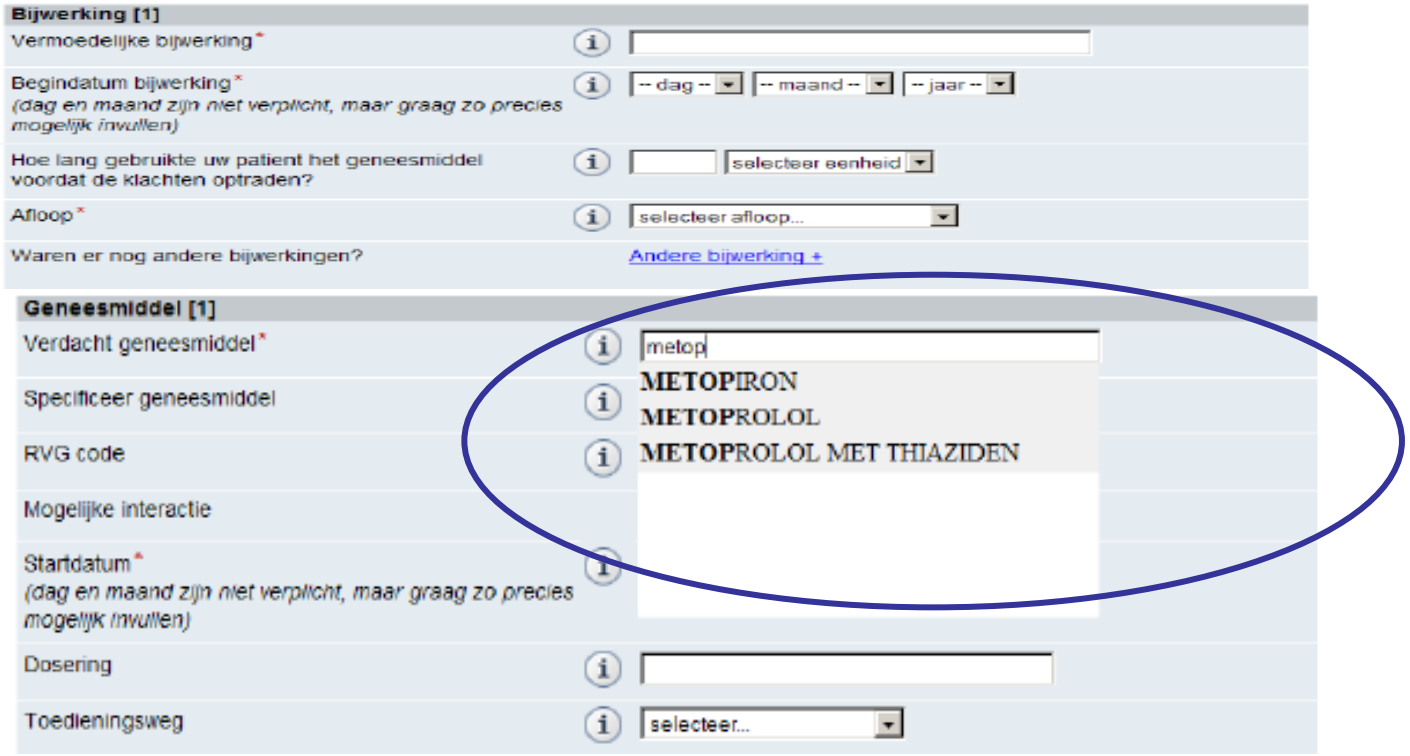
Reason for Use:

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: MEB Reporting Form



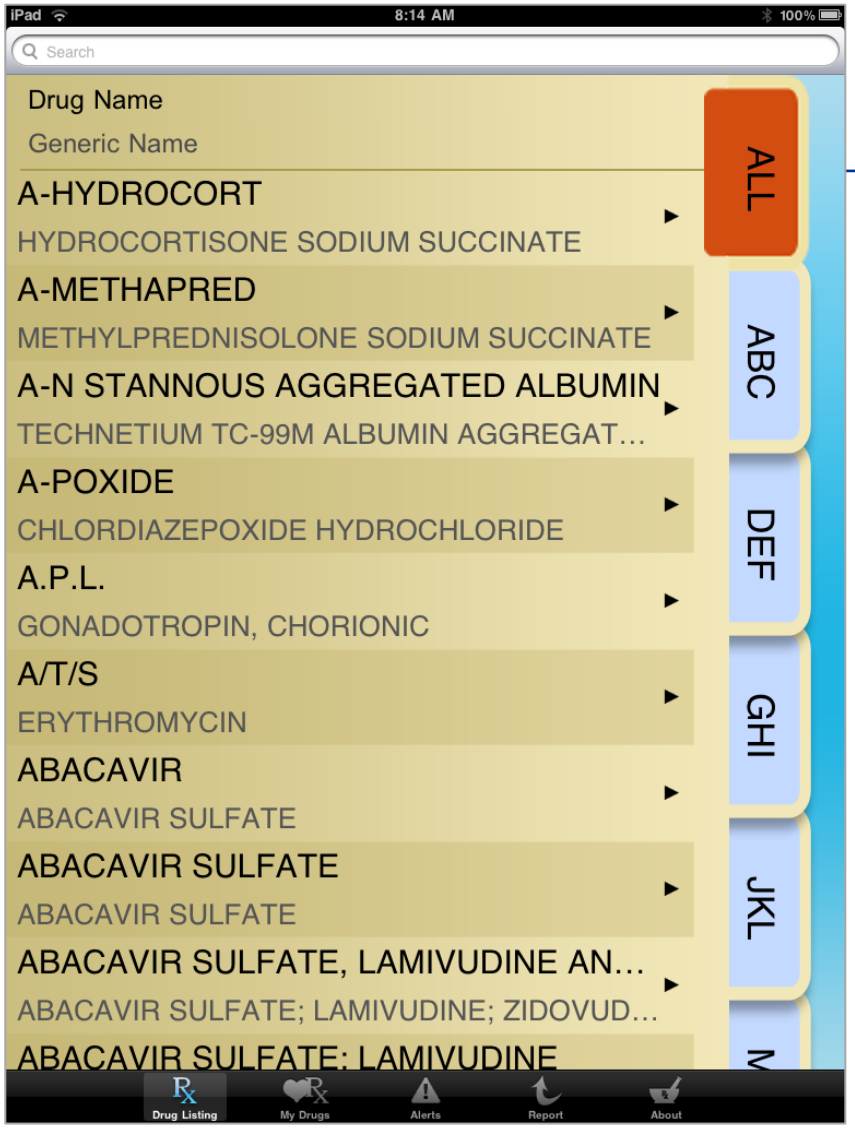
Look up for medicines

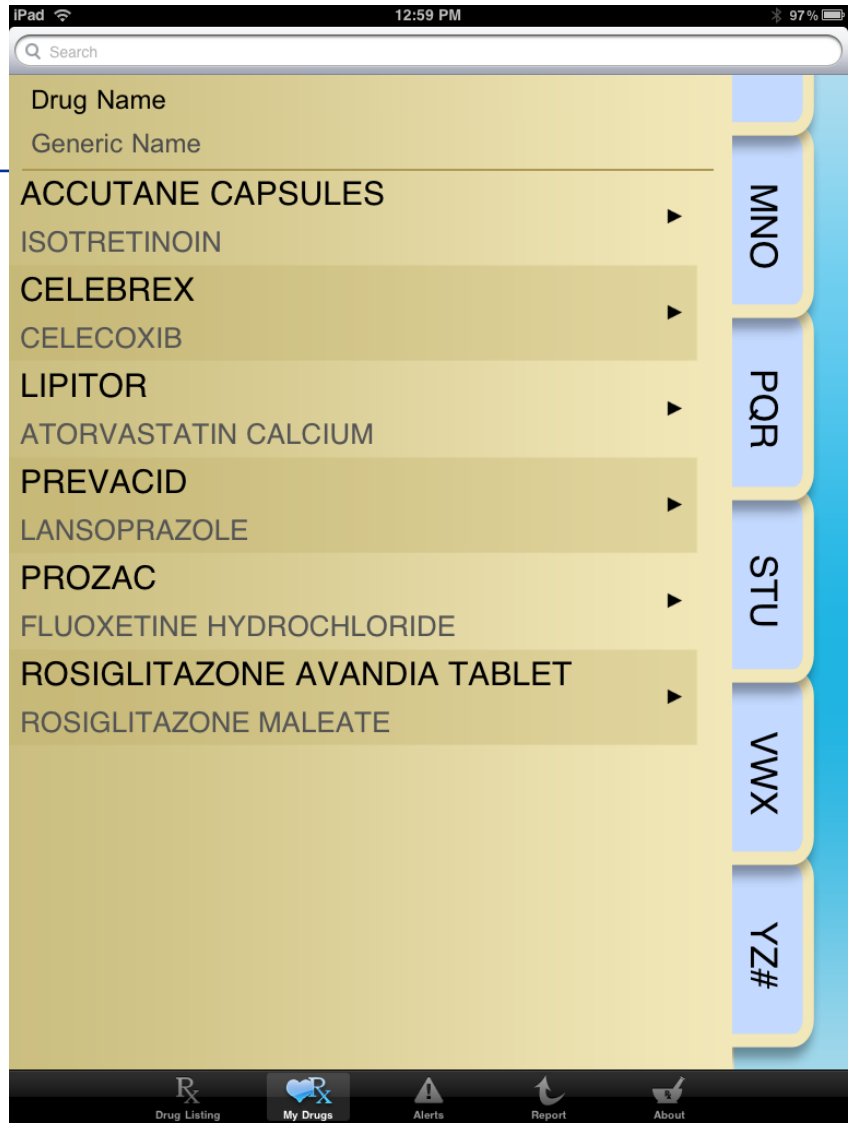
Question to PCWP

- 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

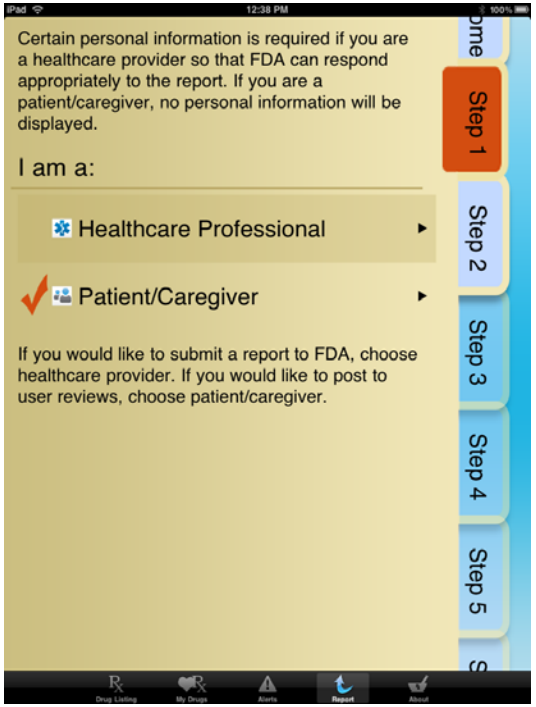


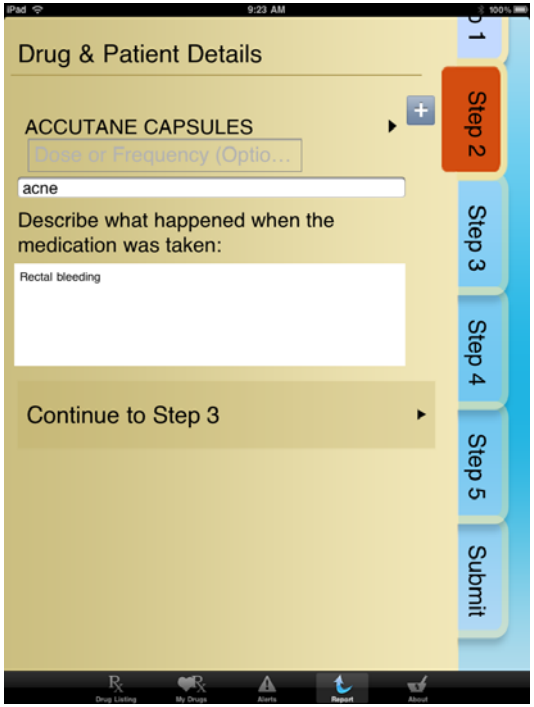


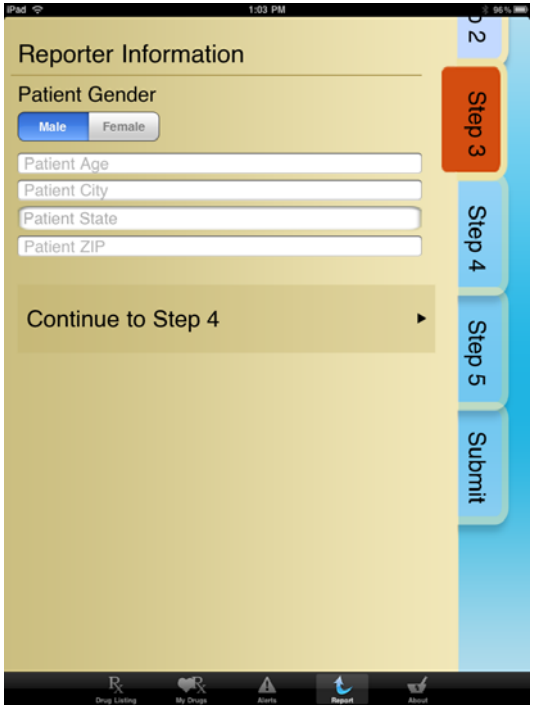
>10k medications

Stores personal medication list

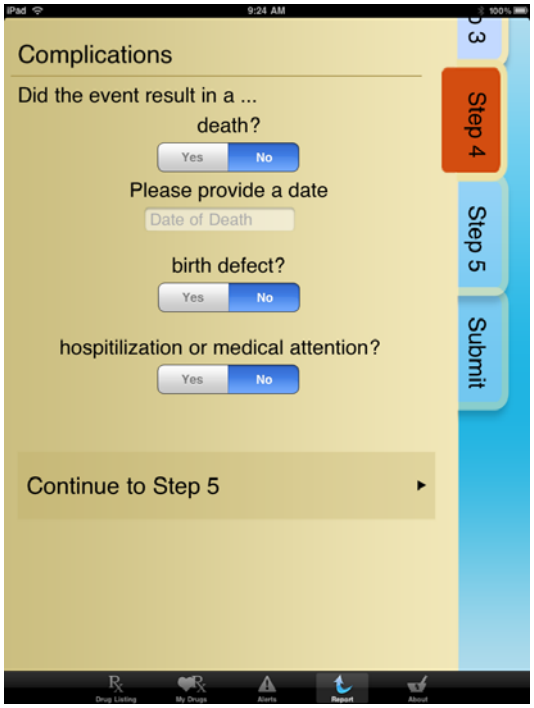
Example: MedWatcher, US

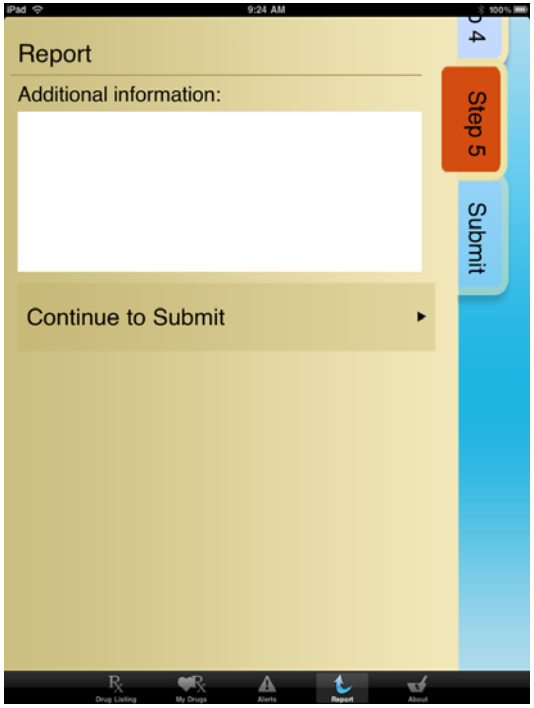


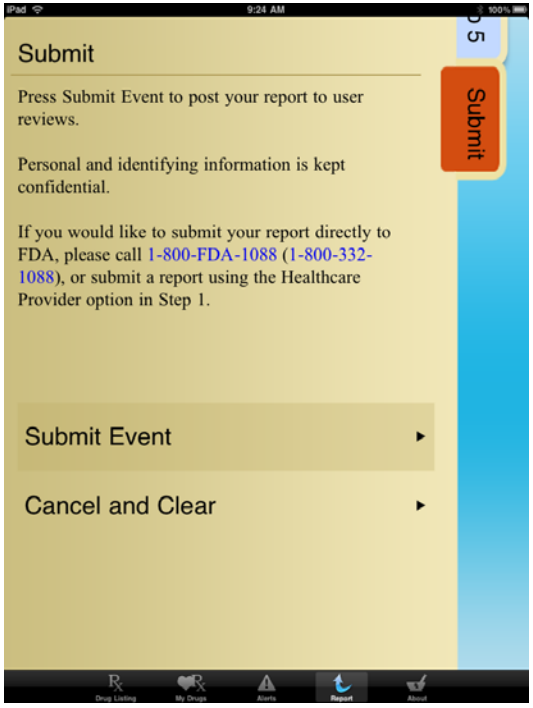




Example: MedWatcher, US





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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
Drug Listing
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Proton Pump Inhibitors (PPI): Class Labeling Change
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www.hhs.gov
U.S. Food and Drug Administration
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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
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2005 Safety Alerts for Human Medical Products
2004 Safety Alerts for Human Medical Products
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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.