



IRISH MEDICINES BOARD

Key concepts on communication / transparency

Dublin, 2 December 2011

Dr Cairíona Fisher

Communication / Transparency

Communication

- List of intensively monitored products
- Labelling
- Safety announcements
- Encouragement of ADR reporting
- Public hearings

Transparency

- Web portals
- Eudravigilance

Stakeholder participation

- Stakeholder meetings
- PRAC
- Consultations



IRISH MEDICINES BOARD

List of intensively monitored products

Art. 23 of the Regulations/Art. 59 of the Directive

‘The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.’

- Both centralised and nationally authorised products on one list.
- List will include link to the SPC and the risk management plan.
- SPC and PIL will include statement: “This medicinal product is subject to additional monitoring” preceded by black symbol which will be followed by an appropriate standardised explanatory sentence.
- Symbol will be chosen by Commission on recommendation of PRAC.



IRISH MEDICINES BOARD

Labelling

Art 59 of the Directive (package leaflet)

“For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system referred to in Article 107a(1), and specifying the different ways of reporting available (electronic reporting, postal address and/or others).

Note that QRD template already includes statements:

If you get any side effects, talk to your <doctor> <or> <,>
<pharmacist><or nurse>. This includes any possible side effects not listed in this leaflet.



IRISH MEDICINES BOARD

Safety announcements

Art 57.1(e) of the Regulation

“assisting Member States with the rapid communication of information concerning pharmacovigilance to health-care professionals and coordinating the safety announcements of the national competent authorities”

- Purpose is to ensure that clear messages on medicines safety are provided in a timely and consistent manner across EU
- Major change in that it extends Agency co-ordination of safety announcements to nationally-authorized products



IRISH MEDICINES BOARD

Safety announcements

Art 57.1(e) of the Regulation

Current ongoing project to:

- Define scope of safety announcements and level of co-ordination required
- Define roles and responsibilities of all the 'players'
- Define procedures for agreeing key messages and making information public
 - Building on existing operating systems and structures, including 'early notification system', incident management plan' and 'rapid alert system'.
 - Establishing links between the EU regulatory network (EMA, MSs and EC) and stakeholders (mainly patients, consumers and healthcare professionals)
 - Streamlining information flows and avoiding divergent messages



INDEPENDENT BOARD

Encouragement of ADR reporting

Recital 21 of the Directive

- “...appropriate to facilitate the reporting of suspected adverse reactions to medicinal products by both healthcare professionals and patients, and to make methods for such reporting available to them.”

Art 59 of the Directive (package leaflet)

- Statement to report adverse reactions to HCP or national reporting system

Article 102 of the Directive (ADR reporting promotion)

- MS to take appropriate measures

Art 106 of the Directive (web portal)

- Information on how to report, including use of web-based forms



IRISH MEDICINES BOARD

Public hearings

Art. 107j of the Directive

"Where the urgency of the matter permits, the PRAC **may hold public hearings**, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation"

"In the public hearing, due regard shall be given to the therapeutic effect of the medicinal product."



IRISH MEDICINES BOARD

Public hearings

Art. 107j of the Directive

Why include public hearings in the legislation:

- Respond to public demand for greater transparency
- Improves accountability of the regulatory system and builds trust
- Provide stakeholders with the possibility of participation in process
- Allows a patient view to inform decision-making

Feedback from stakeholder meetings:

Positively received by patients, consumers, healthcare professionals; hearings should be meaningful; expectations should be realistic.



IRISH MEDICINES BOARD

Public hearings

Art. 107j of the Directive

The issues to be addressed:

Why: transparency and/or involvement

Who: number, type of participants

How: process for announcing, arranging and holding hearings

What: outcome of the hearings



IRISH MEDICINES BOARD

Public hearings

Art. 107j of the Directive

- A 'may' provision
- A first at EU level
- Stepwise approach likely – starting with Article 107 - to gain experience
- Requirement for rules of procedure on the organisation and conduct of public hearings, and a process for participation



IRISH MEDICINES BOARD

Web portals

NCA's web portals (Art. 106 of the Directive), which should contain at least the following information:

- Public assessment reports together with a summary for the public
- SmPCs and package leaflets, conditions and deadlines
- Summaries of risk management plans of products authorised through national procedures
- List of medicinal products under additional monitoring
- Information to healthcare professionals and patients on how to report ADRs, including web-based forms

NCA web portal to:

- Link to European medicines web portal
- Enable electronic reporting of suspected adverse reactions from healthcare professionals and patients



IRISH MEDICINES BOARD

Web portals

European Medicines Web portal (Art. 26 of the Regulation)

- Members of the Committees - CHMP/PRAC/CMD(h), names and qualifications and declarations of interest (as currently)
- Agendas and minutes from each meeting as regards pharmacovigilance activities
- Summary of risk management plans for centralised products
- List of medicinal products subject to additional monitoring
- Locations in EU of pharmacovigilance system master files and contact information for pharmacovigilance queries for all products authorised in EU
- Union reference dates and frequency of submission of PSURs



IRISH MEDICINES BOARD

Web portals

European Medicines Web portal cont/d (Art. 26 of the Regulation)

- Protocols and abstracts of post-authorisation safety studies
- Initiation of Article 107i 'Union' procedures, actives or products concerned, the issue, notification of public hearings
- Conclusions of assessments, recommendations, opinions, agreement and decisions taken by the Committees



IRISH MEDICINES BOARD

Web portals

European Medicines Web portal issues:

- Definition of a portal (a website with content, a static signpost)
- Information overlap with other EU websites
- Synchronisation of content between EU web portal and national web portals
- Design principles
 - Consumer useability
 - Language, multilingual



IRISH MEDICINES BOARD

Art 57.2 of the Regulation

Agency will set up a list of all products authorised in the EU. To this effect:-

- Agency will publish a format for electronic transfer of information by 2 July 2011 (Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004, published 1 July)
- MAHs will submit information on products authorised or registered by 2 July 2012
- MAHs will inform Agency of any new or varied authorisations by 2 July 2012



EudraVigilance

Art 57.2 of the Regulation

Purpose:

- To support EudraVigilance database and signal detection
- To support identification of products in the case of referral procedures



IRISH MEDICINES BOARD

EudraVigilance

Art 57.2 of the Regulation

EMA guidance document - EV Code (EudraVigilance Code) is a unique identifier that identifies an entity within the database. It is made up of:

1. EV Code Organisation
2. EV Code Source
3. ATC Code
4. EV Code Pharmaceutical Dose Form
5. EV Code Administration Route
6. EV Code Substance
7. EV Code Product

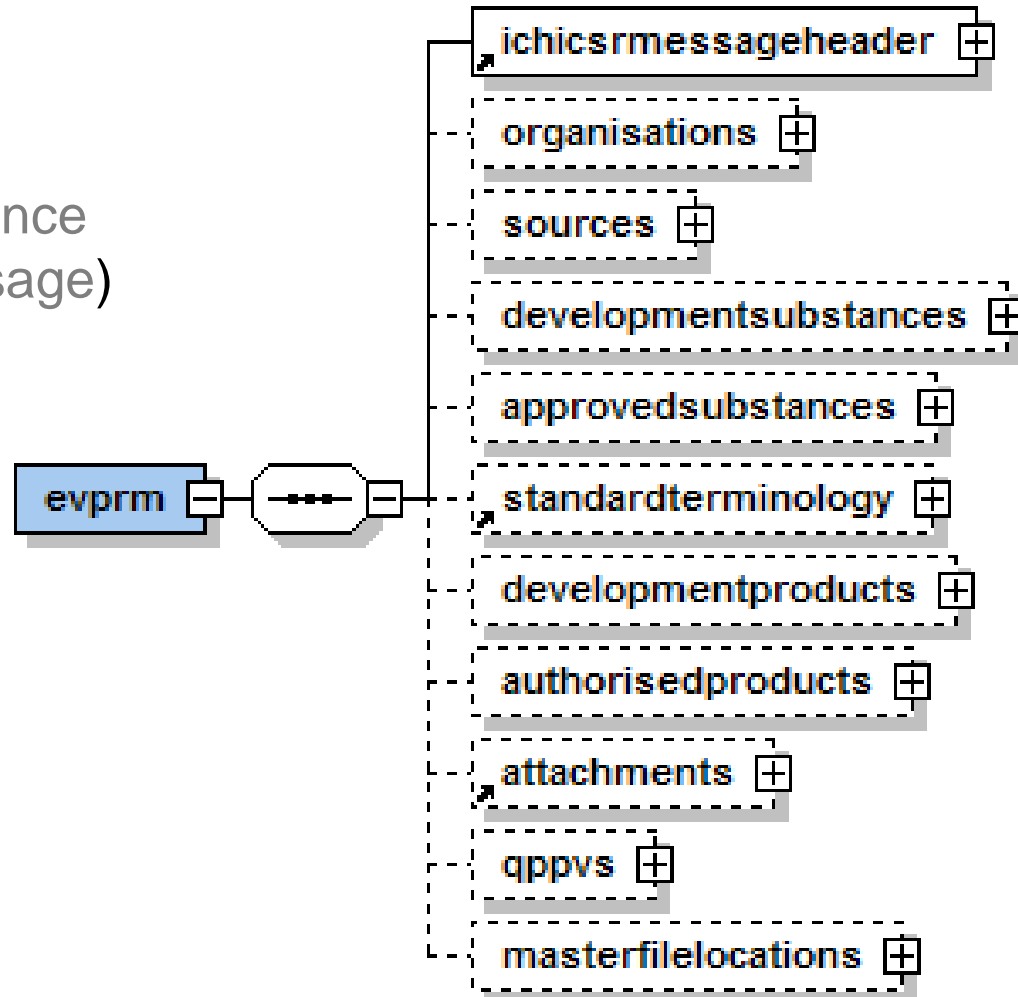


IRISH MEDICINES BOARD

EudraVigilance

Art 57.2 of the Regulation:

EVPRM (EudraVigilance Product Report Message) structure overview



IRISH MEDICINES BOARD

EudraVigilance

Art 57.2 of the Regulation:

Submission of information on medicinal products, attachments:

Annex I	SPC
Annex II	Manufacturer responsible for batch release
Annex III	Conditions of the marketing authorisation
Annex IV	Labelling
Annex V	Package leaflet

...in a single file.



IRISH MEDICINES BOARD

EudraVigilance

Art 57.2 of the Regulation, issues:

- Synchronicity of information on products between EudraVigilance product dictionary and national websites / lists
- Use of standard terminology vs IDMP (Identification of Medicinal Product) standard terminology developed by ISO to support ICH M5, due for publication in 2012, mandatory for use from 2015



IRISH MEDICINES BOARD

Access policy (EMA)

- Allows proactive disclosure of information
 - Maximum data are released proactively
 - Needs of the public are met
 - Requirements of personal data protection are adhered to
- Inform healthcare professionals and the general public by publishing collated adverse reaction data related to spontaneous reports for authorised medicines



EudraVigilance Access

1 - Healthcare professionals and the general public

Phase 1

- Publication of aggregated data for Centrally Authorised Products (updated on a monthly basis)

-> **by end 2011**

Phase 2

- Publication of aggregated data for all Medicinal Products (updated on a monthly basis)

-> **by end 2012**

- Access to defined data elements

2- Marketing Authorisation Holders & Sponsors and Research Organisations

-> **2014/2015**



IRISH MEDICINES BOARD

Stakeholder participation

- Stakeholder meetings: 15 April, 17 June, 20 October, 22 November
- Implementing measures: public consultation published 8 September on 6 IMs, ended 7 November
- Call for expression of interest in PRAC published 30 September, with submission of applications until 1 December
 - member + alternate ‘to represent patient organisations’
 - member + alternate ‘to represent healthcare professionals’
 - 6 independent scientific expert members
- Public consultation on a draft Union reference date list



IRISH MEDICINES BOARD

Stakeholder participation

- Public consultation on GVP modules, 2 'waves' Feb 2012 and later
 - Process-specific communication and transparency provisions in each GVP module
 - Dedicated GVP module proposed on 'public participation', gathering together all of the communication and transparency provisions in the other modules and including wider references to the Patients and Consumers' Working Party and Healthcare Professionals Working Group as PRAC Members and ad hoc experts
- Input from Patients and Consumers' Working Party and Healthcare Professionals Working Group, patient observers in PhVWP, ad hoc consultation on e.g. risk minimisation and communication
- SPC and PIL review by the Commission by 1.1.2013



IRISH MEDICINES BOARD

Communication / Transparency

Communication

- List of intensively monitored products
- Labelling
- Safety announcements
- Encouragement of ADR reporting
- Public hearings

Transparency

- Web portals
- Eudravigilance

Stakeholder participation

- Stakeholder meetings
- PRAC
- Consultations



IRISH MEDICINES BOARD