

European Conference for Rare Disease

# Assessing quality of information on medicines to patients

Dr Isabelle Moulon  
Head of Medical Information Sector  
EMEA

*Lisbon, 28 November 2007*

## EMA provision of information based on the legislation and the recommendations from the EMA patients' group

More information available to the public:

- Summary of EPAR in language understandable by the Public – Questions & Answers
- Assessment Report of applications withdrawn prior to the CHMP opinion and negative decisions – Questions & Answers
- More patient-friendly information on safety issues – Questions & Answers
- Improvement of the package leaflet and labelling
- + Access to Eudravilgiance, transparency provisions of the paediatric regulation

## Background: involvement of patients

A vertical blue bar on the left side of the slide contains five yellow stars, one for each main section of the text.

### Involvement of Patients when the Product Information is prepared by the company:

- Article 59(3) and 61(1) of Directive 2001/83/EC as amended
- Notice to Applicants Chapter 3: Guidance concerning consultation with target patient groups for the package leaflet

### Involvement of Patients when the Product Information is reviewed by the EMEA:

- Article 78(1) and 78(2) of Regulation (EC) no. 726/2004
- Framework of interaction between EMEA and Patients' and Consumers' Organisation (EMEA/354515/2005)

## User consultation



- Under the company's responsibility
- Included in the Marketing Authorisation Application
- Assessed during the evaluation of the application by the CHMP for the centralised procedures

## User consultation



It is a new requirement.



Until November 2005 readability testing of the package leaflet was optional. Reports submitted by companies were reviewed by the Quality Review of Document (QRD) group. It was a starting point for standardisation of the assessment on the readability testing.



However,




Industry needs to build up experience



Regulators need to build up experience

## User consultation: regulators' initiatives

- 
- A vertical blue bar on the left side of the slide, containing five yellow stars arranged vertically.
- The EMEA and the CMD(h)\* organised a workshop in October 2006
  - The EMEA with the QRD group is analysing user consultation submitted at the EMEA during the past year

\* *CMD(h) is the co-ordination group for mutual recognition and the decentralised procedures.*

# User consultation: Regulators' initiatives

## EMA – CMD(h) workshop

A vertical blue bar on the left side of the slide, containing five yellow stars arranged vertically, similar to the flag of the European Union.

### Focus on:


- Layout and design of the package leaflet
- Assessment of user testing
- Justification for not performing user testing

based on examples from centralised and decentralised procedures

### Conclusions:

- Need to further develop experience
- Need to develop guidance for assessors and for industry


## Involvement of patients in the provision of information




Objective: To make sure that the information is clear and understandable by the target audience.




Measures put in place (since May 2007):


- 
- Review of the EPAR summaries (English version),
  - Review of the Package Leaflet at the time of the renewal of the Marketing Authorisation.



Experts are designated by the patients' and consumers' organisations fulfilling the criteria to be involved in EMEA activities. EMEA checks declaration of interest and confidentiality undertaking.




## Package Leaflet



Patients (Experts) perform the review in parallel to the Quality Review of Documents

- The compilation of comments will be performed for both groups (QRD Members & POs) at the same time i.e. by day 75
- Purpose:  
To confirm that the information is clear and understandable by the target audience

## EPAR summaries


- 
- A vertical blue bar on the left side of the slide, containing five yellow stars arranged vertically, similar to the flag of the European Union.
- Patients (Experts) review at the same time as CHMP Rapporteur/Co-Rapporteur and EMEA project managers
  - The EPAR summary will then be sent to the applicant prior to adoption by CHMP i.e. by Day 30
  - Purpose:  
To confirm that the information is clear and understandable by the target audience

# Involvement of patients in the provision of information


Ad hoc involvement:

- Consultation of the EMEA Patients and Consumers' Working Parties (PCWP) on the Package Leaflets for NSAIDs: how to express the warnings on cardiovascular risk.
- Consultation of patients and thalidomide victims during the evaluation of Thalidomide and Revlimid (lenalinomide) on the Package Leaflet and the risk management plan.
- Consultation of patients for the recall of Viracept (nelfinavir)

## NSAIDs and thrombotic risk

- 
- A vertical blue bar with five yellow stars, positioned on the left side of the slide.
- In October 2006 the CHMP agreed that the recommendations for use of non-selective NSAIDs should adequately reflect the current level of knowledge on thrombotic risk
  - The Pharmacovigilance Working Party (PhVWP) came up with a proposed warning and adverse reactions in the Package Leaflet

## The action of the PhVWP



The CHMP Pharmacovigilance Working Party (PhVWP) considered additional warning for Package Leaflets (PLs) of prescription-only NSAIDs and also for NSAIDs available "over the counter" (i.e. without prescription - "OTC") with different wording for naproxen, ibuprofen, diclofenac and others, depending on the risk level.




However, there was a need to find a balanced way to provide the new information on risk without compromising patients' compliance



→ **Patients' feedback needed**



## Patients' and Consumers' Organisations Working Party (PCWP): involved in the wording

- 
- A vertical blue bar on the left side of the slide, containing five yellow stars arranged vertically.
- On request the PCWP reviewed a first draft and acknowledged that communication to patients on this topic was necessary, but required some improvement in terms of clarity and comprehensibility.
  - A simplified common wording for all Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) was agreed by the group and then implemented as a final wording.

# Patients' and Consumers' Organisations Working Party (PCWP): involved in the wording

## Proposed wording for NSAIDs package leaflet (all products, POM and OTC)

- **Warnings**

Medicines, such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [x days *OTC products only*]

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

- **Side effects**

Medicines, such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

## Outcome?



- Will the Package Leaflet improve after “user consultation” and “Patients’ review”?
- What will be the feedback from the Patients, Consumers and the General Public?



Further information is available at:

<http://www.emea.europa.eu/htms/human/patientgroup/Patientwelcome.htm>