# EMEA/CPMP Working Group with Patient Associations

## *Product Information*

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## Scope:

Package Leaflet (PL)
Labelling text on outer & inner packaging

## Topics:

1. Legal Provisions / Boundaries
2. EMEA Tools & Initiatives
3. New European Initiatives

# 1. Legal Provisions / Boundaries

## Directive 2001/83/EC, Title V

- Listing of **particulars** which must appear in the SPC, labelling/packaging and Package Leaflet (PL)
  → content is legally defined & order of PL is fixed
- Legal requirement to include a PL **in the pack** *(unless all PL info is put on the carton)*
- "The PL must be drawn up in acordance with the **Summary of Product Characteristics**"
- "The PL must be written in **clear and understandable** terms for the users and be clearly **legible** in the official language(s) of the Member State"
- PL must be **identical** in all Languages

# European Commission Guidelines

*Examples:*

- Guideline on SPC
- Guideline on Packaging Information
  - Guidance on requirements for label, PL
- Guideline on Readability of Label and PL
  - Guidance on legibility, format, syntax etc …
  - Example of model leaflet
  - Example of method for readability testing
- Guideline on Excipients in Label and PL
- Standard Terms (pharm. forms, containers….)

# 2. EMEA Tools & Initiatives

Setting-up of
- internal linguistic review by scientific staff
- Quality Review of Documents Group (QRD)

QRD: established in June 1996

representatives from
Member States, European Commission, EMEA

Scientific staff with interest/experience in linguistic and readability issues

# QRD Tasks:

- Product Information review in all EU languages *(incl. meeting with Company on EN version)*
- Creation of Product Information Templates
  - based on Dir. 2001/83/EC
  - based on EC model leaflet
  - harmonised lay-out, headings, …
  - standard phrases and terms
  - in all EU languages
  - QRD guidance on how to complete
- Input in drafting/review of relevant CPMP and Commission Guidelines & Legislation
- Publication of QRD Guidance documents

# QRD Guidance Documents *(examples)*

- Guidance documents on terminology and style, non-standard abbreviations etc …
- Position on inclusion of health information in PL
- Addressing paediatric or incapacitated patients
- Guidance on User Testing of PL

➡ How do our PLs 'score' ?

- *PL Quality / Readability ?*
- *RA requirement or Patient Info ?*

23 Reports on PL User Testing received.

# AIM of readability/user testing:

DEMONSTRATE that patients can
**LOCATE** information in the PL,
**UNDERSTAND** it and
**KNOW HOW TO ACT** on it.

Focus on:
- What X is
- How to use X
- Before using X
- Side effects

## Commission Guideline on Readability & User Testing

↓

## EMEA/QRD Guidance on User Testing

Encourage/Promote User Testing
*(→ no strict legal requirement)*
Increase industry awareness

↓

*Positive experience for Companies*

## EFPIA Recommendations for User Testing

# 3. New European Initiatives

## G10 Medicines – Report 7 May 2002

- Recommendation 11 – Package Leaflet

  «*in the context of the current review of Community legislation, the legislation relating to patient information leaflet should be reviewed taking into account views of users as well as regulators and industry*»

## Review of EU Pharmaceutical Legislation:

- Revised order of PL, however, order still fixed
- Proposal: «*results of assessment carried out by target patient groups to be submitted*»

# Conclusions

- Quality & readability of PL improving
  - Impact of QRD, templates and guidelines
  - Impact of User Testing

- Constraints
  - Legal requirements
  - Nature of the product
  - Multilingual & identicallity aspects

- Next steps
  - Review of the legislation & impact on PL/labelling
  - Suggestions from Working Group to better meet the needs of patients