EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the revision of the new package leaflet (PL) template

Contents

- **Regulatory background**
- **New QRD package leaflet template**
  - Origin
  - Contents and structure

Regulatory background

- **Directive 2001/83/EC, as amended:**

  - The **inclusion** in the packaging of all medicinal products of a **package leaflet** shall be **obligatory.** (art 58)

  - The PL must be written and designed to be **clear and understandable**, enabling the users **to act appropriately**, when necessary with the help of health professionals. (art 63.2)

  - The PL must be clearly **legible in the official language or languages of the MS** in which the medicinal product is placed on the market. (art 63.2)

Regulatory background (cont.)

- The PL shall reflect the **results of consultations with target patient groups** to ensure that it is **legible**, **clear** and **easy to use.** (art 59.3)

- The **results of assessments** carried out in cooperation with target patient groups **shall also be provided to the CA.** (art 61.1)

QRD package leaflet template

- **QRD PL template** (annotated) created by the EMA
  - Based on EC Directive 2001
  - Based on EC Guideline on readability and model leaflet
  - QRD Guidance (harmonised lay-out, headings…)
  - A 'translation' of the summary of product characteristics in lay and meaningful language

- **24 clean templates** translated by the MSs
  - **Translations** constantly reviewed by EMA and Member States

Need to improve the PL template

- Based on 5 years experience with “user testing” (e.g. introduce more flexibility to the template by reducing the number of standards statements and enhancing the existing guidance, modify/improve existing headings ‘notoriously’ creating problems)
- Based on feedback received in various forms and through various sources justified the need to improve the QRD template
- Introduction of the concept of benefit (based on the report on benefit-risk of medicines carried out by the European Medicines Agency)
- New requirements related to paediatric information

Summary of changes into the new version of the PL template

- Flexibility has been increased
- More patient-friendly elements introduced
- Side effects section has been improved
- Introduction of section on benefits
- Introduction of section on other sources of information

PL structure and contents

- **Introduction**

  - Identification of the medicinal product:
    - name, strength and pharmaceutical form
  - General recommendations regarding the leaflet
    - one set for prescription only medicines and 1 for OTCs
  - Package leaflet index

- **1. What X is and what it is used for**

  - Identification of the medicinal product:
    - pharmacotherapeutic group
    - therapeutic indications
    - Info on benefits

PL structure and contents (cont.)

- **2. What you need to know before you <take> <use> X**

  - Information needed before taking the product:

    - contraindications + warnings and precautions for use
    - children and adolescents
    - other medicines and X
    - X with food, drink or alcohol
    - special warnings (pregnancy, breastfeeding, driving and using machines) and excipients warnings, if applicable

PL structure and contents (cont.)

- **3. How to <take> <use> X**

  - Instructions for proper use:

    - dosage + method and/or route(s) of administration
    - use in children and teenagers
    - frequency of administration + duration of treatment
    - overdose and/or missing a dose
    - withdrawal effects, if applicable

PL structure and contents (cont.)

- **4. Possible side effects**

  - Most serious side effects to be listed first with clear instructions on what action to take. Most frequent side effects to follow

  - The remainder should be presented on the basis of frequency of occurrence

- **5. How to store X**

  - Storage conditions and expiry date

    - warning against using the product after the expiry date
    - shelf life after reconstitution, if applicable
    - warnings against visible signs of deterioration, if appropriate

PL structure and contents (cont.)

- **6. Contents of the pack and other information**
  - What X contains
    - Full qualitative and quantitative composition of active substance and excipients
  - What X looks like and contents of the pack
    - Pharmaceutical form, physical description, pack sizes
  - Marketing Authorisation Holder (MAH) & Manufacturer
  - List of local representatives (all or none)
  - Date on which the PL was approved
  - Information for medical or healthcare professionals, if appropriate
  - Section on other sources of information (inclusion of product related website for OTC products)

User testing:
Reference documents

- **EC Guideline on the readability of the label and package leaflet (2009)** → to provide applicants with useful advise on the main factors which influence readability (http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf).

User testing:
EMA approach to user testing

- **Demonstrate** that patients can **locate** information in the package leaflet, **understand** it and **know how to act** upon it
- **Mandatory**, and part of the scientific assessment
- **Detailed guidance** has been developed to aid assessors
- Any post-authorisation procedure with significant impact on the package leaflet → can trigger user testing

Patients' contribution to QRD review

Example of relevant comment received

Take special care with X

- X does not reduce the risk of passing HIV to others.

- Request to "remove statement as research shows that antiretroviral therapy does reduce the risk of infection"
- Comment accepted by Rapporteur and passed on to the company
- Applicant accepted to implement comment
- Broader consideration: the revision of this general statement in the PL of X should also apply to the PL of other antiretroviral agents

Current status/future steps

- Translation exercise almost completed
- In selected languages external parties were involved in the review
- Meeting with industry associations on 28/02 to agree on implementation plan
- Possible publication date end of April 2011
- New Pharmacovilance legislation to be considered for future changes

THANK YOU!

Any questions?