EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Package leaflet initiatives

Ensuring safe and effective medicines for an ageing population

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An agency of the European Union

Ensuring consistency between SmPC and PIL

❖ How do we make sure information for old people is captured in the package leaflet =>

- The Quality Review of Documents (QRD) group together with EMA staff is responsible for the review of product information.
- Multiple reviews are performed during the evaluation process to ensure information on special populations is adequately reflected in the PL

Aim of the review in relation to information on old people

- Translate scientific information included in the SmPC into meaningful warnings/precautions in the package leaflet
- Make sure information presented in the SmPC is not missed in the package leaflet
- Ensure information on old people is clearly presented and stands out in the package leaflet.

Basic principles governing the information on older people in the PIL

- The package leaflet can only reflect information deriving from the evaluation dossier as this is presented in the SmPC.

- If no specific information exists in the SmPC still meaningful warnings/precautions can be deducted for inclusion in the package leaflet.

Example:

Old people

Before starting treatment and during treatment your doctor may check your kidneys are working properly.

Experience with information on older people in PL

- If old people not part of the target population =>
  - Statement on lack of specific data in this population + general warning to be cautious
  - Addressed indirectly in other sub-sets of special populations, e.g. renal impairment section
  - Rarely clear warnings and precautions based on (pre-) clinical studies.

Consultation with target patient groups

- The European Commission guideline on Readability requests companies preparing a user testing protocol to recruit participants who are representative of the population treated.

- Moreover, it is recommended to include in the testing older people, if the medicine is particularly relevant to their age group.

Focus on design and layout

- Efforts have been made in recent years to stress the importance of the design and the layout of the package leaflet and its link to the end user.
- EMA is currently analysing package leaflets authorised via the centralised procedure, which also underwent user testing, to establish, amongst others, whether they are suitable for the target population not only from a content, but also from a layout/'manual handling' point of view.

Package leaflets in Braille or other formats

- According to article 56a of Directive 2001/83 the marketing authorisation holder shall ensure that the package leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially sighted.

- The guidance in the QRD template encourages companies to comply with this requirement, however EMA cannot enforce it onto the respective marketing authorisation holders.

European Commission report on shortcomings of PILs

- Directive 2010/84/EU – EC should, in collaboration with the EMA and other stakeholders present by Jan 2013 an assessment report on current shortcomings in the SmPCs and PLs and how they could be improved in order to better meet the needs of patients and HCPs.

- One of the objectives of the report is to identify possible shortcomings, as regards the value as a source of information for healthcare professionals and the public, with a particular focus on older persons.

EMA's involvement in the EC report

- EMA is conducting in parallel a study to analyse deviations found between PLs approved by CHMP (and user tested) and the ones actually placed in the market.
- Preliminary findings show that the actual size of the PL affects considerably the readability and manual handling of a PL.
- All findings will be provided to the contractor and EC for further consideration in the report and final conclusions/actions.

Labelling/packaging

- EMA has set up a checking system of proposed artwork for medicinal products going through the centralised procedure.
- Particular attention is given to the legibility of labels in view of the end users (font size/type, prominence of critical information, use of colours).
- EMA also provides feedback on a case by case basis on the actual packaging and its user 'friendliness'. E.g. certain child-resistant containers can prove really difficult in handling by old people, especially with impaired mobility.

THANK YOU!
Any questions?