Bridging reports - Member state experience

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Presentation content

• Legal aspects for readability in Poland
• Difficulties while assessing justification reports
• What’s important in planning justification report application to regulatory authorities
• Memberstate experience (Polish-Hungarian cooperation)
• Future in Poland
Art. 10 sec. 9

In a special regulation the Minister of Health will describe the way to check readability of PL and the report criteria, taking into consideration EU Guidelines.

- **Readability test report should be present in documentation for new registrations**
Problem with changing „soft” EC guidelines into „hard” regulations in Poland

Example: Ministry of Health is building regulation based on draft of European Commission guidelines on readability – user testing
Difficulties – on both sides

- Poor quality justification – MAH side of the story
- Assessing design and layout – Regulatory side of the story
• Medicinal product X is to be used by hospital personnel only
• The pharmaceutical form *prolonged-release tablet* does not require special instructions for handling (as they are necessary e.g. for inhalers or parenteralia intended for self-administration) nor instructions for preparation or reconstitution. Not one case of wrong use, false administration or dosage due to misunderstanding of the PIL has been reported.
• The wide therapeutic margins and the widespread use in broad patient populations (including adolescents, adults, elderly, patients with renal and/or hepatic impairment) without any safety concerns classify medicinal product X as an unproblematic agent.
Furthermore, given the rare nature of the indication, xxxxxxxxxx, finding a sample of patients in this population in order to conduct patient readability testing is extremely difficult. Based on this fact and the justification provided above, Readability Testing has not been performed, and the applicant feels it is not required.
Assessing design an layout

Leaflet indicators:

• Scores for presentation - text readability and ease of navigation (font, use of text, contrast, format, line spacing, use of columns, justification, use of headers, pictograms, pictures, use of colors)

• Scores for content
  – pointers to further information sources
  – use of lay terms instead of medical jargon
  – inclusion of benefit statement
  – presentation of side effects

Source: http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Patientinformationleaflet(PIL)ofthemoth/index.htm
Assessing design an layout

• Is it enough to assess design and layout
  or
• Should we use more indicators
  and if yes
• Do we have enough knowledge and should we use indicators from field of art, psychology, ergonomics?
What’s important

• Planning readability testing it is important to prepare very detailed PRODUCTS PORTFOLIO
• For all products licensed
• With all safety information
• With instructions for use with certain devices (eg inhalers)
What’s important

• When the big work is done
  – Choice of the product with the most complicated safety information
  – Choice of the routes of administration
    • 1 oral
    • 1 parenteral
    • 1 for inhalation
What’s important

• It is possible to perform readability user testing on 3 products only and cover with justification much more produced products

• To choose wisely means
  – From products for inhalation the one without bridging possibility (rare active substance given only by inhalation)
  – From NSAID the one given parenterally
Memberstate experience

• HU acted as RMS for PL medicinal product to be registered in MRP procedure

• MAH (Polish) justified not performing test for lozartan containing product on example of previously successful testing for valsartan containing product produced by other MAH (Hungarian)
Memberstate experience

• Following reasons were given:
  – Both package leaflets were compiled according to the EMEA QRD template.
  – Valsartan belongs to the same class of antihypertensive agents, called angiotensin II antagonists like Lozartan.
  – These products are intended for prescription, and indicated for mainly treatment of Hypertension.
  – The main warnings concern the history of hypersensitivity, pregnancy and lactation and hepatic impairment.
  – Absorption of both active substances is not affected by food.
  – Usage in elderly patient should be in line with the renal function, and there is limited data on clinical trials with children.
Memberstate experience

- Main source of interactions derived from the concomitant taking of non-steroidal anti-inflammatory drugs and potassium supplements, potassium-containing salt substitutes or any water tablets.
- The most prominent side effects are orthostatic hypotension, vertigo, vasculitis, abdominal pain, diarrhoea, fatigue, oedema, rash, anaphylactic reactions and abnormal hepatic function.

The justification was assessed by my Hungarian QRD friend and me and we found that it is not possible to assess whenever design and layout issues are similar.

THERE WERE NO MOCK UPS COMPARISON
Future in Poland

**Historical disaster**

- For many years the SmPC was not officially approved
- Only the PIL was attached to the Marketing Authorization License
- Lack of the medical editions authorized by MH or my agency, containing approved information for physician and pharmacist (such as USPDI in USA or Medicines in UK)
- Approval of highly technical text in PIL (somehow physician has to know what he/she prescribes)
- Possibility to use only the approved text for advertisement brochures
The MAH side of the story:

- Lack of habit to prepare readable text for patient
- Habit to copy text of SmPC to proper sections of PIL
- Regulatory representative fluctuation
- Lack of habit to use templates
- Lack of knowledge about proper use of Microsoft Office Word functions (track changes, comments)
- Awaiting that the text will be corrected by us (workers of DODI - Section For Product Information Evaluation)
Future in Poland

The DODI side of the story:
• Work overload
• Not enough experts
• Keeping deadly deadlines
• Bad quality of text
  – No proper template use
  – Missing words or sentences
  – Scientific incorrect translations (e.g. terminology)
  – Inaccuracies (incorrect translations – incl. spelling, punctuation, grammatical mistakes)
  – Editorial, stylistic changes (e.g. rephrasing)
Future in Poland

Process of documentation update in Poland

END OF DERROGATION –
December 31, 2008

• It means for MAH only 1 renewal before receiving permanent license
Future in Poland

• Would this last renewal be the time to present readability user test report?
  If yes
  All Patient leaflets will be readability checked before end of 2012

• For some medicinal products the last renewal will be next year
  Are they prepared?
Future in Poland

• As regulators we are prepared to assess readability reports or justification reports
• In case of national industry it means – to perform new test
• In case of foreign industry – we will accept justification of performing test on other language PIL (eg EN) in case Polish text will be adjusted to the tested one
THANK YOU FOR ATTENTION
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