Better packaging and labelling for better informed patients

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Outline

1. BEUC in a nutshell
2. The right to information
3. Users‘ opinions about package leaflets
4. Lessons from the literature
5. European Medicines Agency initiatives
6. EU legislation on pharmaceuticals
7. Recommendations

BEUC

- Representing consumer interests towards the EU institutions since 1962
- 43 members from 31 countries
- 8 Headlines: Health care, Food, Product safety, Environment and sustainability, Collective redress, Digital world, Consumers contracts,Financial services
- PHARMACEUTICALS: information to patients, counterfeit medicines,pharmacovigilance, HTA, e-commerce,competition,European Medicines Agency

The right to information (I)

Consumers have the right to high quality and

NON PROMOTIONAL information about health, medicines and treatments

The right to information (II)

High quality information increases:

- Consumers' empowerment
- Compliance and adherence to treatments
- Patient safety
- Health outcomes

Leaflets as a source of information

Package leaflets are one of the most trusted source of information about the benefits and the risks of medicines

Sources:

- MHRA-IPSOS, Research report on “Risks and benefits of medicines, perceptions, Communication& regulation”, 2006
- Datapharm Survey, 2009

Do users read the package leaflets?

In Italy, Spain, Portugal and Belgium altogether (sample of 10.146 consumers):

- 88.2% of the population read the package leaflets of an OTC medicine used for the first time, 39.4% for medicines they already used before.

- 82.4% of the population read the package leaflets of a prescription medicine used for the first time, 32.2% for medicines they already used before.

- 77.6 % always keep it, 16.5% keep it sometimes, 5.9% throw it away.

Source: Altroconsumo, DECO PROTESTE, OCU,Test-Achats 2007

Why users don’t keep the package leaflets ?

- I will not need it any more
- Too difficult to put it back in the box (40, 9%)
- The PIL was damaged after I used it
- The font was too small (21%)
- The text was too complicated (8,7%)
- I can obtain the same information from other sources (ex. Internet)

Which parts of the package leaflets users read the most?

- Indications (70.3%)
- Contra-indications (67.4%)
- Side effects (53.7%)
- Posology (44.5%)
- Composition (24.3%)
- Possible interactions (21.6%)

Literature review (I)

" Most people do not value the written medicines information they receive"

Source: " A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines"

Raynor DK, Blenkinsopp A, Knapp PR, et al., 2007

Literature review (II)

« Routinely provided inserts are read by the vast majority of patients and have a positive impact on patient satisfaction, regardless of their quality ».

« High quality patient package inserts have a positive impact on knowledge about drugs in those patients who read the insert ».

Source: « *Impact of written drug information in patient package inserts: Acceptance and impact on benefit/risk perception* ».

Robert H. VANDER STICHELE, Ghent University, Faculty of Medicine and Health Sciences, Heymans Institute of Pharmacology, 2004.

Literature review (III)

« Direct measurement of benefit/risk perception with more validated tools is necessary to comprehend the relation between benefit/risk perception and behaviour.

This may be crucial to design (and retest) better patient package inserts, to help patients make informed and shared decisions about adherence to drug treatment, and to assist them in the proper and safe continuation of treatment. »

Source: *« Impact of written drug information in patient package inserts: Acceptance and impact on benefit/risk perception ».*

Robert H. VANDER STICHELE, Ghent University Faculty of Medicine and Health Sciences, Heymans Institute of Pharmacology, 2004.

Asthma patients on the use of package leaflets

- " You throw them away, don't you?"
- "They don't inspire you"
- " Priorities of those who wrote it, not patients"

Source: " We are the experts: people with asthma talk about their medicines information needs".

Raynor DK et al., 2004

Evidence indicates that

- Package leaflets are read by the vast majority of patients and have a positive impact on patient satisfaction, regardless of their quality
- The readability level of much health and medicines information is beyond the average reading ability of people with limited literacy skills. Complex content and poor design cause problems also to literate users
- Benefit/risk perception is an important cognitive concept for understanding patients mental processing of package leaflets
- Package leaflets should be improved

European Medicine Agency initiatives *

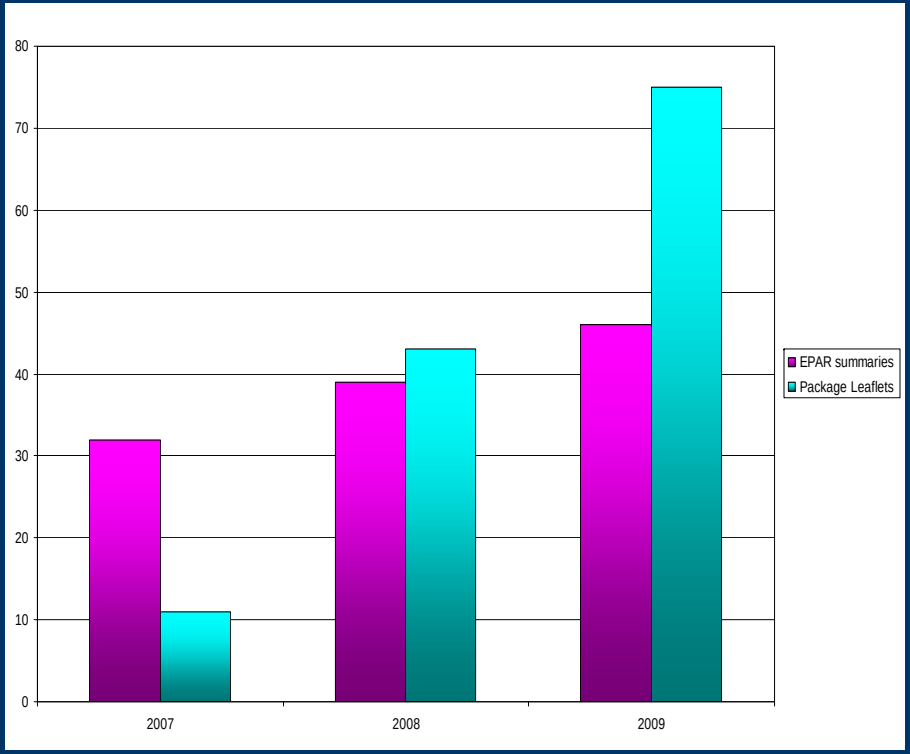
- Comprehensive analysis of user testing results (2005-2009)
- Extensive revision of the package leaflets
- Outcome of the analysis + findings from discussions with stakeholders taken into account for the QRD templates revision
- Revision of the SmPC guideline (published in September 2009).
- Revision of the EC Readability guideline (published in January 2009)
- Public consultation on the QRD template

* Non exhaustive list

EMA patients and consumers' working party

- Review of product information (EPAR summary and package leaflet)

- *" We will continue to work towards providing high-quality information adapted to and oriented towards patients and consumers, who will continue to be involved in the preparation of such information »*



Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations

- ❑ Package leaflet: towards an "information tool"
- ❑ Always communicate benefits and risks together
- ❑ Clear description of benefits and risks, both qualitative and quantitative
- ❑ Patterns which may modify the benefits or the risks should be made clearer
- ❑ Foster dissemination of information from regulators

New Directive on pharmacovigilance (I)

- No summary of essential info or “drug facts box”
- *“(e) a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case”.*
- *“**This medicinal product is subject to additional monitoring**”. This statement shall be preceded by the **black symbol** referred to in Article 23 of Regulation (EC) No 726/2004 and followed by a relevant standardised explanatory sentence.*
- *“For all medicinal products, a standardised text shall be included expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system, specifying the different ways of reporting available (electronic reporting, postal address and/or others) in compliance with Article 107a(1) second subparagraph.”.*

New Directive on pharmacovigilance (II)

" The Commission shall, in collaboration with EMA and national competent authorities and following consultations with organisations representing patients, consumers, doctors and pharmacists, social health insurers, and other interested parties, present to the European Parliament and the Council an assessment report regarding the readability of the summaries of product characteristics and the packaging leaflets and their value to the healthcare professionals and the general public. Following an analysis of the above data, the Commission shall, if appropriate, put forward proposals to improve the layout and the content of the summaries of product characteristics and of the packaging leaflet to ensure they are a valuable source of information the healthcare professionals and the general public as appropriate*".*

European Parliament Report on Information to the general public on prescription medicines

« Within 24 months of the publication of this Directive in the Official Journal of the European Union, the Commission shall present to the European Parliament and the Council an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals. The Commission shall, if appropriate, and on the basis of the report, and consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents ».

ENVI committee, 28 September 2010

Suggestions for improvement (I)

1. Less medical jargon and more straightforward language
2. Better use of simple design techniques (ex. bullet points, paragraphs, short sentences)
3. Standardised frequency indications (based on studies about readers perception)
4. Larger print
5. More visible expiration date and storage information
6. More pictures and pictograms
7. No repetitions

Suggestions for improvement (II)

8. Clearer safety information (see new proposal on pharmacovigilance)
9. Key safety information (ex. Keep the leaflet, if you have questions ask your doctor etc) at the top of the leaflets in all medicines
10. More attention to sight impaired needs
11. Faithful translation
12. Health education information
13. More consistency between leaflets of the same medicine in different countries

Suggestions for improvement (III)

14. Improve users testing

15. Post user testing evaluation (ex. EMEA initiative with Patients and Consumers organizations)

16. Package leaflets (and EPAR summaries) should be made fully available on the medicine agencies web sites in all member states (see EP report on information to patients and new directive on pharmacovigilance)

17. More research and independent scientific evidence

Package leaflets and Health literacy

- Health information needs are highly complex and individual
- Different approaches towards health information depending on age, gender, education,social status,health status
- Health literacy and health inequalities

For the BENEFIT of PATIENTS

- Effective medicines need effective information
- Better patient information for a more rationale use of medicines
- Unbiased and non-promotional information
- Package leaflet should be clear and simple
- Package leaflets should be designed FOR, WITH and AROUND the patient

Thank you!

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More information on www.beuc.eu