PACKAGING AND LABELLING OF NON PRESCRIPTION MEDICINES

BEUC comments to the EMA guidelines

Contact: Ilaria Passarani – health@beuc.eu
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BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Summary

BEUC fully supports the EMA recommendations on pack design and labelling for non prescription medicines.

High quality information provided in the labelling is an essential tool to allow consumer to make informed choices in self-care and to use the medicines correctly. The information should be legible, understandable, user friendly, transparent and non promotional.

Industry product specific web sites should not be allowed in the package leaflet and on the packaging as this can generate confusion for consumers in relation to the source of and the monitoring of the information.

Pictograms and symbols can be useful to communicate certain messages but they should be user tested. The active substance, the contraindications and the maximum duration of treatment are essential information for the safe use of the medicines and should be clearly and prominently displayed.

It is always a challenge to find the right balance between providing complete information and at the same time avoid putting too much information in a small space at the expense of legibility. For this reason critical safety information should be preferred to graphic elements that have no added value for consumers.

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1. Good labelling and pack design for better informed consumers

BEUC fully supports the QRD[1] recommendations on pack design and labelling for centrally authorised non-prescription human medicinal products as presented by the European Medicines Agency[2].

Critical information provided in the packaging is an essential tool to allow consumer to make informed choices in self-care and to use the medicine safely. The information should be legible, understandable, user friendly and non promotional.

The information is necessary for the rational use of the product especially considering that there is no doctor supervision and that in some Member States certain products are sold without the intervention of a pharmacist. No matter the supply arrangements, consumers should always have access to additional and personalised information on the medicine from qualified health care professionals, especially regarding possible contraindications and interactions with other products, including herbal medicines and food supplements.

2. No reference to industry product specific web sites in the leaflets and on the packaging

We take this opportunity to restate[3] our opposition to the inclusion of industry product specific web sites in the package leaflet and on the packaging even if they are not specifically mentioned in the recommendations.

While we acknowledge that - if non promotional and in compliance with EU and national legislation – information from marketing authorisation holders can be considered useful for patients in a self-care situation, it is of outmost importance to maintain a clear distinction between different sources of information and avoid any confusion in relation to the origin of the information. Consumers have the right to know who is responsible for the information provided, what is the purpose of the information and the target audience. This ensures transparency and helps the reader to “navigate” and find his way in the “information jungle”, especially on the internet.

In particular we consider that the reference to pharmaceutical companies’ medicines’ specific web sites might induce the reader to believe that, as for the leaflet and the packaging, also the content of the web site is validated and monitored by the competent authorities while this it is not the case.

In addition the competent authorities do not have the power to verify that the information provided in the web sites is compatible with the summary of product characteristics (SmPC) and is non-promotional. Nor they have the resources to monitor the web sites and the possible changes to their content.

It is also worth considering that if allowed for non-prescription medicines on the basis of Article 62 of the Directive 2001/83/EC this will have to be allowed also for prescription medicines as the provisions regarding optional information apply to all medicines.

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[1] QRD stands for the Working Group on Quality Review of Documents that provides assistance to the European Medicines Agency scientific committees and to companies on linguistic aspects of the product information for medicines. For more information: ttp://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CVMP/people_listing_000044.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e2d

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/04/WC500104662.pdf

[3] BEUC, PGEU, CPME letter on product specific web sites, 19 November 2010.

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3. User tested pictograms and meaningful information with an added value

Symbols and pictograms can be useful in communicating certain messages – for instance in relation to the use of interference with driving or operating machines (see for example the pictograms used in France, Denmark and Sweden) but for them to be useful and to ensure that consumers can act on the information they convey, it is important that they are user tested to guarantee that their meaning is understandable and cannot be confused. In addition it is desirable that they are accompanied by a short explanatory sentence whenever possible. Also, it should be taken into account that the same pictogram can be interpreted differently depending on the country where it is used, for example because of the use of a similar symbol on other products or because of a different cultural tradition.

We have some reservations on the use of a symbol for the pharmaceutical form (point 5.1.1) as we consider it of little added value. In addition if the symbol is not perfectly identical to the actual form it can generate doubts in relation to the quality of the medicine and can lead consumers to think that it may be counterfeit. Many marketing authorisation holders now show on their web site a picture of the pharmaceutical form and compare it with a counterfeit product that for example misses a score line. We also think that the picture indicating the body part has little value for consumers and in order to avoid the use of too many symbols we believe that preference should be given to pictograms of special administration aids (e.g. scoops or spoons).

The route of administration should be presented using terms that are meaningful for consumers and avoiding fantasy names. Specific claims regarding excipients such as "lactose free" should be relevant (e.g. change in formulation) and non promotional.

4. Key information for consumers

It is always a challenge to find the right balance between providing complete information and at the same time avoid putting too much information in a small space at the expense of legibility. For this reason critical safety information should be preferred to graphic elements that have no added value for consumers. In particular, in addition to the elements identified in the draft guidelines, we would like to stress that the following information is key for consumers and should be clearly and prominently displayed:

- the active ingredient (INN) - it should be mentioned every time the brand name is mentioned, including in the sides or flaps and should be legible in terms of font size, contrast and clarity;
- the maximum duration of treatment - it should be clearly indicated in the same field of vision as critical information as it is important for consumer safety;
- contraindications to ensure that consumers do not buy a product that they then find out is not suitable for them;
- the expiry date – consumers often report problems in reading the expiry date which is in many cases just inscribed on the box and not fully visible;
- the information on the appropriate storage of the product and on the storage life (e.g. when a medicine cannot be used after a month from the first time it was opened);
- interactions with alcohol (if relevant);
- interference with driving or operating machines (if relevant);
- special precautions during pregnancy and breastfeeding (if relevant).

END

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