

TGA Medicine Labelling and Packaging Review

– Consultation Paper May 2012

Response from Professor DK Theo Raynor, University of Leeds, UK

Consultation response on “Standardised Information Format”

I am pleased to respond to this consultation on the presentation of information on medicine containers and boxes – information which plays an important role in facilitating safe use of medicines. ¹

The focus of this paper is the objective of the review relating to a proposed **standardised format for information on medicine labels and packaging**. My response will not cover other objectives relating to how the active ingredient is placed on a medicine box, the use of same brand name for a range of products, look alike and sound-alike names, etc.

There are a number of reasons to recommend a standardised information format for medicines packs. Having a format which people can ‘get to know’, and be instantly recognisable as the key source of information has face value. People will then know what information is available, and where to look for it, whenever they get a new medicine.

In both Australia and Europe the leaflets designed to accompany the medicine (Consumer Medicines Information (CMI) in Australia; Patient Information Leaflet (PIL) in the UK) follow a standardised layout and order of information. In the UK we know that almost all patients are now aware of the standardised leaflet and around three-quarters read some or all of the leaflet. ² In Australia, again most people are aware of CMI and two-thirds of people report reading CMI. ³ However, whether people have actually ‘got to know’ the formats is unclear.

Overall, the examples given for glucosamine, ibuprofen, paracetamol and hydrocortisone follow good practice in information writing and design.⁴ However there are issues relating to some difficult words used (both medical and non-medical). There is also sub-optimal formatting in places - and applying best practice in information writing and design in official guidance such as this will encourage producers to do the same. In Europe, our experience is that the precise wording and layout of examples in official guidance on medicine labelling is often followed closely by pharma companies – and they are reluctant to use alternatives. Applying best practice also sets the tone for the rest of the wording and layout in information produced by companies.

The improvements proposed below follow the principles of “universal precautions” to promote health literacy being taken forward in the USA i.e. to offer the same accessible information and services to all patients. ⁵ It is important to note that there is no evidence that the use of simple, plain language is seen as patronising or not being acceptable to people with all levels of education - everybody could benefit from clearer health information. ⁶

Wording

In the examples of a ‘Medicine Information Box’ used in the consultation paper, there are cases where simpler words (whose meaning is the same) could replace more complicated words. A key indicator is whether the word or phrase is conversational – is it a word a health professional would use when talking to the patient? Conversational writing is much more acceptable to lay people, especially to those with lower health literacy.

- **Headings**

In Europe leaflet headings tend to be phrased as questions or statements, and that seems to work well. Hence I propose for the Medicine Information Box:

What is the active medicine? [Active ingredient]
What is X used for? [Uses]
How to take [Directions]
How to store [Storage information]

- **Non-medical words**

I have listed lay language, conversational alternatives to words used in some or all of the examples:

comes from	[derived from]	sometimes	[occasionally]
get	[seek]	talk to	[consult]
happen	[occur]	after	[following]
using too much	[excess use]	before	[previously]
apply thinly	[apply sparingly]	equal to	[equivalent]

- **Medical words**

gut problems	[gastrointestinal]	illness	[condition]
stomach problem	[stomach disorder]	medicines	[medications]
kidney problems	[impaired kidney function]		

- **Phrases**

If you do not get better [If symptoms persist]
Rashes from [Rashes arising from]

- **Lay & medical description**

Stating the lay description first is good practice:

period pain (menstrual cramps) [menstrual cramps (period pain)]

Layout

The distinctive feature of the Medicine Information Box is its layout, and this generally works well. This is especially the 'white on black' headings which clearly delineate each section, aiding navigation (but see suggestions for improved wording above). However, there are some places in which the layout might be improved

Glucosamine

Simple bulleting can efficiently change the perception of these sections and their readability. Currently:

Active ingredient

Glucosamine sulphate sodium chloride complex 1886 mg
(equivalent to glucosamine sulphate 1500 mg)
Chondroitin sulphate bovine sodium 95% 842 mg (chondroitin sulphate sodium 800 mg)

Proposed:

What is the active medicine in Glucosamine?

Glucosamine sulphate sodium chloride complex 1886 mg

- equal to glucosamine sulphate 1500 mg

Chondroitin sulphate bovine sodium 95% 842 mg

- equal to chondroitin sulphate sodium 800 mg

Current:

Directions

Adults- Take 1 easy to swallow tablet twice daily with meals or as professionally prescribed
Children under 12 years – Only as professionally prescribed.
If symptoms persist, see your health care professionals

Proposed:

How to take

Adults - Take 1 tablet twice a day with meals
- or as professionally prescribed
Children under 12 years – Only as professionally prescribed.
If symptoms persist, see your health care professionals

Information in capitals

Section 4.3 suggests headings be “highlighted or bolded so that they are sufficiently emphasised”. It would be more appropriate to say “in bolded lower case” as this is the most effective way to emphasise text – it is particularly important that capitals should not be used. Capitals make words harder to read, as words are most quickly recognised by shape – and words in capitals are all rectangular. It follows that the following changes should also be made:

Keep out of reach of children

[KEEP OUT OF REACH OF CHILDREN]

Caution

[CAUTION]

User Testing

A final point is that application of good practice in information writing and design does not guarantee that patients can find and understand the information they need. ⁷

The technique known as ‘user testing’ developed and first used in Australia ⁷ has been adopted in Europe to improve the readability of both patient information leaflets ⁸ and medicine label wordings ⁹

Before the Medicine Information Box is adopted, it would be appropriate to user test the format with the general public, to ensure that it works in practice.

Statement of Interest

I am co-founder and academic advisor to Luto Research which develops, refines and tests health information materials.

DKTR 13th August 2012

References

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- ⁵ Agency for Healthcare Research and Quality. Health literacy universal precautions toolkit. 2010. www.ahrq.gov/qual/literacy/index.html.
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- ⁷ Sless D, Shrensky R. Writing about medicines for people (3rd ed.) Sydney: Australian Self-Medication Industry; 2006
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- ⁹ Harris E, Enright D. New words for cautionary and advisory labels make them easily understood. *Pharm J* 2011;286:278-279