

## Usability Guidelines for writing CMIs

The Therapeutic Goods Regulations require that information written for consumers about prescription and pharmacist-only medicines be available at the point of supply. This information must comply with the requirements set down in the Regulations, be factual and based on the Product Information and contain no promotional material.

Since 1993, pharmaceutical manufacturers have been providing Consumer Medicine Information (CMI) to help consumers better understand the medicines they take.

Including all the necessary information can make a CMI quite long. But all of it is important. In a well-written CMI, consumers should be able to follow the headings and subheadings to easily find out what they need and act on it.

Guidelines on writing CMI were first developed in 1995 to assist manufacturers when writing their own CMIs. These guidelines were revised in 1997, and now a 3rd edition has been released.

Writing about medicines for people: Usability Guidelines for Consumer Medicine Information, 3rd edition was revised taking into account comments received from stakeholders and the CMI Content/Quality Assurance Reference Group (QARG).

This 3rd edition of the Usability Guidelines is only available in e-format. Key changes include:

- A standard requirement to include a phonetic pronunciation guide for both the brand name and the active ingredient. This was considered a Quality Use of Medicines issue due to the increasing number of similar sounding names.
- Improved explanation on the need for and use of navigation tools for CMI, e.g. headings, fonts, etc.
- Addition of examples of instructions and explanations that may be used in CMIs.
- Clearer guidance on the need for diagnostic testing to ensure quality control of medicine information, including when to test and what must be tested.
- Information on the process for developing core CMIs.

The Usability Guidelines also explain:

- Why CMIs shouldn't be used as a stand-alone document, but as part of a dialogue between a healthcare professional and a consumer;
- CMIs must not be promotional, therefore cannot highlight benefits or include comparative statements;
- Side effects are organised according to the action required by a consumer, rather than being arranged according to frequency of occurrence; and
- Why critical information is repeated in different sections in the CMI.

During the review of the Usability Guidelines, one of the main issues considered was the possible inclusion of 'counselling points' in CMIs. Following consideration of feedback from stakeholders and discussion within the Reference Group, it was decided not to proceed with this proposal for the following reasons:

- Counselling points are needed for health professionals, not consumers;
- Counselling points are not in the Product Information and their inclusion in CMI's was beyond the legal requirement for CMI's;
- In addition, it is important to determine what information is significant for each consumer, and this needed to be done on a case-by-case basis;
- Publications, such as the Australian Medicines Handbook, Australian Pharmaceutical Formulary and AusDI, contain practice or counselling points.

Every Australian pharmaceutical company has been sent a copy of the 3rd edition of the Usability Guidelines in order to encourage its use when writing or updating CMI's. The Usability Guidelines may also be purchased through Amazon.

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