'Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)'

Consultation response

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Please note: The following response will focus primarily on the questions posed for consideration about Consumer Medicine Information (CMI). Written medicine information is a focal area of research within our international research group.
Comments on questions for consideration

(i) What is the purpose and function of CMI?

The Baume report recommendations (50 and 51) resulted in the evolution of Consumer Medicine Information (CMI) and whilst reluctant to make detailed recommendations on the specific nature of CMI, he did believe that “consumers should be well-informed as is possible about the drugs they are taking” (1).

Shenfield and Tasker (1997) further differentiated CMI’s purpose from other written drug information documents by stating it should be “intended to be given to patients by health professionals and is designed to reinforce educational messages given by doctors, pharmacists and other health professionals” (2).

The purpose and function of written medicine information, such as CMI, is to:

- provide consumers with information about their medicines in order to take them safely and effectively (3)
- provide information that can be read at the consumers own pace and referred to when necessary (4, 5)
- encourage consumer autonomy and empowerment by providing up-to-date, evidence-based and accurate medicine information (6-8)
- act as a tool to improve health literacy (9, 10)
- reinforce spoken information provided by health care professionals (11)

(ii) Is the purpose and function of the PI and CMI well understood by prescribers and consumers?

The purpose and function of CMI may not be well understood by consumers and healthcare professionals. There are no published studies directly evaluating healthcare professionals’ and consumers’ understanding of the purpose and function of CMI as defined in (i) above.

Awareness of CMI has increased to approximately two-thirds of consumers since its implementation in the 1990's (12). Approximately 69% of consumers have reported receiving a CMI in the past 6 months (a decrease from 82% in 2005)(13, 14).
(iii) Is the current format for presenting information in PI and CMI relevant and useful to the end-user?

It is evident from Australian research that the current format of CMI is not meeting the needs of the consumer nor of the healthcare professional (10, 15).

The Investigating Consumer Medicine Information (I-CMI) project (12), funded by the Department of Health and Ageing, through the Pharmacy Guild of Australia (under the Fourth Community Pharmacy Agreement), demonstrated the effectiveness of using proven principles of information design, 'plain English' content and improved visual organisation, readability and comprehensibility in the development of alternative CMI. The alternative CMI formats developed:

- better met consumer written medicine information needs
- performed better in comparison to existing CMI when user tested with consumers
- were more likely to be provided by pharmacists to consumers
- consumers were more likely to utilise and retain in comparison to existing CMI

Several issues have been identified that impact the relevance and usefulness of the CMI document itself; whilst other issues pertain to perceptions/attitudes towards CMI (12, 13):

a) Issues relating to relevance and usefulness of CMI:

- perceived legalistic nature of the document
- use of medical jargon may compromise understanding of CMI (16)
- issues with navigation and comprehensibility
- the CMI documents are lengthy and cumbersome (4-7 pages)
- lack of CMI in languages other than English
- not patient-centred
- risk-oriented with a lack of evidence of benefit

b) Attitudinal factors:

- healthcare professionals’ belief that consumers do not want CMI
- perceived lack of value and usefulness as a tool to improve communication and consumer education
- healthcare professionals are ambivalent about providing CMI as it may affect adherence to medications or healthcare professional -patient relationship
- lower prioritisation given to CMI provision by healthcare professionals due to a lack of time in consultations
Addressing these complex factors along with the actual CMI documents is essential to facilitating improvements to the use of CMI.

In doing so, regulators and producers of CMI should consider:

- healthcare professional consultations and patient involvement when writing and updating CMI, through end-user testing processes
- the inclusion of appropriate benefit information to balance risk-oriented content
- a summary version of CMI whilst maintaining a comprehensive CMI when more information is desired
- CMI as a consumer orientated document
- funding for an independent body to oversee evaluation and quality of CMI produced by sponsors
- use of proven principles of information design, ‘plain English’ content and improved visual organisation, readability and comprehensibility when developing CMI.

In addition, professional bodies representing healthcare professionals may need to:

- provide regular education sessions on the usefulness and value of CMI for consumers, encouraging use of CMI as a tool to improve patient health literacy
- regularly remind healthcare professionals of their professional obligations and duty of care in providing CMI to ensure quality use of medicines
- be more actively involved in the further development of CMI

(iv) Consider requiring CMI to be available to the public for all registered medicines?

CMI should be made available for all registered medicines in Australia.

At present, of the registered medicines available over-the-counter (OTC), CMI is only legally required for Pharmacist Only medicines (Schedule 3). Therefore, the availability of CMI for other OTC medicines is inconsistent, which may compromise safe and effective consumer medicine use.

Within the European Union, all medicines regardless of scheduling status, must have written medicine information produced and provided to consumers in the form of a package insert (17).

The need to have written medicine information available for OTC medicines is supported by the following:
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(i) increasing patient self medication (18);
(ii) variable verbal medicine information provision between different OTC medicines by pharmacists (19)
(iii) increased availability of medicines for purchase in non-pharmacy retailers;
(iv) potential inappropriate use of medicines due to lack of opportunity to consult a healthcare professional at the point of purchase in non-pharmacy retailers such as supermarkets;
(v) current OTC product label size constraints (which impact the amount of information that can be included);
(vi) consumers who take other medicines (prescription and non-prescription) and/or have a history of adverse events from a medicine are more likely to use written medicine information leaflets, indicating a need for evidence-based and reliable information (20)
References


