Consumer medicine information

From a consumer perspective, the saying 'we don't know what we don’t know' is particularly apt when it comes to information about medicines. Consumers may be prescribed medicines about which they know little or nothing. These medicines can have significant health repercussions that the patient would not necessarily know to ask about. Consumer Medicines Information (CMI) is intended to inform patients, but it is just one component of effective medical care. In 2016 a media controversy over an asthma medicine which has been associated infrequently with adverse effects in children highlighted the responsibility that doctors and pharmacists share to ensure patients are properly informed.¹

Doctors and pharmacists are responsible for advising patients about the benefits and risks of their medicines particularly when a new medicine is prescribed. However, despite that expectation and the availability of CMI on the internet and sometimes in leaflets, it is not unusual for consumers to be dispensed a medicine without the advice they need to ensure its safe and effective use. Patients with several conditions who are taking multiple medicines will have a greater need for detailed information. The CMI produced by pharmaceutical companies in paper form or online is by and large comprehensive and understandable. However, CMI can tend to emphasise potential harms rather than benefits and it does not include information about off-label indications. There may also be limited information about interactions with other medicines, including complementary medicines.

There are at least four Australian websites which give links to CMI.²⁻⁵ CMI leaflets were inserted into medicine packs, but many companies have since stopped this practice, because of concerns about keeping leaflets up to date and difficulties fitting a legible leaflet inside a medicine pack. However this can have negative consequences when neither the doctor nor the pharmacist provides adequate information and the consumer does not know about, nor knows how to access, the internet-based CMI that has superseded paper-based information. The late Sally Crossing AM, Convenor of Cancer Voices Australia, who initiated the campaign for a return to CMI leaflets, said: ‘We should not have to know to ask for CMIs, especially when sick, ... or be expected to muddle through the internet, when another fail-safe solution is available.’⁶

Payment for provision of CMI by pharmacists was specified as part of the dispensing fee in the Fourth Community Pharmacy Agreement of 2005. More recent pharmacy agreements do not mention CMI. Provision of CMI in written or verbal form is recommended practice for pharmacists although no longer specifically included in the dispensing fee. The CMI guide on the Australian Government Health Department’s website was published in 2000. While it describes what CMI is meant to do, the guide does not specify who should be directly responsible for telling consumers about CMI, or providing access to it.

The Therapeutic Goods Administration states: ⁴

CMI documents may not be available for every product. Sponsors are required to provide CMIs prior to new prescription medicines and specified over-the-counter (OTC) medicines being released to the market. Products that have been registered but not yet released to the market will not have accompanying CMI documents.

For medicines that do have CMIs, TGA regulations require that the CMI be made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.

The issue of access to CMI has prompted a campaign to return CMI leaflets to medicine packaging. The national CMI guide promulgated under the Quality Use of Medicines strategy in 2000 was meant to ensure medicine information was ‘designed to inform consumers about prescription and pharmacist-only medicines’ in a reader-friendly and standardised way.⁷ Seventeen years on, we have an unsafe and less effective situation where CMI leaflets are no longer inserted in packages, and patients are not getting the information they need.

Despite the existence of CMI, uncertainty remains about who should be ensuring it gets to the patient. While discussion with the prescribing doctor usually takes place, it is not easy for a patient to recall all the details needed for safe and effective use of a medicine. Doctors and pharmacists can help consumers by talking about CMI, especially if a medicine is being used for an off-label indication. An Australian study concluded that doctors and pharmacists are still a preferred source of CMI, despite its increasing availability on the internet.⁶

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Adequate health literacy, often dependent on simple advice from a GP or pharmacist, not only benefits the individual’s health but also reduces the risks to the system of waste and costly medication misadventure. Medicines Australia hosted a stakeholder’s meeting on 3 August 2016 to discuss CMI and options to address these major problems. Participants at that meeting agreed to do more work on both the format and content of CMI and the process by which people can access CMI and other information on medicines.

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REFERENCES