

Consumer Medicines Information

An International Perspective

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Consumer medicines information is increasingly relied upon to inform and empower consumers regarding their medicines. Legislation and guidelines are now in operation in the US, European Union (EU) countries and Australasia. The lack of an evidence base has led to a variety of approaches to written information provision across the three continents and each has apparent advantages and disadvantages. This review compares consumer medicines information in the three continents and examines the strengths and weaknesses of each system. It also includes an outline of research conducted by Professor Raynor's team on the impact of the EU legislation. This will be of particular interest in Malta, in view of the imminent membership of the EU.

Introduction

Medicines information leaflets are the bedrock of methods used to inform people about their medicines.¹ Previously the focus was on assisting people to take or use their medicines correctly. The focus is now much wider, as it becomes accepted that people need to become more involved in decisions about the medicines that they take. Such patient empowerment is at the heart of a number of policy moves in the countries of the developed world e.g. in the UK.² The notion is that people not only have a right to full information about their medicines (to allow them to make informed decisions about how and when they take them), but that adherence with medication will be enhanced if people take part in such decisions about their care and treatments.³

There is a relatively small evidence base to inform how written medicines information should be written, designed and delivered.⁴ This is unfortunate, and has meant that recent legislation, guidelines or targets in:

- Europe,
 - US
 - Australia & New Zealand
- have had relatively limited underpinning evidence.

The lack of investment in research into consumer medicines information is in stark contrast to the amount of money spent on the discovery, development and testing of the drugs themselves. Paradoxically, the large amount spent on such developmental work is largely wasted if patients do not take their medicines as intended, as a result of the inadequacy of the information supplied.

The term Consumer Medicines Information (CMI) to describe the patient leaflet supplied with medicines was first coined in New Zealand and then adopted by Australia. This review begins with the story of CMI "down under", followed by the US and the Europe.

Australasia

In Australia, the Therapeutic Goods Act requires that CMI is available with all new medicines.⁵ It is written by the manufacturer, and the content needs to be consistent with the Product Information (PI) and understandable to the patient. However, there is no strict requirement that every piece of information in the PI must be on the leaflet. Despite this, some laser-printed leaflets run to four or five pages. All existing medicines are required to have such a leaflet available by 2003. The legislation requires that CMI is available for all prescription medications, but there is no legal requirement to provide a CMI with every supply. Australia adopted a collaborative approach to the development of CMI, with a Steering Committee, a Quality Assurance Reference Group (QUARG) and consistency working groups, which developed core CMI's for the major drug groups. The Australian legislation makes an explicit requirement that the written information should be complemented with verbal information.⁶

Evidence-based guidelines on writing leaflets were produced by the Communications Research Institute of Australia⁷ and the favoured method of delivery is computer generation in the pharmacy (although package inserts meet the legislative requirements and are still widely used). Computer-generation is the preferred option because it enables the leaflets to be kept up-to-date. There have been a number of problems in Australia relating to computer generation in the pharmacy, due to the cost of buying the printers and supplying the paper. However, community pharmacists have been receiving remuneration for the delivery of CMI from the end of 2002.

New Zealand is working closely with Australia on CMI. The leaflets are not mandatory in New Zealand and there is a system of self-assessment by manufacturers that they need government guidelines. Again, the computer-generated option is preferred. The content of New Zealand leaflets are available on www.medsafe.govt.nz/CMIPage.htm.⁸

United States

In the United States in the mid 1970's there was consumer and professional pressure for legislation which would require package insert leaflets for patients. The commercial sector and some doctors objected and, as a result, a voluntary system was introduced.⁹ These voluntary initiatives involved leaflets written and produced by third parties, such as:

- United States Pharmacopeia,
- American Medical Association
- American Society of Health System Pharmacists.

These are single page leaflets, with generally more brief information than contained in the European and Australian leaflets. The method of delivery most commonly used is through computer generation in the pharmacy.¹⁰

The US Government has set targets for the supply of "useful written information" to patients when they get their first supply of medicine. This was enshrined in Public Law 104-180 (1996), with a first target of 75% by 2000 being achieved. The next target is 95% of patients by 2006.¹¹ In the US the Food and Drugs Administration states that written information is at the core of its efforts to inform patients. The same law defines "useful written information" as being

- scientifically accurate,
- non-promotional,
- specific and comprehensive and
- understandable and legible

As a result of the legislation, a steering committee was convened in 1996, to facilitate the development of an "action plan" for evaluating and improving the usefulness of written information. The action plan identified the types of information to be included, to meet the criteria for being specific and comprehensive. It also provided general guidelines for evaluating the accuracy, legibility and comprehensibility of written information.¹¹ An eight-state study in 1999 subsequently evaluated the written information provided by community pharmacies. This found that 87% of new prescriptions had some

written information provided (other than the labels or stickers). Most were accurate and unbiased and met a threshold set for information quality. However, certain categories of information fell below the threshold and as a result the authors concluded that the quality was variable and there were many areas for improvement.¹² In 2001 a further study of written information provided in community pharmacies was undertaken.¹³ A paper by the same authors used an instrument based on these criteria to assess US leaflets by consumer evaluation of a small subset of leaflets.¹⁴

One exception to the voluntary code in the United States is covered by recent legislation for medicines which the FDA considers "pose serious and public health concerns".¹⁵ These medication guides (or Medguides) have to be produced by the manufacturer and supplied with every prescription. They can be supplied as hard copy or computer generated and the order and headings of the leaflet are prescribed.

European Union

In the European Union legislation was introduced in the 1990's requiring a comprehensive medicines information leaflet for patients, to be supplied inside the pack of every medicine (EC Directive 92/27).¹⁶ This legislation came into effect on January 1st 1999 across all member states. Subsequently, a Guideline on the readability of the leaflets was published.¹⁷ The leaflets defined by this legislation have to be written and supplied by the manufacturer, according to the detail of the legislation. A key point is that all information in the Summary of Product Characteristics (the PI in the United States) needs to be provided, but in a form comprehensible to the patient. This means that all warnings, precautions and contra-indications have to be included.

Before the EU legislation, package insert leaflets were available in certain European countries, notably in the Netherlands, France and Germany. The content and distribution method of these leaflets varied.¹⁸ In the United Kingdom, before the mid-1980's, few

leaflets were supplied with medicines. Then the pharmaceutical industry sponsored guidelines, based on a two-sided A5 leaflet, which contained brief information on one side and more detailed information on the other. These were based on research carried out by Professor Charles George and colleagues in Southampton.¹⁹ However, in the early 90's this country-based initiative was stalled by the publication of European Union legislation. Current UK leaflets can be viewed on www.emc.vhn.net.²⁰

What are the implications of the EU legislation?

The combination of the large amount of information to be included in the leaflets, and the delivery method as a package insert, results in a small, thin and folded leaflet that contains a large amount of information in small type. Research in the UK showed that this method of provision means that the leaflet is perceived by patients to be unimportant,²¹ as the leaflets fall out of a pack like they do with many other goods. It is also difficult to incorporate the leaflets into the wider information giving process.²² When we telephoned people seven days after obtaining a medicine, 83% said they had noticed the leaflet and 74% had kept it. However, only 40% said they had read some and 21% all the leaflet.²¹

In another study based on focus groups of people with asthma, we asked participants to talk about their experiences and views of medicines information. Key points included:

- appearance of the leaflet: "Too small, folded and in the box"
- Order of information: "Things we want to know don't come first"
- Some mistrust of manufacturer's leaflet, thought to be written to protect the manufacturer: "Priorities are those who wrote it, not patients"
- Leaflets can only give general information: "You throw them away don't you", "They don't inspire you", "Never been one for reading the leaflet all the way through"

- Just giving information is not enough: "We need to know 'why'"
- Personal experience was thought to be more important than drug company tests "The people using medicine are best people to know", "People who suffer should help write leaflets"

The EU Readability Guideline 16, issued in 1999 to complement the Directive, included sections on:

- Plain Language
- Good design
- Describing risk
- Testing the leaflets

Guidance on good design and the use of plain language for leaflets in English are on the website www.pecmi.org.²³ PECMI is 'Promoting Excellence in Consumer Medicines Information' a UK group of people with an interest in improving information for consumers around the supply of medicines in the UK, both prescription and self-medication.

In terms of describing risk, the Guideline suggests terms to describe risk as follows:

Very common	10%
Common	1-10%
Uncommon	0.1-1%
Rare	0.01-0.1%
Very rare	0.001%- 0.01%

However, our research in more than 1,000 members of public showed that use of these terms led to gross overestimation of the risk. For example, "Very common" is generally interpreted as being over 50% and "Common" more than 30%.^{24,25} More research is needed to determine the best way of expressing the risk of side effects to patients.

An important part of the Guideline is the recommendation for adopting "User Testing" (also known as Consumer or Diagnostic testing to ensure the effectiveness of the leaflets. This process assesses if information in leaflet can be:

- found, and
- understood

Such performance-based testing is different from content testing; it is based on how the leaflet performs, not what it contains.

Typically, 20 consumers in a target group are questioned on 15 key points from the leaflet:

- Can they find information in the leaflet?
- Can they describe it in their own words?

The aim is for 16 out of 20 consumers to be able to do this. We carried out some pilot 'User Testing' on 3 leaflets, which confirmed that 16/20 is a very hard target to meet.²⁶

What is the way forward?

It is inconceivable that multiply-folded small print package insert leaflets, with all their disadvantages, will continue to be the mainstay of written consumer medicines information provision in the 21st century. Information technologies will allow computer-generated leaflets to become the norm (as described above, they are already the favoured method in the US and Australia). Computer-generated leaflets can be:

- Generated at point of supply
- Handed to patient and used as aide memoire by the pharmacist
- Given only at first supply
- Updated as required
- Personalisation: include patient's name

In the future, individualisation of the information according to the patient's age, sex, sight loss, level of detail, language etc will become possible. The opportunities for web-based information extend the options still further. However, in the short to medium term, leaflets with medicines will continue to be the mainstay of information provided, and further research is needed to maximise the benefits for patients.

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