COMMENT

Patient information and medication labelling: an area of concern

SUJITH J CHANDY*, BINU S MATHEW**

***Associate Professor, Clinical Pharmacology, Christian Medical College, Vellore 632 004 INDIA email: sjchandy@cmcvellore.ac.in **Lecturer, Clinical Pharmacology, Christian Medical College, Vellore 632 004 INDIA**

Abstract

In this era of consumer awareness, the field of health care is still an area of concern. This is especially so when it comes to the quality and extent of information given by the pharmaceutical industry to both health professionals and patients. This article highlights certain ethical considerations in the current practice of communicating medication information, in order to sensitise readers to issues of drug labelling, and to promote the need for better patient information about drugs. Medication labelling is the most common method of patient information. Issues such as what constitutes an ideal label, whether all ingredients need to be mentioned and whether too much information is detrimental will be discussed. Special considerations for a country like India, where literacy levels are poor and multiple systems of medicine exist, will also be addressed.

The common person in India who purchases medication at the chemist is often unaware about the rules and regulations that need to be followed by the pharmaceutical industry in the process of bringing the drug from the scientist's bench to the consumer. The consumer is also inadequately informed about the contents of the medication. These issues were recently highlighted when Baba Ramdev, who is popular among many people as an exponent of yoga and ayurveda, was accused of using the remains of human and animal tissues in medications without proper information on the labels (1). In this article, we would like to highlight the ethical responsibilities of the pharmaceutical industry and the medical community in revealing the ingredients on the label.

Ideal drug labels, internationally and in India

The label of any drug should include, at least, the name of the drug, its contents expressed in the metric system, the contents of the active ingredients, the name, address and license number of the manufacturer, the batch number, and the dates of date of manufacture and expiry (2).

The label on the packaging of a drug is different from the insert in the package. The insert, which must be approved by the Food and Drug Administration (FDA), is the means by which the government regulates communication between the manufacturer and health care providers. It is an exhaustive document that is not intended for patients; however, it is not illegal to give the package insert to patients.

In 2002, the United States Food and Drug Administration (US FDA) enforced revised standardised labelling by introducing improved print and graphics for over 100,000 over-the-counter drug products (3). According to these new guidelines, the drug facts panel should have the name of the drug, its active ingredient(s), purpose(s), use(s), warning(s), directions, other information, inactive ingredients and questions (4). Drugs that fail to follow these labelling requirements will be termed as misbranded, but the US FDA gave 2006 as the deadline for the enforcement of this regulation (4). Countries such as Australia do not make it mandatory to reveal the inactive ingredients (5).

The safety of over the counter drugs is often overestimated. The drug is available to any person approaching a chemist without a prescription. The easy availability of such medication highlights the need for informative and consumer-friendly labels to ensure safe and effective use of the medication by the consumer.

The World Health Organisation (WHO) has reported that 80 per cent of the population in developing countries, particularly in India, is dependent on plant-based traditional medicines for basic health needs (6). The Drugs and Cosmetics Rules was introduced in India as early as 1945. It laid down regulations for the labelling of both modern and traditional medicines.

The contents of the active ingredients had to be spelt out. For instance, for liquid preparations, the oral form was expressed in terms of the contents per single dose or the dose being indicated in 5 ml and parenteral in terms of 1 ml or percentage by volume. Part IX of the Drugs and Cosmetics Rules directs all manufactures of ayurvedic, siddha and unani drugs to display on their labels the true ingredients (official and botanical names) used in manufacture, together with the quantity of each (2). This article focuses more on traditional medicine because of specific practices and various issues in labelling such medicine in India. To be fair though, one must also mention that the labelling of allopathic medicines is also far from perfect.

Ethical issues in labelling and pharmacy practices

Do we need to label all the ingredients of a drug or only the main ingredient? Does the patient have the right to know the other ingredients if the main ingredient is prominently displayed as the name of the drug? Both patients and health care providers must discuss these issues.

Any medication has inactive ingredients that are not consistently inert, as was previously believed, in their biological activity. These ingredients should not therefore be listed as 'inert'. A more

useful and concise term would be 'excipient'. One study reported that pharmacists did substitute formulations irrespective of the excipients in the different formulations, provided the active ingredients were the same (7). In addition manufacturers are not bound to disclose the contents of their formulation.

Examples of known excipient-induced toxicities include renal failure and death from diethylene glycol, osmotic diarrhoea caused by ingested mannitol, hypersensitivity reactions from lanolin, and cardiotoxicity induced by propylene glycol (8). The US FDA insists on inactive ingredients on the label to enable patients to avoid any iatrogenic drug reaction

Many clinics in India put pills or tablets into covers and dispense them without any label. This is a widely prevalent practice. Most patients do not question the doctor or the prescription. If they do ask about the label, the response is that it is best kept undisclosed for the benefit of both the patient and the doctor.

Labelling of ayurvedic preparations

A consumer of any drug could be exposed to risks in the process of consuming the product. A survey conducted by the Harvard medical school in the US revealed that at least 20 per cent of the ayurvedic products contained heavy metals above permissible limits. This was not mentioned on the labels (9).

Ayurvedic drug manufacturers argued that heavy metals such as lead and mercury are therapeutic when present as ingredients in ayurvedic medicine (9). They said that raw plant products could also be contaminated by faulty agricultural and collection practices, which makes it impossible to obtain fully metal-free ayurvedic products.

In response, in October 2005, the ministry of health in India made it mandatory for ayurvedic drug manufacturers to comply with labelling regulations by revealing metal toxicity levels and the amount of each ingredient in products made for export (10). The debate continues because the local consumer still does not have the benefit of a similar label on the ayurvedic drugs sold in the Indian market. This could be a case of discriminating against Indians in the name of promoting traditional medicine.

Rule 161 of the Drugs and Cosmetics Rules contains an exhaustive list for labelling. This includes all the ingredients and their quantity used in manufacture. However, most manufacturers of traditional drugs get away by only quoting the name of the recipe used in the ancient texts (11).

The misconception that excipients are harmless and not worthy of mention is common among drug manufacturers. With an increasing incidence of adverse drug reactions to excipients, there is a greater need for the manufacturers in India to mention every constituent despite its supposedly inert role in the formulation (7). Patients with known hypersensitivity to certain excipients will benefit from this prior information.

Pharmacological combinations and labelling

An average Indian walking into a health facility, determined to avoid any form of allopathic medicine, may have no idea that she or he has been prescribed steroids along with the ayurvedic product. A study conducted between 2000 and 2002 by the National Pharmacovigilance Centre of the All India Institute of Medical Sciences, screened 120 samples of alternative medicines and showed that 38.32 per cent were adulterated with steroids (12).

Such quick fix remedies bring with them the possibility of adverse drug reactions to ingredients that have not been mentioned on the label. The problem is compounded if the patient goes to another hospital and both the patient and the doctor are totally unaware of some of the ingredients in the medication already being consumed.

The right to information

Part IX of the Drugs and Cosmetics Rules 1945 directs all authorities to ensure that manufacturers of ayurvedic, siddha and unani drugs display the true ingredients (official and botanical names) used in manufacture together with the quantity of each (2). It has been argued that this may not benefit people who cannot read.

Opinions differ on whether the consumer should be loaded with all the information that is considered mandatory. Excessive warning could have as negative an effect on safety and public health as inadequate warnings. Giving too much information could make individuals overly cautious and anxious and create a general phobia about medicines and the risks they involve. Any medicine, even paracetamol, has certain adverse drug reactions and toxicities (13). Adverse effects need not always be experienced. Information therefore must be accompanied by greater awareness.

What could be optimum labelling?

Hipppocrates (462-355 BC) famously said, "First do no harm". This binds every medical and pharmaceutical worker to the non-maleficent principle of medical ethics.

How much then should manufacturers put on the label? Our suggestion would be to include every ingredient on the label, whether active or inactive. Information about the presence of heavy metals, animal remnants, human remnants or other toxic substances in the product, should be mandatory. It is not fair to make this information available only to people who can read. The medical and pharmaceutical community have a heightened responsibility to educate the consumer who cannot read about the nature of the drug being consumed. This can be done through the media, interactive community meetings and other forums.

Our law has been unable to strictly enforce labelling regulations. Authorities must be more vigilant to ensure that the pharmaceutical and medical communities do not compromise their responsibilities towards the common person. Manufacturers should be asked to standardise labelling within a time frame, after which they could face a penalty or the charge of misbranding. Such measures also require more accredited laboratories in India with both equipment and expertise to analyse drugs for their ingredients. In this era of communication, it is time the same standards are applied to all medication used by Indians.

References

1. Subramanian Nithya. For safe ayurvedic drugs, laws need to be strengthened. *The Hindu* 2006 Jan 6. [cited 2006 Mar 20]. Available from: http://www.thehindubusinessline.com/2006/01/06/stories/2006010600830800.htm
2. Drugs and Cosmetics Rules, 1945 (amended till 30th June 2005). Part IX. Labelling and packing of drugs other than homeopathic medicines. Rule 94 – 106 [cited 2006 Mar 20]. Available from: http://www.cdsco.nic.in/html/Drugs&CosmeticAct.pdf. p115-129
3. US Food and Drug Administration. New OTC drug facts label. *FDA Consumer Magazine*, 2002 Jul-Aug. [cited 2006 Mar 20]. Available from: http://0-www.fda.gov.lilac.une.edu/fdac/features/2002/402_otc.html
4. CCL Industries Inc. FDA drug facts: impact and options. [cited 2006 Mar 20]. Available from: http://www.cc;omd/cp,/label_market_drug_facts.html
5. Commonwealth of Australia. Therapeutic Goods Act 1989 [cited 2006 Mar 20]. Available from: http://www.tga.gov.au
6. The Research Council for Complementary Medicine [homepage on the Internet]. Bodeker Gerard C. Traditional health systems and national policy [updated 2003 Nov; cited 2006 Mar 20]. Available from: http://www.rccm.org.uk/static/Article_Gerry_Bodekar.aspx
7. Napke E, Stevens DG. Excipients and additives: hidden hazards in drug products and in product substitution. *Can Med Assoc J* 1984; 131: 1449-52.
8. Osterberg RE, See NA,Toxicity of excipients: a Food and Drug Administration perspective. *Int J Toxicol*2003; 22: 377-80
9. Saper RB, Kales SN, Paquin J, Burns MJ, Eisenberg DM, Davis RB et al. Heavy metal content of ayurvedic herbal medicine products. *JAMA* 2004; 292: 2868-2873.
10. Ramachandran R. For better regulation. *Frontline* 2006 Jan [cited 2006 Mar 20]; 23(2): Available from: http://www.flonnet.com/fl2302/stories/20060210002004500.htm
11. Consumer Online Foundation. Modern safeguard for traditional medicine. Traditional drugs and labelling standards [cited 2006 Mar 20]. Available from: http://www.consumeronline.org/guest/focus/linkdetails.asp?ID=ayurvedic_focus3
12. Gupta S K, Kaleekal T, Joshi S. Misuse of corticosteroids in some of the drugs dispensed as preparations from alternative systems of medicine in India. *Pharmacoepidemiol Drug Saft* 2000; 9: 599-602.
13. Insel PA. Analgesics, antipyretics and anti-inflammatory drugs. In:Goodman and Gilman, editors. The pharmacological basis of therapeutics. 9th ed. New York: McGraw-Hill; 1996. p631-633.