

***Review of the
Australian Consumer Product Safety System***

***Submission by the
Pharmaceutical Society of Australia***

November 2004



*PO Box 21
CURTIN ACT 2605
Tel: 02 6283 4777
Fax: 02 6285 2869
www.psa.org.au
ABN: 49 008 532 072
Chief Executive Officer: Kerry Deans*

The Pharmaceutical Society of Australia (PSA) is the national professional organisation representing 16,000 pharmacists in all areas of professional practice. The PSA is the leading advocacy organisation for pharmacists, influencing attitudes, opinions and policies through representation, networking, consultation, continuing education, practice support, standards, guidelines and a range of publications and health promotion programs and resources.

Provision of information in relation to drug recalls

The discussion paper explains that an area of improvement required in Australia's consumer product safety regulatory system is for it "to be able to deal with potential safety hazards more swiftly, with a greater emphasis on the prevention of problems" (p. 5). Product recalls are currently one type of mechanism used to deal with potential or actual safety hazards and this issue is referred to in Appendix A (pp. 53–5).

PSA acknowledges the vital role played by the Therapeutic Goods Administration (TGA) in relation to drug recalls which are issued from time to time. However, a problem routinely encountered by pharmacists when recalls are initiated is that the dissemination of information is fragmented and uncoordinated and often reaches the media before pharmacists, doctors and other health professionals. This creates confusion and 'panic' in the minds of consumers and frustration for pharmacists who may not have all of the relevant information necessary to provide professional advice to consumers regarding what the immediate implications are to their health, appropriate follow-up actions (eg. whether they should immediately seek medical advice) and/or what alternatives are available, as well as other administrative tasks such as handling refunds and storage of the recalled products.

PSA advocates for an improved process to be established between pharmaceutical companies and the TGA to ensure that the circumstances of the recall and other appropriate clinical information can be disseminated simultaneously to pharmacists, doctors and consumers/media. Further, we believe it is unacceptable for pharmacists to carry the commercial burden by being left 'out-of-pocket' for extended periods of time and suggest sponsors must take appropriate action swiftly to prevent this from occurring.

'Unsafe goods'

The discussion paper touches on the need to revise the definition of 'unsafe goods' (pp. 35–6). PSA understands that currently, action (under trade practices provisions) can be taken where goods 'will or may cause injury'. Thus goods can be banned or recalled if defective but not if they are "unsafe as a result of foreseeable misuse".

Under the *Therapeutic Goods Act 1989*, 'therapeutic goods' are generally considered to be goods presented for therapeutic use which means use in "preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals". Therefore these goods have the general property of "influencing, inhibiting or modifying a physiological process in persons or animals". Prescription and non-prescription medicines represent a major proportion of all therapeutic goods registered for marketing and use in Australia.

All medicines possess a range of chemical and biological characteristics but their use or effectiveness in humans (and animals) is restricted to a standard dosage range based on the safety profile of the particular substance as well as other individual (human) factors (eg. age, health status).

Some legitimate and licit medicines are subject to or have a high potential for deliberate misuse, either by ingestion of a higher (than standard) dose or through use/administration by an unintended and/or unsafe route. In the absence of any intervention, continued misuse of a particular product is foreseeable based on observation of local trends of misuse, overseas experience and data, and knowledge of the physiological consequences being sought by misusers.

While such medicines are likely to continue to provide benefits for people with genuine therapeutic need, sustained or increasing levels of misuse can impact on public health and safety in the longer term. Unfortunately, at present such medicines cannot be recalled or removed from the market since they are not defective based on their inherent safety profile although we would certainly consider them to be “unsafe as a result of foreseeable misuse”.¹

PSA would therefore wish to ensure that the definition of ‘unsafe goods’ is appropriate for all goods including therapeutic goods.

International agreements

The discussion paper mentions Australia’s obligations under multilateral or bilateral agreements which can impact on the regulation of consumer product safety (pp. 59–60).

PSA is a strong advocate of Australia’s National Medicines Policy,² particularly the Quality Use of Medicines (QUM) arm. Briefly, the definition of QUM involves:

- Judicious selection of management options – ie. consideration of the place of medicines in treating illness and maintaining health, recognising that for the management of many disorders non-drug therapies may be the best option;
- Appropriate choice of medicines, where a medicine is considered necessary – ie. when medicines are required, selecting the best option from the range available taking into account the individual, the clinical condition, risks, benefits, dosage, length of treatment, co-morbidities, other therapies and monitoring considerations. Appropriate selection also requires a consideration of costs, both human and

¹ Temazepam gel capsules are one example where the product had met all the safety, quality and efficacy criteria (and approved for the short-term management of insomnia) but there was a rising incidence of misuse by injection of the viscous contents of the gel capsules and consequential harm (eg. vascular and tissue injury, necrotic ulcers, ischaemia; some damage being severe enough to require amputation of digits or limbs).

Despite significant concerns expressed by PSA and many other groups (including, for example, the Australian Pharmaceutical Advisory Council Sub-committee on the Intentional Misuse of Pharmaceuticals, the Commonwealth Department of Health and Ageing and the Victorian Department of Human Services), TGA did not have the power to deregister the product from the Australian market. In this instance, the relevant pharmaceutical companies eventually withdrew their products from the market in recognition of QUM principles.

² The National Medicines Policy aims to “meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians” and includes four central objectives, viz.:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry.

For more information, see www.health.gov.au.

economic. These costs should be considered both for the individual, the community and the health system as a whole; and

- Safe and effective use – ie. ensuring best possible outcomes of therapy by monitoring outcomes, minimising misuse, overuse and underuse, as well as improving the ability of all individuals to take appropriate actions to solve medication-related problems eg. adverse effects and managing multiple medications.

The QUM policy is unique to Australia and is a core principle underpinning the professional practice of pharmacists with benefits intended for and flowing to Australian consumers.

Where the regulation and operation of a consumer product safety scheme, particularly one where medicinal products are involved, is likely to be affected by international agreements, PSA believes that such arrangements must not compromise Australia's principles, specifically the QUM policy.

In summary, PSA is committed to seeing the pharmacy sector meet its obligations under a new consumer product safety system for Australia. We would be pleased to assist in the development of relevant information and its dissemination to pharmacists to ensure they fulfil their expected role under any such system for the benefit of Australian consumers.