

RMI SUBMISSION ON THE DRAFT ORDER: PACKAGING REQUIREMENTS FOR SPECIFIED THERAPEUTIC PRODUCTS

PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the national body representing New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

4. INTERPRETATION

The draft defines "immediate packaging" and "outer packaging" as having "...the same meaning as in the Administration and Interpretation Rule". However, the draft Rule released for consultation in 2006 does not include either term in Schedule 1 Part 1 (Definitions), but does refer to "primary pack" and "container".

5. APPLICATION AND 6. EXEMPTIONS

The RMI notes that the Draft Order is in line with the current New Zealand Medicines Regulations 1984 with respect to which prescription medicines are subject to the packaging requirements of this order and to which are exempt.

8. POISONS PACKAGING REQUIREMENTS FOR THERAPEUTIC PRODUCTS CONTAINING SCHEDULED SUBSTANCES

The immediate packaging of a therapeutic product, to which this clause applies, must comply with Australian Standard AS 2216 – 1997, *Packaging for Poisonous Substances*.

The RMI notes that there is no New Zealand (or joint New Zealand Australia) Standard for packaging for poisonous substances and that the current Medicines Regulations do not include performance standards for poisons bottle. The current New Zealand requirements are limited to visual and tactile identification.

The RMI supports the objective of the Australian Standard to ensure poisonous substances are packaged in containers that will not leak, are appropriately marked and will maintain their integrity during the life of the substance.

10. SPECIAL PACKAGING REQUIREMENTS FOR MEDICINES CLASSIFIED AS CONTROLLED DRUGS IN THE SCHEDULING STANDARD

This clause requires that the outer packaging of medicines, defined as Controlled Drugs in the Scheduling Standard (Schedule 8), is sealed in such a way that a sealed pack is readily distinguishable from a pack which has been opened.

The Misuse of Drugs Act 1975 (MODA) will continue to specify which drugs are Controlled Drugs in New Zealand. The Misuse of Drugs Regulations 1977 currently specifies labelling requirements which are additional to those of the current Medicines Act and the draft ANZTPA Labelling Order.

The labelling requirements of the MODA apply to all packaging – immediate to outer – and overlabelling is frequently required to make packaging compliant. However, there are occasions where overlabelling cannot be performed on all containers, for example on containers within a tamperproof pack as required by this draft order. Labelling exemptions are not allowed for controlled drugs. Thus, the product cannot be supplied in New Zealand.

The RMI strongly recommends that the Misuse of Drugs Regulations 1977 are amended in respect of the labelling requirements for those controlled drugs which also require a prescription written by an authorised prescriber.

Section 10 (2) refers to “medical practitioner”. This should be substituted with “authorised prescriber” to include prescribing in New Zealand by midwives and designated prescribers.