



RMI SUBMISSION ON CONSULTATION PAPER ON PRODUCT VIGILANCE IN THE AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY (ANZTPA)

PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of 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.

SUBMISSION

The RMI notes that the Consultation Paper, rather than being prescriptive, is positioned as a high level document providing an overview of product vigilance as proposed under the ANZTPA. It is also noted that there will be further consultation with stakeholders when detailed guidelines have been developed.

The RMI strongly supports the ANZTPA’s commitment to “developing and operating a comprehensive [risk-based] product vigilance system that is in line with best international practice”.

The RMI’s submission is limited to comment on the product vigilance requirements for high-risk medicines, being those Class 2 medicines evaluated by the Prescription Medicines stream.

1. Product Vigilance Data from Product Licence Holders

1.1 Medicines and Blood

The proposed pre-licence and post-licence risk management activities as outlined in this section are generally acceptable to the RMI and reflect international best practice. In particular, a move towards adopting ICH guidelines is strongly supported by the RMI.

The RMI does not support ANZTPA imposing any additional “local” requirements (or local interpretation of international requirements), unless absolutely necessary to safeguard consumers.

1.3 Licence Holder Product Vigilance Requirements for All Therapeutic Products

The RMI strongly agrees that “where Product Information and Consumer Medicine Information is required, Licence Holders must ensure the currency of these documents is maintained with regard to safety information”. High fees, such as those currently charged by the TGA for safety related notifications (SRNs), can be seen as a financial barrier to the timely updating of PI and CMI, especially by some suppliers of generic medicines. The RMI strongly recommends that fees for SRNs are reduced under the ANZTPA to reflect the actual cost to the Authority of the activity and to ensure that SRNs are notified in a timely manner by all Product Licence holders.

Currently, Medsafe allows sponsors to submit a “self-assessable change notification” for the update or addition of safety information with no change to approved product details. The self-assessable change notification route allows changes to be made in a timely and comparatively more cost efficient manner.

The RMI recommends that the ANZTPA adopts a self-assessable change notification system for safety related notifications.

2. Management of a Spontaneous Reporting Programme

2.1 Collection of Reports

The RMI supports the proposal that standard forms are used for reporting adverse reactions and strongly recommends that the ANZTPA follows best international practice – CIOMS, ICH Guidelines.

7. Product Vigilance-Related Research Activities

The RMI supports the ANZTPA having “the capacity to request, commission or perform a number of research activities to identify and quantify safety issues related to therapeutic products”. However, the RMI is concerned that under the proposed full-cost recovery model there is the potential for research activities to be instigated that could not be justified on safety grounds alone but can be undertaken because of the availability of uncapped third party (industry) financing.

The RMI strongly recommends that the ANZTPA Product Vigilance guidelines include a system of controls to ensure that the appropriate research is undertaken and that industry can have confidence that there is no “gold-plating” occurring.

Product vigilance related research activities have a significant public good component. Therefore, the RMI recommends that such activities should be funded from the community (through general taxation) relative to the public good and not be funded by industry alone. This would give confidence to all stakeholders that the commissioning of research to identify and quantify safety issues is focussed on achieving the greatest benefit to patients.

9. Availability of Product Vigilance Information

The RMI supports increased transparency through public availability of product vigilance information in line with international best practice. Furthermore, the availability of product vigilance information on their products is an essential requirement of Product Licence holders. The RMI, therefore, strongly recommends that ANZTPA has a robust system for reporting product vigilance information (in full and in a timely manner) to Product Licence holders.

CONCLUSION

The RMI strongly supports the adoption of international best practice in all aspects of the ANZTPA's regulation of therapeutic products, including product vigilance. The RMI looks forward to being actively involved in future consultation on the draft Rules, Orders and guidelines for product vigilance under the ANZTPA.