

CONSULTATION ON MICROBIOLOGICAL STANDARDS FOR MEDICINES 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 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.

PROPOSAL 1 – PRESERVATIVE EFFICACY

The Ph Eur/BP and USP-NF have effectively harmonised the methodology for preservative efficacy testing. However, the sampling times and acceptance criteria are not harmonised.

Further, the sampling times and acceptance criteria of the USP-NF, particularly for parenteral and ophthalmic preparations, are not currently accepted by the TGA (and are not expected to be accepted by the ANZTPA) as being stringent enough to ensure preservative efficacy in multidose medicines.

It is considered (para 3.2.2) that for products that currently meet USP-NF it will be relatively straightforward to modify sampling times and acceptance criteria as required to comply with Ph Eur/BP.

It is noted that under certain circumstances, the ANZTPA will exempt products from complying with Ph Eur/BP. In particular:

- products which are unable to meet Criteria A of the Ph Eur/BP (e.g. because of adverse effects associated with the preservative/s) may be permitted by the ANZTPA to comply with Criteria B instead
- products currently on the market, which are unable to meet the requirements of Criteria B, may be exempted if they meet agreed criteria

The RMI supports Proposal 1 whereby:

All sterile and non-sterile multidose prescription medicines should comply with the requirements detailed in "Efficacy of Antimicrobial Preservation" (Appendix XVI C and Supplementary Chapter 1 J of the BP, inclusive of 5.1.3 of the Ph Eur), and not Chapter <51> Antimicrobial Effectiveness Test of the USP-NF. (Page 16).

In particular, the ANZTPA will require medicines to comply with the sampling times and acceptance criteria of the Ph Eur/BP and not the USP-NF, for the efficacy of antimicrobial preservation, unless otherwise approved. (para 3.2.1).

The ANZTPA will consider, on a case-by-case basis, an exemption from the standard to allow medicines to not fully comply with the Ph Eur/BP acceptance criteria where the risk of adverse reaction is demonstrated to outweigh the benefit of a preservation system that does not comply with the acceptance criteria of the Ph Eur/BP (para 3.4.1).

PROPOSAL 2 – MICROBIAL ATTRIBUTES FOR NON-STERILE MEDICINES

The RMI supports Proposal 2 for prescription medicines that

Non-sterile medicines that are included within the scope of the 'harmonised' pharmacopoeial text should comply with the BP, Ph Eur or the USP-NF 'harmonised' text on Microbial Attributes (i.e. methods and acceptance criteria).

PROPOSAL 3 – STERILITY TESTING AND BACTERIAL ENDOTOXIN TESTING

The RMI supports the proposal that

Medicines that are required to be sterile shall comply with the requirements of the BP, Ph Eur, or the USP-NF 'harmonised' text on Test for Sterility and the Bacterial Endotoxin Text (where applicable).

This proposal is equivalent to the default standard that will apply to sterile medicines.

Submission on behalf of the Researched Medicines Industry Association

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