

# Royal Society of New Zealand response to MEDSAFE fees increase proposal

***February 2006.***

The Royal Society of New Zealand is an independent, national academy of sciences, and a federation of scientific and technological societies. We are instituted under an Act of Parliament to provide scientific advice and promote science and technology in NZ. The following submission to the Fees Increase Proposal by MEDSAFE has been circulated for consultation among relevant Constituent Societies and the RSNZ Council, and we submit this as the view of the Royal Society of New Zealand.

The RSNZ is concerned that following implementation of the proposed fees increases, scientific research will be disproportionately disadvantaged. We are submitting this response to the proposal to point out the risks within research organisations of:

1. erosion to the safety systems for controlled access to drugs,
2. prohibitive fees for low-cost research or smaller trials on new medicines and
3. cost of complying with ethical animal husbandry.

We appreciate that fees must be charged by MEDSAFE to licence individuals to possess and deal in controlled drugs. For the purpose of a pharmacy this is obviously necessary for safe distribution of controlled substances to those entitled to drugs (e.g. patients with prescriptions), and has a commercial aspect, hence the relevance of a user-pays application of fees. However, in the research laboratory, controlled drugs are used for anaesthetics and euthanasia of animals, under strict control of animal ethics committees, and qualified research technicians must have access to these drugs for the performance of (sometimes routine) experiments. Such experiments are performed often by not-for-profit organisations and charities. Research in New Zealand is funded via a contestable system, and funds are competitively sought, such that there are very slim margins for sudden changes to budgets (such as the proposed fees increases).

The status quo enables safe control of drugs in research laboratories through a minimal but convenient number of 'dealers' who are licenced to

distribute, from a locked safe, the exact amount of drug required for a treatment or trial, to qualified researchers. In many cases, individuals are known to each other, and an atmosphere develops of responsible behaviour regarding the use of drugs. Volumes, dates, times etc are recorded. Such a system prevents the distributed stockpiling of drugs. It also reduces the misuse of drugs, because people are known to each other, and records are kept in good order.

1. The substantial increase in the fees payable by research organisations may result in: a) fewer licensees on a site for dealing in the controlled substances, thereby making it more inconvenient for researchers to access the drugs required, b) individuals stockpiling small amounts of drugs in a distributed manner (for their own convenience) and c) the misuse of drugs due to the necessity of licensed people to dispense drugs to people they do not personally know. These may erode the safety systems for controlled access to drugs in laboratories.
2. Small research trials and those involved with the development of new medicines will bear the brunt of fee increases as research budgets may not stretch to cover new fees that could not be expected when budgets were set. If the application to distribute a new medicine (which increases from \$15,300 to \$122,625 incl GST) were applied to clinical trials of novel drugs, then researchers may not afford the costs of the research and development of new treatments. This could stymie research in an innovative area that the government has otherwise attempted to promote.
3. The RSNZ endorses the ethical use of animals in research, and we consider that researchers should be enabled to follow ethical guidelines and comply with the Ethics Committees, rather than have barriers put up against their compliance.

Since the proposed fee increases will impact disproportionately on researchers; potentially substantially changing the atmosphere of responsible, safe use of drugs, the RSNZ suggests that a "research exemption" be considered for not-for-profit researchers and/or organisations. This exempt category should have reduced fees, so the ethical and responsible use of the drugs in research laboratories is encouraged. If necessary, fee increases could be phased in over several years so researchers would have time to apply for funding to cover the new costs in their budgets. However, the high level of fees currently in the proposal are likely to be onerous for many research organisations thereby stopping innovative new research.