



Erin Murphy, PTAC Secretary
PHARMAC
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Submission from the Access to Medicines NGO Coalition (ATM) on the PHARMAC review of Pharmacology and Therapeutics Advisory Committee (PTAC) Guidelines and Terms of Reference

Dear Erin,

Review objectives as outlined in the background information are stated as: this review aims to ensure that the PTAC Guidelines:

- Enable PTAC & PTAC Subcommittees to carry out their obligations as described in the NZPHD Act and the Crown Entities Act 2004;
- Support PTAC & Subcommittee members in providing free and frank, objective advice to Pharmac;
- Enable the PHARMAC Board to access high quality, clinical expertise via PTAC & PTAC Subcommittees to support evidence-based decision-making about medicines funding;
- Align with the principles, goals and outcomes identified in *Medicines New Zealand*

With these objectives in mind, each of the sections below is framed by them as the lens in which the changes and revised set of guidelines are analysed by ATM.

In addition, ATM feels it is necessary for the sake of clarity to note that the review process being the second project specified by *Actioning Medicines New Zealand* is centred on proposed changes rather than PTAC's Operational Guidelines per se.

Re: summary of major changes proposed:

Being that PTAC is established under the NZPHD Act. Section 50(1) of the Act and Subcommittee's are established under clause 14(1) (a) of Schedule 5 of the Crown Entities Act 2004 with the latter empowering the PHARMAC Board to "appoint committee's to advise it on any matters relating to the entity's functions" there is concern on whether;

- PTAC's role and function could be undermined by the creation of a Subcommittee when:
 - E.g. the PHARMAC Board receives a decision from PTAC which is found to be unsatisfactory and creates a new Subcommittee in order to navigate around PTAC to influence the possibility of receiving alternative advice for expediency reasons;

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Members: ADDvocate, Alzheimers New Zealand, Arthritis New Zealand, Asthma New Zealand, Balance, Breast Cancer Aotearoa Coalition, Cancer Society, Carers New Zealand, Continence Association, Cystic Fibrosis New Zealand, Diabetes New Zealand, Diabetes Youth, Epilepsy New Zealand, IDFNZ, Kidney Kids, LAM Trust, Leukaemia and Blood Foundation, Lysosomal Diseases New Zealand, Multiple Sclerosis Society of New Zealand, Myeloma Matters, New Zealand AIDS Foundation, New Zealand Organisation for Rare Disorders, Parkinsons New Zealand, Prader-Willi Syndrome, Prostate Cancer Foundation, Schizophrenia New Zealand.

- Doing so creates an environment where power imbalances and competitive pressures determine how decision-making is informed within PHARMAC – essentially pitting two critical elements of the institution against one another;
- ATM recognises the need for the PHARMAC Board to have flexibility on creating Subcommittee’s when matters relating to the entity’s functions require advice outside of the scope and mandate of PTAC:
 - The review guidelines and Terms of Reference (TOR) must protect PTAC and consumers from any such environment being created on matters which lie within the scope and mandate of PTAC i.e. providing expert clinical advice to the PHARMAC Board on medicines, to avoid the potential risk of PTAC being undermined;
- ATM understands that PHARMAC and the *Actioning Medicines New Zealand* system is centred on rationing at its socio-economic foundation. However, we feel creating environments where parties are potentially exposed to competition with one another due to the degree of freedom those who hold executive powers (DG and PHARMAC Board) have in making sentinel decisions is not desirable:
 - ATM feels it more durable to ensure TOR protocols necessitate a higher degree of consensual decision-making between each party i.e. between PTAC and PHARMAC and is explicit in not allowing the creation of a Subcommittee on any matter relating to the entity’s function; rather only when it relates to a topic for which PTAC is not suitably equipped to consider.
 - In addition, ATM feels the PTAC Committee should have the ability to organise a Subcommittee when PTAC is not in session in urgent cases (rather than a PHARMAC Board controlled appointment process) on matters relating to PTAC’s mandate; this may require the establishment of a smaller working group whose role is to act on matters of urgency;
- Equally, in reference to the potential of conflict that may arise between the DG of Health and PHARMAC Board when new members are considered – a higher degree of consensus via protocols may be advantageous to negate any blurring of the lines between the use of executive powers and the decision-making process.

Re: proposed revised set of guidelines to be renamed *Terms of Reference* for PTAC and PTAC Subcommittees

- Issue about the decision criteria of PHARMAC to be handed down as the decision criteria for PTAC based on new set of guiding principles (*Actioning Medicines New Zealand*) and yet the decision criteria not changed on PHARMAC website or in the Review of PTAC Guidelines consultation document:
 - Current 9 criteria do not incorporate the principles based criteria (refer to bullet point 4 on first page); therefore, when is the alignment of PTAC Guidelines going to be matched to the principles, goals and actions outlined in *Actioning Medicines New Zealand Strategy*? This needs to be made explicit and clear in the TOR for PTAC (and in PHARMAC’s own decision criteria) in order to comply with the strategy;
 - The danger implicit in this not occurring is failure to incorporate into PHARMAC and PTAC decisions the social justice, equity and human rights based principles as required by the strategy. A flow on danger is the current focus on whole populations will leave out subpopulations and even in some cases individuals when the interest of these groups do need to be addressed in accordance with the expanding range of decision principles set out in the strategy; and in accordance with PHARMAC’s primary objective under the Act;
- ATM feels there should be greater differentiation between decisions based on therapeutic value *and* those made on financial implications based on the principles inherent in the Actioning Strategy.
- Gaps in the TOR which raise issues include:
 - TOR 3.1.2 states “The minutes of each PTAC meeting shall *usually* be provided to the PHARMAC Board at the next Board meeting following finalisation of the minutes” – for this to be of value in ensuring minutes are made available which ATM feels is necessary for clarity of PTAC discussions and how decisions are reached, both a timeframe and requirement (not *usually*) need to be entrenched into the process to benefit the PHARMAC Board’s awareness of PTAC process; again, the risk is that without this clarity from sharing information on decision-making the parties become vulnerable to conflict based on misunderstandings;
 - TOR 2.2.4 states “PTAC and its Subcommittees may reply on persuasive rather than conclusive evidence, if persuasive evidence is the best that can be reasonably obtained” – if decisions are to be made on persuasive evidence in the absence of conclusive evidence how will this be applied i.e. what will be considered persuasive and conclusive evidence? Will this require PTAC or a Subcommittee to acknowledge this in their eventual decision to the Board?
 - ATM notes there are International Standards for levels of evidence for any evidence based practice and this should be applied to this process to enable clarity rather than the use of the term “persuasive”.

We trust our concerns and points raised will be considered in the review process and we thank you for providing this opportunity to contribute to the proposed changes in the guidelines and TOR for PTAC.

Kind regards

A handwritten signature in purple ink that reads "Paterson". The signature is written in a cursive style with a large initial 'P' and a long horizontal stroke.

Adam Paterson
ATM Secretary