Medicines New Zealand Submission on a possible joint regulatory scheme under ANZTPA

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ANZTPA
Therapeutic Goods Administration
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By email to anztpa.submission@anztpa.org

Submission on the Description of a possible joint regulatory scheme for therapeutic products under ANZTPA.

Thank you for the opportunity to comment on the content of the joint regulator ANZTPA.

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines. A central objective of Medicines New Zealand is to promote the benefits of a strong research based industry in New Zealand.

Since the activities of Medicines New Zealand members are primarily focused on prescription medicines, this submission concentrates on those proposals that relate to prescription medicines, rather than non-prescription medicines (referred to in the consultation document as Class 1 medicines), biologicals, and medical devices.

We would like to discuss our submission with you at an appropriate time, as well as participate in any industry working groups that are established to progress ANZTPA.

Yours sincerely

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General Manager

Medicines New Zealand Submission on a possible joint regulatory scheme under ANZTPA

Executive Summary

We agree with the principles underpinning the joint agency as set out in the consultation document. Medicines New Zealand believe that ANZTPA offers an opportunity to realise the strengths of both countries' regulatory regimes, to streamline and increase the efficiency and robustness of prescription medicines approvals. This will improve access to prescription medicines, and enhance the reputation of New Zealand and Australian manufacturers and therapeutic products on the world market.

To do this ANZTPA must:

- utilise abbreviated assessment processes for NMAs as well as for new indications, similar to those used by Medsafe, where products have already been approved by at least one recognised major international regulator. This will reduce duplication of prescription medicine assessment where products have already been approved overseas, while allowing independent assessments to be undertaken where appropriate. An abbreviated process would also free up resource within the regulator to focus on the full evaluations.

- use the most efficient, effective and timely assessment processes consistent with international best practice in order for improved access to prescription medicines. ANZTPA should base any requirements for regulatory approval on those used by other major international regulators such as the EMA and FDA, it should not establish additional or different requirements.

- reduce time of evaluation by limiting pre-evaluation checks to administrative and fee checks only. There should be no evaluation undertaken during the pre-assessment stage and the timeframes for the overall process should be transparent.

- be cost effective with fees reflecting the level of regulatory activity required. Efficiencies gained by integrating and streamlining the two regulatory agencies should result in product approval fees being no more than the higher of the two fees currently charged.

- use appropriate levels of risk-management according to the benefits and risks from the use of the medicines. For example, self-assessable processes must be maintained for inserting additional safety information into data sheets, similar to those used by Medsafe.

- manage operational risk by using a common quality systems approach to the assessment process and post-marketing regulation to ensure consistency in assessment decisions, accountability, and appropriate outcomes. Each country's systems should be compatible to enable work-sharing.

- maintain advertising to consumers, and self-regulation of promotional activities as currently conducted in each country.

- incorporate a single centralised independent science approval process for high risk clinical trials, along the lines of the SCOTT committee in New Zealand and the CTX in Australia. The approval scheme should also incorporate a self-certification or exemption process for low-risk trials. There must be a fast and efficient clinical trial approval scheme to continue to attract global R&D investment in Australia and New Zealand, and grow that investment.

Harmonisation processes that could be initiated before the formation of ANZTPA could be in abbreviated assessment processes, along the lines of that used by Medsafe; and a project to harmonise the medicine recall procedure. Whilst discussion on packaging and labelling of products is outside the scope of this consultation, we have previously asked that any review of packaging and labelling is considered a joint project.

Medicines New Zealand Submission on a possible joint regulatory scheme under ANZTPA

Comments on the *Description of a possible joint regulatory scheme for therapeutic products under ANZTPA.*

General comments

Medicines New Zealand supports the formation of ANZTPA because we believe that ANZTPA offers an opportunity to realise the strengths of both countries' regulatory regimes, to streamline and increase the efficiency and robustness of prescription medicine approvals. This will improve access to prescription medicines, and enhance the reputation of New Zealand and Australian manufacturers and therapeutic products on the world market. We agree with the principles underpinning the joint agency as set out in the consultation document.

As this consultation is a discussion on the framework of the new agency, our comments are at a high level. The issue for New Zealand is more in the detail of the regulatory regime and we would strongly support the formation of a core working group, including representatives from Medicines New Zealand to provide guidance on the detail of the framework going forward.

We note that this document does not include proposals for transition arrangements. We believe that this needs to be discussed early in the consultation process to ensure a seamless transition and to avoid "grandfathering" products into the market that would not meet the new regulatory standards under ANZTPA.

We would also like ANZTPA to manage operational risk by using a quality systems approach to the assessment process and post-marketing regulation to ensure consistency in assessment decisions, accountability and appropriate outcomes. There should be similar outcomes for products assessed independent of which country the assessment was made. Business process flow systems should be the same and be compatible to enable work-sharing.

Specific Comments

Our comments are listed under the main headings of the consultation document.

Medicines

Standards (page 10)

Medicines New Zealand supports the adoption of standards, but they must be aligned with international standards and there should not be any local Australia/New Zealand standards. Having only international standards reduces regulatory impediments to the Australia and New Zealand markets for manufacturers and ensures ANZTPA is on an "equal footing" with other international regulators.

There may be occasions where a product does not comply with an international standard, but a manufacturer wants to apply for a product approval because there is an unmet clinical need for the product. We recommend that there should be a process for applying for an exemption from meeting a standard in specific cases and where this is justified on the grounds of the benefit - risk balance.

Medicines New Zealand Submission on a possible joint regulatory scheme under ANZTPA

Manufacture of Medicines (page 10)

There are differences between the current GMP requirements for sponsors between Australia and New Zealand. Currently Medsafe routinely accepts Australian GMP clearances and GMP certification from other recognised overseas regulatory agencies, whereas in Australia sponsors are required to seek GMP pre-clearance for each site despite previous clearance of the site for another sponsor. To avoid unnecessary duplication, we recommended that ANZTPA use a simplified GMP clearance process where sponsors can automatically obtain GMP clearance where a site has been inspected and certified by a PIC/S member country.

We agree to exemptions to manufacturing licensing, in line with those in Australia.

Product Approvals (page 13)

ANZTPA should use the most efficient, effective and timely assessment processes consistent with international best practice. We support a risk based approach to the assessment of medicines according to the benefits and risks from the use of the medicine to determine the level of assessment required and the level of post-market regulation.

The Product Approval (page 16)

Medicines New Zealand accepts annual charges for product approvals to cover the cost of post-market regulatory activities, in line with the current TGA system. However we believe there should be lower fees or exemption from fees for low volume products and/or orphan products. Imposing fees on low volume products or orphan products may mean that it is not viable for the manufacturer to continue to make the product available. There should be clear guidelines on which products would qualify for reduced fees.

Class 2 Medicines (page 17)

We agree that the level of assessment needs to be appropriate to the benefits and risks from the use of the medicine.

As well as considering the benefits and risk from the use of a medicine, we strongly recommend that ANZTPA also considers any previous approvals by recognised international regulators, and utilises an abbreviated assessment process, similar to the one used by Medsafe where products have already been approved by at least <u>one</u> recognised international regulator. The reason is that there are efficiency gains in the assessment process where a product has already been approved overseas. Independent assessments would still be undertaken by ANZTPA where appropriate**.** We suggest harmonising the abbreviated assessment process as a joint ANZTPA project.

In order to improve the efficiency of the assessment process, we recommended a quality systems approach to the assessment process to ensure consistency in assessment decisions, accountability and appropriate outcomes.

We would support the general principle that ANZTPA could make a decision to grant an approval

for a medicine, with recourse to an expert committee only where ANZTPA required external expert advice. This process is along the lines of how Medsafe operates with the MAAC in New Zealand.

We support abbreviated processes or certifications for "variations" to an approved medicine. See pg 7 of this submission for more detail.

Provisional Approval (page 19)

We strongly support the requirement for ANZTPA to grant provisional approval for some medicines. We recommend that provisional approval could be granted for medicines where there is an "unmet clinical need" rather than only for conditions which are "life-threatening". We believe that determining life threatening conditions could be problematic.

We recommend that orphan drugs are assessed in line with international practice and that fees are waivered in the instances of evaluating orphan medicines.

Statutory Timeframes for Approval (page 19)

We would recommend that timelines be included in guidelines rather than at the statutory level. Although statutory timelines can encourage the regulator to perform within certain parameters, conversely it can lead to inefficiencies where the regulator is forced to complete evaluations by a certain date. We want to avoid the situation where evaluations are "completed" in order to meet a deadline but it is at the expense of supplementary queries being raised later in the assessment process.

We would recommend reducing time to assessment by limiting pre-assessment checks to administrative and fee checks only, i.e. with no 'evaluation' undertaken during the pre-assessment stage. Feedback from our members is that the pre-assessment carried out by the TGA does not necessarily lead to reduced overall assessment time.

The overriding issue for the industry is that timeframes for the overall process should be transparent.

Conditions (page 19)

We accept conditions on a product approval, along the lines of the current TGA process. We note that many of the conditions are stated elsewhere in New Zealand legislation. When considering imposing conditions on providing information about overseas regulatory action, ANZTPA will need to be specific about the information required to avoid receiving unessential information.

Specific Conditions (page 20)

We note that specific conditions could relate to advertising of medicines. We strongly support retention of ASA standards for advertising therapeutic products in New Zealand, and would recommended the TAPS and industry self-regulatory system used in New Zealand. This has

proved to be an efficient system, delivering satisfactory outcomes for both industry and consumers. Unlike the current Australian processes, the complaints procedure in NZ is accessible to consumers and allows rapid resolution of issues.

We note that training and education requirements are an example of specific condition that ANZTPA could impose. Our concern with this is that ANZTPA could impose unreasonable conditions which could mean that it is not viable for the manufacturer to continue to make the product available. We believe that any training and education conditions should be discussed and mutually agreed with the manufacturers.

Variation to an Approval (pg 21)

We support variations to an approval, where the variation results in a separate and distinct product. As with product approvals, we support a risk based approach to the assessment of the "variations". Some variations, for example a change in recommended dosage or new indications, could be handled by way of an abbreviated assessment process, whereas for low risk variations we support a self-assessable process, along the lines of that used by Medsafe. Timeframes for assessing the variations to a product approval should reflect the level of assessment required.

We would recommend that timelines for variation applications be included in guidelines rather than at the statutory level (see our comments above under Statutory timeframes for approval). Should statutory timeframes be implemented, it is important that where ANZTPA fails to meet a statutory timeframe, the variation should automatically be considered to be approved.

Data Protection (page 22)

Given the current legislation in New Zealand (Official Information Act) and in Australia (Freedom of Information Act), we consider that the confidentiality of manufacturer's information should be protected at a level *no lower than* at present in New Zealand. We also believe that data protection timelines should be aligned with international best practice for pharmaceuticals and biologicals.

Medical Devices (page 25)

This section is not relevant to our member companies.

Blood and Blood Components (page 37)

We will not be commenting on this section. We are aware that some of our member companies will be commenting separately.

Biologicals (page 38)

We note that the framework for biologicals is a new feature in the New Zealand regulatory environment and the framework proposed is along the lines of that operating in Australia. We would like confirmation that recombinant prescription medicines are excluded from the

definition, as they currently are in Australia.

We recommend that assessments of biosimilars be based on the requirements and conditions of marketing approval established by the major regulators such as the FDA and EMA.

Obtaining Information (page 43)

We support the requirement for manufacturers to supply information in a timely manner. We understand that ANZTPA will be required to comply with the current legislation in New Zealand (Official Information Act) and in Australia (Freedom of Information Act), and also provide requested information within the statutory timeframes.

Exemptions from Product Approvals (page 43)

We support the need to provide access to unapproved medicines in specific circumstances. We would are interested in the regulatory controls ANZTPA will apply to enable access to unapproved products by medical practitioner authorised to prescribe particular medicines, or for the treatment of a specific people. We recommend that exemptions are used in extreme clinical conditions. We presume there will be further consultation on the specific exemptions and controls but the process should be streamlined as much as possible so as not to delay patient access to the medicine.

We support clinical trials of unapproved medicines. New Zealand and Australia need a fast and efficient clinical trial approval scheme that will attract global R&D investment, and to grow that investment. We would recommend that clinical trials are assessed by a single centralised independent science committee, along the lines of the SCOTT committee in New Zealand and the CTX process in Australia. We agree that there should be a self-certification or exemption process for low risk trials (for example, Phase 3 clinical trials).

Post marketing monitoring and compliance (page 44)

We note that Medsafe and the TGA have already initiated projects concerning post-marketing monitoring and compliance (a Joint Adverse Event Notification System (JAENS), a common medicines recall portal and early warning system for potential safety signals for medicines)

Once again a quality system approach should be used to ensure consistency in post-marketing regulatory decisions between New Zealand and Australia.

Risk Management (page 45)

Medicines New Zealand strongly supports a range of risk management approaches depending on the benefits and risks of the medicine.

Recalls and Public Notification (page 46)

Whilst we note the development of a common recalls portal we would like to see the continuation of the consultation on the Uniform Recall Procedure for Medicines and Medical

Devices in New Zealand. The current procedure is outdated and in need of modernising, and a project to update the recall procedure is on hold. We appreciate that this is outside the scope of the consultation at this time, however the updating of the recall procedure could be reinitiated as an ANZTPA project.

Promotion of Therapeutic Products (page 47)

Medicines New Zealand supports maintaining advertising to consumers, and self regulation of promotional activities along the lines of the TAPS industry self-regulatory system used in New Zealand.

We note that there will be further consultation on the promotion of medicines.

Fees and Charges (page 48)

We note that full cost recovery is a feature of the TGA at present and this is proposed with ANZTPA. Full cost recovery was signaled in ANZTPA consultation prior to 2007.

ANZTPA should be cost effective with fees reflecting the level of pre-marketing and post-marketing activity required. It is difficult to comment of the appropriate level of fees when the detail of the regulatory system is unknown. However due to efficiency gains by integrating and streamling the two regulatory agencies we would expect that fees would be no more than the higher of the two fees currently charged.