

Submission from

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On behalf of
Researched Medicines Industry Association of NZ Incorporated

ANZTPA consultation paper on fees and charges – submission template **Please enter your comments under the specific proposals to which they relate.**

Note: It is not necessary to comment on all proposals.

PROPOSAL 1:

Application fees and processing fees for applications involving similar levels of work effort will be standardised around common pricing points.

Comment:

Agree

PROPOSAL 2:

The Authority's business models will, as far as possible, avoid the use of separate application and evaluation/assessment fees.

Comment:

Agree to paying a single fee providing detail is provided on how the fee is structured i.e. \$x for application plus \$y evaluation = \$total fee. Provision of this breakdown is important for transparency, particularly as it is proposed (Proposal 8) that application fees will be non-refundable while evaluation fees will be refundable up to a point (depending on the amount of work the Authority has performed on the application at the time it is withdrawn).

PROPOSAL 3:

Rounding for fees and charges in both countries will be as follows:

- fees under \$100 will be rounded up to the next full dollar increment;
- fees from \$100 to \$1,000 will be rounded up to the next five dollar increment, and
- fees over \$1,000 will be rounded up to the next ten dollar increment.

Comment:

Agree in principle although propose that Swedish rounding be used (i.e. rounding down or up, as appropriate) rather than only rounding up to the next increment.

PROPOSAL 4:

An instalment payment option will be developed for evaluations and assessments that usually involve periods of greater than three months duration, based on the principle that assessment work would cease if payment were not received as scheduled.

Comment:

The RMI accepts the proposal to develop an instalment option and agrees that, under such an option, assessment work would cease if payments are not made as required.

PROPOSAL 5:

Fees for major evaluations and assessments that are subject to performance targets should be linked to meeting these targets, with 75% of the total fee payable on application and the remaining 25% payable only where the Authority completes work within the target period.

Comment:

The RMI considers the achievement of performance targets for major evaluations and assessments by the Authority to be of high importance.

However, the RMI does not accept the proposal that 25% of the fee be rebated if performance targets are not met. As the Authority intends to recover the full costs of the regulatory scheme from industry, any rebate will ultimately come from fees paid by industry and not from the Authority. The RMI, therefore, fails to see how the proposal provides "... sufficient incentive for the Authority to meet targets..." (para 95).

The RMI recommends that the achievement of performance targets be a key performance indicator for the Managing Director and Board.

PROPOSAL 6:

Where the fees charged in relation to the use of unapproved therapeutic products do not recover the full cost, the shortfall will be recovered through annual licence charges.

Comment:

The New Zealand and Australian Governments agreed "...that the cost of the regulatory scheme administered by the Authority will be fully funded through fees and charges paid by industry participants" (para 3). Thus, it is expected that the fees charged by the Authority for approval and monitoring of clinical trials will reflect the actual cost to the Authority of performing this function. Where there are costs associated with the use of unapproved therapeutic products outside of clinical trials, this could be considered a

public good and as per the NZ Treasury Guidelines, “there is a good case for recovering the costs of a public good from the community as a whole, either by general taxation, or (where the benefits are localised) from local government revenue”.

Annual licence charges, applied to product licences, are cost reflective and are intended to recover the cost of **post-market** and scheme support activities. The RMI does not consider it appropriate that annual charges be used by the Authority as a convenient source of funds to recover a shortfall which is not the result of post-market or scheme support, activities.

Thus, the RMI does not support the proposal that “where the fees charged in relation to the use of unapproved therapeutic goods do not recover the full cost, the shortfall be recovered through annual licence charges”.

The RMI recommends that the funds received from annual licence charges be ring-fenced to cover the costs associated with post-market activities and scheme support only, including pharmacovigilance and monitoring and enforcement of compliance standards.

PROPOSAL 7:

The Authority will operate an orphan therapeutic products scheme similar to that currently operating in Australia.

Comment:

The RMI agrees with the proposal that the Authority operates an orphan therapeutic products scheme similar to that currently operating in Australia.

The RMI is opposed to full cost recovery of the regulatory scheme from industry. Fee waivers for orphan drugs should be considered a public good and as stated in the New Zealand Treasury Guidelines “there is a good case for recovering the cost of a public good from the community as a whole...”.

However, the RMI accepts that under a full cost-recovery model the cost of an orphan therapeutic products scheme would be recovered from across all product licences.

The RMI recommends that the cost should be recovered from fees for product licence applications not from annual charges.

The RMI also recommends that the definition of an orphan disease is stated in the Medicines Rule as the prevalence rather than the total number of affected individuals. Further, the RMI recommends the prevalence for orphan designation be 7.5 affected individuals per 10,000 of population, in line with the current definition in the United States.

PROPOSAL 8:

Application processing fees will be non-refundable. A screening fee of up to 20% of the evaluation fee (based on the regulatory and administrative work performed) will apply if an application is withdrawn by the sponsor prior to acceptance for evaluation.

Comment:

The RMI accepts that application processing fees will be non-refundable and that, depending on the amount of work that has been performed, a screening fee will be applied if an application is withdrawn by the sponsor prior to acceptance for evaluation. If no work has been performed, the evaluation fee should be refunded in full.

The RMI considers that a screening fee “of up to 20%” of the evaluation fee may be appropriate for low risk products but is considered excessive for screening of an application for approval of a new chemical entity.

PROPOSAL 9:

Initiatives adopted by the Authority to assist smaller companies will be designed, as far as is possible, to avoid cross-subsidisation from fees paid by other regulated companies.

Comment:

The RMI agrees that if the Authority adopts initiatives to assist SMEs, these initiatives **should not** be cross-subsidised through fees paid by other companies.

Assistance for SMEs is the role of government (e.g. through the Ministry of Economic Development, etc) and is **not** the role of a regulator especially where the full cost of the regulator’s activities is recovered from industry.

PROPOSAL 10:

The annual charge payable by the sponsor for a product licence (which may cover a group of related products where such grouping is permitted) will reflect the cost of post-market surveillance and regulatory management activities.

Comment:

Post-market surveillance should be considered a public good, the cost of which is recovered from the community as a whole rather than from industry. However, the RMI agrees that under a full cost recovery model the annual licence charge should reflect the cost of post market-surveillance and regulatory management activities.

The RMI recommends, therefore, that interim product licences have a reduced annual charge that is more cost-reflective of the actual activity that will be undertaken by the Authority. The RMI acknowledges the rationale provided in paragraph 114 that a desire to avoid paying two annual licence fees could be an incentive for companies to apply for a full ANZTPA licence. However, in reality, the rate limiting step for companies moving toward a full ANZTPA product licence will be the level of resource required to harmonise

product approvals and to collate the information and documentation required to support the application.

It is noted in paragraph 116 that once fees and charges are set in the Rules, the Authority will have no power to waive or reduce fees and, as the charges are in respect of a financial year, charges would not be pro-rated which does not meet the objective of annual charges being cost reflective.

As the Rule covering fees and charges has not yet been written, the RMI strongly recommends that when the Rules are being drawn up provisions are included for pro-rating charges where a product is not supplied and/or manufactured for the full year.

PROPOSAL 11:

The annual product licence charge for products in a particular risk category will be calculated by dividing the Authority's post-market surveillance and regulatory management cost for a risk category by the number of products in the risk category that have significant turnover.

Comment:

It is proposed that the annual licence charge will be determined by dividing the post-market costs by the number of products in the category with **significant** turnover. There is no definition of "significant" provided nor is there an indication of the percentage of products that may be considered to have significant turnover. The smaller the number of products used for the denominator the greater the annual licence charge will be. An inflated annual charge may then be applied to the majority of product licences in a category potentially resulting in an over collection of revenue by the Authority.

PROPOSAL 12:

The Ministerial Council Rules should permit the Authority to recover from the original product sponsor any costs associated with product recalls and investigations relating to a product for which the licence has been cancelled.

Comment:

The RMI generally agrees that the Authority be able to recover the costs of a product recall and any investigations relating to a product, for which the licence has been cancelled, from the sponsor at the time of the cancellation of the licence. However, there should be a limitation on the period after which the licence is cancelled that the sponsor remains financially liable and this period, for pharmaceuticals, should be linked to the approved shelf-life of the product.

PROPOSAL 13:

The low turnover assistance arrangements at commencement of the joint scheme will include:

- a low turnover exemption, obtained by applying to the Authority, where the product licence annual charge exceeds 6.8% of the wholesale turnover for the product (or cost of manufacture if the product is supplied at no charge);
- an application fee of A\$100 to apply for an assessment for a low turnover exemption;
- capping of the total amount paid by a sponsor for low turnover application fees at A\$11,500 per annum, with the cap phased out over the transition period;
- removal of first year annual charges, with applicable product application and evaluation fees being increased to cover some handling costs for initial licensing; and
- a low product licence annual charge category of A\$100 for products that a sponsor certifies are not in the supply chain (subject to penalties for incorrect certification).

Comment:

The RMI supports the proposal to :

- introduce a new annual charge category of A \$100 for products that a sponsor certifies are not in the supply chain
- remove the first year annual charges with applicable product application and evaluation fees being increased to cover some handling cost for initial licensing
- maintain the existing TGA low turnover assistance arrangements at the commencement of the joint scheme with a view to reviewing these arrangements after 3 years (of the 5 year transition period).

PROPOSAL 16:

Product licence application fees and product licence annual charges should be cost reflective.

Comment:

The RMI agrees in general with the proposal that product licence application fees and annual charges should be cost reflective in that approximately 60% of the Authority’s total revenue for Class 2 prescription medicines comes from pre-market fees with the remaining 40% from annual charges. However, the RMI’s support for this proposal must be taken in the context of our comments regarding Proposal 17, below, and our opposition to full cost-recovery from industry.

PROPOSAL 17:

The fee for an evaluation of a product licence application for a new generic medicine will be cost reflective and will not be set as a percentage of the evaluation fee for a new innovative prescription medicine.

Comment:

The RMI rejects proposal 17 and strongly recommends that the fee for evaluation of a product licence application for a new generic medicine be set as a percentage of the evaluation fee for a new innovative prescription medicine.

The proposed ANZTPA fee for evaluation of a generic medicine is about 39% of the fee for an NCE and this proposed fee is “ ... cost-reflective and is not pegged to the cost for a new

innovative medicine...” (para 185). The proportional fees charged by other international regulatory agencies for evaluation of a generic is 50-60% of an NCE.

Setting the Authority’s fee for generic evaluation at 50-60% of the NCE fee would ensure effective protection of the innovative industry against unfair competition as per Article 39.3 of the World Trade Organisation’s “Trade Related Aspects of Intellectual Property Rights” (TRIPS).

Article 39.3 states: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which requires a considerable effort, shall protect such data against unfair commercial use...”. A significantly lower cost for evaluating generic products, based only on the costs of evaluating an abridged data package referenced to information generated by the innovator and evaluated by the Authority at the expense of the innovator, provides generic suppliers with an unfair commercial advantage.

This unfair commercial advantage provided to generics also does not meet the New Zealand Treasury’s objectives for user charges to deal equitably with the taxpayer, those who benefit from the output, and or those whose actions give rise to it (p3, Guidelines for Setting Charges in the Public Sector 2002).

As the complexity of NCEs and the data requirements demanded by regulators increases in the future, it will be imperative that the fee for evaluation of a generic remains pegged as a fixed percentage (50-60%) of the fee for an NCE evaluation. If the fixed ratio is not maintained, the unequal burden of costs borne by the research-based industry will restrict the introduction of innovative new medicines into Australasia.

The RMI recommends that the cost of evaluating a generic prescription medicine under the ANZTPA should be increased to 50-60% of the evaluation fee for an NCE.

The RMI recommends that the revenue collected in excess of the cost of evaluating generic medicines is applied against the cost of evaluating new chemical entities.

PROPOSAL 18:

Fees for product licence variations will be set to recover the cost of evaluation and handling and will be charged on a “per submission” basis.

Comment:

The RMI agrees with the proposal that fees for product licence variations will be set to recover the cost of evaluation and handling and will be charged on a “per submission” basis i.e. the fee charged is independent of the number of product licences affected.

Paragraph 181 includes a table of indicative fees and charges for Class 2 Prescription Medicines. With regard to this table:

the RMI recommends that under the ANZTPA:

- *there needs to be a greater number of categories for product variations other than just major (A\$ 65,000) and minor (A\$ 3,700) as the current structure does not truly reflect the different costs associated with the range of different activities within each category*
- *that there is a lower fee applied to product licence applications and variations where overseas evaluation reports are used by the Authority, thus reflecting the actual cost of the activity undertaken by the Authority.*

The RMI does not accept a proposed fee of A\$10,100 for a product licence application for an additional trade name as it does not appear to be in any way cost reflective of the Authority's activity which is primarily administrative.

The RMI also seeks justification for the designation of "higher risk" for biologics resulting in higher annual charges as a result of increased testing, etc.

PROPOSAL 32:

The fee for an application for rescheduling of a medicine will be set below the cost of performing the review in recognition of the fact that the applicant does not obtain an exclusive benefit. Any residual cost will be met from annual licence charges on all products.

Comment:

Where the rescheduling of a medicine provides a public good it could be argued that some of the cost of the rescheduling decision should be borne by the community as a whole, i.e. the taxpayer.

A decision by an individual product licence holder to seek rescheduling is one of free choice. Recovering the shortfall from annual licence charges would amount to cross-subsidisation by the entire sector(s), especially as the benefit of the rescheduling decision would be limited to only a relatively small number of products.

The RMI does not support using monies from annual charges to recover costs that are not related to post market activities or scheme support.

PROPOSAL 33:

The Authority will not charge a fee for an application to convert from an interim product licence to a full ANZTPA product licence, provided the application does not require an evaluation to be undertaken.

Comment:

The RMI supports in principle the proposal that the Authority will not charge a fee for an application to convert from an interim product licence to a full ANZTPA product licence, provided the application does not require an evaluation to be undertaken.

However, the RMI seeks clarification of what, in this instance, is considered to be evaluation – is this limited to applications where the sponsor provides justification for a product that has previously had an application for approval rejected in whole or in part by either the TGA or Medsafe?

The RMI recommends that detailed information about what is considered to be evaluation in this context is supplied to industry as soon as possible along with an indicative fee structure for performing these activities.