Report on the 2008 review of fees payable under the Medicines Act 1981

Medsafe - May 2008

Report on the 2008 review of fees payable under the Medicines Act 1981

1. Background

The Ministry of Health (MoH) is responsible for administering the Medicines Act 1981 and Medicines Regulations 1984. Its functions in relation to this legislation are funded from a mixture of Crown funding and third party revenue collected from fees set under the Medicines Act 1981.

The Medicines Act provides for the charging of fees in relation to applications for licences and for the approval of new and changed medicines, new and changed related products and clinical trials. The schedule of fees payable is contained in regulation 61 of the Medicines Regulations 1984.

Regulation 61A of the Medicines Regulations 1984 provides that the Director General of Health may waive or refund, in whole or in part, a fee otherwise payable under regulation 61. In exercising this power the Director-General is obliged to have regard to the degree of complexity and time required to consider an application, and the interests of public health in New Zealand.

A 'standard' waiver is applied in a number of instances to reduce the fee for approval of a new or changed medicine or related product in order to recognise the reduced time required to consider the application. For example, a partial waiver is routinely applied to applications for approval of new non-prescription medicines. A partial fee waiver is also available for applications made under a recently introduced abbreviated process for new prescription medicines already approved by a recognised overseas regulator.

The actual fee payable for an application of a particular type, after application of any applicable standard waiver, is set out in a schedule of fees published on the Medsafe website.

The current fees came into effect on 21 August 2006. Many fees increased significantly at that time due, in large part, to the fact that most of the fees had been set in 1991 and had remained unchanged since that time. The anticipated implementation of the joint regulatory scheme to be administered by the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA) also had an influence on the setting of fees in 2006.

With the establishment of ANZTPA now on hold, a further review is required. Medsafe has given an undertaking to the Regulations Review Committee to complete a review to establish the appropriate fee levels to achieve cost recovery in the current environment.

It has also been identified that in many cases the way in which the actual fee payable for a particular application is calculated is complex and consideration should be given to

rationalising the fee schedule. The current review is therefore looking at both the fee levels and the way in which fees and waivers are applied.

2. Scope of the fees review

Medsafe has undertaken a review to identify the level of fees needed to achieve cost recovery whilst maintaining consistency with the:

- *Guidelines for Setting Charges in the Public Sector* issued by the NZ Treasury in December 2002 (available at www.treasury.govt.nz/publicsector/charges/); and

- *Guidelines on Costing and Charging for Public Sector Goods and Services* issued by the Audit Office in 1989 (available at www.oag.govt.nz/reports/good-practice-guides).

The review covers:

- fees to accompany applications for approval of new and changed medicines and related products (made under sections 20 to 24 of the Medicines Act 1981 and administered by Medsafe) and for approval of clinical trials (made under section 30 of the Medicines Act 1981 and administered by Medsafe); and

- fees to accompany applications for licences to manufacture or pack medicines (made under section 17 of the Medicines Act 1981 and administered by Medsafe);

- fees to accompany applications for licences to sell medicines by wholesale or retail, hawk medicines or operate a pharmacy (made under section 17 of the Medicines Act 1981 and administered by Medicines Control).

The approach taken in completing the fees review has been to develop a three-year expenditure budget, allocate the expenditure budget to outputs that are either crown-funded or industry-funded, and use the costs for the industry-funded outputs, together with estimates about annual application volumes for each type of application, as a basis for setting fees for a three-year period. Background financial information is provided in Section 5 of this paper.

The review has also included consideration of the efficiency of the cost-recovery mechanism for applications for approval of new and changed medicines and related products. Efficiency is currently compromised due to the complexity of the fees schedule and proposals for simplifying the fee schedule are detailed in section 4 of this paper.

3. Basis of costings and estimated operating budget

3.1 Basis of the cost estimates

In delivering the services that are to be cost recovered from industry under the Medicines Act, MoH incurs direct and indirect costs. Direct costs include personnel and

operating costs. Indirect costs include MoH corporate overhead costs, accommodation, and depreciation.

3.1.1 Medsafe cost estimates

Direct and indirect costs are allocated to Medsafe's outputs each year and form part of the cost of producing the outputs. The steps undertaken by Medsafe in calculating the costs of the services provided to industry for the next three years are as follows:

- Estimate the time spent by each staff member on each of Medsafe's outputs on a full-time equivalent (FTE) basis, and allocate personnel costs to each output;
- Allocate direct operating costs to relevant outputs; and
- Allocate indirect costs to outputs based on the FTE percentage of each output.

Within each output, volumes of each type of fee have been estimated on historical trends. Specific fee levels have been derived by dividing the total cost of each output by the estimated volume of applications. Where there are application sub-types within an output, the fees have been based on an estimate of the relative amount of work required for each sub-type. An example of this is Changed Medicine Notifications where the fee for a medium change is twice that for a minor change, and a major change is three times the fee for a minor change.

3.1.2 Medicines Control cost estimates

The costs for each type of licence application are based on the number of FTEs involved in processing applications of that type. Personnel and operating costs are allocated to each licence activity based on the average cost per FTE (including direct and indirect costs) and the proportion of the total FTEs involved in processing each application type.

3.2 The current situation

3.2.1 Medsafe

The total forecast expenditure for 2008/09 is $12.29 million (GST excl) of which $7.95m is budgeted to come from fees charged to industry, assuming the proposed fee changes are implemented. This represents a 17% reduction in fee revenue compared with actual fee revenue in the 12 months to 31 March 2008.

The forecast expenditure is based on historical costs for Medsafe, with adjustments for increased costs in the current work programmes. It is not expected that any new areas of work activity will be undertaken in the near future, and no costs for new initiatives are included.

The $12.29m 2008/09 expenditure forecast is an increase of 8.6% over the 2007/08 budget. The increase is predominately due to increased personnel costs, which is a combination of an annual increase in salaries (3.1%), budgeting for a full establishment of staff, and increases above the standard inflationary increase for several multi-year contracts that are up for renewal. Depreciation costs are also forecast to increase as the IT servers for Medsafe are being replaced in 2008/09. The SMARTI database system has already been fully depreciated and no depreciation cost has been included in the budget for the next three years. Fees will need to increase to cover the cost of

depreciation when the system is replaced.

3.2.2 Medicines Control

Medicines Control has a forecast expenditure budget of $1.9 million (GST excl) for the 2008/09 year of which approximately $1.7 million is budgeted to come from fees for applications for licences under the Medicines Act 1981 (to sell medicines by wholesale or retail, hawk medicines or operate a pharmacy) and licences issued under the Misuse of Drugs Act 1975.

The costs for these licensing activities are expected to remain static in the short term, with increases in personnel and operating expenses expected to be offset by efficiencies in the licensing process. Consequently the fees for these licences will not change.

3.3 Medsafe's estimated operating budget

The total forecast expenditure in 2008/09 is $12.29 million GST exclusive. The break-down of this expenditure is shown in Table 1.

Table 1: Forecast expenditure for Medsafe		
AREA	**2008/09 FORECAST EXPENDITURE ($' million)**	**% of total**
Personnel costs	$5.50	45%
Operating costs	$5.25	43%
Corporate overheads	$1.54	13%
Total	**$12.29**	

The forecast expenditure has been allocated to outputs that are either recoverable from industry or are funded by the Crown, as detailed in Table 2.

Table 2: Forecast expenditure by output for Medsafe	
OUTPUT	**2008/09 FORECAST COST ($' million)**
New Medicine Applications – medicine containing a new drug substance	$1.45
New Medicine Applications – prescription medicine not containing a new drug substance	$2.09
New Medicine Applications – non-prescription medicine	$0.53
Changed Medicine Notifications	$2.75
Clinical Trials	$0.58

Manufacturing Assessment (manufacturer and packer licensing)	$0.55
Total Industry Funded Activities	**$7.95**
Crown Funded Activities	$4.34
Total	**$12.29**

3.4 Memorandum accounting

Medsafe introduced a memorandum account for industry revenue effective 1 July 2007. It is expected that there will be a $1.2m surplus in revenue in the 2007/08 year, predominately due to the establishment of ANZTPA being placed on hold in July 2007. To adjust for this surplus in revenue, Medsafe is setting the fee levels for the next three-year period based on predicted 2008/09 year expenditure. This means there is a projected deficit in revenue in the 2009/10 and 2010/11 years that will offset the surplus revenue in 2007/08. The projected deficit over the three-year period is $1.04m, leaving a projected remaining surplus of $0.16m. This has been done to offset the risk of lower than projected application volumes over this period, but the continued use of the memorandum account will ensure that over time, revenue collected will equal the costs incurred.

4. Proposed changes to fee levels and the way fees are applied

4.1 Applications for approval of new medicines and related products

A standard fee is currently charged for an application for approval of a single dose form of a new medicine or related product. An additional fee is charged for each additional strength or flavour of that dose form.

It is proposed that a standard fee would continue to be payable for an application for approval of a single dose form of a new medicine or related product. However, where an application is made, at the same time, for one or more additional strengths or flavours of the medicine or related product, or for an additional trade name to be registered for the product, it is proposed that no additional fee will be charged.

The single fee would apply **only** when the applications for the additional strengths, flavours or names are made at the same time as the first application. Subsequent applications for approval of additional strengths, flavours or trade names would continue to attract a fee.

A fee would continue to apply to an application relating to an additional dose form of a medicine or related product, regardless of whether the application is submitted at the same time as the 'parent' application or subsequently. Such an application is processed as a separate new medicine or related product application.

The following tables show the current and proposed fees for each type of new medicine or related product application. Where a waiver is applied routinely in recognition of the

amount of work involved in considering an application of that kind, the fee shown in the table is the actual fees payable (after application of the waiver), and not the fee stated in the Medicines Regulations 1984.

4.1.1 New medicine containing a new drug substance

Table 3: Fees for applications for approval of new medicines containing new drug substances			
Application description	**Current fee (GST Inclusive)**	**Proposed Fee (GST Inclusive)**	**Estimated annual volumes**
A **full** application for consent under Section 20 for a single dose form of a new medicine containing a new drug substance, with any number of additional strengths, flavours or product names	$122,625[1]	$88,875	9
An **abbreviated process** application for consent under Section 20 for a single dose form of a new medicine containing a new drug substance, with any number of additional strengths, flavours or product names	$33,750	$33,750	17
An application for **provisional** consent under Section 23 for a new prescription medicine, with any number of additional strengths, flavours or product names	$8,437	$16,875	8
An application for **renewal** of the provisional consent granted for a medicine	$500	$1,000	21
An application for consent under Section 20 for a medicine for which provisional consent is currently granted	Full fee less $8,437	$33,750	0

The 28% decrease in the fee for an application for approval of a new medicine containing a new drug substance from $122,625 to $88,875 reflects the fact that the fee set in 2006 was intended to substantially cover the cost of completing the work, to international best-practice standards, in the joint regulatory environment. The proposed fee is intended to recover the costs incurred by Medsafe in administering current legislation using existing resources.

Application volumes have a significant impact on the level of fee required to recover the costs associated with maintaining capacity to deal with such large and complex applications. Uncertainty around application volumes for new prescription medicines is exacerbated by the fact that Medsafe has recently introduced an abbreviated process application and approval process for medicines already approved by a recognised overseas regulator. It is proposed that the fee for an abbreviated process application will remain at the level set when the abbreviated process was introduced.

[1] Additional fee payable for additional strengths, flavours etc.

The level of uptake of the abbreviated process is not yet known, but it has been assumed (based on estimates provided by industry in late 2007 in relation to anticipated volumes of full and abbreviated process applications) that 65% of an estimated 26 applications for approval of new medicines containing a new drug substance will be abbreviated process applications.

4.1.2 New prescription medicine that does not contain a new drug substance

Table 4: Fees for applications for approval of new prescription medicines that do not contain a new drug substance

Application description	Current fee (GST Inclusive)	Proposed Fee (GST Inclusive)	Estimated annual volumes
A **full** application for consent under Section 20 for a single dose form of a new prescription medicine that does not contain a new drug substance, with any number of additional strengths, flavours or product names	$43,875[1]	$43,875	40
An **abbreviated process** application for consent under Section 20 for a single dose form of a new prescription medicine that does not contain a new drug substance, with any number of additional strengths, flavours or product names	$16,875	$16,875	35
An application for an additional strength, flavour, classification, combination pack or trade name submitted separately, where this application includes the registration of a new method of manufacture, or is supported by the submission of bioequivalence or clinical studies	Up to $20,000	$16,875	3
An application for an additional strength, flavour, classification or trade name submitted separately, where the application is not supported by the submission of bioequivalence or clinical studies	Up to $6,400	$2,400	4

A review of costs has indicated that the current fee for approval of a new prescription medicine that does not contain a new drug substance should remain unchanged at $43,875 for a full application as this would achieve cost recovery if volume assumptions are correct.

The uncertainties around application volumes described in section 4.1.1 also apply to applications for new prescription medicines that do not contain a new drug substance. The level of uptake of the abbreviated process for these medicines is not yet known, but it has been assumed that just under half of an estimated 75 applications will be abbreviated process applications.

[1] Additional fee payable for additional strengths, flavours etc

4.1.3 New non-prescription medicine

Table 5: Fees for applications for approval of new non-prescription medicines			
Application description	**Current fee (GST Inclusive)**	**Proposed Fee (GST Inclusive)**	**Estimated annual volumes**
An application for consent under Section 20 for a single dose form of a new non-prescription medicine, with any number of additional strengths, flavours or product names, where the application is supported by the submission of bioequivalence or clinical studies	$7,650	$16,875	0
An application for consent under Section 20 for a single dose form of a new non-prescription medicine, with any number of additional strengths, flavours or product names, where the application is not supported by the submission of bioequivalence or clinical studies	$7,650[1]	$10,350	40
An application for an additional strength, flavour, classification, or trade name submitted separately	Up to $6,400	$2,400	37

It is proposed that the application fee for a new non-prescription medicine (where the application is not supported by bioequivalence or clinical studies) should increase by 35% to $10,350 in order to recover the costs of dealing with applications of this type. The increase has resulted from overall cost increases and a re-balancing of cost allocations.

4.1.4 New related product

Table 6: Fees for applications for approval of new related products			
Application description	**Current fee (GST Inclusive)**	**Proposed Fee (GST Inclusive)**	**Estimated annual volumes**
An application for consent for a new related product, with any number of additional strengths, flavours or product names	$5,500[1]	$5,500	17
An application for an additional strength, flavour, or trade name submitted separately	Up to $5,500	$2,400	8

[1] Additional fee payable for additional strengths, flavours etc

4.2 Applications for approval of changes to medicines or related products

Medsafe proposes to make changes to the way in which fees for changed medicine notifications are calculated in order to simplify the administrative processes associated with preparing and processing applications. This is expected to reduce compliance costs for applicants as well as improving administrative efficiency for Medsafe.

Currently, each type of change has a specific fee. Under this proposal, the types of changes required to be notified are divided into four categories (major, medium, minor and self-assessable). A list of changes proposed for inclusion in each changed medicine notification (CMN) category is provided in Appendix 1 to this paper. Different fees would apply to notifications in each of the four categories as shown in Table 7.

Whilst the Medicines Regulations specify a single fee for changed medicine notifications, a standard waiver would be applied to reduce the fee to the level indicated in Table 7.

Table 7: Changed medicine notification categories and fees

CMN Category		Proposed Fee
Category A	Major changes that represent the largest evaluation workload	$2,400 for ***each*** Category A change (Fee does not cover any other changes notified at the same time).
Category B	Medium changes that represent an intermediate evaluation workload	$1,600 for ***up to two*** Category B changes notified at the same time
Category C	Minor changes that represent a smaller evaluation workload	$800 for ***up to three*** Category C changes notified at the same time
Category D	Self-assessable changes	$400 for **each product** affected by a change or identical set of changes notified at the same time

The fees are based on the amount of work involved in considering an application of that kind. It is proposed that minor (Category C) changes may be grouped, with up to three changes covered by a single $800 fee. A second $800 fee would apply if more than three changes were made. For example, if a single notification included five Category C changes, the fee would be $1,600. If a notification included one, two or three Category C changes and one or two Category B changes, the fee would be $2,400 ($800 plus $1,600).

Where a change or set of changes affects additional strengths of the same dose form of a product in an identical manner and is supported by the provision of a single dataset, a single fee will apply.

Where a change or set of changes affects more than one product in an identical manner, and a complete and identical set of supporting documents is supplied for each product affected, a single fee will apply. This means that there would no longer be an administrative fee for additional products affected by the same change(s), and the concept of 'consequential changes' would no longer apply.

Where a change or set of changes affects a range of products or product strengths, but requires the provision of different datasets, then each change must be applied for separately for each product or strength.

The $400 fee for Category D (self-assessable) changes would not apply if self-assessable changes were notified at the same time as any Category A, B or C changes to the same product.

The option of choosing more than one change for a single fee replaces both the administrative fees previously charged for additional products and the submission of 'consequential changes' for the same fee.

4.3 Application for approval of a clinical trial

The current and proposed fees for an application for approval of a clinical trial are shown in Table 8.

Table 8: Fee for an application for approval of a clinical trial

	Current fee (GST Inclusive)	Proposed Fee (GST Inclusive)	Estimated annual volumes
Application for approval of a clinical trial	$9,843	$6,525	105

It is proposed that the fee to accompany an application for approval of a clinical trial should decrease by 34% to $6,525 as a result of a re-balancing of cost allocations.

4.4 Application for a licence under the Medicines Act 1981

It is proposed that, with the exception of the licence to pack medicines, fees to accompany licence applications would remain unchanged. The licence to pack medicines is proposed to increase by 60% to $1,356 in order to recover the cost of processing an application, including auditing of the premises.

It is also proposed that the entry in Schedule 5A to the Medicines Regulations 1984 relating to a combined licence to pack and sell medicines by retail should be removed as such combined licences are no longer issued. Table 9 shows the current and proposed fees for each type of licence issued under the Medicines Act 1981.

Table 9: Proposed fees for applications for licences issued under the Medicines Act 1981		
Application type	**Current fee (GST Inclusive)**	**Proposed Fee (GST Inclusive)**
Licence to manufacture medicines	$13,750	$ 13,750
Licence to pack medicines	$ 845	$ 1,356
Licence to sell medicines by wholesale	$ 1,054	$1,054
Licence to sell medicines by retail	$ 845	$ 845
Licence to hawk medicines	$ 845	$ 845
Licence to operate a pharmacy	$ 1,030	$ 1,030

4.5 Other fees specified in Regulation 61

It is proposed that the fees specified in subclauses (2), (9) and (10) of regulation 61 of the Medicines Regulations 1984 would remain unchanged.

APPENDIX 1

CHANGED MEDICINE NOTIFICATIONS - PROPOSED CATEGORIES

Note:

(1) Each dot point under a heading describes a separate change to which a fee would apply.

(2) Any notifiable change to a Related Product is a Category C change.

Category A: Major changes
Formulation • where the change is required to be supported by bioequivalence, stability or safety data
Active ingredient • new manufacturing site, where the provision of a Drug Master File or equivalent is required
Finished product • new manufacturing site • manufacturing process involving a change to the type of process used
Indications/dosage • change to indications or dosage unless specified in Category C
Contraindications, Warnings and Precautions • relaxation of contraindications, warnings or precautions (clinical data required)

Category B: Medium changes
Formulation • any change not specified in Category A or Category C
Active ingredient • changed manufacturing process/route of synthesis • change to any single step in the manufacturing process for a biological medicine • new site of lyophilisation or revalidation of a lyophilisation site for a biological medicine
Active ingredient specifications/test methods • change to the method used to assay potency • change to the specifications used to describe potency • change to the standard used in assessment of potency for a biological medicine ingredient • change to the method used to assess other physical or chemical properties of a drug substance • addition, removal or change of a specification used to describe physical or chemical properties of a biological medicine

Finished product

- adoption of different specifications/test methods for product controlled according to a pharmacopoeial monograph
- revised specifications/test methods for product not controlled according to a pharmacopoeial monograph
- manufacturing process change where there is no change to the type of process or type of equipment used

Product stability and packaging

- revised shelf life and/or storage conditions
- new container or closure type
- new pack size and/or packaging material with supporting stability data

Category C: Minor changes

Product name

Formulation

- updating the strains for an influenza vaccine

Active ingredient

- new manufacturing site for a non-prescripition medicine
- new manufacturing site where an EU Certificate of Suitability is provided
- changed manufacturing process where an EU Certificate of Suitability is provided
- changed batch size, retest period, or intermediate material supplier or specifications
- changed specifications and test methods other than for a biological medicine

Excipient

- specifications and test methods

Finished product

- packing site

Indications/dosage

- revised wording but no actual change to indications or dosage
- new or revised indications for a generic medicine to match those approved for the innovator

Labelling

- any labelling change not specified in Category D (i.e. not self-assessable)
- request for labelling exemption or renewal of labeling exemption

TSE risk

- potential increase in the TSE risk status of any ingredient in the product

Category D: Self-assessable changes
Active ingredients • tightening of specification limits
Excipient • revised specifications/test methods for a substance controlled according to a pharmacopoeial monograph as a result of an updated monograph or a change to compliance with a different pharmacopoeial monograph
Finished product specifications/test methods • revised specifications/test methods for a product controlled according to a pharmacopoeial monograph (as a result of an updated monograph or a change to compliance with a different pharmacopoeial monograph) with no change in manufacturing process, dissolution or bioavailability • tightening of limits for active substance • adoption of additional specifications/test methods
Product stability and packaging • decrease in storage temperature from <30°C to <25°C • new pack size where a stability study is not required and there is no effect on dose delivery or dose measurement
Data sheet • editorial changes that do not include a change to approved product details • update to, or addition of, safety information • expansion of pharmacodynamic or pharmacokinetic data
Labelling • redesign of label with no change to product name, expression of strength, dose form, dosage instructions or indications
Other • change of sponsor