

Ministry of Health

Report on the Fees Review Exercise in
Relation to Medsafe

April 2008

30 April 2008

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Acting Manager
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PO Box 5013
WELLINGTON

Dear Susan

Medsafe Fees Review Exercise

In accordance with our terms of engagement dated 9 April 2008, we have prepared the attached brief report on the fees review Medsafe has undertaken with regard to its proposed level of fees under the Medicines Act 1981 for a three year period from Financial Year (FY) 2009 – FY2011.

The scope and basis of our work is set out in the attached report. Our review was carried out in the period 9 April 2008 to 24 April 2008.

Should you have any queries or require any additional information please do not hesitate to contact us.

Yours sincerely,



Alan Dent
Partner

Table of Contents

1.	Introduction and Scope	1
2.	Background	2
3.	Basis of Calculation	3
3.1.	Introduction.....	3
3.2.	Medicines Control	3
3.3.	Evaluations and Compliance Licensing.....	5
4.	Areas of Judgement.....	7
4.1.	Medicines Control	7
4.2.	Evaluations and Compliance Licensing.....	8
5.	Areas of Concern.....	11
5.1.	Medicines Control	11
5.2.	Evaluation and Compliance Licensing	11
6.	Guideline Compliance.....	13
7.	Conclusion.....	14
6.	Restrictions and Disclaimers.....	15
6.1	Post Date Events	15
6.2	Restrictions	15
6.3	Purpose of Report	15
6.4	Information	15
6.5	Disclaimer.....	16
	Appendix 1 – Information Sources.....	17
	Appendix 2 – Issues Register	18

Glossary of Terms

RMI	Researched Medicines Industry Association Inc.
Medsafe	New Zealand Medicines and Medical Devices Safety Authority
MCO	Medicines Control Officers
GST	Goods and Services Tax
FTE	Full Time Equivalent (employees)
FY	Financial Year

1. Introduction and Scope

Deloitte has been engaged by the Ministry of Health (“MOH” or “the Ministry”) to undertake an independent scrutiny of the Ministry’s review of fees set under the Medicines Act 1981. The fees relate to functions that are administered by Medsafe (applications to approve new and changed medicines and related products and clinical trials, or applications for a manufacturing or packing licence), or by Medicines Control Officers (licences to sell medicines by wholesale, licences to retail or hawk medicines, or pharmacy licences). Deloitte has been asked to independently review the new charges and the basis for these, as a means for Medsafe satisfying stakeholders that the new charges are fair and reasonable.

Specifically, Deloitte was engaged as an independent party to:

- review the costing model used to derive fee levels;
- comment on the appropriateness of the methodology and underlying assumptions;
- confirm that the process complies with the following guidelines:
 - 2002 Treasury Guidelines for Setting Charges in the Public Sector;
 - 1989 Audit Office Guidelines on Costing and Charging for Public Sector Goods and Services;
 - five general principles established in reports of the Regulations Review Committee.

This report describes the approach we have followed, identifies any issues or concerns; and sets out our opinion as to the reasonableness of the level of fees set and the basis for these.

As part of our review of the calculations that support the proposed Medsafe fees review, we have:

- Reviewed the computational accuracy of the costing models;
- Checked the consistency of the calculations with assumptions documentation provided to us by Medsafe;
- Where possible, verified input assumptions against source data; and
- Documented any issues we identified in the issues register attached in Appendix Two of this report.

Our Process has included a review of various documents set out in Appendix One provided to us by Medsafe. We have also met with Brian Strickland to discuss our preliminary questions.

2. Background

The Ministry is responsible for administering the Medicines Act 1981 in New Zealand. Regulatory functions are performed by Medsafe (a business unit of the MOH) and by Medicines Control Officers located within the Ministry but external to Medsafe. Medsafe has two offices in New Zealand, employing 70 staff. It has a total budget of \$11 million of which approximately \$8 million is from fees charged to the industry under the Medicines Act, 1981.

Charging to third parties is governed by regulations set under the Medicines Act 1981. The Medicines Act provides for the charging of fees in relation to applications for the approval of new and changed medicines and clinical trials and for licences to hawk, wholesale and retail medicines as well as pharmacy licences. These fees were most recently reviewed in 2006 as part of the process anticipating the formation of a joint trans-Tasman Australia New Zealand Therapeutic Products Authority.

The structure of the charging scheme has changed since the most recent review, particularly in the classification of applications and the charging conditions under each application type, making direct comparison of the movement in fees difficult. We have concentrated on assessing the consistency of the calculation process, rather than the relative movements in fees or allocated costs.

The application fees that can be compared are outlined in the table below:

Application Type	Current Fee (incl. GST)	Proposed Fee (incl. GST)
Licence to Wholesale	1,054	1,054
Licence to Hawk	845	845
Licence to Retail	845	845
Pharmacy Licence	1,030	1,030
High Risk Full Fee	122,625	88,875
High Risk Abridged Fee	33,750	33,750
High Risk Additional Dose	43,875	43,875
Intermediate Risk Full Fee	43,875	43,875
Intermediate Risk Abridged Fee	16,875	16,875
Low Risk Full Fee	7,650	10,350
Low Risk – New Related Product	5,500	5,500
Self Assessable Change	400	400
Minor Change	800	800
Major Change	3,200	2,400
Clinical Trials	9,843	6,525
Manufacture Licence	13,750	13,750
Pack Licence	845	1,356
Compliance Audit	135 per hour	169 per hour

3. Basis of Calculation

3.1. Introduction

The objective of the Ministry fees review project is to:

- develop a 3 year expenditure budget for Medsafe and MCOs;
- allocate the expenditure budget to outputs that are either Crown or industry funded; and
- use the costs for the industry funded outputs as the basis to set fees for the 3 year period.

The review covers all fees set under the Medicines Act 1981, including all fees charged by Medsafe and licence fees to sell medicines by retail, wholesale, and hawk, which are charged by the Medicines Control Officers (MCO).

The two general groups of fees set and administered by the Ministry are:

1. Medicines Control; and
2. Evaluation Activities and Compliance licensing.

3.2. Medicines Control

The Medicines Control fees review model covers applications for:

- Wholesale licences
- Licences to Hawk
- Retail Licences
- Pharmacy Licences

The Medicines Control (MCO) model calculates the proposed licensing fees for the next three years based on FY2008 operating costs and FY2009 personnel costs.

The model takes the MCO 2007/08 operating budget and allocates these costs to each type of licence application based on the number of FTEs involved in each activity. In addition, personnel costs are allocated to each licence type based on the average cost per FTE and the proportion of FTEs required to process each application type.

The number of FTEs required for each licence type is calculated based on assumptions regarding the annual volume of applications, the hours required to process each type of application, and staff productivity levels.

The MCO operating budget supports 18.79 FTEs; 13.6 of whom can be allocated to a particular licensing activity and 10.6 of these are involved in processing applications under the Medicines Act. The remaining 3 licence specific FTEs work on licences categorised under the Misuse of Drugs Act and hence are outside the scope of this engagement.

The proportion of the MCO operating budget that is not allocated to a specific licensing activity is funded by the Crown e.g. Drug Abuse Containment, enforcement/prosecutions, and proportionate costs for the 6 FTEs that are not allocated to a specific licence.

Assumptions

The key assumptions for the MCO model include:

- Operating costs and overheads remain constant at 2007/08 levels
- Personnel costs remain constant at 2008/09 levels
- Salary growth from 2007/08 to 2008/09 = 3.1%
- Staff training = 3% annual salary cost
- ACC = 0.6% annual salary cost
- Superannuation = 6% annual salary cost
- Staff productivity = 80%
- Average working day = 7 hours 35 minutes
- Working days per year = 222
- Licence volumes stay constant at 2006/07 levels
- Hours to process each application type unchanged from last fees review round.

The model accurately incorporates the assumptions as documented in the information provided to us by the Ministry in the file titled *Medicines Control Fees methodology.doc*.

3.3. Evaluations and Compliance Licensing

The Evaluations and Compliance Licensing fees review model covers applications for:

- High Risk Medicines (Full fee, Abridged fee, Additional dose, Type 1 additions, Provisional consents, Provisional consent renewals)
- Intermediate Risk Medicines (Full fee, Abridged fee, Line extensions Type 1)
- Low Risk Medicines (Full fee, Line extension Type 2, New related product)
- Change Notifications (Major, Medium, Minor)
- Clinical Trials
- Licences to Pack Medicines
- Licence to Manufacture Medicines
- Compliance Audits

It should be noted that Compliance Audit fees are not under regulation but are included in the model reviewed by us.

The fees review model splits Medsafe's costs into Industry and Crown funded costs, with the Industry funded costs being allocated to different licence types on a proportionate FTE basis.

Revenue from each application type was calculated based on estimates of future application volumes and the proposed level of fees. These revenues were then matched against the allocated industry funded costs for each application type, and the level of fees adjusted to ensure that industry members are not overpaying for the services and that Medsafe would be able to recover its costs in the next three years.

Assumptions

The key assumptions for the evaluations and compliance licensing model are outlined in the review documentation provided by Medsafe titled *Fees Review 2008 summary.doc*. As part of this engagement, we have reviewed the consistency of the evaluations and compliance licensing models with the documentation. Our comments are outlined below.

Personnel Costs

The assumptions discussed in the review documentation for the increase in salaries, training, ACC, annual leave and temporary staff are in line with the calculations in the expenditure model.

Superannuation is based on each employee's own current scheme. There are a few minor errors in the current calculation of superannuation, as referenced in the issues register in Appendix Two. Kiwisaver has not been considered in the model. This is discussed further under section 5.

Operating Costs

The assumptions discussed in the review documentation for general operating costs are in line with the calculations in the expenditure model.

The change in occupancy costs has been correctly calculated in the model, but both the increase in value and percentage difference is incorrectly reported in the review documentation. This is mentioned in the issues register in Appendix Two.

The total prosecution budget in FY2008 was \$200,000 which incorporated \$50,000 for compliance and \$150,000 for investigations. The review documentation states that the new budget in FY2009 of \$160,000 is slightly higher. This is true for the investigation budget itself, but overall the prosecution budget is lower than in FY2008.

All other assumptions mentioned in the review are incorporated correctly in the model. However the following specific costs are not mentioned in the review documentation:

- The Medicines Adverse Reactions Committee has the 2007/08 budget of \$43,000 set for the following three years;
- The publishing (prescriber update) cost is set at the 2007/08 budget of \$50,000 for the following three years;
- The Medicines Classifications Committee has an increased budget from \$16,000 to \$25,000 for the following three years;
- Medical Devices (inc WAND) has an unchanged budget of \$67,000 for the following three years;
- Inspection Audits has an unchanged budget of \$60,000 for the following three years;
- The Medicines Assessment Advisors Committee has an unchanged budget of \$340,000 for the following three years.

Through discussion with Medsafe we are confident that these costs are accurately incorporated in the model.

Revenue assumptions

Due to the abridged fees being introduced in March 2008 for applications under a revised business role, the model assumes these fees have not been changed. The full fees, however, have been adjusted to ensure they reflect the increased time and cost required to complete the applications. The full fees are also adjusted to ensure that the higher, intermediate and lower risk applications have the correct relative fees for the relative time taken for each.

In the updated version of the fees review model provided to us (*Medsafe 2008 fees review – Revenue v2.xls*) Medsafe updated the fees and application categories for line extension and subsequent additional strength applications. There are now two types of line extensions, Type 1 which is for major additions that apply to high and intermediate risk applications and Type 2 which is for minor additions that apply to low risk applications. The Type 1 charge is based on the abridged intermediate risk application fee and the Type 2 charge is based on the major change notification fee (and is only marginally higher than in the original model). These updated volume and fee assumptions need to be incorporated into the review documentation.

4. Areas of Judgement

We were asked to review the costing models for computational accuracy, consistency against the stated assumptions, and to reconcile input data back to source documents.

Appendix Two sets out the results of this review outlining any errors we identified and whether they have an impact on the final outputs.

We were also asked to discuss any key areas of judgement in the calculation of the proposed fees and comment on the appropriateness of the methodology and underlying assumptions.

The following is a discussion of the appropriateness of the methodology and key areas of judgement.

4.1. Medicines Control

Cost base

The Medicines Control model calculates the proposed level of fees for the next three years based on the FY2008 MCO Operating Budget and FY2008 personnel costs escalated to FY2009 figures.

At present the FY2009 other personnel costs (e.g. training, ACC, Superannuation) are incorrectly calculated. This is further discussed in the issues register in the Appendix Two.

However, despite this calculation error, the proposed level of fees for the three years to the end of FY2011 are calculated based on FY2008 costs with no escalation for future cost growth built into the fees. In addition, the personnel costs are based on FY2009 costs with no further escalation for the FY2010 and FY2011 years built into the calculation. This means that while the MCO will cover its current costs, there is no allowance for future cost growth built into the proposed fees and the Ministry risks running at a loss for these licence applications in out years.

Medsafe advised us that MCO is currently under-spending its operating budget by approximately 9% and this margin is considered sufficient to cover any cost increases over the coming three years.

Hours per Application

A key judgement area in the calculation of the proposed application fees is the assumptions around how long it takes to process each application. The wholesale and pharmacy licences are estimated to take 10 hours each, and the retail and hawk licences are assumed to require 8 hours each. These assumptions have not changed since the previous fees review, and when asked what further testing of these assumptions has occurred since the last review, Medsafe advise that there has been no significant change in any process that would necessitate these assumptions being changed.

We believe this rationale to be appropriate, however we note that these assumptions are key drivers of the cost of each licence and hence if the time is underestimated, the Ministry carries the risk of under recovering costs and vice versa.

4.2. Evaluations and Compliance Licensing

High-Risk Medicine Application Volumes

A key judgement area in the calculation of the high-risk medicines application fee is the volume assumptions for the new abridged and current full fee applications. There is no historical evidence of the volume impact of introducing an abridged fee, so Medsafe asked the Researched Medicines Industry Association (RMI) how many applications it expects to lodge in the next three years. Medsafe took the 2009 figure provided by RMI and increased this estimation slightly to account for the lodgement of applications by entities other than RMI. We believe the methodology applied to develop these volume assumptions is appropriate, notwithstanding the errors noted in the issues register in Appendix Two.

Intermediate-Risk Medicine Application Volumes

The assumed number of intermediate-risk medicine applications is 70 per annum. This has been estimated using the volume for full fee applications from the last three years, however due to the unusually high volumes in 2006 (prior to the previous fees review), it has been assumed that the volumes from the last three years are more representative of four standard years. We are satisfied that this assumed volume for intermediate-risk applications is appropriate in light of the long term average volume for intermediate-risk medicine applications.

The type of applications has been split in half with 35 expected to be full applications and 35 abridged applications. This is an approximation, as no historical data is available for the number of abridged fees. Medsafe has advised us that the proportionate split between full and abridged applications is not analogous to the historical relationship between full and non-full fee applications and hence this volume split is a key judgement area for the intermediate risk applications - reliant solely on the professional judgement of senior Medsafe staff. There is no historical basis on which we can assess the reasonableness of this proportionate volume estimation.

Low-Risk Medicine Application Volumes

Medsafe has estimated the low-risk medicine application volumes over the next three years to be equivalent to the average volume over the period 2001 – 2007. We are satisfied that this methodology is appropriate and has been accurately applied in the fees review models.

Changed Medicine Application Volumes

There is currently a fee for each type of changed medicine notification application. Medsafe has reviewed the change notification categories and has developed a new system. There are now three different categories of change notifications – minor, medium and major changes. For a minor change, three changes are allowed per notification. For a medium change, two changes are allowed and for a major change, one change is allowed.

In the updated fees review model (*Medsafe 2008 fees review – Revenue v.2.xls*) Medsafe has taken historical CMN notification volume data and identified the number of changes made per notification in order to assess what volume of historical notifications would be charged under each new category of the new scheme. These volumes have been used as estimates for the three year period.

There is a high degree of judgement required to estimate and sense check these volumes, particularly because it is difficult to predict what incentives this new notification system will create for industry and therefore what changes in behaviour it may drive. We are satisfied however, that Medsafe has analysed historical data in sufficient detail to have made reasonable estimations of future volumes for each change notification category.

Clinical Trial and Manufacturing Assessment Application Volumes

We are satisfied that the methodology applied to develop the volume assumptions for Clinical Trials and Manufacturing Assessments (Pack and Manufacture Licences and Audits) is appropriate and reasonable.

Cost Recovery and Specific Application Fees

Cost Recovery

A key judgement area for the Evaluation fees model is the individual level of fees set for each specific application type or sub-type. The fee for each application category (e.g. high, medium, low risk medicines) has been calculated on a cost recovery basis at an aggregate level. However each application sub-type (e.g. full fees, abridged fees, provisional consents, major change, minor change etc) has not been individually costed. This means the proposed level of fees will cause Medsafe to break-even at an aggregate level over the next three years; however fees from one application sub-type may be subsidising the costs of evaluating another sub-type within each application category.

Costing data is not available in sufficient granularity, nor is it meaningful, to estimate the cost of each specific application sub-type because in reality costs (e.g. personnel costs) are incurred by the higher level application type rather than each specific sub-type. Hence we are satisfied that the level of detail applied to calculating the cost recovery basis for each fee type, while not precise down to each application sub-type, achieves the purpose of cost recovery for Medsafe as a whole.

Specific Application Fees

The fees calculated for each application sub-type have been estimated relative to a base fee – either the existing abridged fee or the existing major change notification fee. Senior Medsafe staff have estimated the level of effort each application sub-type requires relative to the base fee, and have set application fees accordingly.

For example: a high risk abridged application has been held constant at \$30,000 (excl. GST). A high risk full fee is expected to require more than twice as much effort as an abridged application but less than three times, hence the full fee is set at \$79,000 (excl. GST). A full fee intermediate risk application is set at the same price as a high risk additional dose application because the relative effort to process these applications is the same. Also, the minor change notification application has been held constant at \$711 (excl. GST), the medium change notification is twice the price and the major is three times the price.

This fee setting methodology is not an exact science, however we are confident that relying on the professional judgement of the Senior Medsafe staff to assign relative effort levels to each application sub-type is an adequate approach, particularly given the fact that at an aggregate level the proposed fees are recovering Medsafe's costs over the three year period.

Backlog

Medsafe has provided \$500k out of a separate budget to cover the cost of processing the current backlog of applications.

In addition, Medsafe has included \$200k of additional costs in FY2010 and FY2011 to allow for the procurement of external resource on an ongoing basis to manage the peaks and troughs of application flow and the impact of this on Medsafe personnel. This \$200k provision is allocated on a proportionate FTE basis across all evaluation licence types in the model. We consider this appropriate given the focus of this external assistance is on a range of evaluation licences depending on where Medsafe is under the most pressure at any point in time.

5. Areas of Concern

The areas we have identified that are of outstanding concern in relation to the proposed fees are identified below.

Kiwisaver

Superannuation is currently considered only for those on public sector superannuation plans. There has not been any provision for Kiwisaver schemes within the costing models. We have been advised that the Ministry of Health plans to provide the standard 1% to employees in Kiwisaver in the 2008 year, rising to 4% by 2011. Current public sector super schemes provide 3% from the employer so there is unlikely to be a high uptake of Kiwisaver until at least 3% is provided for in 2010. Currently there is no provision made in the costing models for the potential impact of Kiwisaver from FY2010 onwards, nor for the sign up of new employees (who will need to opt out and into the public sector super scheme if they want to receive a higher contribution).

5.1. Medicines Control

Medicines Control Cost Base Assumptions

The Medicines Control fees review model calculates the licence fee for the coming three years using FY2009 personnel costs. In order for the fees to operate on a cost recovery basis, the model implicitly assumes that personnel costs will remain constant for FY2010 and FY2011. In reality this is unlikely and it does not align with the assumptions in Medsafe's evaluation fees calculation where salaries are assumed to increase 3.1% per annum.

We understand the rationale applied by the Ministry, in relation to the constant FY2008 operating cost base used to calculate Medicines Control fees. We note however that there is potential for the MOH to under recover on these fees if operating costs increase by more than 9% over 3 years.

5.2. Evaluation and Compliance Licensing.

Recruitment Costs

We have been advised by Medsafe that the \$50,000 cost each year for recruitment is sufficient for an average year. However in FY2009 there are six vacancies which need to be filled which Medsafe has advised is higher than an average year. We believe that the FY2009 year should have an increased recruitment budget.

Changed Medicine Notification Fees

The current fees review model estimates Medsafe will make a net loss in the order of \$910k in the three year period under review. Approximately 63% of this loss is generated from changed medicine notification applications which the model anticipates will generate a net loss of \$570k.

While we are happy with the method applied to calculating the volume of changed medicine notifications, a small increase in the fees could significantly reduce the loss generated by this notification category. Changed medicine notification revenue is most sensitive to the level of fees set for medium changes, and we believe that if the fees for the medium change notification were raised by 5% it would significantly reduce the loss this application type contributes to Medsafe as a whole. If the medium change fee is increased \$1500 (excl. GST) it would reduce the current \$570k loss by approximately \$200k over the three years.

Depreciation

The Medsafe Evaluation fees review model calculates depreciation based on the current Fixed Asset Register. Subject to the issues raised in the issues register in Appendix Two, this approach is standard practise. The concern we have however, is that the existing SMARTI database is currently fully depreciated and no allowance is being made for any future replacement costs of this system. Medsafe advise that if the system needs replacing this will cost approximately \$1m and will happen through a separate project budget.

We are comfortable with the current treatment given that industry has in effect already paid for the existing SMARTI system, however we acknowledge that at some stage the cost of replacing/upgrading the system will need to be recovered and will be a cost industry has to meet at that point in time.

Volume Risk

We are satisfied with the methodology applied by Medsafe in estimating application volumes for the three years under review, however we note that Medsafe carries the risk of under-recovery in the situation where volumes drop below estimated levels. Medsafe has calculated fees and volumes such that the \$1.2m surplus it is expecting to make in FY2008, will be offset by the losses incurred over FY2009 - FY2011, with the net effect being a small surplus over the three years.

Initially, Medsafe expected the proposed fees would come into effect from 1 July 2008. We have been advised that this is unlikely and hence Medsafe will continue to over recover its costs at the current fee levels for some of FY2009. This will increase the small surplus being made over the three year period. We believe this surplus will compensate Medsafe for the risk it carries should volumes fall in the next three years. Therefore we believe that on the grounds that the proposed fees are in effect no later than 1 April 2009, this surplus does not go against the cost recovery basis on which Medsafe is setting its proposed fees.

6. Guideline Compliance

Deloitte is required to confirm that the Medsafe fees review process has complied with the following guidelines:

- 2002 Treasury Guidelines for Setting Charges in the Public Sector;
- 1989 Audit Office Guidelines on costing and Charging for Public Sector Goods and Services; and
- Five general principles established in reports of the Regulations Review Committee.

Upon analysis of the above guidelines, we believe the following themes have been provided for in Medsafe's review:

- Treasury guideline 7.5 discusses the provision of Memorandum accounts. Memorandum accounts are to be used whenever possible. The key points which are relevant for Medsafe include:
 - Memorandum accounts allow an even-handed regime which allows for both short-term surpluses and deficits, consistent with a long-run perspective. This is Medsafe's intention over the next three years. It has provided for a surplus in FY2009 followed by two years of deficits.
 - The guideline states that Memorandum accounts should be used when third parties are to be charged for services provided on a full cost-recovery basis. This is the situation for Medsafe, providing services at a full cost-recovery basis.
- Treasury guideline 5.1 lists a number of objectives for user charges. We believe that these are all provided for by the review. As part of Ministry of Health policy, Medsafe reviews all contracts on a three yearly basis and puts these up for tender in order to satisfy the Treasury's objective that Medsafe actively look for new ways to lower costs and find appropriate providers.
- Audit Office Guideline 2 (a) discusses the basis of charging. The guideline states that where outputs can easily be divided into homogenous units the basis of charging a fee should be the average cost of the product or service being provided. If there is a large variation, average cost may not be the appropriate basis for fee calculation. We believe that charging an average cost for the applications is appropriate for Medsafe.

7. Conclusion

Our review of the proposed charging regime has led us to form the following conclusions:

- A number of significant changes have been applied to the structure of the charging regime administered by Medsafe, in particular to changed medicine notifications and the introduction of abridged fees for new medicines, making the estimation of future volumes difficult. It is especially difficult to accurately anticipate the impact of the structural changes on industry behaviour in lodging applications;
- Sufficient enquiry and analysis has been undertaken by Medsafe staff in developing the volume assumptions for each application type to satisfy us that all due diligence has been applied and that although inherently uncertain, the methodology applied is appropriate;
- Although the proposed fees cause Medsafe to incur a loss over the three year period, the use of a memorandum account to carry forward the net surplus generated in this current financial year and the beginning of FY2009 will cause Medsafe to achieve a net surplus over the three year period. We believe this surplus does not contradict the cost recovery basis on which Medsafe has set its fees, but rather provides a small degree of compensation and comfort around the risk it carries due to the uncertainty of application volumes and future costs.
- The static nature and lack of escalation built into the costing assumptions for the Medicines Control fees for the next three years, makes the risk of under-recovery for these fees more likely; and
- There are a number of computational errors contained in the fees review models as they stand that need to be corrected by Medsafe (see Appendix Two);

6. Restrictions and Disclaimers

6.1 Post Date Events

Our report is issued on the understanding that Medsafe and the Ministry of Health has disclosed to us all matters of which they are aware concerning Medsafe's current and future financial. We have no responsibility to update our work for events and circumstances occurring after that date but we will be pleased to discuss further instructions as may be required.

6.2 Restrictions

At our discretion, we reserve the right, but are under no obligation, to review all information or calculations included or referred to in our report and, if we consider it necessary, to review our conclusions in the light of any information existing at the date of our report which is disclosed to us or becomes known to us after that date.

6.3 Purpose of Report

We understand that the purpose of this report is to review the calculation of licensing fees.

Neither our report, working papers or other related documents produced as part of this assignment are intended for circulation or publication beyond the New Zealand Ministry of Health and the Minister, nor are they to be reproduced or used for any purpose other than that outlined above without our prior written permission in each specific instance.

The Ministry may release this report if requested to under the Official Information Act 1982, and the report is not to be used for any purpose other than that outlined above.

We will not assume any responsibility or liability for losses occasioned to the Ministry of Health or to any other parties as a result of the circulation, publication, reproduction or use of our report contrary to the provisions of this paragraph. In any event our total liability to all and any parties for any reasons whatsoever will be limited to the fee charged for this engagement.

6.4 Information

In preparing our report, we have relied upon and assumed, without independent verification, the accuracy and completeness of all information that has been available from public sources and all information that is furnished to us by the Ministry of Health.

We have evaluated that information through analysis, enquiry and examination; however, we have not verified the accuracy or completeness of any such information nor conducted an appraisal of any assets or liabilities. We have not carried out any form of audit on the accounting or other records of the Ministry of Health.

6.5 Disclaimer

In no way will we guarantee or otherwise warrant that any forecasts of future profits, cash flows or financial position of Medsafe or the Medicines Control Team will be achieved. Forecasts are inherently uncertain. They are predictions of future events which cannot be assured. They are based upon assumptions, many of which are beyond the control of the management of the Ministry of Health or Medsafe. Actual results will vary from the forecasts and these variations may be significantly more or less favourable.

Under no circumstances shall we be liable for any loss, damage, cost or expense whatsoever or howsoever, caused, incurred, sustained or arising from fraudulent acts or misrepresentation or wilful default on the part of the Ministry of Health or Medsafe, including its advisors or employees.

Appendix 1 - Information Sources

Information Sources:

- Medicines Control Fees Methodology.doc
- Fees Review 2008 summary.doc
- Medsafe 2008 fees review – Expenditure.xls
- Medsafe 2008 fees review – Revenue.xls
- Medsafe 2008 fees review – Revenue v2.xls
- Medicines Control fees review 2008.xls
- Medicines Control fees review 2008 v.2.xls

Appendix 2 - Issues Register

Issues Register – Medsafe Fees Review 2008

STRICTLY CONFIDENTIAL

FILES REVIEWED:	Medicines Control Fees Review 2008.xls	92.5 KB (Original Controlled Version)
	Medicines Control Fees Review 2008 v.2.xls	168 KB (Updated Version)
	Medsafe 2008 fee review - Expenditure.xls	713 KB (Original Controlled Version)
	Medsafe 2008 fees review - Revenue.xls	93 KB (Original Controlled Version)
	Medsafe 2008 fees review – Revenue v.2.xls	93 KB (Updated Version)
	Medicines Control Fees Review 2008 v.3 updated for Deloitte draft report.xls	168 KB (Corrected Version)
	Medsafe 2008 fee review v3 - updated for Deloitte draft report.xls	773 KB (Corrected Version)
	Medsafe 2008 fees review - Revenue v.3 updated for Deloitte draft report.xls	93 KB (Corrected Version)

Impact Key Outputs?:

- | | |
|---|--|
| Y | This issue flows through the model and has an impact on the key outputs contained on the key output worksheets and needs to be resolved |
| N | This issue does not flow through the model to the key outputs contained on the key output worksheets but should be resolved at a future date |

Ref #	Cell Ref	Label	Issue Raised	Impact Key Outputs?	Proposed Solution / Comment	Client Response	Resolved?
General Comment							
1.		Input formatting	General modelling best practise distinguishes between hardcoded input assumptions and calculated values by formatting the two differently. In these Medsafe models, there are many hardcoded values and input assumption cells that could be more easily identified by giving them a unique formatting style e.g. blue font, or a specific shaded cell colour.	N	This issue does not alter the key outputs at all, but simply helps to identify inputs against calculated values.	Agree - and have highlighted the input cells	Yes – apart from in Medsafe 2008 fees review – Revenue.xls, Workbook clinical trials, In cells F26 and G26 – both are purple highlighted but are not input cells
Medicines Control Fees Review 2008.xls							
Proposed Licensing Fees worksheet							
2.	Column H & Column M	GST & GST ex	Calculations give correct outputs however, hardcoded numbers are used for the GST calculations.	N	Have an input cell that references GST as being 12.5% and use this in the formula to keep the calculation dynamic.	Agree - have corrected	Yes
Productive Hours Calc worksheet							
3.	B11	Net working Hours/year	Hardcoded numbers	N	Add hours/day input cell and link formula to it.	Agree - have corrected	Yes

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Staff worksheet							
4.	Columns L, M & N	Training, ACC & Super	Training, ACC and Superannuation costs being used in the personnel cost calculation are being based off current salaries, but the wage costs are based off uplifted wages (by 3.1%).	Y	Calculate the Training, ACC and Super costs off the New Salary Base figures in column K.	Agree - and have changed. Adds \$2,451 of additional costs, so does not materially change the calculations	Yes
Medicines Control Fees Review 2008 v.2.xls							
MCO FTE Reconciliation							
5.	C21	Ministry Licence	This cell is not calculating properly. Now that the pharmacy licence fees are calculated in this spreadsheet, it can not be assumed that the total FTEs excludes pharmacy licencers.	N	This cell needs to reference the sum of all FTEs EXCEPT Pharmacy licencers.	Agree - MCO FTE Reconciliation has not been updated from previous review. Have changed the sheet now to compare Licence FTE requirements to the total MCO FTEs. Model shows that of the 18.79FTEs, 13.63FTEs are involved with licence activities, leaving 5.16 FTEs to do other Crown funded activities	Yes

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6.	C18	Total Pharmacy Licensing FTEs	This total does not match the number of FTEs allocated to Pharmacy Licensing in the fees calculation. This is probably because these cells have not been updated in this updated version of the fees model.	N	This cell needs to reconcile with the FTEs calculated in the Proposed Licensing tab.	Agree - see note 5	Yes
Medsafe 2008 fee review – Expenditure.xls							
Personnel Costs 0809							
7.	I6	Salary Increase Interim Manager	This salary does not increase 3.1% in 08/09. It is inconsistent with all other salary calculations	Y	Make formula consistent with other cells in column I. Formula should read =H6*3.1%	Disagree - The salary for the Interim Manager in 08/09 is higher than the current level (to allow for permanent to this position) so does not require the 3.1% annual increase in the first year.	Yes
8.	F94	Vacancies	The formula in this cell does not sum the correct cells. It excludes the vacant support services E.A position.	N	This cell should not include cell F13 in the formula, but should include F14 instead.	Agree - have corrected	Yes
Personnel Summary							
9.	D4	GM and Support Services	The formula reference states one vacancy but should be two. It references 'Personnel Costs 0809' F14 and F7 and should include F13 which is an extra vacancy.	Y	Include F13 in the formula and exclude F14 from the formula	Agree - have corrected, although doesn't impact on costing	Yes
10.	D29	Sum total of Vacancies	The formula in this cell sums D20:28 but doesn't include D19. It is one vacancy short.	N	Include D19 in the sum formula.	Agree - have corrected, although doesn't impact on costing	Yes

Ref #	Cell Ref	Label	Issue Raised	Impact Key Outputs?	Proposed Solution / Comment	Client Response	Resolved?
Operating Costs 0809							
11.	E81, E82, E85, E86, E88, E89, E90, E91, E93, E94, E97	Operating Specific Costs	The cell references are hard codes for 09/10 and 10/11 expenses, whereas the others are formulas.	N	Make these dynamic formulas, eg E81 should be =D81.	Agree - have corrected	Original issue resolved. But new issue in cell E91 – This was previously 200,000 in Y2 but is now 0.
12.	F81, F82, F85, F86, F88, F89, F90, F91, F93, F94, F97	Operating – Specific Costs	The cell references are hard codes for 09/10 and 10/11 expenses, whereas the others are formulas.	N	Make these dynamic formulas, eg F81 should be =E81.	Agree - have corrected	Yes
13.	D35	Investigations – Australian Travel	The budget has been lowered by 25%. On the comment it still states 7 Aus trips at 4k, whereas the total is \$21k not \$28k	N	Change comment to match cell contents.	Agree - have corrected	Yes – comment removed
2007_08(MBU)							
14.	B27, B28	Contractors and Sector & Public Consultation	Contractors and Sector & Public Consultation are not included in the VLookup list on Sheet3. This is causing N/A errors to appear. This does not effect current key outputs because the budget is \$0, but if the budget was updated this may cause an error.	N	Update VLookup list in sheet 3 to include these entries.	Agree - have corrected	Yes

Depreciation							
15.	M7:M65	5 month depreciation	These cells are currently calculating the correct values, but if this sheet is updated in future periods, the current formula may not continue to calculate correctly. If the 5 months payment was larger than NBV @31/1/2008, value @ 30/6/08 would be a negative number and asset would be over depreciated.	N	Formula in column M needs to take minimum of: 1. NBV @ 31/1/08; and 2. 5 month depreciation amount	Agree - have corrected	A note has been added to warn of using in future periods, but formula has not been corrected.
Expenditure Summary year to year							
16.	I32	SMARTI/Infinity	The Medsafe fees review document states operating costs increase by 5% in 09/10 and 10/11 but in 10/11 there is only a 1% increase from 09/10	Y	Change the formula to =H32*1.05	Agree - have corrected, although doesn't impact on costing	Yes
17.	E49, H49, I49	Total operating expenses	Temps and Recruitment in Operating Costs 0809 (E4,5 F4,5) increased by 2%, which is not increased in Expenditure summary. In the Medsafe review document it has a fixed cost for temps and recruitment each year.	Y	Remove the 2% inflation in E4, 5 and F4, 5 or change the review document and inflate the expenditure in the expenditure summary.	Agree - have corrected, although doesn't impact on costing	No – operating costs 0809 in cell E4/5 and F4/5 still has inflation and in Expenditure summary inflation is not included.
Medsafe 2008 fees review – Revenue.xls							
Higher Risk							
18.	C21:D26	Volume	The volume of the applications is hardcoded for the 09/10 and 10/11 years. This should be changed to a formula to keep the model as dynamic as possible.	N	Change C21 to =B21 and D21 to =C21 and the same for the other inputs	Agree - have corrected	Yes

19.	B22:D22	Volume description	Input assumption in model does not match description in assumptions document. Abridged application volume input in model = 17, but the description says 14 RMI plus 4 non RMI abridged applications = 18.	Y	Either change the amount in B22:D22 to 18 or change the description in F22 and A18 to 17	Agree - have changed assumption documentation to be RMI plus 3 non RMI abridged applications	Yes
Intermediate							
20.	C16:D19	Volume	The volume of the applications is hardcoded for the 09/10 and 10/11 years. This should be changed to a formula to keep the model as dynamic as possible.	N	Change C16 to =B16 and D16 to =C16 and the same for the other inputs.	Agree - have corrected	Yes
Lower Risk							
21.	C18:D21	Volume	The volume of the applications is hardcoded for the 09/10 and 10/11 years. This should be changed to a formula to keep the model as dynamic as possible.	N	Change C18 to =B18 and D18 to =C18 and the same for the other inputs	Agree - have corrected	Yes
Compliance							
22.	D10:E10	Volume per annum for licence to manufacture	The volume for licence to manufacture applications is hardcoded for the 09/10 and 10/11 years. This should be changed to a formula to keep the model as dynamic as possible and format the 08/09 value as an input.	N	Change D10 to =C10 and E10 to =D10	Agree - have corrected	Yes
23.	D15:E15	Volume per annum for licence to pack	The volume for licence to pack applications is hardcoded for the 09/10 and 10/11 years. This should be changed to a formula to keep the model as dynamic as possible and format the 08/09 value as an input..	N	Change D15 to =C15 and E15 to =D15	Agree - have corrected	Yes
24.	C16:E16	Fee for licence to pack	Revenue input assumption is incorrect. This calculation should use a fee of \$1205, as per cell C6, but it is currently using \$1200.	Y	Change to \$1205, using =c6.	Agree - have corrected. Change to costing model minor	Yes
25.	C22:E22	Chargeable Audit Annual Revenue	This annual revenue figure is hardcoded in the model which means if any of the assumptions that drive this figure are changed (e.g. % of time taken is increased to 35%), this calculation will not reflect the changes.	Y	These cells should either be linked to cell B52, or should include a formula that calculates \$150 an hour * 58 hours average per audit * 20 audits referencing these figures from input cells.	Agree - have corrected to be linked to cell B52	Yes