Fee Setting Model – Methodology and Assumptions Testing

New Zealand Medicines and Medical Devices Safety Authority

18 December 2020

pwc

Carol Sander

New Zealand Medicines and Medical Devices Safety Authority
133 Molesworth Street
Thorndon
Wellington 6011
New Zealand

18 December 2020

Fee setting model – methodology and assumptions testing

Dear Carol,

In accordance with the CSO signed on 10 December 2020, we have attached our report summarising the outcomes and observations arising from our testing of the New Zealand Medicines and Medical Devices Safety Authority's (Medsafe) Fee Setting Model (the model). Our report should be read in conjunction with the important notice set out in Appendix A.

We appreciate the time and effort that you and your colleagues have spent assisting us during this work.

If you would like to discuss any specific details of points raised in this document, please give either of me a call and we will be happy to answer any questions.

Yours sincerely

Darryl Pollard
Director
E: darryl.j.pollard@pwc.com
M: 022 367 7883

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1. Executive summary

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is currently conducting a review of fees payable for the activities included in the Medicines Act 1981. The key observations highlighted during the three stages of the Medsafe fee-setting model testing are set out below:

Methodology assessment

Medsafe's fee setting approach is generally well aligned with published fee setting guidance from the Office of the Controller and Auditor-General and the Treasury. However, the transparency and equity of the fee setting process could be improved by using a consistent cost recovery approach to set each fee.

Assumptions testing

Generally, the approach used to set assumptions in the Medsafe fee-setting process appear reasonable and are consistent with the methodology used to set fees. Potential improvements to the assumption approaches used in the model include:

- forecasting FTEs and service volumes for each year in the three-year cycle – the current approach assumes constant FTEs and volumes across all three years
- escalating personnel costs by 1.9% to reflect the approach adopted at a wider Ministry of Health level – the current approach escalates personnel costs at 2.0%
- applying unique growth rates to individual operating and overhead costs to reflect the type of cost – the current approach escalates all operating and overhead costs by 1.5% over 2022 and 2023
- applying a consistent cost recovery approach to set all fees – the current approach uses bespoke approaches for standard change medicine notifications (CMN), Section 24(5) service, admin and licensing fees rather than the best practice cost recovery approach.

Model testing

The model testing highlighted that the overall logic of the model appears consistent with the methodology used to set fees. The test did identify:

- several minor calculation issues, which currently or could potentially cause errors in the model's accuracy
- areas in the model that could better reflect best spreadsheeting practice, improving transparency and usability.

All issues identified have been raised with Medsafe, which has since updated the model to correct a number of the identified issues.

There were no further matters identified that suggest that the model is not mathematically viable.

2. Introduction

This section outlines the purpose of this report, and is split into the following parts:

- background
- purpose and scope
- limitations.

2.1. Background

The Medicines Act 1981 (the Act) allows fees to be charged for specific regulatory activities. Fee levels are established by the Medicines Regulations 1984.

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is currently conducting a review of fees payable for the activities included in the Act. Fees should be set to allow for the recovery of the cost incurred when delivering the covered activities. The fees review will use the fee setting model to make recommendations on any appropriate changes to the fees set by the regulations.

Medsafe has engaged PwC to provide an independent test of the model's methodology, assumptions and arithmetical accuracy as part of this review.

2.2. Purpose and scope

The model was tested by conducting the following three stages:

- methodology review – review the broad approach and rationale underpinning how Medsafe allocates costs and prices services against best practices and government expectations
- assumptions testing – testing the specific approach used to determine assumption, such as growth and allocation drivers, against the intended methodology
- model testing – testing the fee setting model to assess the logic of the modelling against the methodology, identify potential calculation errors and test that the assumptions flow through the model as intended.

Further detail on each stage is outlined in greater detail in each relevant section below.

2.3. Limitations of the testing process

The model testing procedures completed as a part of this engagement have been carried out with the objective of supporting an overriding conclusion that, based solely on the work carried out, no matters have come to our attention to suggest that the model is not mathematically reliable. However, it is not practicable to test a model to an extent whereby it can be guaranteed that all errors have been detected and accordingly we will give no such guarantee. Further limitations to our testing procedures are as follows:

- our work does not include any work in the nature of a financial audit and we do not verify any of the assets or liabilities involved
- we make no comment on how closely the results actually achieved compare with the projections in the model
- we have not review the projections produced by the model, or made any comment in any form on the outputs produced by the model, other than to confirm that the outputs generated by the model appear to be consistent with the input assumptions for the input assumptions considered
- we have not checked whether the accounting assumptions and outputs from the model are in accordance with New Zealand Generally Accepted Accounting Principles (GAAP).

Appendix B provides detail on the model testing procedures completed.

3. Methodology assessment

3.1. Overview

This stage assesses whether the fee setting methodology aligns with best practice and government guidance / expectations. This provides a review of the logic underpinning the approach and tests the robustness of the thinking.

The key activities undertaken in this assessment included:

- obtaining a high-level understanding of the approach through discussions with key internal stakeholders. This will build an initial understanding of the purpose of the methodology and the core elements underpinning the rationale behind the methodology
- assessing the logic behind the approach
- assessing the approach against best practice principles, guidance, and any specific government requirements or expectations.

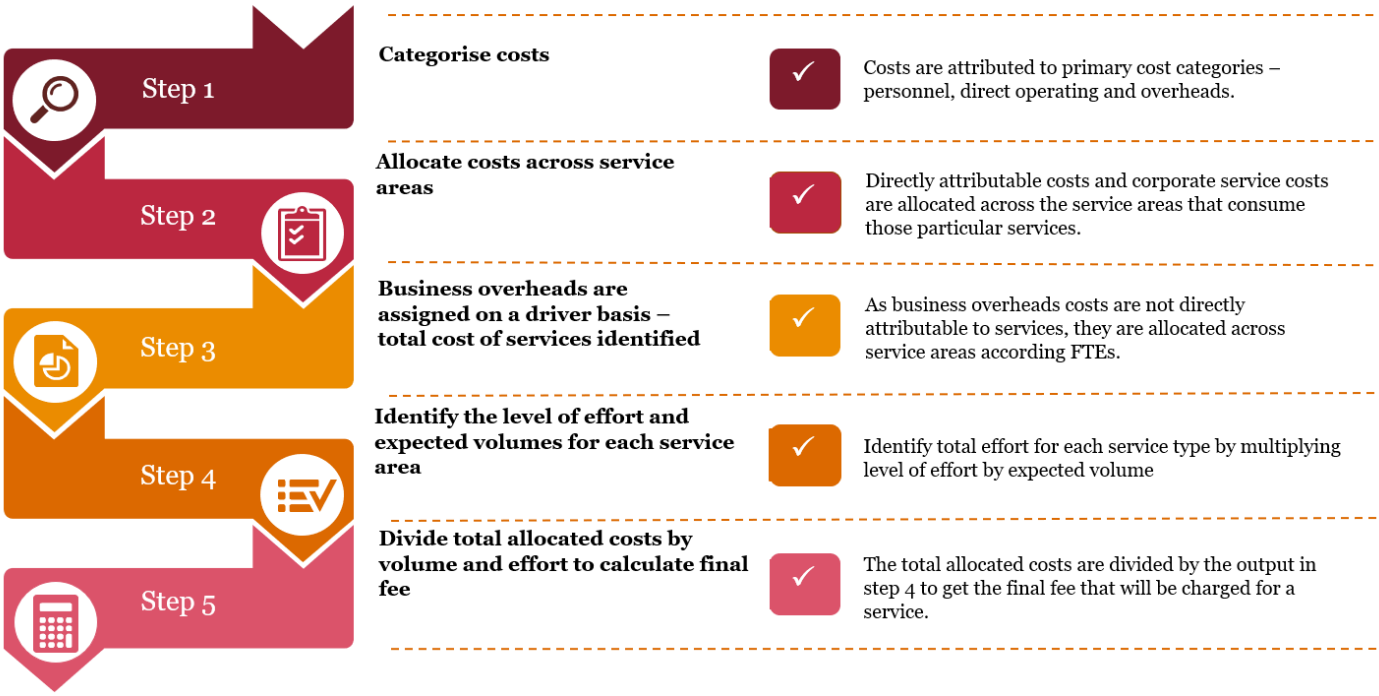
The methodology assessment is split into the following subsections:

- fee setting model methodology – describes Medsafe's methodology to set fees
- best practice fee setting – identifies a best practice fee setting principles framework within a government context
- assessment against the framework – assesses Medsafe's fee-setting methodology against the best practice framework.

3.2. Fee setting model methodology

Medsafe's fee setting methodology can be summarised as a five-step process, which is illustrated in the diagram below.

Figure One: Medsafe's fee setting approach



Each step in the diagram is set out in more detail below.

Step 1: Categorise costs

Medsafe has attributed its costs to three categories – personnel, direct operating and overheads. These categories are treated differently for cost allocation purposes.

Step 2: Allocate personnel and other operating costs across service types

Personnel and other operating costs are allocated across broad service types and general Medsafe overheads as follows:

- personnel costs are allocated according to hours / effort spent in each service type on an individual employee basis
- operating costs are directly attributed to each service type.

This creates both a cost and FTE number profile for each service type.

Step 3: Allocate business overheads

Corporate overheads (eg Ministry of Health HR team costs), the general Medsafe overheads identified in step 2 and funding required to recover the existing memorandum account deficit are allocated to each service type according to FTEs. When added to costs identified in step 2, this identifies a total expected cost for each service type.

Step 4: Identify effort and volume for services

Each of the service types comprises multiple unique services and as a result, multiple individual fees. For majority of these unique services, Medsafe calculated an effort-weighted volume by identifying a volume estimate and effort estimate for the services.

Medsafe did not calculate an effort weighted volume for standard Changed Medicine Notification Services (CMNs), Section 24(5) Fees, admin fees (a subset of clinical fees) and Licenses.

Step 5: Determine a fee for each service

Medsafe then calculate a fee for new medicine application services and clinical trials (which equate to circa half of the forecast expenditures) according to the following equation:

$$Service\ fee = \left(\frac{Total\ service\ area\ cost}{\sum Effort\ weighted\ volume\ for\ services\ within\ area}\right) * effort\ weighted\ volume\ for\ service$$

Due to data limitations and an inability to easily identify required effort for certain services, Medsafe takes an alternative approach for the following service types:

- *standard Change Medicine Notification (CMN) services* – fees are calculated by inflating the 2019 average price for each service by CPI inflation between 2017 quarter three and 2020 quarter two
- *admin fees (a subset of the clinical service type)* – admin fee price per unit is assumed to remain constant. The expected revenue from these admin fees are then stripped out of the total clinical service type cost, and the remaining services under clinical are priced according to the equation set out above
- *Section 24(5) services* – fees are calculated by assuming each individual service has a fee that is equivalent to a proportion of the fee required to fully evaluate other higher-risk medicines (which has a fee calculated according to the service fee formula set out above). The proportion of the full evaluation of other higher risk medicines for each section 24(5) is based on an assumed comparative level of effort eg 66%.
- *licensing services* – fees are calculated by inflating the 2017 fee for each service by CPI inflation between 2017 quarter three and 2020 quarter two.

3.3. Best practice fee setting

This subsection sets out the best practice fee setting in a government context and develops a framework which is used to assess Medsafe's fee setting methodology.

In a government context, best practice fee setting encompasses:

- adhering to commonly used economic principles relevant to cost recovery
- complying with the relevant empowering legislation and regulations
- aligning with published guidance on charging within the public sector, in particular:
    - the Treasury's guidelines for setting charges in the public sector (the Treasury's Guidelines)
    - the Office of the Controller and Auditor-General's charging fees for public sector goods and services (the OAG's Good Practice guide).

Principles of best practice

Pricing and fee setting within a government context is fundamentally about adopting an approach that aligns and attributes delivery costs of an agency to the services that it is responsible for. These costs are used to allocate a charge to users that reflects the costs of delivering individual services in a transparent and equitable manner. There are broadly two cost types that need to be considered within any costing/pricing methodology:

- direct costs – costs that are specifically incurred in delivering the individual service/output
- indirect costs – costs that are 'shared' across the agency between individual services in delivering its activities. These may be either a core need to deliver activities, such as IT expenditure, or a general cost for the organisation to operate that does not directly impact on activities, such as audit expenditure.

From a cost allocation perspective, direct costs have a clear causal link to services. As long as the underlying links are accurate, this is a simple matching exercise. For indirect costs, there is a greater need to understand cost drivers and provide transparency over how these costs have been allocated. Decisions made on the cost allocation drivers used must also be understood to ensure that the end charge is fair and reasonable.

Public sector guidance and assessment framework

The guidance contained in the Treasury's Guidelines and the OAG's Good Practice Guide is broadly complementary and, in combination, forms a comprehensive picture of cost recovery best practice within a New Zealand public sector environment. We have distilled this material into a framework against which to assess Medsafe's fee setting model.

The assessment framework is set out in the diagram below. Given that the framework includes authority as one of its key principles, we have not separately assessed compliance with relevant empowering regulation and regulations.

Principle	*Origin*	*Description in document*
Equity	Section 1.3 of the Treasury's Guidelines	Equity is achieved by generally sourcing funding for services from those that use them. Medsafe can also demonstrate authority to charge under the Medicines Act 1981.
Transparency	Section 1.3 of the Treasury's Guidelines	Transparency is achieved through providing clear and accessible information about funding decisions, including costs and charges.
Efficiency	Section 1.3 of the Treasury's Guidelines and section 2.19-2.28 of the OAG's good practice guide	Efficiency is achieved by delivering high service standards at a sustainable cost, and understanding when cost recovery is an appropriate funding option.
Authority	Section 1.3 of the Treasury's Guidelines and section 2.3-2.18 of the OAG's good practice guide	A public entity must have legal authority to charge a fee for the goods or services that it is legally obliged to provide.
Accountability	Section 2.29-2.55 of the OAG's good practice guide	A public entity is accountable to parliament and the public. To be accountable, entities need to ensure that their processes for identifying costs and setting fees are transparent.
Consultation	Section 1.3 of the Treasury's Guidelines	Consultation is achieved when the entity is engaged in meaningful consultation with stakeholders, and there is opportunity for stakeholders to contribute to the policy and design of the cost recovery activity.

3.4. Assessment against the framework

Medsafe's fee setting approach is generally well aligned with OAG and Treasury guidance. However, the transparency and equity of the fee setting process could be improved by using a consistent approach to set each fee. The diagram below sets out specific observations and considerations relating to each principle.

Principle	*Commentary*
Equity 	Costs are clearly accounted for and allocated to the intended activity, ensuring minimal cross-subsidisation between fee payer groups. However, this could be improved by ensuring all service fees (including CMN, Section 24(5) and Licenses) are calculated directly from costs ie setting all fees to recover costs. Recovering Medsafe's memorandum account deficit in the new three-year fee cycle may be considered inequitable as future users will incur the costs to provide services for past users. However, this appears to be a reasonable approach given: • the alternative would be to recover the deficit via government funding and paid by the general tax payer • future users of the services are likely to be similar to past users of the services Medsafe's fee setting process targets a future memorandum account balance of zero. This implicitly seeks equitable outcomes by recovering costs from current users.
Transparency 	Medsafe's fee setting approach is relatively simple and easy to understand, both of which lend to a transparent and easy to understand fee setting process. Transparency could be further improved by ensuring all service fees (including CMN, Section 24(5) and Licenses) are calculated using the same cost recovery approach. Transparency is also heavily dependent on public consultation, including clearly articulating the fee setting approach and any account surpluses / deficits to the public. Please see the consultation principle assessment.
Efficiency 	Medsafe's fee setting approach demonstrates efficiency by illustrating an understanding of the direct and indirect costs that are required to provide each service. The fee setting process also aligns to this principle by reviewing fees on a 3-yearly basis. Alignment to this principle could be further improved by demonstrating an understanding of the effort required to provide CMN and Section 24(5) and using this to calculate the fees required to recover associated costs.
Authority 	The Medicines Act 1981 gives broad powers to Medsafe to set and collect fees. The model's methodology aligns with the powers granted within the Act.
Accountability 	Medsafe clearly identifying surpluses / deficits in the memorandum account and their approach to fee setting is generally simplistic. This improves the public's and Parliament's ability to hold them accountable
Consultation	We have not reviewed Medsafe's consultation approach as a part of this engagement. However, we understand that Medsafe is currently drafting a public consultation document.

4. Assumption testing

4.1. Overview

This stage tests the approach used to determine assumptions used and the consistency of those assumptions with the defined fee setting methodology.

The key activities undertaken in this testing area included:

- understanding the key assumptions / drivers used
- assessing the consistency of the identified assumptions to the defined methodology
- identifying the relevance of specific assumptions (source, timing etc).

4.2. Assumptions and observations

Key observations

Generally, the approach used to set assumptions in the Medsafe fee-setting process appear reasonable and are consistent with the methodology used to set fees. Potential improvements to the assumption approaches used in the model include:

- forecasting FTEs and service volumes for each year in the three-year cycle – the current approach assumes constant FTEs and volumes across all three years
- escalating personnel costs in 2022 and 2023 by 1.9% to reflect the approach adopted at a wider Ministry of Health level – the current approach escalates personnel costs at 2.0%
- applying unique growth rates to individual operating and overhead costs to reflect the type of cost – the current approach escalates all operating and overhead costs by 1.5% over 2022 and 2023
- applying a consistent cost recovery approach to set all fees – the current approach uses bespoke approaches for standard CMN, Section 24(5) and licensing fees rather than the best practice cost recovery approach.

Detailed observations

The tables below set out the key assumptions used in the fee setting process and our key observations relating to those assumptions. These are split into the following categories:

- personnel expenditure forecast assumptions
- operating expenditure forecast assumptions
- overheads and allocation assumptions
- fee setting and volume assumptions.

Personnel expenditure forecast assumptions

Personnel costs are forecast by taking current 2020 FTEs and salaries, inflating the salaries and adding on-costs. The FTEs and associated costs are then distributed across service types. Table 1 below sets out the relevant assumptions used in this process and associated observations.

Table 1

Description	Assumption	Observations
Forecast FTE numbers	The FTE numbers used in the model were extracted from the human resources system as at October 2020. These FTE numbers are assumed to remain constant across all three years in the fee setting model.	Using the current FTE number is an appropriate starting point. However, this forecasting process could be improved by considering and reflecting how the workforce may need to change in response to any expected service volume or type of changes. This is mitigated by the expectation of relatively consistent service volumes.
FTE allocation by effort to service types	Each staff member's expected effort was determined on a case-by-case basis through discussions with team leaders, who have specialist knowledge of resources required to deliver their team's respective activities. Each FTE's level of experience and skill were considered when determining the effort contributed to each service type. Where relevant, statutory guidelines were used to determine the amount of effort required to complete a task.	This approach seems reasonable. The accuracy of this effort-allocation exercise could be improved by using historical time sheeting or potentially service delivery information. However, given information is not available at this level of detail, the Medsafe approach appears reasonable.
Base 2021 salary	Salaries for each employee were extracted from the human resources system in October 2020. These salaries were then uplifted by 1.9% - which reflects the approach adopted at a wider Ministry of Health level.	This approach appears reasonable. This approach could be refined by adjusting each staff's salary by a unique growth factor to reflect actual expectations. However, the materiality of such a change may be minimal.
Staff training budget	The allowance of $600 per FTE for training is based on Ministry of Health budgeting practices.	This approach appears reasonable given that it uses Ministry of Health budgeting practices. We did not assess whether the Ministry of Health's approach reflects actual training costs.
ACC staff costs	0.4% of salary cost, reflecting actual historical costs incurred.	This approach appears reasonable.
Employer superannuation contributions	The model assumes that Medsafe pays 3.64% of each staff's salary costs in superannuation contributions.	This percentage of salary a is within the bounds of possible employer contributions. We have not tested whether this reflects actual employee superannuation costs contributed by Medsafe.
Vacancy loading	The model does not assume any consistent outstanding vacancies.	This approach appears reasonable given that the fee-setting model is premised on cost recovery, and the forecast personnel cost is set to reflect expected effort required to deliver the required services.
2022 and 2023 forecast personnel expenses	The model uses the above information to calculate total expected personnel expenditure in 2021, and then escalates this cost by 2.0%	This assumption used is high-level in nature. This approach could be improved by adjusting each staff's salary by a unique growth factor to

	each year to forecast 2022 and 2023 personnel expenditure.	reflect actual expectations and applying a different growth factor to the training expense. The 2.0% growth factor is inconsistent with the 1.9% adjustment made to forecast the base salary and Ministry of Health budgeting practices.

Operating expenditure forecast assumptions

Operating expenditure is forecast by estimating all Medsafe related operating costs and then identifying the service types where the costs are incurred. Table 2 below sets out the relevant assumptions used in this process and associated observations.

Table 2

Description	Assumption	Observations
Base operating expenditure	Medsafe used the following approach to develop a 2021 forecast for each relevant operating line item: • used either the 2017 fee review expenditure estimates or the 2020/21 budget to identify a base cost estimate • adjusted the base estimate on a case-by-case basis to reflect any expectations that have changed since the 2020/21 budget setting process eg COVID preventing travel.	This approach seems reasonable given that an existing figure has been used as a starting point and then adjusted for future expectations. We have not undertaken a detailed assessment of the underlying rationale for each line item.
Operating expenditure to service types	Each operating line item is allocated across service types on a case-by-case basis through discussions with team leaders, who have specialist knowledge of resources required to deliver their team's respective activities.	This approach appears reasonable.
2022 and 2023 forecast operating expenditure	The model uses the above information to calculate total expected operating expenditure in 2021, and then escalates this cost by 1.5% each year to forecast 2022 and 2023 operating expenditure.	This assumption is high-level in nature and may not reflect how costs will change within the three-year cycle. This approach could be improved by applying a unique growth rate to each operating cost. In practice, it is unlikely that all costs would escalate at the same growth rate.

Overheads, allocation and other cost assumptions

Overhead expenditure is forecast by assuming Medsafe incurs a certain proportion of the Ministry of Health's business sustaining costs, and then allocating these costs across service types according to the FTE distribution. Table 3 below sets out the relevant assumptions used in this process and associated observations.

Table 3

Description	Assumption	Observations
Overhead base expenditure	Base business overhead expenditure is set according to the Ministry of Health's standard overhead allocation of $41,757 per FTE. Other overheads include apportioned RPA costs and additional office staff. These costs are apportioned to Medsafe according to Medsafes FTEs relative to total FTEs.	This approach appears reasonable given that costs are shared throughout the organisation in an equitable manner, without allocating additional corporate overheads to cost recovery types. While using FTE as a corporate overhead allocation driver is in line with common cost allocation practices, this approach could be improved by disaggregating the overhead cost and allocating each component according to a cost-specific driver (eg asset depreciation to those business types which use the asset). It is important to note that we have not undertaken testing of the corporate overhead allocation methodology.
Overhead allocation	Overhead costs are allocated across service types according to the FTE distribution.	This approach appears reasonable and follows standard practice.
2022 and 2023 forecast overhead expenditure	The model uses the above information to calculate total overhead expenditure in 2021, and then escalates this cost by 1.5% each year to forecast 2022 and 2023 operating expenditure.	This assumption is high-level in nature and may not reflect how costs will change within the three-year cycle. Given that a portion of the overhead costs incurred will be people-related costs (eg HR team), using the standard Ministry 1.9% may be more appropriate for certain costs. This approach could therefore be improved by applying a unique growth rate to individual components of the overhead allocation.

Fee setting and volume assumptions

Majority of the fees are forecast on a cost recovery basis using expected volumes and level of effort to deliver the service. Certain other fees (standard CMN, Schedule 24(5)s and licenses) have been set using alternative approaches as detailed in the methodology section. Table 4 below sets out the relevant assumptions used in this process and associated observations.

Table 4

Description	Assumption	Observations
Volumes estimates	Volumes for each service in 2021 is forecast on a case-by-case using of either: • the five-year average when the trend was consistent • the most recent year (2019) when there was a significant deviation from the average • an estimate based off the trend in recent years. The volumes for each service are assumed to remain constant across 2021-2023.	This approach appears reasonable for forecasting 2021 service volumes. However, it could be improved for 2022 and 2023 forecasts by making assumptions as to how volumes may be expected to change within the three-year cycle (eg constant, 5-year compound annual growth rate, other).
Effort required to complete each service	Effort required to provide each service is estimated on a case-by-case basis through discussions with team leaders, who have specialist knowledge of resources required to deliver their team's respective activities.	This approach appears reasonable. The accuracy of this effort allocation exercise could be improved by using historical time sheeting information. However, given information is not available in this level of detail, the Medsafe approach appears to be a pragmatic solution.
Standard CMN fees	Change medicine notification fees are set by taking the average 2019 price for the service and growing it by 4.2% (based on CPI inflation over the period between 2017 quarter three and 2020 quarter two.	This approach could be improved by setting each fee in a way that directly relates it to the expenditure it is intended to recover. If a direct cost recovery approach is unable to be implemented, then it should be noted that CPI inflation may not be an appropriate growth rate for the fee given it is based on a broad basket of goods and services. Costs to deliver CMN services may escalate at a different rate to standard CPI inflation.
Section 24(5) fees	Section 24(5) fees are set by assuming each service fee is equivalent to a proportion of the fee required to fully evaluate other higher-risk medicines.	This approach provides an approximation of how the fee should be set. However, a more appropriate approach would be to set each fee in a way that directly relates it to the expenditure that it is intended to recover.
Licensing fees	Each licensing fee is set by inflating the current fee by 4.2% (based on CPI inflation over the period between 2017 quarter three and 2020 quarter two.	This approach could be improved by setting each fee in a way that directly relates it to the expenditure it is intended to recover. If a direct cost recovery approach is unable to be implemented, then it should be noted that CPI inflation may not be an appropriate growth rate for the fee given it is based on a broad basket of goods and services. Costs to deliver licensing services may escalate at a different rate to standard CPI inflation.

5. Model testing

5.1. Overview

This stage considers the Excel model used to execute the fee methodology and tests it to determine whether it is 'fit for purpose'. Key activities completed in this section included:

- obtaining a high-level understanding of the model, how it was constructed and its purpose
- checking whether the calculations in the model appear in all material respects logical, internally consistent and arithmetically correct
- checking whether the model's overall functionality appears to align with the purposes for which the model has been developed
- checking that the model appears to allow changes in assumptions to correctly flow through to results.

Further details on the testing procedures and the limitations of the testing procedures are set out in Appendix B.

5.2. Observations

After undertaking the Procedures, we believe that the overall logic of the model appears consistent. However, the tests identified several types for improvement, which have been categorised as follows:

- arithmetic issues, which currently or could potentially cause errors in the model's accuracy
- further observations, which have a lower probability of materially impacting the model's accuracy.

These points have been discussed with Medsafe and are explained in detail over the following sections. The detailed record of our findings and accompanying recommendations are outlined in Appendix C. After presenting our initial observations to Medsafe, the model has been amended to rectify the issues identified that were materially impacting the model's outputs. Medsafe has indicated it intends to adopt the best practice recommendations at a later date prior to the finalisation of the consultation document. There were no further matters identified that suggest that the model is not mathematically viable.

We did not provide a subsequent review of the amended model.

Below summarises the issues identified and provides general recommendations on how to better avoid such issues in the future.

Arithmetic issues

Issues identified

The model currently contains arithmetic errors from incorporating unintended values in calculations from references to incorrect cells and double counting.

Recommendations

To improve this, calculations should be separated out into multiple steps and simplified to decrease the likelihood of reference errors and double counting.

Further observations

Issues identified

The model utilises a logical flow and clear structure to a reasonable degree, but there are additional improvements that could be made to the Model's structure and design. We observed instances where the model contained:

- missing inputs, formulae and titles

- unclear titles and section layout / alignment
- a lack of clear input and calculation format
- links to external workbooks
- redundant calculations and columns that do not contribute to outputs
- hard-coded assumptions / inputs within formulae
- calculations prone to error (eg unnecessarily large arrays)
- error checks with types for improvements.

While many of these issues do not impact the model's current outputs, the issues identified in the further observations section can lead to future user errors from incorrect entry of information, or a failure to update inputs and calculations throughout the model.

The model contained hard-coding within formulae, which increases the risk of updates to assumptions not being reflected throughout the model.

Recommendations

We recommended that values used as categorical identifiers for formulae (also known as 'mapping') refer to easily visible and traceable inputs, rather than directly hard-coding mapping values. We also recommended that hard-coded inputs contained within formulae are separated out into their own easily identifiable input cells. Collectively, these solutions will improve ease of future use when updating the model.

Future usability of the model would be improved if inputs were separated and clearly identifiable. This would improve transparency, ease of updates and running scenarios within the model. Aspects that do not contribute to the model's outputs should also be removed to reduce the likelihood of an error occurring. The likelihood of errors occurring in calculations could be reduced through the use of best practice modelling techniques such as mapping to manipulate appropriate values.

Appendix A. - Important Notice

This report has been prepared by PricewaterhouseCoopers Consulting (New Zealand) LP (PwC) for the sole use of Medsafe and the Ministry of Health, to summarise the results of the testing of the Medsafe fee setting model. The report has been compiled based on instructions received from Medsafe, and information provided by Medsafe. We accept no liability to any party should it be used for any purpose other than that for which it was prepared.

This document is strictly confidential and (save to the extent required by applicable law and/or regulation) must not be released to any third party without our express written consent which is at our sole discretion.

To the fullest extent permitted by law, PwC accepts no duty of care to any third party in connection with the provision of this report and/or any related information or explanation (together, the “Information”). Accordingly, regardless of the form of action, whether in contract, tort (including without limitation, negligence) or otherwise, and to the extent permitted by applicable law, PwC accepts no liability of any kind to any third party and disclaims all responsibility for the consequences of any third party acting or refraining to act in reliance on the Information.

The analysis and findings in the report rely upon the information provided by Medsafe as well as assumptions that have been discussed and agreed upon with Medsafe through the course of our engagement. All assumptions will be the sole responsibility of Medsafe.

In preparation of the report we have relied upon information provided to us by Medsafe.

PwC has not independently verified the accuracy or reasonableness of information, inputs and assumptions provided to us, and have not conducted any form of audit in respect of the organisation for which work is completed. Accordingly, we express no opinion on the reliability, accuracy, or completeness of the information provided to us and upon which PwC has relied. Responsibility for the reliability, accuracy and completeness of such information remains with Medsafe.

The statements and opinions expressed herein have been made in good faith, and on the basis that all information relied upon is true and accurate in all material respects, and not misleading by reason of omission or otherwise.

The statements and opinions expressed in this report are based on information available as at the date of the report.

We reserve the right, but will be under no obligation, to review or amend our document, if any additional information, which was in existence on the date of this report was not brought to our attention, or subsequently comes to light.

This report is issued pursuant to the terms and conditions set out in the signed Consultancy Services Order signed on **10 December 2020**.

Appendix B. - Model testing procedures

Model testing procedures

We have only completed these tests in relation to the model's mathematical accuracy and have not determined the appropriateness of the data used in the model. The specific model assessment tasks are split into the following categories:

- model specification and structure
    - develop high level understanding of the nature of key operations, key risks and value drivers
- detailed testing of worksheets
    - identify all inputs, including any hard-coded inputs
    - assess key calculation logic and consider reasonableness
    - formulae checks:
        - formulae appear in correct cells (e.g. years, line items)
        - formulae copied across columns correctly (especially absolute vs relative cell references)
        - formulae contain no inputs
        - range names correct
        - identify any circular references
        - consider consistency of repeated worksheets
        - run automated testing tools
- reasonableness of output
    - high level consideration of the prima facie reasonableness of the Model's outputs given the input assumptions
- code check
    - check cells have correct:
        - format
        - units ($NZ vs $US, $ vs $'000 vs $M, nominal vs real etc)
- assumptions
    - identify where equivalent input assumptions are repeated and check on a test basis that they contain the same values.