



Complaint regarding the Medicines Regulations 1984

Interim Report of the Regulations Review
Committee

Forty-eighth Parliament
(Dr Richard Worth, Chairperson)
April 2008

Presented to the House of Representatives

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1 Introduction

Recommendation

The Regulations Review Committee recommends that the House of Representatives takes note of this interim report.

We received a complaint regarding clause 61 of the Medicines Regulations 1984 in September 2007 from the Researched Medicines Industry Association of New Zealand (RMI). Clause 61 is made pursuant to section 105 of the Medicines Act 1981 and sets various fees for the purposes of the Act.

Clause 61 was amended on 21 August 2006, increasing a number of the fees. The application fee for ministerial consent to sell new medicines under section 20 of the Act was increased from \$15,300 to \$122,625. This increase in fees was based on recovering a portion of the anticipated actual cost of completing the evaluation work once this task was transferred to the Australia New Zealand Therapeutic Products Authority (ANZTPA).

The RMI argues that there is now little prospect of the ANZTPA being established as the Therapeutic Products and Medicines Bill 2007 was not supported at the select committee stage. Therefore the methodology supporting the fee increases was flawed. The RMI calls for the regulations to be amended to set the fees “at a level commensurate with the situation in New Zealand having regard to the constrained market conditions, market size, public health considerations, and level of service provided by Medsafe”.

Complaint process

Under Standing Order 316, where a complaint is made to us by a person aggrieved at the operation of a regulation, we must consider whether it relates, on the face of it, to one of the grounds on which we may draw a regulation to the special attention of the House.

In this case the RMI considers that the ground in Standing Order 315(2)(h) applies to the notice: that the regulation was not made in compliance with particular notice and consultation procedures prescribed by the Medicines Act 1981.¹ We advised the RMI that we considered Standing Order ground 315(2)(a) to be relevant: not in accordance with the general objects and intentions of the Medicines Act 1981.

Evidence

We received a written submission from the RMI dated 20 September 2007. The submission was released to the Ministry of Health on 17 October 2007 for comment. We received written submissions from the ministry on 3 December 2007. In response to questions from

¹ Appendix B contains the relevant Standing Orders.

the committee, the ministry made a further written submission dated 15 January 2008. The RMI made a further written submission in response to the first ministry submission on 29 January 2008.

We heard evidence relating to the complaint on 11 March 2008 from all parties.²

² Appendix D contains a transcript of the hearing.

2 The complaint

Complainant's concerns

The RMI has two main concerns about the reliance on the proposed ANZTPA regime as a basis for amending the fee set under clause 61(3) of the regulations:

1. The regulatory impact statement for this amendment refers to the backlog of applications submitted to Medsafe and not determined prior to the start of the ANZTPA and states that “there will be a significant shortfall in funding to cover the cost of completing this work unless fees for applications submitted in the lead-up to commencement of the joint scheme are increased to a level that more closely approximates the anticipated ANZTPA fee”.
2. The methodology for setting the increased fee is derived purely by setting the fee at a percentage of the fee charged by the Australian Therapeutic Goods Administration.

The increased fees have been in place since 21 August 2006, anticipating the establishment of the ANZTPA. There is no longer any prospect of an ANZTPA being established, and the RMI considers that the fee set under clause 61(3) does not take into account the actual costs incurred by the medicines approval unit of the Ministry of Health (Medsafe) in providing evaluation services under the Medicines Act 1981. Instead, it argues, the fee takes into account matters that are not relevant to the provision of those services.

Grounds for complaint

In its initial submission, the RMI based its complaint on Standing Order ground 315(2)(h), that the regulation was not made in compliance with particular notice and consultation procedures prescribed by statute. The RMI argues that the consultation documents justified increases in the fees by reference to the new evaluation system to be established under the ANZTPA. As the ANZTPA has not been established the consultation process was flawed.

The essence of the RMI complaint is that the fee increases implemented in August 2006 cannot be demonstrated to reflect Medsafe’s costs in providing medicine evaluation services.

It is well established that any fee charged by a publicly funded agency for providing a service must not exceed the costs of providing that service unless this is specifically provided for in primary legislation. To do otherwise conflicts with the principle that only Parliament can impose taxes.³

³ See section 22 of the Constitution Act 1986 and the Office of the Auditor-General’s report *Guidelines on Costing and Charging for Public Sector Goods and Services*.

If a fee is set in circumstances where the costs of providing the service have not been properly established, then the fee may exceed costs and may be a matter more appropriately dealt with by primary legislation. A regulation setting such a fee is unlikely to be in accordance with the objects and intentions of the empowering Act, unless the Act specifically empowers fees of this nature.

For these reasons we consider the more appropriate grounds for this complaint are Standing Order 315(2)(a) and (f).

3 Response from the Ministry of Health

The Ministry of Health confirmed that the fees had been set in anticipation of the establishment of the ANZTPA, and argued that “the best available proxy for the likely fee levels for the evaluation of new medicines under the joint scheme was the existing Australian Therapeutic Goods Administration (TGA) fee schedule which has taken into account the resourcing required to provide a more robust system with a higher level of protection than New Zealand is currently able to achieve on its own, as well as improved capacity to process applications more efficiently.”⁴

The ministry also noted that we had asked a number of questions relating to the 2006 fee increases in the regulations in our scrutiny role before receiving this complaint, and that the ministry had demonstrated compliance with the Audit Office Guidelines at that time.

The ministry acknowledged the concerns of the RMI, and advised that the Government was considering the changes to the regulatory framework that would be required in the event that ANZTPA did not progress, including changes to cost recovery arrangements. The ministry also advised of a fee waiver mechanism that was available in some circumstances.

In response to further questions from the committee on compensation for over-recovery of fees since August 2006, the ministry advised that a memorandum account approach will be used to monitor under- or over-recovery of revenue for two to three years. The ministry also advised that a review of fees collected under the regulations would be conducted during 2008.

⁴ Submission from Ministry of Health received 3 December 2007, para 14.

4 Hearing and interim conclusion

It became clear to us at the hearing that there was considerable common ground between the RMI and the ministry.

The RMI acknowledged the difficult position that the ministry found itself in with the move away from ANZTPA. The RMI clarified that it sought fees that were set on the basis of sound analysis of the costs of the ministry in providing medicine evaluation services. It confirmed that it did not seek compensation for fees that may have been set in excess of costs. The RMI's main concern was that properly revised fees should be set as soon as possible.

The ministry acknowledged that the fees may not reflect the current operating environment of the medicine evaluation unit, Medsafe. At the hearing the ministry made a commitment to progress a review of the fees set under clause 61 of the regulations. The ministry subsequently provided us with a timeline for this project stating that key elements of the review would be completed by 1 May 2008 and that the regulations were expected to be in place between 1 October 2008 and 1 March 2009.

This timeframe seems realistic and reasonable. Provided that the ministry's review of the fees regulations is undertaken in accordance with this timeline and complies with the principles established under the Audit Office Guidelines, we are satisfied that this complaint has been resolved.

Recommendation

The Regulations Review Committee recommends that the House of Representatives takes note of this interim report.

Appendix A

Committee members

Dr Richard Worth (Chairperson)

Hon Mark Burton

Hon Marian Hobbs

Eric Roy

Dr Pita Sharples

Lesley Soper

Lindsay Tisch

Committee staff

Claire MacMillan, Clerk of Committee

Tim Workman, Legislative Counsel

Appendix B

Standing Orders relevant to the Regulations Review Committee

314 Functions of Regulations Review Committee

- (1) The Regulations Review Committee examines all regulations.
- (2) A Minister may refer draft regulations to the committee for consideration and the committee may report on the draft regulations to the Minister.
- (3) In respect of a bill before another committee, the committee may consider—
 - (a) any regulation-making power,
 - (b) any provision that contains a delegated power to make instruments of a legislative character, and
 - (c) any matter relating to regulations,—and report on it to the committee that is considering the bill.
- (4) The committee may consider any matter relating to regulations and report on it to the House.
- (5) The committee investigates complaints about the operation of regulations, in accordance with Standing Order 379, and may report on the complaints to the House.

315 Drawing attention to a regulation

- (1) In examining a regulation, the committee considers whether it ought to be drawn to the special attention of the House on one or more of the grounds set out in paragraph (2).
- (2) The grounds are, that the regulation—
 - (a) is not in accordance with the general objects and intentions of the statute under which it is made:
 - (b) trespasses unduly on personal rights and liberties:
 - (c) appears to make some unusual or unexpected use of the powers conferred by the statute under which it is made:
 - (d) unduly makes the rights and liberties of persons dependent upon administrative decisions which are not subject to review on their merits by a judicial or other independent tribunal:

- (e) excludes the jurisdiction of the courts without explicit authorisation in the enabling statute:
- (f) contains matter more appropriate for parliamentary enactment:
- (g) is retrospective where this is not expressly authorised by the empowering statute:
- (h) was not made in compliance with particular notice and consultation procedures prescribed by statute:
- (i) for any other reason concerning its form or purport, calls for elucidation.

316 Procedure where complaint made concerning regulation

- (1) Where a complaint is made to the committee or to the chairperson of the committee by a person or organisation aggrieved at the operation of a regulation, the complaint must be placed before the committee at its next meeting for the committee to consider whether, on the face of it, the complaint relates to one of the grounds on which the committee may draw a regulation to the special attention of the House.
- (2) The person or organisation making the complaint is given an opportunity to address the committee on the regulation unless the committee agrees by unanimous resolution not to proceed with the complaint.

Appendix C

Medicines Regulations 1984

[61 Fees

- [(1) The licence fees set out in Schedule 5A are payable for the licences to which they relate.]
- (2) The amount to be deposited with the Medicines Review Committee pursuant to section 13(2) of the Act shall be \$9,000.
- (3) The fee to accompany an application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be [[\$122,625]] where any active ingredient of the medicine that is the subject of the application is not generally available as at the date of that application.
- (4) The fee to accompany any other application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be [[\$43,875]].
- (5) The fee to accompany an application made under section 21 of the Act (as applied by section 96(1) of the Act) for the Minister's consent under section 20 of the Act in relation to a related product shall be \$5,500.
- (6) The fee to accompany an application made under section 23 of the Act for the Minister's provisional consent shall be [[\$8,437]].
- (7) The fee to accompany a notice deposited with the Director-General under section 24 of the Act shall be [[\$3,200]].
- (8) The fee to accompany an application made under section 30 of the Act for the approval of a clinical trial, and of the persons (in that section called investigators) who will conduct that trial, shall be [[\$9,843]].
- (9) For the purposes of section 70(4) of the Act, the fee for a copy of a certificate of an analyst, or (as the case may be) a copy of a report made by an analyst in respect of a sample, shall be \$60.
- (10) For the purposes of section 97(1) of the Act, the fee for procuring a sample of any medicine and submitting it for analysis shall be \$600.
- (11) For the purposes of subclause (3) of this regulation, not generally available means not legally available other than pursuant to an exemption granted under any or all of sections 25, 26, 27, 28, 29, 30, 31, 32, 32A, or 33 of the Act.]

History

Regulation 61 was substituted, as from 29 August 1991, by reg 2 Medicines Regulations 1984, Amendment No 4 (SR 1991/134).

Subclause (1)(g) was inserted, as from 18 September 2004, by reg 8 Medicines Amendment Regulations 2004 (SR 2004/300). See reg 12 of those Regulations for the transitional provision.

Subclause (1) was substituted, as from 21 August 2006, by reg 5(1) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Subclause (3) was amended, as from 21 August 2006, by reg 5(2) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188) by substituting the expression “\$122,625” for the expression “\$15,300”.

Subclause (4) was amended, as from 21 August 2006, by reg 5(3) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188) by substituting the expression “\$43,875” for the expression “\$7, 800”.

Subclause (6) was amended, as from 21 August 2006, by reg 5(4) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188) by substituting the expression “\$8,437” for the expression “\$5,000”.

Subclause (7) was amended, as from 21 August 2006, by reg 5(5) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188) by substituting the expression “\$3,200” for the expression “\$1,600”.

Subclause (8) was amended, as from 21 August 2006, by reg 5(6) Medicines (Fees) Amendment Regulations 2006 (SR 2006/188) by substituting the expression “\$9,843” for the expression “\$2,800”.

Appendix D

Transcript

**Complaint regarding Clause 61 (Fees) of the
Medicines Regulations 1984**

Regulations Review Committee

11 March 2008

Members

Dr Richard Worth (Chairperson)
Hon Marian Hobbs (Deputy Chairperson)
Moana Mackey (replaced Mark Burton)
Lesley Soper
Lindsay Tisch

Staff

Claire MacMillan
Tim Workman

Witnesses*Researched Medicines Industry*

Hon Ken Shirley, Chief Executive Officer
Debbie Wyber, Manager Technical & Scientific Affairs

Ministry of Health

Dr Stewart Jessamine, Manager, Medsafe
Dr Susan Martindale, Principal Advisor, Regulation, Medsafe
Brian Strickland, Manager, Business Performance

FTR: 15:35:07

Worth Welcome, Mr Shirley; would you introduce your team and start? Let me just say by way of introduction that we are somewhat pressed for time, as usual. We've decided to allocate quarter of an hour for your side, quarter of an hour to the ministry, 5 minutes for your response, and then to give you one week—both sides—if there's anything further you want to provide us with. And we'll strictly hold to that timetable. We have a reporter from Hansard present. We'll send you a transcript, and if there are changes that you seek to have made to the transcript, then you can come back to us and we can arrange for that to finally form part of a correct record. Mr Shirley, when you're ready.

Shirley Well, thank you, Dr Worth and committee members, and thank you for the opportunity to present our case to the Regulations Review Committee. The

time outlined I think will be more than adequate. I'll be as brief as I can. You have the written material there.

Essentially, our complaint's laid with your committee with regard to the cost to register medicines in this country, and the first point we wish to make is on the *raison d'être* for the increase. The increase went from \$15,300 or something thereabouts to \$122,000 in one jump, and the whole justification for that was the anticipation of the joint agency with Australia, ANZTPA. And of course with that in political limbo—we don't intend getting into the arguments about that, but the reality is that it's in political limbo—our members feel somewhat aggrieved that they are facing these incredible cost increases without the validity for the increase in place.

The second point I'd make is that we feel that the level of the increase is unreasonable in the context of the New Zealand market. Our members would not argue for a moment that \$15,000 was too low. It was certainly too low, and we would expect a significant increase given the importance of, and the work required in, the evaluation of medicines. And it's well known that Medsafe is actually running at a loss. We don't expect to be subsidised by the taxpayer for registering our medicines in the market place. But the size of the increase, we feel, isn't justified, and it has actually resulted in a significant fall-off in the new chemical entities that are being applied for consent to distribute. And that is important from a public health point of view. Prior to the fee increase, for the year ended 31 August 2006, there had been 23 new chemical entities applied for. For the following 12 months after the fee increase, that had fallen to 9, and for the 6 months through to 29 February there's only been 6 new chemical entities lodged as applications for consent to distribute.

I think the more telling point is that 49 percent of medicines subsidised by Pharmac—that is, they're on the schedule for public funding—had sales, and that's ex-manufacturer sales, not profits, of less than the \$122,000. So the expectation is that you actually have to pay more to register it to distribute than the value of the product—not profit; value of the total profit. It just commercially will not happen.

The third point I would make is that I believe our member companies have been overcharged, and we note that Medsafe's profit through to the year ending 30 June 2008—this is a projection—is \$782,000, but I understand that's a fairly accurate tracking, and that's 12.5 percent of the Medsafe budget for the evaluation of medicines. And of course all of that is coming from our industry, and the point is that it goes into the consolidated fund, or into the public coffers. So it's effectively another form of taxation. It's not as if it's given back to our members—it's a fee that we're saying is excessive and Medsafe's making a profit and that's going into the public coffers. And we say that's really not on.

If we look at other jurisdictions—I think that's probably an important thing to do—Singapore: population of 4 million people, modern economy, their

registration costs, fees are NZ\$67,000, about half of what is under the new schedule here that has been filed. So we certainly appreciate that Medsafe has responded with an extended abbreviated process in the interim period that we all find ourselves in—and the industry has a lot of sympathy for Medsafe; they're really the meat and the mustard in the impasse that has developed—but the problem with the extended abbreviated process, while it's important that we have it for the short to medium term, is it is very inflexible and it is very restrictive. You know, it's not the same as the full registration process. So I think, Mr Chairman, those are really the key points we wish to make in support of the written material that we've already submitted and you've had an opportunity to study.

Worth OK, thank you very much.

Hobbs Thanks very much, Mr Shirley. I accept the argument you put up about the fees rate because of therapeutics. My problem comes in here. You say the level of increase is too much for the market, but as I understand it when we set fees they are based on cost recovery. So Medsafe—and you would've seen Ministry of Health, and this is a suggestion here after paragraph 35—gave their justification for the fees recovery. What would help me is not that you argue that, you know, the industry can't accept it, which may well be a valid argument, but the way that these run their arguments is that the fees have to be justified in terms of cost recovery. Are there any things in there that you would query in terms of their justification?

Shirley Yes, there's a considerable amount that we would query, and I'll actually call on Debbie Wyber, our technical manager, who's very conversant with these details.

Hobbs Thank you.

Worth I think it would be helpful, just before we do that—Marian Hobbs has asked you a question about these tables at paragraph 35. Is it correct that we're more concerned with table 2 than any other table?

Hobbs The evaluation one.

Worth This is the document which is from the ministry headed "Response to Regulatory Review Committee Request for Information".

Hobbs I'm also actually looking really at paragraphs 21 onwards, which is the establishment.

Worth Right.

Hobbs It's the ones to do with the establishment costs for licensing and establishing the cost for evaluation. It's those things there.

Worth But your focus is only on evaluation fees?

- Wyber It is.
- Shirley Indeed.
- Worth I've understood that. Now if you can just show us, on table 2, where your concerns lie. Do they lie in those first three columns: provisional consent, new medicine, biological, chemical—
- Wyber It's the biological and chemical, the 122—
- Worth It's that one there; it's just that one?
- Wyber Primarily that one. We do have some issues with other ones, but it's essentially the biological and chemical, which are the new chemical entities.
- Hobbs Could you suggest any fees that you think that should be? I'm not telling you to—
- Wyber I guess our biggest problem is, as Ken said, we do understand that Medsafe could not operate at that level, and we do understand that the Government has a policy of full cost recovery. Our concern was that the fees were set with a view to moving towards the joint agency—
- Hobbs I understand that.
- Wyber —and therefore they had to, because Medsafe would be taking the backlog into the joint agency, pay joint agency rates in terms of salaries and rental, and all that sort of thing. They had to start accommodating in terms of that. As that hasn't happened, and as the fees were set by, for example, setting the fee for an application for new chemical or biological medicine—that's the 122; it was set at approximately 50 percent of the current TGA fee. It wasn't set against the costs that Medsafe—well, not that we'd been able to ascertain. We've never actually been told “this is how much it costs in New Zealand to evaluate a new chemical entity on average.” Instead it was taken, because of the fact that we were moving towards a joint agency at the time, against that. And that's part of our problem.
- Shirley And another point to that is, I understand, that a lot of the backlog was actually the generic copies, and therefore our members feel somewhat aggrieved as the innovators of innovative new medicines at having to cover the costs of the generic copiers—
- Hobbs Yes.
- Shirley —who are the bulk of the backlog.
- Hobbs In your additional letter you said then that you were quite happy with paragraphs 16 and 18 of—when you said that the RMI strongly supports this proposal where the fees more accurately reflect the cost of the work

- performed. So that was to do with the ones that you were copying from other—
- Wyber No, that's to do with the extended abbreviated one where we, as the innovator, are using approvals from overseas—
- Hobbs For similar medicines overseas?
- Wyber For exactly the same medicine. The only thing that would be different is that the labelling would be to meet medicine requirements. So it's our product, you know, our individual member's product, either in New Zealand or what they're selling in, say, Australia.
- Hobbs So you'd be happy enough for that one, but you're not happy for when we think up something absolutely new, there is nothing to compare it with, and the cost for assessing that, or evaluating that, you think has not been tabled about how they reached that cost.
- Wyber That's right.
- Hobbs And you can't find any way in which they reached that cost?
- Wyber Only, as I say, by setting it against a TGA figure, which, as I say, was because of the fact that if they had to take that application into the joint agency, then that was approximately what it would cost under the joint agency to finish evaluating it.
- Hobbs In paragraph 29, and it's the last question I'm going to ask, it just says applying the costing model used for licensing activities—this is under the establishing costs for evaluation. So it says in paragraph 29, applying the costing model used for licensing activities would not have taken account of the anticipated changes in the cost base associated with the planned transfer. That's all of the therapeutic stuff?
- Wyber That's right.
- Hobbs And that's your argument again?
- Wyber Exactly. There were licensing activities; there was a costing model done. But once again, as it says here, it wasn't—the cost structure under the joint agency was very different to the cost structure under Medsafe, and as we still have Medsafe at the moment, we feel we should be paying for that cost structure.
- Hobbs I just had to make it really clear in my head. Thank you.
- Tisch Just a supplementary question to Marian's. What do you think the fee structure would be if the TGA wasn't involved? Do you have an idea in your mind of what that figure would be, knowing that the premise of these evaluation fees is based on going into an arrangement which is not going to

- happen, or certainly not at this stage? You know, we're looking at a 700 percent increase in fees here. What is the figure that you think that should be, bearing in mind cost recovery on existing costs, as opposed to an anticipation of going into the TGA?
- Shirley Well, I think you need only look at comparisons of other jurisdictions, and I cited earlier the Singaporean—they do a full evaluation of new chemical entities with full cost recovery for NZ\$67,000—half of what's being asked under this fee structure.
- Tisch OK. I'm going to ask that same question—
- Shirley So, are we less efficient? Or can we not do—
- Tisch I'll ask the same question of the ministry when they come to the table, so they know what I'm going to ask. Also, then, on page 3 of your report to us dated September, you talk about the RIS, the regulatory impact statement, and you make the point there, there will be a significant shortfall in funding to cover the cost of completing the work unless fees for applications submitted in the lead-up to commencement—da da da da da; I don't need to read the whole thing. Further down in the next paragraph you say, the RIS did not consider the possibility of it not proceeding. Now, I guess it's all based on the premise we're proceeding, so the regulatory impact statement will focus on that. You would argue, I guess, in your next paragraph there that they didn't consider the possibility of it not proceeding.
- Shirley There was no plan B.
- Tisch No plan B. Righto. Of course, once again to the ministry, when they come, in their document they say—and it doesn't have a page number, but it's under their 37 when we get to it—there that a business compliance cost statement was not required because no new fees were being introduced. So here we've got an RIS that says: "Ah, we've got cost recoveries based on the new regime, but nothing if the status quo prevails.", and then, on the other hand: "We've got no business cost, the BCCS.", which is in the ministry paper, which says: "Well, we won't do one of those because there's no new fees; they're only existing fees." So do you have a view about that? You probably haven't read that if you just got the document just now.
- Wyber Well, no, it is strictly true because medicines regulations already had fees, and we were paying, as we say, \$15,300. So it wasn't a new fee; it was the level of the fee. Had we gone to the joint agency we would no longer have had the Medicines Act or the medicines regulations, so then it would have been a completely different set-up. But as it was, they were just amending existing fees in the regulations.
- Worth In your final page of your original complaint, you ask that the regulation be amended and the fees for evaluation set at a level commensurate with the situation in New Zealand, taking regard of the constrained market

- conditions, market size, public health considerations, and level of service provided by Medsafe. This is a similar question to the one that Lindsay Tisch asked. Let's assume that your complaint has merit. How would you like us to do justice to your complaint, on an assumption that there has been an overpayment because the fees were based on a set of circumstances that proved not to occur? Are you actually seeking from us a recommendation that a specific amount be refunded?
- Shirley No, we're actually not seeking a refund, and I don't believe our members are seeking a refund. What we're looking for is a regime going forward that is commensurate with the market realities here, provides full cost recovery for the Crown agency involved in doing the evaluations, but is commercially sound so the industry can carry out business in the New Zealand market.
- Worth Is it impracticable to contemplate a refund?
- Shirley I don't think our members would reject the offer, but we're not specifically seeking it.
- Hobbs You just said something then, Ken. You said that it must be commercially sensitive, taking cognisance of the commercial market, but that's not what cost recovery is, is it? You see the argument I'm trying to make?
- Shirley Yes I do, but equally the New Zealand regulator has to recognise that the New Zealand market historically has been, in terms of publicly funding new innovative medicines, low and slow. That is the reality. Our members are, for a market where there's really efficiency in a lucrative market, happy to register and meet quite significant costs in registering new medicines. But New Zealand, unfortunately, is a very hostile commercial market for new pharmaceuticals—innovative pharmaceuticals.
- Hobbs But that might be heading towards policy, rather than to—that's almost a policy argument, rather than straight on the cost recovery issue.
- Shirley Yes, but unfortunately I think the two can't be separated, because there is a demand, the demand needs to be met, it needs to be met in a commercial environment, and if the regulatory regime, including the registration process, means that it doesn't make sense, the New Zealand consumer of pharmaceutical products will suffer.
- Worth All right, we'll have to stop you there, Mr Shirley. Thank you very much. I wonder if the ministry officials would come forward. We'll give you a right of reply in a moment, as I said.
- Shirley Thank you very much.
- Worth Well, welcome; thank you for coming. Could you please introduce your team.

- Jessamine My name's Dr Stewart Jessamine; I'm the interim manager at Medsafe. On my left I have Dr Susan Martindale, who's our chief adviser in regulation, and Brian Strickland, who is our business performance manager.
- Worth We've read the papers, so the floor is yours.
- Hobbs You can speak for ever, because I love that accent!
- Jessamine I suspect you want me to say something vaguely sensible! Essentially, prior to setting the fees, we were in an environment where ANZTPA was our preferred—and remains the Government's preferred—option for regulation of therapeutic products in Australia and New Zealand. And going into that model we sought external advice on how best to set fees, given that we were moving into an environment where we were operating at fees that were unrealistic. We were carrying an extensive backlog of product applications, such that applications we would be receiving in 2005 and 2006 would not be completed until we were proposed to be in the ANZTPA environment. And in that backlog somewhere around 25 percent of the backlog was actually high-risk, new chemical entities from innovator brand new companies, so that they were a proportion of that work.

So we examined what we do, we examined our volumes, we tried to set a fee that we thought did meet the market but also met what we estimated our costs are likely to be to clear that backlog and perform work against a background of variability of applications. And reviewing our data we found that in fact new medicines applications have been falling since 2004, other than in 2006 when we put the fee up and in the month before we put the fee up everybody tried to get in and get one at the old fees. So we've actually—and this is an international environment in which we operate—but there's a lot of variability of applications year by year, and to make matters worse we were very concerned that in the ANZTPA environment, should it have gone ahead, a product that had already been approved by the TGA would automatically have been given approval in New Zealand. And so our legitimate expectation in setting a fee was that most companies would submit their applications in Australia, because Australia has a statutory time line by which time the application must be completed, and that they would then gamble on ANZTPA coming along around about that time and gain entry to the New Zealand market, having paid only one fee.

Now, part of the deal with ANZTPA, and part of the deal with doing medicines regulation, is we believe that you have to have the capacity and the capability to do this work inside New Zealand. And so we then have to factor into that the requirement that we must keep our capability level high and pay people to sit in the office and clear the backlog of work. And the risk—we simply can't shed staff and hope to pick them up again if we get the fees all wrong. So, you know, we do acknowledge, obviously, that ANZTPA's now on hold, and that has changed our environment.

When RMI brought this to our attention we set about looking at ways that we could try and mitigate this fee environment, and came up with—as they’ve said—an abbreviated approval process for products that have been already assessed and approved by other recognised regulators around the world. We still have the little issue of the fact that the Medicines Act requires companies to submit certain data to the Minister, and that the Minister must be satisfied that these medicines reach standards of safety, quality, and efficacy as required. So it’s not that we’re moving into an environment where we simply rubber-stamp someone else’s decision; we still are fully evaluating that data, and that still requires numbers on seats.

What we expect to happen with that is, in fact, that we defer applications coming in to New Zealand, in that the cost run and the compliance cost eventually in the New Zealand market will be lower if you’re prepared to wait until an application has been submitted in another recognised country and approved. Then we expect to be able to do it cheaper and faster than we had previously done.

The second thing we’ve committed to do is to actually conduct a fees review, examining the current environment in which we’re in, operating under the current requirements that we have for costs controls. That project is just kicking off now.

- Worth Has started, or is about to start?
- Jessamine The first meeting of the project group that’s managing it should happen in the next week—I’d say about to start.
- Worth And the time line for its completion is?
- Jessamine Ultimately, of course, this will require changes to the regulations again—
- Martindale We would normally expect a time frame of approximately 6 months to achieve a new regulation, because we would first have to draw up the proposals, then there would be a 6 to 8-week consultation period, analysis of submission, two Cabinet processes to go through—one before consultation and one after—and, obviously, a small drafting task for the regulation. That is, as a rough rule of thumb, what we would normally find is the time it takes.
- Worth In respect of the application that is made by a member company in the RMI tomorrow, are they to be charged at these rates, which it now seems common ground are not appropriate rates, or will the fee waiver mechanisms operate to provide a more appropriate level of cost?
- Jessamine The fee waiver and system came in place on 3 March, so effectively the company now gets to decide which strategy it wishes to pursue. If it wishes to submit an application to Medsafe now, then it would pay the full \$122,000-odd. If it chooses to wait until the medicine has been assessed and approved by a recognised regulatory authority in Europe, Canada, the

- United States, or Australia, it can then come in at that point in time with the lower fee of \$33,000-odd. But it's for the company. The company has the option of which of the two parts, which—
- Martindale And in addition, to address the historical situation where companies prior to the introduction of the abbreviated process may have lodged applications at the full fee, we have said we will refund the fee if that application is indeed eligible to be treated under the abbreviated process. Because the product is approved elsewhere in one of those trusted regulatory domains, then we will refund the difference between the abbreviated fee and the full fee.
- Worth And as a matter of policy does the ministry wish to encourage applications to be made in New Zealand, or is it more convenient from your perspective that applications are judged offshore?
- Jessamine The Medicines Act requires the applications to be made in New Zealand, and it requires that companies submit certain data to the Minister of Health before gaining market approval. That will always be a requirement. However, we believe that with the scheme as is written, where the company is still required to submit the kinds and extent of data that we currently require by legislation and by guideline, the abbreviated scheme fits that requirement at this point in time.
- Tisch I've got four points. First, in your executive summary of your letter dated 14 September 2006, under clause 3 of the executive summary you say there that the previous fee structure for evaluation and licensing activity under the Medicines Act and Misuse of Drugs Act has remained unchanged since 1991 and 1977, respectively. You go on to say further: "These fees fell well short of recovering the costs in most cases." My question is, why weren't there fee increases at the time when you made the statement that you weren't getting cost recovery? Why do it now, when the last fee structures were in 1977 and 1991? Why do it now, when you've been operating and haven't been able to recover your costs, which you're entitled to do?
- Jessamine Absolutely. In fact, we've been attempting to introduce new legislation around the Medicines Act since 1992. So I'm afraid it's always been a touch of jam tomorrow for us: that we've always been on the threshold of introducing new legislation that would have introduced new fee structures, and never quite getting there. So, basically, we realised that ANZTPA looked like it was getting there; it looked like it was progressing. We recognised at that point in time we had to address the fees and that if we were to wait until ANZTPA was established to address the fees, the increase would potentially have been greater. So we picked that moment as the time to make an interim fee adjustment to signal to industry that we're moving to that new environment.
- Tisch OK. On your same document, in clause 32 you say there: "...the evaluation of applications for approval of new prescription (innovative and generic) medicines received after 1 July 2006 are expected to be undertaken by

ANZTPA staff under the transitional system. It is important that the fees for such applications are set at levels that will substantially recover the costs of the work.” Now that everything’s on hold, that statement there, that the premise is that you’ve increased the fees—this is not going ahead, so are you prepared to re-evaluate the fee structure on the current status quo position without taking into account what may happen in months or years ahead?

Jessamine Of course, the fees went up shortly after that, and in fact since that point in time performance wise we’ve been managing reasonably well to meet targets around approvals of these products. We still have a substantial backlog, however, that predates that increase in fees, of which a handful are new chemical entities—most are generic medicines, as Mr Shirley’s already indicated. And our expectations—even at that point in time; if we look forward now our costs do continue to increase inside Medsafe—are that we would be reflecting those increased costs in our new fees review structure to try to address any difference between what we were historically charging and what we are currently charging.

Tisch In your summary document—we received it in December—your number 13, the paragraph before says: “Because Medsafe does not have a sustainable regulatory capacity for evaluation, it has developed a backlog of applications awaiting evaluation.” So now that the fee structures are in place, what is the status of the backlog?

Jessamine The backlog is decreasing. It’s decreasing because we’ve changed some of the process that we do. We have, for instance, recently advertised for a number of new positions to give us some excess capacity. We also constructed a project to separate out how we deal with applications submitted before the fees increase from those that came after the increase, and are actually purchasing external evaluation from experts outside of Medsafe to deal with the backlog that predates the fee increase, to try to clear the backlog, as well.

Tisch Are the fee increases actually covering costs now?

Jessamine Well, in reality what happened was that in the month leading up to the fee increase, the equivalent of something like 3 years’ applications arrived at Medsafe’s door under the old fee structure. That’s contributing dramatically to some of the backlog. More than 50 percent of the backlog is actually applications that we received in the month preceding the date for implementation of the new fees. Yes, the new fees are covering our costs. Obviously, we’re proposing that we accept that there is a projection that we will over-recover in this area, and we’re proposing to move to a memorandum of account so that over time we can manage the risks associated with variability of numbers of applications and adjust fees accordingly, so that we’re effectively in an environment where we can change the fees more flexibly and we’re in better control.

- Hobbs Adjusting downwards?
- Jessamine Well, downwards or upwards, depending on the cost environment in which we find ourselves.
- Worth I gathered from that last answer that you haven't yet established a memorandum account.
- Jessamine Sorry, the memorandum account is—
- Strickland That's going to be introduced for the current financial year we're in. So any surplus that we have this financial year won't be returned to the consolidated account but carried forward and adjusted for fees. So any surplus will result in lower fees.
- Worth Yes, we're familiar with these accounts. When will the account be established? It hasn't been yet, I gathered from your answer.
- Strickland It'll be part of the 2007-08 year end process, so it will be reflected for this current financial year that remains.
- Worth Ending 30 June 2008?
- Strickland Yes.
- Tisch Just one more question that relates to my previous questions to the other group. Your regulatory impact statement says that there'll be a shortfall in funding—that's what it says—on the basis, of course, that everything goes ahead. It hasn't gone ahead, so there is a cross-subsidy occurring now, which the other submitters are having to pay the price for, part of which is being done to reduce the backlog. Am I right? It certainly appears that way to me.
- Jessamine Do you want to finish the question, and then I'll come back to that?
- Tisch OK. And then I come back to the other question in your own document that says that a business compliance cost statement was not required because there were no new fees. I understand how that process works, but here you've got a regulatory impact statement on one hand that says that there'll have to be fee increases to have cost recovery—of course we're moving to a new regime—then, on the other hand, you say: "Of course, there are no fees and we haven't done a BCCS." Can you answer that question? Has there been a cross-subsidy with the new fees? It has reduced your backlog. Fees will probably have to go up in the future—that's a question mark. But everything comes back, as we understand here, on the premise that this was moving to a new regime, so there's a cross-subsidy that's occurring now.
- Jessamine The backlog actually is a separate project, which is being funded using money that's—the increased fees associated with new chemical entities is

not funding the backlog project. So it's not cross-subsidising. In fact, the total excess that we are projecting around this is actually being collected not only from the new chemical entity applications but also from increased numbers of applications in a whole variety of different areas, including changes to existing medicines and increased numbers of applications for generic medicines. In fact, our projections for the total number of applications that we expected for the types of medicines that the RMI companies represent is actually pretty much—is very similar to—what we actually projected when we set the fees back in 2006.

Martindale Would you like me to talk about the BCCS question?

Jessamine Yes, please.

Martindale It's my understanding that what we were required to do—and indeed did do—is to address the question of the impact that the increased level of fees would have through the material in the regulatory impact statement. But because we were not introducing a new type of fee, the advice that we had was that no BCCS is required, since that is normally done when, for example, if there had been no fee for a new chemical entity you would look at what impact was associated with industry gearing up to become familiar with the idea that they had to pay a fee and any transaction costs associated with that payment. So the impact associated with the level of the fee is appropriately dealt with in the RIS, but there isn't an impact of the kind that needs to be dealt with in the BCCS.

Tisch You see, there are two parts to this. There's not only an increase in the fee, which it could be said is a tax, but there's also the extra compliance that's associated with the organisation having to make it put on more staff or do more research or whatever. That's the compliance area, which just for the fees increased by 700 percent in the case here from \$15,000 through up to \$122,000. That's a huge increase. So it's not just the fee; there's also a cost on the organisation, as well. That's where the compliance comes. That's in addition to what the actual fee's about. That's why I was asking a question about the BCCS.

So your understanding and your advice was that there was no requirement for you to undertake a BCCS?

Martindale My understanding is that, yes, BCCSs are not required in a situation where there is in existence a fee structure, and the only change is associated with the magnitude of the fee.

Hobbs I've got four questions. My focus with both submitters is really on what constitutes cost recovery, because that's what we understand fees to be set by. In paragraph 4 of your submission, in the final sentence you say "The new fee structure achieves comparability with similar fees in other jurisdictions." That ain't anything to do with cost recovery in New Zealand, is it? Can you explain the justification for that?

- Jessamine No, I think you are right. We have always said it costs what it costs to do this process, and that the process involves a technical evaluation of a great deal of data. I'm not sure if you would be aware that the average new medicines application of the nature we are talking about here is somewhere in the order of a quarter of a metric tonne of paper. It is a pile of paper somewhere around about the size and volume of this desk in front of me.
- Hobbs A good carbon footprint!
- Jessamine We will be working on that, but essentially it is a very large volume of data, and our job is to go through or as much of, or, if need be, all of that data to make an assessment of the safety quality and efficacy. So it is a large volume of work. We are one of only a dozen or so countries that do a full evaluation of all the data, and even in that case, for instance, New Zealand does a very light evaluation of toxicology, which is the animal studies of that data, because we simply don't have the staffing ability to attract the staff to do that. To us, cost recovery is the cost of employing the staff, storage, maintaining expert advisory committees, and maintaining the infrastructure for us to do that work.
- In different countries it is interesting; the example of Singapore has been given of \$67,000-odd. Our understanding is that Singapore and ourselves do a slightly different job. But even if we didn't, the cost of doing the same job in larger markets is substantially more expensive, and the job in Europe is in the order of NZ\$500,000 to NZ\$600,000. In America it is higher than that again, I believe; it is in excess of NZ\$1 million. But the point is that the applications that are submitted in Europe, in New Zealand, and in the United States are exactly the same. There are not different sizes. They contain essentially the same data in essentially the same format, and they use essentially the same skills to evaluate that data.
- Hobbs So the difference in cost is surely the cost of the advisers and the cost of the infrastructure to manage it.
- Jessamine Exactly, in each country. But even then—
- Hobbs And then ours should be lower.
- Jessamine The issue is, well, is the cost of all that work in the United States really 10 times higher than it is in New Zealand? The infrastructure is partly driven by what we do, partly driven by the legislation, and partly, as you have already identified, driven by policy around the cost recovery model.
- Hobbs But you are telling me, am I hearing you say, that although you have looked at the comparability between them, because you are dealing essentially with the same thing and the same techniques, it isn't that the comparability establishes the price; it's just that it is comparable.
- Jessamine It is comparable. We kind of knew that as soon as we put the fees up, people would say: "This is outrageous; it is too large." But what we were

really saying is: “Yes, the piece of work is the size that it is, and this is the cost of doing it in New Zealand, and it is comparable to other countries.”

Hobbs I have heard both you and the Researched Medicines Industry—RMI—talk about what the market, or what the industry can stand. I have heard you say that is also part of the justification of fees. It is almost as though there is a mix of cost recovery and market capability to pay. I don’t find that very transparent.

Jessamine We as regulators have to be aware that our job is to make sure that medicines that get on to the market are the safest, highest quality, most efficacious medicines that we possibly can. But, by the same token, across the Tasman 10 years or so ago, the regulator was accused—was it by Senator Bohm—that the safest medicine was the one that you never approved. We have got to recognise that access to medicines is a fundamental part of medical care and public health in New Zealand. And so in considering these, we do have to consider that product has to be available in New Zealand to be able to deliver benefit to public health. We do have to accept that we cannot set any fee that we care to think about.

Martindale I think we try to do that. When we couch our regulatory impact statement, we try to look at what the cost is and volume, and therefore what the fee needs to be, and therefore, what is the impact of that? We also try to assess that against other markers—for example, what might an average company spend on advertising their product? How significant is this fee in the context of the business that that fee-payer has? But, nevertheless, we are focused on cost recovery rather than—

Tisch Yes, but I think you’ve gone beyond that, haven’t you, because the new regime didn’t happen, and everything that you say is based on the premise that you are going into a new arrangement. This is the point that Marian is making: that never happened, yet the fees are based on that happening. In your correspondence, in your submission to us, that is what you say. You say: “The new fee structure ensures that costs associated ... will increase, based on moving to a new regime.”

Soper And what would your remark be on Mr Shirley’s comment that 49 percent of medicines had annual sales of less than that new fee?

Jessamine Well, we don’t actually at that level—we are not party to that information normally, as to the volume of sales and the cost of sales. The cost of the medicine and the possible cost of purchasing that medicine to the New Zealand health care budget is not something that Medsafe looks at—and quite appropriately so, in my opinion. We are set up to look at straight-out safety quality and efficacy—not cost; not any of those deliverables. That industry is constantly telling us that we are part of the global market, that we are part of a global response and the applications we get are the same as submitted in other countries, that the cost of developing a medicine to the point that we see a submission is somewhere between US\$800 million and

US\$1 billion, and that probably the same again is spent on advertising of those products. We tend to be saying that this is what we believe is the cost. Quite regularly we were projecting a cost into an environment where we were moving into ANZTPA. That hasn't happened, although it still remains on the statutes, and, in fact, the hold around on it was based on the Australian—as much as anything else on the fact that we were moving into an environment when there was an Australian election about to occur, so there was no progress possible. By now we are looking at how we can address that by a fees review, by introducing an abbreviated scheme, which allows differential access at a lower fee.

- Worth Just two questions. The first is, I guess you accept that this present fee structure in the regulations cannot be supported, because it was based on a set of circumstances that haven't occurred. You accept that, don't you?
- Jessamine We accept that the circumstances which were projected to occur have not occurred.
- Worth And that's what lies behind your commitment to undertake the fees review.
- Hobbs And set up a memorandum account.
- Worth I think from our perspective we must extract some form of undertaking from you in respect of the timeliness of that review, and that is why I asked you those earlier questions. I would just like you to reflect on what might be reasonable in that regard. You, of course, cannot be held accountable for when new regulations are promulgated, because that is the act of the executive—we understand that. We would like from you an unequivocal statement, which is from your perspective reasonable in terms of your resources—whether you are going to engage consultants, as you did with Deloitte—as to when that fees review can be completed. Is, for example, 6 months from the end of this month unreasonable? Would you say that is too long, because, quite clearly, the industry can feel a justified concern. I think we all accept that. It is probably a question that I should ask you, isn't it, because this is going to be your burden, primarily, I think.
- Martindale Yes, together with my colleagues. It would be helpful if we could respond to that later. I can give you a kind of off-the-top-of-the-head figure now, and we can confirm or adjust that when we do some finer-level calculations.
- Worth All right, why don't you give us the off-the-head view, and then come back to us within that 7-day time frame? What would your off-the-head view be?
- Martindale I think the tightest that we could achieve completion of a fees review would be 6 months from the end of March—
- Worth Right.
- Martindale That is my suspicion, just based on the sheer amount of work and the resources that could be deployed.

- Worth Would you engage Deloitte again, as you did in connection with other fee evaluation work?
- Martindale We would need to go out with a tender process, which adds to the time line, because we can't just choose a particular player. So one of the considerations is, to what extent do we feel we need an external kind of validity check on the work?
- Worth You may not need that, in the context of the frameworks that are already there. But I accept it is a possibility.
- Martindale So that's why I would just like that chance to reflect, if I may.
- Worth Are there any other questions from members of the committee? Do the officials have any questions?
- Workman Just one question. Within that 6-month period, would you say that your costs are better reflected by the amended fee, or what you had before?
- Jessamine The abbreviated process fee, or the other \$15,000 fee?
- Workman The \$15,000 that has now gone up to \$122,000.
- Jessamine The \$15,000 fee is most definitely not an accurate reflection of our costs. My expectation is that the fees review will deliver something within the two. I expect it to be less than the current fee of \$122,000, but as to how much less, we will need to do the work to really find out.
- Worth We've also sensed Mr Shirley's broad acceptance of that and in an earlier comment you made. Thank you very much.
- Soper At the end of 6 months the abbreviated fee plus the fee waiver you see as dealing with the situation?
- Jessamine Yes, and that's likely to continue out indefinitely. It's not a stopgap; it's the beginning of a new approach.
- Soper It's not a stopgap? It will be an arrangement during the 6 months and then would continue?
- Jessamine Yes, most definitely.
- Worth Thank you very much. Mr Shirley is there anything new that you would like to speak about, or are you sufficiently happy?
- Shirley Just perhaps 2 minutes, if I may. Thank you, chairman. I think it has been a very good hearing. Thank you for that. I am very pleased to hear the comments, and we welcome the proposal to have a fees review and we acknowledge that Dr Jessamine, since he has been in the position, has been very interactive with the industry and very helpful on a number of fronts. We do appreciate that. I guess, in a way, the fact that Medsafe is adopting

this review is an acknowledgment that the fee, as it was put up by regulation, was excessive and not warranted. We have heard the indication here that it is expected to be certainly more than \$15,000, but certainly less than the \$122,000.

Hobbs Don't divide it by two.

Shirley Indeed. So that's very pleasing. We are, I guess, concerned about the 6 months. I know it takes a process and it takes time, but the clock is ticking all the while, and these things often get pushed out by other pressing needs. We would certainly be looking for an early resolve to what is clearly an unjustified situation.

Worth All right. Thank you very much. Now I indicated that if either party has any further material it would like to provide, then that should be provided by 5 p.m. on 18 March. Of course, we are expecting that material from Medsafe. We have just had a testimonial of Dr Jessamine from Mr Shirley, so that will be heartening for you. I would like to thank you for the way you have given your material to us, for the way you have answered our questions, and we will now take time to consider. Thank you very much.

conclusion of evidence