Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

FILE COPY

File Reference 2011/011177

Attention: [redacted]

Eska Australia
Unit 32 A&B of 2-6 Chaplin Drive
LANE COVE NSW 2066
Australia

Dear [redacted]

CANCELLATION OF ENTRY FROM THE REGISTER
Notice under section 41GN(1) of the *Therapeutic Goods Act 1989* of the cancellation of a medical device from the Australian Register of Therapeutic Goods.

Device Name:	Eska Adapter Femoral Stem Prosthesis
ARTG Number - Name:	118441 - Eska Australia - Prosthesis, internal, joint, hip, femoral component
Sponsor:	Eska Australia
Manufacturer:	Eska Implants GmbH and Co

1. As a delegate of the Secretary to the Department of Health and Ageing for the purposes of Section 41GN of the Therapeutic Goods Act 1989 (The Act), I am writing to inform you that I am cancelling the entry of the Eska Adapter Femoral Stem Prosthesis (The Device) from the Australian Register of Therapeutic Goods (The Register).

Decision

2. I am cancelling the entry of The Device because I am satisfied that it's safety and performance are unacceptable.

Background

3. In a letter dated 30 August 2011 [unsigned copy in **Attachment A**], I notified Eska Australia that I proposed to cancel the entry of the Device from the Register because I was satisfied that the safety and performance of the Device are unacceptable. The letter explained why I came to that conclusion and provided 20 working days within which to make further submissions in relation to the proposed cancellation. The letter also explained that the 20 working day deadline was reasonable because Eska Australia had

already been provided an opportunity to make submissions in relation to the Device on two previous occasions.

4. In a letter dated 13 September 2011, Orthodynamics GMBH, acting on behalf of Eska Australia requested a four week extension on the 20 day deadline. The extension was requested in order to complete an external testing program and further investigate and review the manufacturing history of the products supplied in Australia.
5. The TGA replied that additional information would be considered, but that we would proceed with the cancellation process after the 20 days had elapsed. Our reply explained that Eska and Orhodynamics had already been given several opportunities to produce information.
6. The TGA has not received any further material from ESKA Australia or the manufacturer to satisfy the TGA that the safety and performance of the Device was acceptable.

Legislative Overview

7. Under Subsection 41GN(1)(e) of the Therapeutic Goods Act, the Secretary of the Department of Health and Aging has the power to cancel the entry of a medical device from The Register if she is satisfied that the safety or performance of the medical device is unacceptable.
8. Before cancelling the medical device from the Register, the Secretary must inform the person in relation to whom the medical device is included in the Register (the Sponsor) that she proposes the cancellation, setting out the reasons for it; and give the Sponsor reasonable opportunity to make submissions in relation to the proposed cancellation.
9. If after considering any submissions from the Sponsor, the Secretary is still satisfied that the safety and performance of the Device are unacceptable, then the entry of the Device in the Register can be cancelled.
10. Section 41GO allows the Secretary to limit the cancellation to some medical devices of the kind covered by the ARTG entry.

Material Considered

11. As outlined in my letter dated 30 August 2011, in coming to my decision I have considered the following material:
    a. Sections 41GN and 41GO of the Therapeutic Goods Act 1989 (see **Attachment B**).
    b. The 2010 Annual Report of the Australian National Joint Replacement Registry (NJRR); and detailed individual reports from the NJRR regarding the safety and performance of The Device;
    c. A letter from the TGA to Eska Australia dated 29 September 2010, and Eska Australia's response dated 29 October 2010.
    d. The advice of the OEWG after they considered the NJRR Implant Analysis Report for The Device, the complete response from Eska Australia and a case summary prepared by the TGA during a meeting that took place on 24 November 2010.
    e. A letter from the TGA to Eska Australia dated January 2011 advising Eska of the OEWG's recommendations and seeking further information; and the response to that letter provided by Orthodynamics GmbH on 25 February 2011.

f. The further advice of the OEWG after they considered the information provided by Orthodynamics mentioned in (e) above at a meeting that took place on 25 May 2011.

g. The letter from Orthodynamics to the TGA dated 13 September 2011.

Findings in relation to facts

12. The findings in relation to facts are provided in my letter dated 30 August 2011 **[Attachment A]** and are still valid.

13. The manufacturer of the Device – Orthodynamics - wrote to the TGA on 13 September 2011. The letter explained that "a potential source of 3rd body wear had been identified which may have affected the products supplied to Australia" and requested a 4 week extension to complete "an external testing program and a further internal investigation and review of the manufacturing history of the products supplied to Australia". The TGA's position in relation to the request for extension is stated in our reply dated 19 September 2011:

> *"...we believe that ESKA Australia and Orthodynamics have already been provided with ample opportunity to make a case for the performance of the implant. Therefore we are not inclined to wait any longer to begin the proceedings to cancel the registration of the implant.*
>
> *Further, we are of the view that however they may be interpreted, the results of the tests planned cannot outweigh the "real life" results reported by the National Joint Replacement Registry.*
>
> *We would welcome any submission that you may have about the implant's performance, results of testing and so on, and if these arrive before the cancellation proceedings are finalised we will happily consider them."*

Reasons for decision

14. As mentioned in paragraphs 8-10 of this letter, Section 41GN of the Therapeutic Goods Acts provides the Secretary of the Department of Health and Ageing the authority to cancel the entry of a medical device from the Australian Register of Therapeutic Goods if "the Secretary is satisfied that the safety or performance of the kind of device is unacceptable". The secretary must inform the Sponsor in writing of the proposal to cancel, provide a reasonable opportunity to make submissions and any submissions must be considered before the device is cancelled.

15. As outlined in paragraphs 3-6, 12 and 13 of this letter, I have provided written notification of the proposal to cancel, I have provided reasonable opportunity to make further submissions; and I have reconsidered all of the evidence regarding the revision rate of the implant. Therefore I have complied with the provisions in Subsections 41GN(2) and 41GN(3) of the Act. After this process, I am still satisfied that the safety and performance of the Adapter Femoral Stem Prosthesis is not acceptable, therefore Section 41GN(1)(e) of the Act applies.

Conclusion

16. I have complied with the provisions in Section 41GN of the Act for cancellation of entries of kinds of medical devices from the Register after notice of proposed cancellation. After

this process I continue to be satisfied that the safety and performance of the Device is unacceptable. Therefore I have decided to cancel the entry of the Device from the Register.

Date of effect

17. Pursuant to section 41GQ(b) of the Act the date of the effect of the cancellation will be no earlier than 21 working days from the date of this notice.

18. As mentioned in paragraph 10 of this letter, Section 41GO allows the Secretary to limit the cancellation to some medical devices of the kind covered by the ARTG entry. Please advise as soon as possible whether other medical devices are being supplied under ARTG number 118441. If so, the cancellation will be effected as an exclusion to the registration – This means that you will be able to supply other hip joint femoral components under this ARTG number except the Eska Adapter Femoral Stem Prosthesis.

19. You will receive a copy of the Gazettal notification of the cancellation.

Review Rights

20. See Attachment C

Other Matters

21. **Important:** Supply of the Device without a current entry on the ARTG will place you in breach of the Act and penalties apply. Under section 41MI of the Act it is an offence for a sponsor to import or supply in Australia medical devices for use in humans that are not included in the ARTG in relation to that person.

22. If you require further information regarding this matter, please contact

Dr Jorge Garcia
e-mail: jorge.garcia@tga.gov.au
Telephone: +61 2 6232 8432

Yours sincerely

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[redacted]
Head, Monitoring and Compliance Group
Therapeutic Goods Administration
(Delegate of the Secretary to the Department of Health and Ageing for the purposes of Section 41GN of the Therapeutic Goods Act 1989)

Date: SIGNED ON 25/10/2011

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

ATTACHMENT A

File Reference 2011/011177

Attention: [redacted]
Eska Australia
Unit 32 A&B of 2-6 Chaplin Drive
LANE COVE NSW 2066

Dear [redacted]

Proposal to cancel the entry of a medical device from the Australian Register of Therapeutic Goods under Section 41GN of the Therapeutic Goods Act.

Device Name:	Eska Adapter Femoral Stem Prosthesis
ARTG Number - Name:	118441 - Eska Australia - Prosthesis, internal, joint, hip, femoral component
Sponsor:	Eska Australia
Manufacturer:	Eska Implants GmbH and Co

1. As a delegate of the Secretary to the Department of Health and Ageing for the purposes of Section 41GN of the Therapeutic Goods Act 1989 (the Act), I am writing to inform you that I propose to cancel the entry of the Eska Adapter Femoral Stem Prosthesis (the Device) from the Australian Register of Therapeutic Goods (the Register).

Decision

2. I am proposing to cancel the entry of the Device because I am satisfied that it's safety and performance is unacceptable.

Background

3. The TGA has reviewed orthopaedic implants that were identified in the 2010 Annual Report of the Australian National Joint Replacement Registry (NJRR) as having higher than expected revision rates. The Report and detailed information about implants that were identified as having higher than expected revision rates are available at http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp
4. The Device was one of the implants identified in the report as having higher than expected revision rates identified in 2010 Annual Report of the NJRR (Text, Tables and Diagrams in pages 147-152 of the report). Both the cementless and the cemented versions of the Device are identified as having higher than expected revision rates.

5. On 29 September 2010, the TGA wrote to Eska Australia about the fact that the Device had been identified in the NJRR report. The TGA letter included a comprehensive Implant Analysis Report from the NJRR about the performance of the Device in Australia and asked questions about complaint and adverse event reports, clinical trial results and other clinical evidence and for a statement from Eska Australia or the manufacturer in relation to any benefits afforded by the use of the Device that may compensate for the seemingly higher revision rates. The TGA received a response from Eska Australia on 29 October 2010.
6. The NJRR Implant Analysis Report for the Device, the complete response from Eska Australia and a case summary prepared by the TGA were presented to the Orthopaedic Expert Working Group (OEWG) for consideration at a meeting that took place on 24 November 2010. The OEWG is a group of orthopaedic surgeons, nominated by the Australian Orthopaedic Association, who advise the TGA on matters relating to the safety and performance of orthopaedic implants.
7. The OEWG expressed concern about the high revision rates being experienced with the Device in Australia and advised that Eska Australia had not made a convincing argument in favour of the safety and performance of the Device. On 17 January 2011, the TGA notified Eska Australia about the advice of the OEWG and that the TGA would have to make a decision about the ongoing availability of the Device in Australia. The letter also advised Eska Australia to review their previous submission and resubmit. The TGA received a further submission from the manufacturer of the Device – Orthodynamics – on 25 February 2011.
8. The OEWG considered all of the available information about the Device, including the Orthodynamics submission mentioned in 7 above once again at a meeting that took place on 25 May 2011. The submission from Orthodynamics failed to abate the OEWG's concern about the revision rates associated with the use of the Device.
9. After considering the information before me and the advice provided by the OEWG and the TGA's own experts, I am satisfied that the safety and performance of the Adapter Femoral Stem Prosthesis is unacceptable and propose to cancel the product from the Australian Register of Therapeutic Goods.

Legislative Overview

10. Under Subsection 41GN(1)(e) of the Therapeutic Goods Act, the Secretary of the Department of Health and Aging has the power to cancel the entry of a medical device from the Register if she is satisfied that the safety or performance of the medical device is unacceptable.
11. Before cancelling the medical device from the Register, the Secretary must inform the person in relation to whom the medical device is included in the Register (the Sponsor) that she proposes the cancellation, setting out the reasons for it; and give the Sponsor reasonable opportunity to make submissions in relation to the proposed cancellation.

Material Considered

12. In coming to my decision I have considered the following material:
    h. Section 41GN of the Therapeutic Goods Act 1989 (see **Attachment A**).

i. The 2010 Annual Report of the Australian National Joint Replacement Registry (NJRR); and detailed individual reports from the NJRR regarding the safety and performance of the Device;

j. A letter from the TGA to Eska Australia dated 29 September 2010, and Eska Australia's response dated 29 October 2010.

k. The advice of the OEWG after they considered the NJRR Implant Analysis Report for the Device, the complete response from Eska Australia and a case summary prepared by the TGA during a meeting that took place on 24 November 2010.

l. A letter from the TGA to Eska Australia dated January 2011 advising Eska of the OEWG's recommendations and seeking further information; and the response to that letter provided by Orthodynamics GmbH on 25 February 2011.

m. The further advice of the OEWG after they considered the Orthodynamics mentioned in (e) above at a meeting that took place on 25 May 2011.

Findings in relation to facts

13. The 2010 Annual Report of the NJRR identifies both the cemented and cementless versions of the Device as implants that are experiencing higher than anticipated rates of revision. The revision rates are 2.11 and 4.04 revisions per 100 observed years for the cementless and the cemented versions of the Device respectively. Compared to the average performance of all other similar implants used in Australia, the adjusted hazard ratios are 6.10 and 1.99 for the cemented and the cementless version of the Device respectively. This means that compared to the average for all other similar prostheses, the risk of revision for a person who has received the cemented version of the Device is 6.10 times higher; and the risk of revision for a person who has received the cementless version of the Device is 1.99 times higher. These findings are statistically significant at the 0.1% level. Therefore, I find that the revision rate of the device is significantly higher than that of other implants of the same type. This is a concern because revision surgery is associated with significant morbidity and mortality.

14. The implant analysis report from the NJRR for the cementless version of the Device indicates that the 23 recorded revisions are evenly distributed among implanting hospitals. This means that the high rate of revisions is not related to the surgical technique of individual surgeons. The cumulative revision rate for the Device is rising steadily and the rate of revisions for the Device relative to the rate of revisions for all other similar devices (the hazard ratio) is also increasing with time. The proportion of revisions due to pain, leg length discrepancy, metal sensitivity, wear and implant breakage are all higher than the proportion of revisions for similar reasons in similar implants. Therefore, I find that the difference in risk of revision between the Device and similar implants increases with time since original implantation and that the pattern of usage does not explain the seemingly poor performance of the Device in Australia. Finally I find that the reasons for revision, particularly the relatively high number of revisions due to wear and implant breakage support a view that there are problems with the design of the implant that are leading to a high revision rate.

15. The implant analysis report from the NJRR for the cemented version of the Device indicates that the implanting hospitals that have used the Device the most are those hospitals that have recorded the most number of revisions. This is to be expected, and indicates again that the high rate of revisions is not related to the surgical technique of individual surgeons. The cumulative revision rate of the device even at two years is very high relative to similar implants, has risen at an unacceptable rate and analysis of the

trend in the cumulative revision graph for the Device would indicate that the revision rate is likely to continue to rise rapidly in the future. The relative number of revisions due to loosening, pain and dislocation are much higher than that of all other similar implants and supports the view that there are problems with the implant itself that are leading to high revision rates.

16. The approach used in your response dated 29 October 2010 was to explain, on a case by case basis why the implants have been revised, and then to provide published literature that suggests that this femoral stem prosthesis has had good results elsewhere in the world. You have claimed that all of the revisions in the "Type of Revision" table that were provided to you by the TGA on 29 September 2010 were due to surgical error or inexperience, but you have not provided any supporting evidence (eg a cross reference to investigation reports, implant retrieval analysis etc) for the assertions. For the reasons given in paragraphs 14 and 15 I do not believe that surgical technique is responsible for the high revision rates attributed to the use of the Device.

17. In the same response ESKA supplied a table summarising the available literature and copies of key publications. The relationship between the implants used in the papers provided and Device is not clear in many of cases. Even so, the paper by Sielewicz et al reveals that the studies described were not without their complications (eg loosening, intraoperative stem fracture, pain). Götze et al report a cumulative survival rate of 90 ± 8 % for the acetabular component and 86 ± 5 % for the femoral component at 14.9 years. 137 patients were followed in this study and the authors state that four prostheses were revised due to implant fracture. These results call into question the performance of the Device. Further, the authors conclude that:

    "The long term results of the spongy metal cup are good, whereas the high loosening and fracture rate of fully coated stem are a source of concern especially with regard to the difficult revision scenario with frequent massive bone loss."

18. On 25 January 2011 Orthodynamics GmbH, the current German manufacturer of the implant, provided a further, more comprehensive response addressing the comparatively high revision rate of the Eska Adapter femoral stem prosthesis. In that submission Orthodynamics argues that the poor performance of the implant in Australia may be related to the high use of Metal on Metal bearings. Adapter femoral stems have been used in conjunction with Bionik metal femoral head in combination with Eska metal acetabular components. It is claimed that the Bionik femoral head had problems which have now been addressed through design changes, and that the Device has been "unfairly blamed" for the poor performance of the Bionik femoral head component. The main points are that the manufacturer concedes that the results are poor and that these needed addressing by changing the design of the Device and the components that are used in conjunction with the Device.

19. The OEWG made several observations about the NJRR data, and the submission made by Eska Australia and Orthodynamics:

    a. Orthodynamics had recognised several design issues with various components and made modifications in July 2007, September 2008 and most recently in February 2009. However, the cumulative revision rate appears to be getting steadily worse and diverging from the cumulative revision rate of all other similar implants. Revisions due to pain, leg length discrepancy, metal sensitivity, wear and implant breakage are occurring in relatively higher proportions compared to similar implants.

b. Mechanical testing commissioned by Orthodynamics has revealed that the stem/adaptor interface is prone to fretting and this appears to be confirmed by the data from the Australian Registry which reports relatively large numbers of revisions due to neck failure and problems with the Adapter stem rather than a particular femoral head in combination with the stem. Therefore, the explanation given by Orthodynamics that the poor performance of the Bionik head was unfairly attributed to poor performance of the Adapter Stem was not regarded to be convincing.

The OEWG concluded that the information provided by Eska Australia and Orthodynamics did not allay their concerns about the number of revisions of Adapter Femoral Stems reported by the NJRR.

20. As a result of the facts outlined in paragraphs 13-19 above I am satisfied that:

a. The revision rate of both the cemented and cementless versions the Adapter Femoral Stem Prosthesis is unacceptably high.

b. Eska Australia and Orthodymics were provided with ample time and opportunity to make submissions in relation to the revision rate of the implant, both in relation to the revision rate itself and in relation to unique design features that may compensate for the higher risk of revision.

c. Both the TGA and the Orthopaedic Expert Working Group that advises the TGA considered all the evidence, including the Eska Australia and Orthodynamics submissions carefully, and that after these considerations the revision rates of the Adapter Femoral Stem Prosthesis is regarded to be unacceptable and that the arguments in favour of continuing to use the implant are not convincing.

d. Since revision surgery is associated with considerable morbidity and a low but not insignificant mortality rate, the high rate of revision of the Adapter Femoral Stem indicates that both the performance and the safety of the implant are unacceptable.

Reasons for decision

21. Section 41GN(1)(e) of the Act provides the Secretary of the Department of Health and Ageing the authority to cancel the entry of a medical device from the Australian Register of Therapeutic Goods if "the Secretary is satisfied that the safety or performance of the kind of device is unacceptable".

22. As outlined in paragraph 20 of this letter, I am satisfied that the safety and performance of the Adapter Femoral Stem Prosthesis is not acceptable, and therefore Section 41GN(1)(e) applies.

Conclusion

23. I am proposing to cancel the entry of the Eska Adapter Femoral Stem Prosthesis from the Australian Register of Therapeutic Goods because, for the reasons set out in paragraphs 13-20 of this letter, I am satisfied that the safety and performance of this implant is unacceptable.

ATTACHMENT A (Cont'd)

Actions Required

24. Before cancelling the entry of a medical device under Section 41GN, the Secretary must inform the Sponsor in writing about the proposal to cancel and set out the reasons for it. The Secretary must also give the Sponsor a reasonable opportunity to make submissions in relation to the proposed cancellation.

25. If you wish to make a submission in relation to this proposal to cancel I request that you do so **in writing** and submit it **within 20 working days of the date of this letter** to:

    Dr Jorge Garcia
    Director, Biomaterials and Engineering Section
    Therapeutic Goods Administration
    PO Box 100, Woden, ACT 2606
    e-mail: jorge.garcia@tga.gov.au
    Telephone : +61 2 6232 8432

26. I believe that the 20 working day deadline is reasonable because Eska Australia and the manufacturer were provided the opportunity to make submissions in relation to the implant on two previous occasions. I also wish to stress that your previous submissions have already been given careful consideration by the TGA and the Orthopaedic Expert Working Group. Therefore any further submission should provide new evidence and/or highlight facts that you believe have been overlooked. It is not necessary to repeat your previous submissions.

Date of effect

27. The cancellation will NOT take effect until any submission that you wish to make in relation to this proposal has been considered. If the TGA does not receive a submission within 20 working days of the date of this letter, then the TGA will consider moving to cancel the Device from the Register.

Other Matters

28. If you require further information regarding this matter, please contact Dr Garcia on the telephone or e-mail provided in paragraph 25.

Yours sincerely

[redacted]
Head, Monitoring and Compliance Group
Therapeutic Goods Administration
(Delegate of the Secretary to the Department of Health and Ageing for the purposes of Section 41GN of the Therapeutic Goods Act 1989)

Date:30th August, 2011.

ATTACHMENT B

41GN Cancellation of entries of kinds of medical devices from the Register after notice of proposed cancellation

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) medical devices that were devices of that kind when the kind of device was included in the Register have changed so those medical devices are no longer devices of that kind; or

(b) the person in relation to whom the kind of medical device is included in the Register refuses or fails to comply with a condition to which that inclusion is subject; or

(c) the Secretary gives to the person a notice under section 41JA:

(i) that requires the person to give to the Secretary information or documents relating to the kind of device; and

(ii) in respect of which section 41GM does not apply;

and the person fails to comply with that notice within a further 10 working days from the day specified in that notice; or

(d) the person contravenes subsection 41MP(1) or 41MPA(1) in relation to the kind of device; or

(e) the Secretary is satisfied that the safety or performance of the kind of device is unacceptable; or

(f) the Secretary is satisfied that any certification, or part of a certification, under section 41FD in relation to the application for inclusion of the kind of device in the Register is incorrect, or is no longer correct, in a material particular.

Note: The matters that must be certified under section 41FD include compliance with the essential principles and the application of conformity assessment procedures, being able to substantiate the compliance and application, and compliance with advertising requirements.

(2) However, before cancelling the entry of the kind of device from the Register, the Secretary must:

(a) inform the person in writing that the Secretary proposes the cancellation and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed cancellation.

(3) The Secretary is not to make a decision relating to the proposed cancellation until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

41GO Limiting cancellation of entries from Register to some medical devices of a particular kind

(1) If the Secretary is satisfied that the ground for cancelling the entry of a kind of medical device from the Register applies only to some medical devices of that kind, the Secretary must limit the cancellation to the medical devices to which that ground or any other ground for cancellation applies.

(2) If the cancellation of the entry of a kind of medical device from the Register is limited to some medical devices of that kind, the Secretary:

(a) must vary the entry in the Register accordingly; and

(b) must not delete the entry from the Register because of the cancellation.

41GP Publication of cancellation of entry from Register

The Secretary must cause to be published in the Gazette, as soon as practicable after cancelling an entry from the Register of a kind of medical device, or of some devices of a particular kind, a notice setting out particulars of the cancellation.

41GQ Date of effect of cancellation of entries from Register

If the Secretary cancels an entry of a kind of medical device, or some devices of a particular kind, from the Register, the cancellation has effect:

(a) if the cancellation is under section 41GK or 41GL—on the day on which the notice of cancellation is given to the person in relation to whom the kind of device was included in the Register; or

(b) in any other case—on such later day as is specified in the notice, being a day not earlier than 20 working days after the notice is given to the person.

ATTACHMENT C:

This decision is an "initial decision" within the meaning of Section 60 of the *Therapeutic Goods Act 1989* (the Act). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. The Act requires the decision to be notified in the *Gazette*. The decision will be notified in the *Gazette* as soon as practicable after the cancellation takes effect (see the section in this letter entitled "Date of effect"). Any appeal should be made in writing within 90 days after this decision is notified in the *Gazette* and should be sent to the following address:

The Parliamentary Secretary of the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed

"REQUEST FOR RECONSIDERATION UNDER SECTION 60
OF THE THERAPEUTIC GOODS ACT 1989".

You should include with your request for reconsideration any information that you would like the Minister to consider. Under subsection 60(3A) of the Act, the Minister is not able to consider any information that you provide after making the request unless the information is provided in response to a request from the Minister or it is information that indicates that the quality, safety or efficacy of the relevant goods is unacceptable.

The Parliamentary Secretary may either personally deal with the appeal for the Minister or send it tobe dealt with by one of the Minister's delegates within the Department. If you are dissatisfied with the result of the decision on reconsideration then, subject to the *Administrative Appeals Tribunal Act 1975,* you may appeal to the Tibunal for review of that decision.