Submission No: 12

Australian Government

Department of Health and Ageing

SECRETARY

JOINT COMMITTEE OF
17 AUG 2004
PUBLIC ACCOUNTS & AUDIT

Ref: 2005/005597

Mr Russell Chafer
Secretary
Joint Committee of Public Accounts and Audit
Parliament House
CANBERRA ACT 2600

Dear Mr Chafer

JCPAA PUBLIC HEARING OF 5 APRIL 2005
REVIEW OF AUDITOR-GENERAL'S REPORT NO 18 OF 2004/2005:
REGULATION OF NON-PRESCRIPTION MEDICINAL PRODUCTS

I am writing to you in relation to the Department's attendance at the JCPAA public hearing on 5 April 2005, and to respond to matters taken on notice at the hearing. I understand that agreement was reached between our officers regarding the timing of the Department's responses in this regard.

In my opening statement to the Committee, and during the course of discussion on matters raised by the Committee, I noted that the Department had established an Audit Sub-committee to oversee and report on the Therapeutic Goods Administration's (TGA's) implementation of the ANAO recommendations, and that a consultant was to be engaged to assist with this work.

In response to requests from the Committee Chair, I advised that the Department would provide the Committee with an overview of progress with the implementation of the ANAO recommendations.

This work is well advanced. The consultant has undertaken a detailed review of the TGA implementation activities planned and conducted against each of the ANAO recommendations to determine:

- the effectiveness of the TGA responses in addressing the recommendations; and
- enhancements that may be required to improve the effectiveness of the responses.

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The high level conclusion to date from the review is that the TGA has planned activities against all 26 ANAO recommendations, and that a lot of work has already been performed and procedures continue to be updated.

Completion of approximately half of the recommendations is pending the implementation of standard operating procedures, planned for August 2005.

Further work is required to fully implement the recommendations and embed the changes into the TGA's regulatory practice framework.

The consultant has also concluded that many of the planned activities could be further enhanced to give effect to the broader intent of the recommendations, particularly as they relate to wider aspects of the TGA's operations. To this end, the consultant has developed additional recommendations for the TGA to build into its implementation plans.

A second phase of the consultancy is now underway to assist the TGA in finalising the implementation of all recommendations.

The Department's Audit Committee will continue to monitor the progress in implementing the recommendations. This process will be ongoing, and the Department will provide a further progress update to the Committee later in 2005.

In relation to other matters taken on notice at the public hearing, the Department notes that a majority of these relate to the Good Manufacturing Practice (GMP) audit practices and processes. The Committee's deliberations on these matters may be assisted by some additional contextual commentary provided at **Attachment A**.

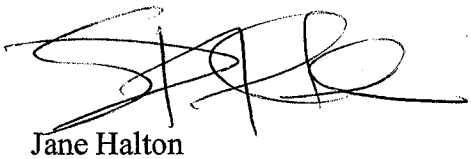
The relevant Hansard references and the corresponding Departmental responses are at **Attachment B**. Some of the responses reflect the context within which the GMP audit activities are undertaken. This attachment also includes two examples of reports as requested by Senator Watson. Please note that one of these reports is classified *Commercial-in-Confidence*, and it would be appreciated if the material therein could be protected accordingly.

The public hearing also included some discussion about whether there was a need to have a separate audit committee for the TGA. I have considered this matter further in the context of the work undertaken by the consultant, and in line with my comments at the hearing, I remain of the view that the Department's Audit Committee should be responsible for all aspects of the Department's operations, including the TGA.

The Department would be available to provide the Committee with any additional information that it may require on the TGA's regulatory operations.

If you have any questions regarding the matters set out in this letter, please contact Mr Phillip Jones, Assistant Secretary, Audit & Fraud Control Branch, on ☎6289 7877 in the first instance.

Yours sincerely



Jane Halton
Secretary

12 August 2005

ATTACHMENT A

DEPARTMENT OF HEALTH AND AGEING – CONTEXTUAL INFORMATION ON TGA GOOD MANUFACTURING PRACTICE (GMP) AUDIT

In broad terms, the regulatory responsibilities of the TGA are directed towards the safety, quality and efficacy of therapeutic goods marketed in Australia, with a significant emphasis placed on the compliance by manufacturers with the relevant standards governing the manufacture of those therapeutic goods.

A condition of entry of therapeutic goods on the Australian Register of Therapeutic Goods (ie for marketing in Australia) is that the manufacturer must meet GMP requirements and be licensed by the TGA for the manufacture of those goods.

The GMP audit activities are focussed primarily on the manufacturers and their processes, rather than on specific therapeutic goods. Other pre and post-market regulatory activities of the TGA have more product specific foci.

As many manufacturers produce a mix of prescription and non-prescription medicines, together with other products and devices, the GMP audit effort is generally directed to the overall quality mechanisms applied throughout the manufacturing processes to ensure compliance with standards, and to provide assurance in relation to the manufactured products.

Australia has Codes of GMP and Quality System requirements for the manufacture of medicinal products, sunscreen products, human blood and tissues, active pharmaceutical ingredients and medical devices. Each Code/Quality System sets out requirements relating to quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall and self inspection.

The observance of these requirements is necessary through all stages of manufacture to consistently provide a high level of assurance of the quality, safety and efficacy of therapeutic goods.

Compliance with the Codes of GMP and/or Quality System requirements in Australia is ascertained by carrying out regular on-site audits of manufacturers. The purpose of the audits is to assess compliance with the relevant manufacturing standard, the conditions specified in the manufacturing licence, and compliance with the relevant marketing authorisations. Each audit involves a detailed examination of the operations and procedures of the factory, and includes a detailed review of all processing activities, process validation, batch documentation and quality control testing.

Where critical and/or several major deficiencies have been found to warrant an "unacceptable" compliance rating at the close-out of the audit, the manufacturer's licence may be suspended or revoked, or some additional conditions imposed on the licence if there is a possibility of sub-standard and/or unsafe products being manufactured.

JCPAA HEARING - 5 APRIL 2005
ANAO REPORT NO 18 OF 2004/2005 - REGULATION OF NON-PRESCRIPTION MEDICINAL PRODUCTS

MATTERS TAKEN ON NOTICE BY DEPARTMENT OF HEALTH AND AGEING

<table>
<tr><th>Hansard Reference</th><th>Matter taken on Notice and Response</th></tr>
<tr><td>PA 33/34</td><td>Matter on Notice
Question from the Chair to Mr Slater on the number of staff doing non-prescription medicine manufacture audits.
Response
In the context of the explanation provided at the hearing regarding the difficulty of differentiating between staff attribution to manufacturers of all therapeutic goods, as at 27 May 2005, the total number of auditors and specialists involved in the auditing of Australian and overseas manufacturers was 58 (25 auditors and 33 specialists).</td></tr>
<tr><td>PA 35</td><td>Matter on Notice
Request from the Chair for more information on the number of medicine manufacturer audits, including prescription and devices (Table 3.1 at page 50 of the ANAO report refers).
Response
The tables below provide the additional information. Note - Other includes medicinal gas, sunscreen and active pharmaceutical ingredients manufacturers, as well as testing laboratories.
Summary - audits of Australian manufacturers
<table><tr><th></th><th>1999</th><th>2000</th><th>2001</th><th>2002</th><th>2003</th></tr><tr><td>Blood/tissue</td><td>78</td><td>40</td><td>91</td><td>74</td><td>113</td></tr><tr><td>Device</td><td>49</td><td>40</td><td>45</td><td>31</td><td>30</td></tr><tr><td>Medicine - Non-prescription</td><td>105</td><td>98</td><td>80</td><td>72</td><td>70</td></tr><tr><td>Medicine - Prescription</td><td>54</td><td>61</td><td>79</td><td>87</td><td>89</td></tr><tr><td>Other</td><td>34</td><td>24</td><td>18</td><td>15</td><td>11</td></tr><tr><td>Total</td><td>320</td><td>263</td><td>313</td><td>279</td><td>313</td></tr></table>
Summary - audits of overseas manufacturers
<table><tr><th></th><th>1999</th><th>2000</th><th>2001</th><th>2002</th><th>2003</th></tr><tr><td>Blood/tissue</td><td>2</td><td>2</td><td>0</td><td>1</td><td>5</td></tr><tr><td>Device</td><td>6</td><td>20</td><td>2</td><td>3</td><td>6</td></tr><tr><td>Medicine - Non-prescription</td><td>35</td><td>55</td><td>47</td><td>51</td><td>23</td></tr><tr><td>Medicine - Prescription</td><td>12</td><td>16</td><td>16</td><td>9</td><td>4</td></tr><tr><td>Other</td><td>3</td><td>1</td><td>11</td><td>13</td><td>13</td></tr><tr><td>Total</td><td>58</td><td>94</td><td>76</td><td>77</td><td>51</td></tr></table></td></tr>
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PA 36 (& 63)	**Matters on Notice** The Chair requested the Department to report back to the JCPAA on progress with actions on the recommendations, including the work undertaken by the consultant. **Response** An update on progress with the implementation of the ANAO recommendations, including the work of the consultant, is provided in the letter covering this attachment.
PA 44, 45 and 51	**Matters on Notice** 1. Senator Watson asked (PA 44) "In relation to the charter of good manufacturing practice, how many serious adverse reports or warnings have you issued in the past four years?" (Confirmed by the Chair to relate to non-prescription products). 2. Senator Watson also asked (PA 45) "Could you give the committee copies of what you regard as the serious reports?" 3. The Acting Chair asked (PA 51) "In the last 12 months, have there been any critical deficiencies onshore or offshore? … What was the incidence level?" **Response** Having regard to the context in which compliance ratings are determined at the close-out of an audit (the commentary in the covering letter refers), the numbers of "unacceptable" compliance ratings for Australian and overseas manufacturers of non-prescription medicines for the period 1 January 2001 to 31 December 2004 were thirteen (13) for Australian manufacturers and nine (9) for overseas manufacturers. Copies of two final GMP audit reports with unacceptable ratings are attached.
PA 46	**Matter on Notice** Senator Moore requested information for the Committee on the new TGA information systems, confirmation of the new systems being up to date, with (integrated) data on previous audits, products, manufacturers etc, and with clear data records that show up to date information of the form the ANAO sought. **Response** The TGA is giving priority to migrating data into the new Manufacturer Information System. This data migration process includes ensuring that the available information is as accurate as possible. While some input is required from manufacturers and sponsors to assist the data validation process, there are cases where the required information is not forthcoming. The TGA estimates that full data migration will be achieved by mid-September 2005. The report on progress with the ANAO recommendations accompanying these responses also addresses matters relating to the new TGA information systems.
PA 48	**Matter on Notice** Ms Grierson asked "… how many unannounced audits did you actually undertake in 2004" **Response** Thirteen
PA 55/56	**Matter on Notice** The Department undertook to make informal inquiries of other agencies regarding actions relating to Pan, and provide "best intelligence" on other actions to the JCPAA for them to follow-up with relevant agency heads. **Response** The Department advises that there are a number of court actions proceeding in relation to Pan Pharmaceutical Ltd, Mr Jim Selim and Mr Shyama Jain. The Department is not aware of matters relating to other agencies, but suggests that the Committee seek advice from the Attorney-General's Department and the Director of Public Prosecutions in relation to any matters that other agencies may have in hand.

PA 61	**Matter on Notice** Ms Grierson asked "How much of the budget would be spent on training annually?" **Response** The expenditure to date in 2004-05 on training for the TGA as a whole was $265,511, with $20,263 attributable to the Manufacturer Assessment Section (MAS), the area responsible for audits of manufacturers. It is to be noted that these costs relate primarily to externally supplied training. However, additional training for MAS auditors is delivered via in-house arrangements, through both intensive periodic training meetings and ongoing on-the-job learning. In relation to the periodic training meetings, there were two week long sessions conducted during 2004/2005, at an approximate total cost (travel, accommodation etc) of $20,300, exclusive of salary related costs.