



Fw: IDC - Mercury LBI - Friday 23 July [SEC=UNCLASSIFIED]

TGA International

09/12/2010 04:23 PM

Sent by: [REDACTED]

This is the first of two emails I will send - this is our response to the questions posed by the UNEP secretariat after the first INC in June.

Kind regards,

International Coordination Team
Office of Parliamentary and Strategic Support
Therapeutic Goods Administration

E-mail: tga.international@tga.gov.au

----- Forwarded by [REDACTED] on 09/12/2010 04:21 PM -----



TGA
International
Sent by: [REDACTED]

To: [REDACTED]@environment.gov.au>

cc: [REDACTED]@environment.gov.au>

[REDACTED]@environment.gov.au>

11/11/2010
02:14 PM

Subject: Re: IDC - Mercury LBI - Friday 23 July [SEC=UNCLASSIFIED]

Dear [REDACTED]

Please find attached TGA's contribution to the mercury data gaps identified by the UNEP Secretariat.

Should you have any queries or concerns relating to this information, we would be very happy to discuss these at our meeting tomorrow (Friday 12 November at 3pm).

TGA participants at tomorrow's meeting will be:

[REDACTED] Chief Regulatory Officer
[REDACTED] Office of Devices Authorisation
[REDACTED] Office of Scientific Evaluation
[REDACTED] Office of Laboratories and Scientific Services

[REDACTED] will also be there, representing the International Coordination team.

Please note that we are correctly identified as stakeholders for the Regulation sector (arrangements for labelling products containing mercury), but mistakenly included as a stakeholder for the sector for unintentional emission (biomedical waste incineration).

Kind regards,

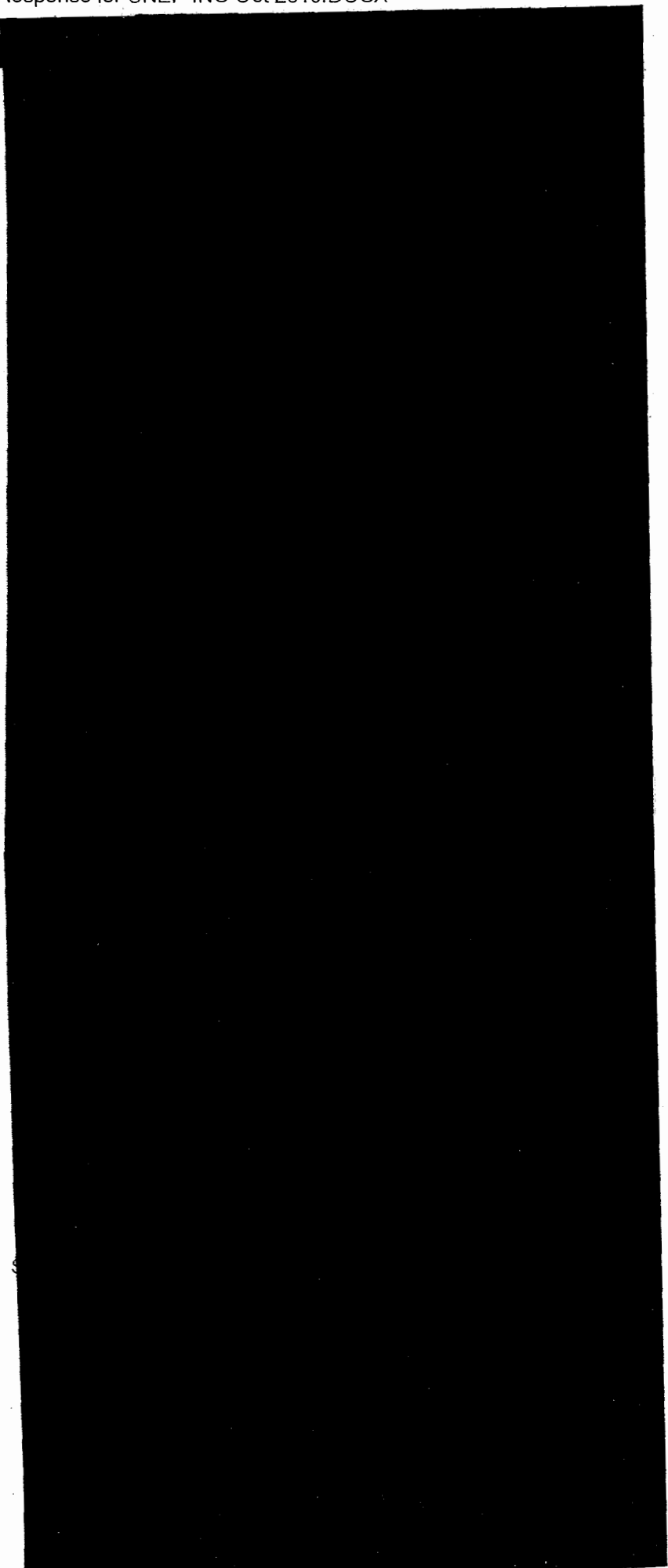
International Coordination Team
Office of Parliamentary and Strategic Support
Therapeutic Goods Administration

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Document 1



30/07/2010 01:42 PM



Dear Colleagues

Following up from the INC - Mercury LBI meeting on Friday 23 July, we would like to request for your assistance in addressing the mercury data gaps that the UNEP Secretariat has identified.

Mercury data gaps - Request for information by the UNEP Secretariat

- You would recall from my original email on 16 July, that the UNEP Secretariat has requested governments to provide information on a number of issues that were discussed at INC 1 by 31 August 2010. To be more precise, the information is to fill in the data gaps on mercury issues. I've attached another copy of the UNEP letter which lists what information is needed.

An overview of the issues, details listed in the letter, where information is needed include:

- a. Monitoring efforts relating to fish and marine mammals in the food supply.
- b. Projects relating to artisanal and small-scale gold mining.
- c. Collation of data of mercury releases. (DEWHA has provided the Secretariat a copy of [REDACTED] report)
- d. Information on mercury-containing products and all known processes and technologies that use mercury; and information on alternatives to those products, processes and technologies, as well as on the costs and availability of such alternatives. (UNEP Secretariat is seeking to update the following document:)

<<OEWG_2_Agenda Item 3_Report on the major mercury-containing products and processes - addendum,.pdf>>
- e. A cost-benefit analysis of existing alternatives to mercury-based products, processes and technologies (obviously we will not be able to provide a full response to the Secretariat on this topic)
- f. Approaches to regulating the use of mercury in products. (DEWHA will be seeking views from agencies on this question)
- g. Analysis of possible funding sources, including the private sector.

<<UNEP letter - Request for information from Governments.pdf>>

If are able to assist us in providing data/information on any of the above topics please let me know.

Understandably the 31 August deadline may not be attained for all the requested information, so no need to panic. If we are able to provide information but at a later date, I'm sure the Secretariat will be forgiving!

FYI - Additional Information for the IDC

- Attached is a copy of the final report, commissioned by DEWHA, on the: Study of mercury, sources, transportation and fate in Australia by [REDACTED] Macquarie University.

<<FINAL Report - Study of Mercury Sources, Transportation and Fate in Australia.pdf>>

This report has not been officially released. However, a copy has been submitted to the UNEP Secretariat, coordinating the International Negotiating Committee (INC) for a LBI on Mercury, for their information.

- As requested by the IDC, I have included the link to the INC webpage, which lists the INC meetings and documents (agenda and information / research papers). Perhaps add this webpage to your Favourites list!
<http://www.unep.org/hazardoussubstances/MercuryNot/MercuryNegotiations/tabid/3320/language/en-US/Default.aspx>

If you have any questions, please contact either myself or [REDACTED] (currently away - back in office 12 August).

Thank you

Regards

[REDACTED]

[REDACTED]

Assistant Director
Chemical Partnerships Section
Department of the Environment, Water, Heritage and the Arts

[REDACTED]

From: [REDACTED]

Sent: Friday, 16 July 2010 3:18 PM

[REDACTED]

Cc: [REDACTED]

Subject: IDC - LBI Mercury - Friday 23 July [SEC=UNCLASSIFIED]

Dear Colleagues

The first meeting of the Intergovernmental Negotiating Committee (INC 1) for a LBI on Mercury was held in June 2010, Stockholm. With formal negotiations now underway, we have substantial work ahead of us to prepare for INC 2 on the 24-28 January 2011, Chiba, Japan - post xmas/ new year holidays!!

We are scheduling an IDC next week on **Friday, 23 July, at DEWHA, John Gorton Building, Parkes** to provide a debrief on INC 1 and discuss next steps for INC 2. Attached is the draft agenda (**attachment 1**). Let me know if you would like any additional items to be included on the agenda.

As part of our next steps, we have compiled a list of data gaps on mercury issues in Australia that we need to address for INC 2 (**attachment 2**). We are seeking comments on the questions and identifying the appropriate stakeholders. In relation to addressing the data gaps, the UNEP Secretariat has requested governments to provide information on a number of issues that were discussed at INC 1. The information being sought is in the attached UNEP document (**attachment 3**).

Please contact me on [REDACTED] or email: [REDACTED]@environment.gov.au, if you, and/or any of your colleagues, intend on participating in the IDC by **Wednesday 21 June**.

Kind regards

[REDACTED]

<< File: Attachment 3 - Invitation-input-info-GOV-Final-copy.pdf >> << File: Attachment 1 - IDC agenda - 23 July 2010.doc >> << File: Attachment 2 - Data gaps matrix July 2010.doc >>

[REDACTED]

Assistant Director
Chemical Partnerships Section
Department of the Environment, Water, Heritage and the Arts

[REDACTED]

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[REDACTED]



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

**UNEP legally binding instrument on
mercury:**

**Request for information regarding medical
equipment and therapeutic products**



Version 1.5
25 October 2010

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REVISION HISTORY

| Version No | Date | Brief description of revision |
|------------|----------|----------------------------------|
| 1.0 | 08/10/10 | Creation of new document |
| 1.1 | 11/10/10 | Internal peer-review |
| 1.2 | 14/10/10 | Intra-TGA peer-review |
| 1.3 | 20/10/10 | Incorporation of report from ODA |
| 1.4 | 22/10/10 | Suggested final modifications |
| 1.5 | 25/10/10 | Final editorial changes |

NOTE FOR VIEWING THIS DOCUMENT

The tables included in this document contain listed and registered products containing mercury compounds. Data in these tables pertaining to the quantities of mercury compounds are commercial-in-confidence information, and should be removed or blacked-out prior to external circulation of this document.

1 INTRODUCTION

On 20 February 2009, the United Nations Environment Programme's (UNEP) Governing Council agreed on a plan for a global approach to reduce population and ecosystem exposure to mercury. On 6 July 2010, UNEP issued an invitation to Governments to contribute information in preparation for the second session of the UNEP Intergovernmental Negotiating Committee to prepare a legally binding instrument on mercury. Following an Inter-departmental Conference (IDC) with relevant Australian Government stakeholders on 23 July 2010, a data gaps matrix was prepared (see Appendix 1), outlining the specific data gaps to be addressed in Australia's response to UNEP.

The data gaps matrix identified therapeutic goods (including vaccines) and medical equipment as key sectors for intentional use of mercury for which UNEP is seeking information. The following document contains a discussion of each of the relevant data gaps for these products, using data available to the TGA at the time of preparation.

2 CURRENT REGULATORY ARRANGEMENTS WITH REGARD TO MERCURY IN MEDICINES

Medicines are regulated by relevant work areas in the TGA according to their relative risk, and are listed or registered on the Australian Register of Therapeutic Goods (ARTG). Registered medicines (prescription, non-prescription and complementary) are deemed higher risk products and are evaluated in terms of quality, safety and efficacy prior to availability in the Australian market. Listed medicines, which meet TGA requirements for quality and safety, are entered directly onto the ARTG by sponsors (export only medicines, and most complementary medicines, are listed). Sponsors of listed medicines are not required to submit efficacy data for evaluation prior to listing. A major class of therapeutic products containing mercury compounds are vaccines, which were identified as a separate item in the Data Gaps matrix. Specific policies and guidance documents apply to the regulation of mercury in vaccines. Thus, they will be discussed separately in Section 4 below.

Broadly speaking, mercury-containing medicines are regulated similarly across all three product types (prescription, non-prescription and complementary medicines), with some individual differences. There is no Australian Government position on the use of mercury in most therapeutic goods. However, the Australian Government has issued advice on the use of mercury (as thiomersal) in influenza vaccines; refer to Section 4 below for details.

No specific regulatory arrangements with regard to mercury, apart from vaccines, exist for prescription, non-prescription or complementary medicines in Australia. The quality, safety (and efficacy for registered products) of mercury-containing products must be demonstrated according to relevant scientific guidelines, as is the case for any other medicine registered or listed in Australia. As an example, prescription medicines are regulated with reference to numerous international guidelines produced by the ICH and EMA¹, which have been adopted by the TGA following consultation with internal and external stakeholders.

¹ EMA = European Medicines Agency, ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

Medicines may potentially contain low levels of free mercury, either due to degradation of an excipient mercury compound or from environmental contamination. The latter is particularly relevant for complementary medicines derived from fish products, *e.g.* omega-3 fatty acids. In Australia, the levels of free mercury or inorganic mercuric compounds (as impurities) in medicines are regulated using international pharmacopoeial monographs (*e.g.* from the British Pharmacopeia; BP), in which maximum allowable limits are specified. Guidance for the specific limits of inorganic mercury can be obtained from monographs for heavy metals, some specific products, and some common mercury compounds (thiomersal, phenylmercuric acetate and phenylmercuric nitrate).

2.1 SCHEDULING OF MERCURY-CONTAINING MEDICINES

The Poisons Standard 2010² is an Australian Government Legislative Instrument and consists of decisions regarding the classification of drugs and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. Mercury-containing products are scheduled according to the level of risk of exposure to humans. The following scheduling decisions apply to mercury-containing compounds listed or registered in the ARTG.

Schedule 2

MERCURY for external use in preparations containing 0.5 per cent or less of mercury.

Schedule 4

MERCURY for cosmetic or therapeutic use except:

- (a) when separately specified in these Schedules; or
- (b) in a sealed device which prevents access to the mercury.

Schedule 7

MERCURY except:

- (a) when separately specified in this Schedule;
- (b) when included in Schedule 2, 4 or 6;
- (c) in preparations containing 0.01 per cent or less of mercury in organic form as a preservative;
- (d) mercury (metallic) in scientific instruments;
- (e) dental amalgams; or
- (f) in a sealed device, for therapeutic use, which prevents access to the mercury.

PHENYLMERCURIC ACETATE except in preparations containing 0.01 per cent or less of mercury as a preservative.

The requirements of this Standard do not apply to products which contain mercury at not more than 1 mg per litre or kilogram.

3 USE OF MERCURY IN THERAPEUTIC PRODUCTS

The ARTG was searched to identify all therapeutic goods registered or listed for use in Australia containing mercury compounds. These products are discussed below in terms of the regulatory classification of the product, *i.e.* prescription and non-prescription or complementary. Importantly, the products listed below reflect those approved for use in Australia, but the TGA does not possess information regarding the actual use of these.

² Poisons Standard 2010 (Federal Register of Legislative Instruments F2010L02386); www.frli.gov.au

products in the community (*i.e.* some listed or registered products may no longer be sold in Australia, but the Sponsor has not requested their removal from the ARTG). There are no mercury-containing skin-lightening products listed or registered on the ARTG.

Although limited data were available, it appears that other compounds can be substituted for mercury compounds in many cases, when the mercury compound is used as a preservative. Data collected by the Food and Drug Administration in the USA (FDA) indicated that most mercury-containing non-homeopathic products registered in the USA in 1999 were no longer marketed at that time, or the use of the mercury compound was being replaced with non-mercury preservatives such as benzalkonium chloride³.

3.1 NATURE OF MERCURY COMPOUNDS IN THERAPEUTIC GOODS

Mercury is present in therapeutic goods, *i.e.* medicines, in Australia as organic compounds such as thiomersal, merbromin, phenylmercuric acetate, phenylmercuric nitrate, and in some homeopathic products as Hahnemann's soluble mercury and mercuric iodide - red. In most cases, these compounds are present at low levels as a non-active ingredient (*i.e.* excipient), usually as a preservative. Some mercury compounds (merbromin, mercuric iodide (red) and Hahnemann's soluble mercury) are included as active ingredients, as discussed in the relevant subsections below.

3.2 PRESCRIPTION AND NON-PRESCRIPTION MEDICINES

As at 23 September 2010, there are approximately 12,600 registered medicines (prescription, non-prescription and complementary; not including vaccines), on the ARTG for use in Australia. Of these, 12 are prescription medicines and 10 are non-prescription medicines containing mercury compounds, as shown in Tables 1 and 2 below. One product (ear drops) is a listed medicine for export only, but is included in the list for completeness. The majority contain mercury compounds as excipients and not active ingredients, generally as preservatives (phenylmercuric acetate, phenylmercuric nitrate and thiomersal), and include ear and eye drops, nasal sprays and drops, an injectable antibiotic and an injectable treatment for rheumatoid arthritis. Four products are topical antiseptics containing merbromin as the active ingredient. These nasal sprays and merbromin-containing products are manufactured in Australia; the remainder are imported from countries in the EU, with final packaging and/or quality control taking place in Australia in some cases.

3.3 COMPLEMENTARY MEDICINES

Of the more than 11,000 listed complementary medicines on the ARTG as at 23 September 2010, eleven contain mercury compounds (Hahnemann's soluble mercury and mercuric iodide - red) as active ingredients. These products are listed in Table 3 below. All are homeopathic products intended for use in a wide range of illnesses and contain homeopathic preparations of mercury at less than material doses. As the products are administered to patients at trace levels following several rounds of serial dilution, the total amount of mercury required for their manufacture is generally considered to be minimal³. Approximately half of the products are manufactured in Australia, and the remainder are imported from Germany.

³ Quantitative and qualitative analysis of mercury compounds in the list: Mercury compounds in drugs and food (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments/totheFDCA/FDAMA/ucm100219.htm>).

Table 1 Prescription medicines containing mercury compounds

| ARTG No. | Product | Indication | Sponsor | Country of manufacture | Mercury compound | Quantity ^a |
|--------------------|--|--|---|---------------------------------|------------------------|-----------------------|
| 27362 | GOLD CROSS MERCUROCHROME solution merbromin paint (50 ml bottle) | Weak disinfectant for skin infections | Biotech Pharmaceuticals Pty Ltd | Australia | Merbromin | |
| 21265 | ORION MERCUROCHROME solution 10% merbromin paint (15 ml bottle) | General antiseptic, topical treatment for local infections | Orion Laboratories Pty Ltd | Australia | Merbromin | |
| 21263 | ORION MERCUROCHROME 2% solution merbromin paint (50 ml bottle) | Not specified | Orion Laboratories Pty Ltd | Australia | Merbromin | |
| 19666 | CILICAINE syringe procaine penicillin 1.5 g injection syringe | Treatment of moderately severe infections. | Sigma Pharmaceuticals Australia Pty Ltd | France, Italy, Austria, Germany | Phenylmercuric acetate | |
| 24324 ^b | CHLOROMYXIN ear drops chloramphenicol polymyxin B sulphate (5 mL bottle) | Short-term treatment of infections in otitis externa | Pfizer Australia Pty Ltd | Australia | Phenylmercuric acetate | |
| 23201 | BLEPIAMIDE eye drops (5 ml bottle) | Corticosteroid & anti-infectives | Allergan Australia Pty Ltd | Ireland, Australia ^c | Phenylmercuric nitrate | |
| 57082 | CHLOROMYCETIN chloramphenicol 5 mg/ml ear drops (5 ml bottle) | Treatment of otitis externa | Pfizer Australia Pty Ltd | England, Spain | Phenylmercuric nitrate | |
| 57090 | CHLOROMYCETIN chloramphenicol 5 mg/ml eye drops (10 ml bottle) | Ocular bacterial infections | Pfizer Australia Pty Ltd | England, Spain | Phenylmercuric nitrate | |
| 27518 | MYOCRISIN sodium aurothiomalate 10 mg/0.5 ml injection ampoule | Rheumatoid arthritis, Still's disease | Sanofi-Aventis Australia Pty Ltd | England, Italy | Phenylmercuric nitrate | |
| 27519 | MYOCRISIN sodium aurothiomalate 20 mg/0.5 ml injection ampoule | Rheumatoid arthritis, Still's disease | Sanofi-Aventis Australia Pty Ltd | England, Italy | Phenylmercuric nitrate | |
| 27521 | MYOCRISIN sodium aurothiomalate 50 mg/0.5 ml injection ampoule | Rheumatoid arthritis, Still's disease | Sanofi-Aventis Australia Pty Ltd | England, Italy | Phenylmercuric nitrate | |
| 46863 | OCUFEN flurbiprofen sodium 0.03% eye drops (5 ml bottle) | Inhibition of intraoperative miosis | Allergan Australia Pty Ltd | England, Ireland | Thiomersal | |

^aQuantity of mercury compound; ^bListed medicine for export only; ^cPackaging & labelling only

Table 2 Non-prescription medicines containing mercury compounds

| ARTG No. | Product | Indication | Sponsor | Country of manufacture | Mercury compound | Quantity ^a |
|----------|--|---|---|----------------------------|------------------------|-----------------------|
| 14230 | DAVID CRAIG MERCUROCHROME 1% solution (50, 100, 500 mL bottles) | Antiseptic | Biotech Pharmaceuticals Pty Ltd | Australia | Merbromin | |
| 19661 | CILORSIG chloramphenicol 5 mg/mL eye drops (10 mL bottle) | Bacterial conjunctivitis & other superficial ocular infections | Sigma Pharmaceuticals Australia Pty Ltd | Germany, Spain | Phenylmercuric acetate | |
| 18349 | DRIXINE Paediatric Nasal drops (15 mL bottle) | Symptomatic relief of nasal & nasopharyngeal congestion associated with the common cold, hayfever & sinusitis, ... etc. | Schering-Plough Pty Ltd | Australia | Phenylmercuric acetate | |
| 26981 | DRIXINE Adult metered dose aerosol spray (15 mL bottle) | Symptomatic relief of nasal & nasopharyngeal congestion associated with the common cold, hayfever & sinusitis, ... etc. | Schering-Plough Pty Ltd | Australia | Phenylmercuric acetate | |
| 18838 | DRIXINE Adult nasal spray (15, 30 mL bottle) | Symptomatic relief of nasal & nasopharyngeal congestion associated with the common cold, hayfever & sinusitis, ... etc. | Schering-Plough Pty Ltd | Australia | Phenylmercuric acetate | |
| 18835 | DRIXINE Adult nasal drops (15 mL bottle) | Symptomatic relief of nasal & nasopharyngeal congestion associated with the common cold, hayfever & sinusitis, ... etc. | Schering-Plough Pty Ltd | Australia | Phenylmercuric acetate | |
| 13658 | NYAL DECONGESTANT Nasal spray phenylephrine hydrochloride (15 mL bottle) | Relieves nasal congestion in colds, flu, allergy, hayfever & sinusitis | Valeant Pharmaceuticals Australasia Pty Ltd | Australia | Thiomersal | |
| 29660 | MURINE RELIEF berberine hydrochloride eye drops (15 mL bottle) | Relief from mild irritation & soreness associated with wind, dust, smoke, air pollution, sun, swimming & allergy. | Aspen Pharmacare Australia Pty Ltd | Italy | Thiomersal | |
| 29784 | MURINE POOL EYES berberine hydrochloride eye drops (15 mL bottle) | Not specified | Aspen Pharmacare Australia Pty Ltd | Not specified ^b | Thiomersal | |
| 23236 | PREFRIN-Z LIQUIFILM eye drops (15 mL bottle) | Relief of minor eye irritations caused by colds, hay fever, dust, sun, smog, contact lenses, sun, wind, swimming & allergy. | Allergan Australia Pty Ltd | Ireland | Thiomersal | |

^aQuantity of mercury compound; ^bIt was assumed to be the same as product no. 29660.

Table 3 Complementary (listed) medicines containing mercury compounds

| ARTG No. | Product | Indication | Sponsor | Country of manufacture | Form of mercury | Quantity ^a |
|----------|---|--|---------------------------------|------------------------|-----------------------------|-----------------------|
| 148695 | Traumeel | Symptomatic relief of soft tissue trauma, sprains & swelling, muscular aches & pains, arthritic pain, mild to moderate acne. | Brauer Professional Pty Ltd | Germany | Hahnemann's soluble mercury | |
| 96701 | Traumcel S | Mouth ulcers, tonsillitis, soft tissue trauma, sprains, influenza, arthritis pain. | Brauer Professional Pty Ltd | Germany | Hahnemann's soluble mercury | |
| 93556 | Cutis compositum | Mild to moderate acne, dry skin, eczema, dermatitis. | Brauer Professional Pty Ltd | Germany | Hahnemann's soluble mercury | |
| 152670 | Traumeel Gel | Symptomatic relief of soft tissue trauma, sprains & swelling, muscular aches & pains, arthritic pain, mild to moderate acne. | Brauer Professional Pty Ltd | Germany | Hahnemann's soluble mercury | |
| 68612 | Digestive Detoxification Tonic | Detoxification & elimination of accumulated wastes & toxins | Brauer Natural Medicine Pty Ltd | Australia | Hahnemann's soluble mercury | |
| 78958 | Immune antinplex | Fevers & inflammations associated with infectious diseases | Brauer Natural Medicine Pty Ltd | Australia | Hahnemann's soluble mercury | |
| 124134 | Respatona sore throat oral spray | Symptomatic relief of sore throat | Brauer Natural Medicine Pty Ltd | Australia | Hahnemann's soluble mercury | |
| 96240 | Digestive hepato-D | Hepatic insufficiency, hepatic congestions & biliary disorders | Brauer Natural Medicine Pty Ltd | Australia | Hahnemann's soluble mercury | |
| 145143 | Brauer natural medicine joint & muscle oral spray | Muscular aches & pains, arthritis pain | Brauer Natural Medicine Pty Ltd | Australia | Hahnemann's soluble mercury | |
| 79386 | Immune Lymplex | Disorders of the lymphatic system | Brauer Natural Medicine Pty Ltd | Australia | Mercuric iodide - red | |
| 94405 | Euphorbium compositum nasal spray | Symptomatic relief of rhinitis, sinusitis, recurrent upper respiratory tract infections & glue ear. | Brauer Professional Pty Ltd | Germany | Mercuric iodide - red | |

^aQuantity of mercury compound in parent preparation. The preparations have been serially diluted several times such that mercury is present at less than material doses.

4 USE OF MERCURY IN VACCINES

Thiomersal, which is an ethyl mercury compound, has been used as a preservative in vaccines since the 1930s. As of 23 September 2010, there are 149 vaccines registered on the ARTG, and 32 listed for export only. Of these, 24 registered vaccines and 12 listed vaccines for export contain thiomersal, as shown in Tables 4 and 5 below. The majority of the registered vaccines are imported from countries in the EU, one from Japan, and six are manufactured in Australia. All vaccines for export are manufactured in Australia. Almost half of these vaccines are influenza vaccines, but vaccines against Hepatitis B, Japanese encephalitis, Q fever, *Bordetella pertussis*, *Plasmodium falciparum* and *Haemophilus influenzae* are also included. The latter three organisms are responsible for whooping cough, malaria and bacterial meningitis, respectively; these three vaccines are for export only. Thiomersal-free equivalents of many of the registered influenza and Hepatitis B vaccines have also been subsequently included in the ARTG. Many of these vaccines may therefore no longer be marketed in Australia.

Two guidance documents are used by the TGA for regulation of thiomersal in vaccines. The TGA has adopted (in 2002) the EMA guidance document *Points to Consider on the Reduction, Elimination or Substitution of Thiomersal in Vaccines* (CPMP/BWP/2517/00) for regulatory purposes. Thus, the TGA supports the position that thiomersal use in vaccines should be reduced, minimised or eliminated wherever possible. However, this document discusses cases in which the use of thiomersal in vaccines is required (multi-dose vials for use in health emergencies and in developing nations), or even preferable (thiomersal stabilisation of the surface antigen of Hepatitis B virus). In 2009, the Australian Technology Advisory Group on Immunisation (ATAGI), an expert committee under the Department of Health and Ageing portfolio, published advice regarding the use of influenza vaccines containing thiomersal⁴. This statement endorsed the use of thiomersal in influenza vaccines, in line with similar endorsements by the World Health Organization and other developed nations.

⁴[www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/\\$File/ATAGI_Thio_statm%20_091009.pdf](http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/$File/ATAGI_Thio_statm%20_091009.pdf)

Table 4 Vaccines containing mercury (as thiomersal)

| ARTG No. | Product | Sponsor | Country of manufacture | Quantity ^a |
|----------|--|---|---------------------------------|-----------------------|
| 143423 | EMERFLU pandemic influenza vaccine (H5N1); suspension for injection (0.5 mL) | Sanofi Pasteur Pty Ltd | France | |
| 13027 | ENGERIX-B hepatitis B surface antigen recombinant (yeast); Multidose vial (10 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 13029 | ENGERIX-B hepatitis B; Injection vial (1 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 13031 | ENGERIX-B PAEDIATRIC DOSE hepatitis B; Injection vial (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 64230 | ENGERIX-B PAEDIATRIC DOSE hepatitis B; Injection syringe (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 64231 | ENGERIX-B hepatitis B; Injection syringe (1 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 73476 | ENGERIX-B hepatitis B; Multidose vial (10 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 73477 | ENGERIX-B hepatitis B; Injection vial (1 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 73478 | ENGERIX-B PAEDIATRIC DOSE hepatitis B; Injection vial (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 73479 | ENGERIX-B PAEDIATRIC DOSE hepatitis B; Injection syringe (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 73480 | ENGERIX-B hepatitis B; Injection syringe (1 mL) | GlaxoSmithKline Australia Pty Ltd | Belgium | |
| 66552 | FLUARIX Inactivated split influenza vaccine; injection syringe (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Germany Belgium | |
| 82884 | FLUARIX Inactivated split influenza vaccine suspension; pre-filled syringe (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Germany Belgium | |
| 29215 | FLUVAX inactivated influenza vaccine (split virion) 0.5 mL injection syringe | CSL Ltd | Australia | |
| 92695 | FLUVIRIN inactivated influenza vaccine (surface antigen); injection syringe (0.5 mL) | Novartis Vaccines & Diagnostics Pty Ltd | England, Italy | |
| 49681 | JAPANESE ENCEPHALITIS VIRUS VACCINE INACTIVATED (JE-VAX) powder for injection | Sanofi Pasteur Pty Ltd | Japan | |
| 145924 | PANDEMRIX pandemic influenza vaccine split virion, inactivated, AS03 adjuvanted; suspension for injection (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | England, Germany, Belgium | |
| 174554 | PANDEMRIX H1N1 pandemic influenza vaccine; suspension for injection (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Germany, Belgium | |
| 137704 | PANVAX pandemic influenza vaccine; suspension for injection (10 mL) | CSL Ltd | Australia | |
| 163897 | PANVAX H1N1 VACCINE, H1N1 pandemic influenza vaccine; multi-dose injection vial (10 mL) | CSL Ltd | Australia | |
| 165345 | PANVAX H1N1 VACCINE, H1N1 pandemic influenza vaccine; multi-dose injection vial (5 mL) | CSL Ltd | Australia | |
| 100517 | Q-VAX Q Fever Vaccine; injection syringe (0.5 mL) | CSL Ltd | Australia | |
| 100518 | Q-VAX Skin Test; injection vial (0.5 mL) | CSL Ltd | Australia | |
| 71824 | XFLU Inactivated split influenza vaccine; injection syringe (0.5 mL) | GlaxoSmithKline Australia Pty Ltd | Germany Belgium | |

^aQuantity of mercury compound

Table 5 Vaccines listed for export only containing mercury (as thiomersal)

| ARTG No. | Product | Sponsor | Country of manufacture | Quantity ^a |
|----------|--|---------------------------------------|------------------------|-----------------------|
| 56388 | BIOGRIP S Influenza vaccine (split virion); injection syringe (0.5 mL) | CSL Ltd | Australia | |
| 22600 | Bulk pooled B. Pertussis concentrate | CSL Ltd | Australia | |
| 165270 | CSL Bulk Influenza A (H1N1) Monovalent Vaccine with Thiomersal | CSL Ltd | Australia | |
| 106754 | CSL Bulk Influenza vaccine (split virion inactivated) | CSL Ltd | Australia | |
| 52841 | HB-VAX II Hepatitis B vaccine recombinant; injection vial (0.5 mL) | Merck Sharp & Dohme Australia Pty Ltd | Australia ^b | |
| 42346 | H-B-VAX II HEPATITIS B VACCINE RECOMBINANT; injection vial (0.5 mL) | Merck Sharp & Dohme Australia Pty Ltd | Australia ^b | |
| 42345 | H-B-VAX II HEPATITIS B VACCINE RECOMBINANT; injection vial (1 mL) | Merck Sharp & Dohme Australia Pty Ltd | Australia ^b | |
| 76771 | H-B-VAX II HEPATITIS B VACCINE RECOMBINANT; injection vial (1 mL) | Merck Sharp & Dohme Australia Pty Ltd | Australia ^b | |
| 72902 | Nilgrip Inactivated influenza vaccine (split virion); injection syringe/vial (5 mL multi-dose vial, 0.5 mL pre-filled syringe) | CSL Ltd | Australia | |
| 156431 | Nilgrip Inactivated influenza vaccine (split virion); (5 mL multi-dose vial) | CSL Ltd | Australia | |
| 42451 | PedvaxHIB Haemophilus B conjugate meningococcal protein conjugate vaccine; powder for injection | Merck Sharp & Dohme Australia Pty Ltd | Australia ^b | |
| 54540 | Three component blood-stage vaccine injection against P. Falciparum malaria; vial | Saramane Pty Ltd | Australia | |

^aQuantity of mercury compound

^bPackaging & labelling only (site of manufacture of active dosage form not specified)

5 USE OF MERCURY IN MEDICAL EQUIPMENT

In Australia, the medical devices regulatory framework does not impose any additional requirements for medical devices containing mercury.

However, any medical device which does contain mercury must still meet the Essential Principles for safety, efficacy and performance. In particular, the manufacturer of such a device must be able to demonstrate that:

- Use of the device does not compromise health and safety,
- Design and construction of the device conforms with safety principles,
- Benefits of the device must outweigh any side effects,
- The choice of materials used in the device are appropriate,
- Risks associated with leaching, or ingress/egress of substances are minimised.

Unlike medicines, the TGA does not hold a record of all medical devices that contain mercury (or any other specific substance or material).

However, there are two main types of medical devices supplied in Australia that the TGA does know specifically contain mercury:

- Thermometers containing mercury for taking body temperature, and
- Sphygmomanometers containing mercury for monitoring blood pressure.

Such products included in the ARTG, as at 22 October 2010, are shown in Table 6 below.

Table 6 Thermometers & Sphygmomanometers included in the ARTG which contain mercury

| ARTG No. | Product | Class | Sponsor | Manufacturer |
|----------|---------------------------------|----------|---|---|
| 97188 | Thermometer, capillary, mercury | Class Im | Boian Surgical Pty Ltd | Shanghai Hua Chen Medical Instruments Co Ltd |
| 98471 | Sphygmomanometer, mercury | Class Im | Livingstone International Pty Ltd | Wenzhou Bokang Instruments Co Ltd |
| 101420 | Thermometer, capillary, mercury | Class Im | Kendall a Division of Tyco Healthcare Pty Ltd | Shanghai Hua Chen Medical Instruments Co Ltd |
| 121249 | Sphygmomanometer, mercury | Class Im | Livingstone International Pty Ltd | Wenzhou Kanju Medical Instruments Co Ltd |
| 122404 | Sphygmomanometer, mercury | Class Im | Surgical Access Pty Ltd | AC Cossor & Son (Surgical) Ltd |
| 123390 | Thermometer, capillary, mercury | Class Im | Livingstone International Pty Ltd | Shanghai Hua Chen Medical Instruments Co Ltd |
| 123645 | Thermometer, capillary, mercury | Class Im | Livingstone International Pty Ltd | Wuxi Hongguang Medical Equipment Co Ltd |
| 130798 | Sphygmomanometer, mercury | Class Im | L R Instruments Pty Ltd | Erka Kallmeyer Medizintechnik GmbH & Co KG |
| 133265 | Sphygmomanometer, mercury | Class Im | Mentone Educational Centre | Tanaka Sangyo Co Ltd |
| 138160 | Thermometer, capillary, mercury | Class Im | Livingstone International Pty Ltd | Shanxi Medical Instrument Factory |
| 143480 | Thermometer, capillary, mercury | Class Im | Tollot Pty Ltd T/a Aaxis Pacific | Shanghai Zecheng Electron Apparatus Co Ltd |
| 143943 | Sphygmomanometer, mercury | Class Im | Surgical House | Chin Kou Medical Instrument Company Limited |
| 144620 | Sphygmomanometer, mercury | Class Im | Medical Industries Australia Pty Ltd | Wenzhou Hongshun Industries & Trade Co |
| 147760 | Thermometer, capillary, mercury | Class Im | Arthur Bailey Surgico Pty Limited | G H Zeal Ltd |
| 152068 | Sphygmomanometer, mercury | Class Im | L R Instruments Pty Ltd | Tanaka Sangyo Co Ltd |
| 159888 | Sphygmomanometer, mercury | Class Im | Med & Surgical Requisites Pty Ltd | W A BAUM CO INC |
| 168801 | Sphygmomanometer, mercury | Class Im | Tollot Pty Ltd T/a Aaxis Pacific | Shanghai Caremate Medical Device Co Ltd |
| 172532 | Thermometer, capillary, mercury | Class Im | Budget Distributors Pty Ltd | Wuxi Medical Instrument Factory |
| 174673 | Sphygmomanometer, mercury | Class Im | Oliver Medical Pty Ltd | Ningbo Free Trade Zone Tenso Medical Instruments Co Ltd |

Mercury is a major component of dental amalgam. The TGA does not collect information regarding the level of use or methods of disposal of amalgam products by dentists in Australia. Four dental amalgam products, specifically listing mercury as an ingredient, are included on the ARTG (one for export only) as at 22 October 2010, as summarised in Table 7 below. As for medicines, the inclusion of these products on the ARTG does not necessarily reflect actual use in dental practice. Two of these products are manufactured in Australia, and the other two are manufactured in the USA and Switzerland.

Table 7 Dental amalgam products included on the ARTG

| ARTG No. | Product | Sponsor | Country of manufacture | Quantity |
|---------------------|--------------------------------------|------------------------|------------------------|----------|
| 99936 | Dental amalgam, capsule | Kerr Australia Pty Ltd | USA | |
| 143117 | Dental alloy – Dental amalgam, alloy | SDI Ltd | Australia | |
| 146286 | Dental amalgam, capsule | Henry Schein Halas | Switzerland | |
| 161552 ^b | Dental amalgam, alloy | SDI Ltd | Australia | |

^aBased on the difference of all other components from 100%

^bListed device for export only

Two other products containing mercury are included in the ARTG and regulated in Australia as devices. These are personal lubricants, and contain phenylmercuric nitrate, and are described in Table 8 below. One is manufactured in Australia, the other in New Zealand. As for other products included in the ARTG, their inclusion on the ARTG does not necessarily reflect actual availability of these products for sale in Australia.

Table 8 Other devices containing phenylmercuric nitrate

| ARTG No. | Product | Sponsor | Country of manufacture | Quantity |
|----------|-----------|---|------------------------|----------|
| 134081 | Lubricant | Soul Pattinson (Manufacturing) Pty Ltd | Australia | |
| 144229 | Lubricant | Allied Master Chemists of Australia Ltd | New Zealand | |

There are likely to be many other medical devices supplied in Australia that also contain mercury in some form. For example, the following types of medical devices may contain elements of mercury:

- Medical devices that use batteries which contain mercury
- Medical devices that incorporate lamps which contain mercury. Typically these may include fluorescent lamps such as those found in backlit LCD displays or monitors.
- Medical devices containing electronic components that use mercury; such as tilt switches, thermostat probes, reed relays, and some printed circuit boards.
- Medical devices that utilise a thermometer containing mercury.
- Medical devices that utilise a pressure gauge containing mercury; such as barometers, manometers and vacuum gauges.

There have been some specific questions raised relating to mercury in medical equipment:

| Question | TGA Answer |
|--|--|
| 1. What are the current regulatory arrangements in regard to mercury, if any? | There are no specific regulatory arrangements for medical devices containing mercury. |
| 2. How widespread is the use of medical equipment containing mercury in Australia? | The TGA does not hold information relating to how many medical devices contain mercury. Provision of information regarding substances contained in devices is not a legislative requirement. The information TGA has relating to particular medical devices which contain mercury has been provided voluntarily. |
| 3. Specifically, which types of equipment still contain mercury? | The TGA is aware of a small number of thermometers and sphygmomanometers supplied in Australia that contain mercury. It is likely that other types of devices supplied in Australia do contain some form of mercury, however the TGA is unable to identify specific products as we don't collect this information. |
| 4. Are there any types of medical equipment which contain mercury because there is no substitute? | The TGA does not collect this information. |
| 5. Is there an incentive within the sector to move away from mercury containing equipment? | The regulatory framework for medical devices does not provide such an incentive. |
| 6. Are there medical facilities that have their own policies in place on the purchase of equipment containing mercury? | The TGA is not involved in the regulation of medical practice or procurement procedures of healthcare facilities. |
| 7. Is there an Australian Government position on the use of medical equipment containing mercury? | The TGA is not aware of a position with regard to the regulation of medical devices containing mercury. |

APPENDIX 1. IDENTIFIED DATA GAPS TO BE ADDRESSED FOR INC 2

| Sector – Elemental mercury production – primary | |
|--|---|
| Question/Data Gap | Stakeholders |
| Can we confirm that no primary elemental mercury production occurs in Australia? | <ul style="list-style-type: none"> • DRET • Minerals Council of Australia |

| Sector – Elemental mercury production – by product | |
|--|--|
| Question/Data Gap | Stakeholders |
| <p>How much by-product mercury is generated from:</p> <ul style="list-style-type: none"> • Non-ferrous metal production? • Gold production? • Petroleum extraction? • Petroleum refining? <p>What is done with the recovered mercury?</p> <p>If it is stored, how is it stored?</p> <p>Where is it stored in Australia? Is any stored overseas?</p> <p>What mercury-related licensing requirements are applied by the States and Territories on these processes?</p> <p>If it is on-sold, who are those buyers and how much is sold?</p> | <ul style="list-style-type: none"> • DRET • Minerals Council of Australia • Australian Petroleum Production and Exploration Association • Australian Institute of Petroleum • States and Territories – licensing/regulation |

| Sector – Elemental mercury import and export | |
|--|--|
| Question/Data Gap | Stakeholders |
| <p>Do Australian chemical companies import & export elemental mercury?</p> <p>If so, who are they, from where do they source the mercury (national suppliers or imports), and how much do they import & export?</p> <p>Is there a market for elemental mercury within Australia? If so, who is purchasing elemental mercury, where does it go and is the intended use known?</p> <p>If elemental mercury is exported, who is purchasing elemental mercury, where does it go and is the intended use known?</p> | <ul style="list-style-type: none"> • DRET • DFAT • DAFF • Customs • PACIA |

| Sector – Elemental mercury recycling | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>How much mercury recycling is undertaken in Australia?</p> <p>What articles does the mercury come from?</p> <p>What agreements/arrangements are in place to collect/receive the articles containing mercury?</p> <p>How are the articles transported to the recycling facility?</p> <p>How is the mercury stored, transported?</p> <p>Where does the mercury go?</p> <p>What mercury-related licensing requirements are applied by the States and Territories?</p> | <ul style="list-style-type: none"> • DRET • Australian Council of Recyclers • CMA Ecocycle • Fluorocycle • State and Territories – licensing/regulation |

| Sector – Trade | |
|--|---|
| Question/Data Gap | Stakeholders |
| <p>How is trade data on mercury and mercury containing products collected?</p> <p>What existing controls could be used to control/limit/prevent imports and exports of mercury and mercury containing products?</p> <p>What additional arrangements would need to be put in place?</p> | <ul style="list-style-type: none"> • DFAT • DAFF • Customs |

| Sector – Trade | |
|---|---|
| Question/Data Gap | Stakeholders |
| <p>How will we be able to detect products containing mercury?</p> | <ul style="list-style-type: none"> • Dr Peter Nelson |

| Sector – Intentional Use – Artisanal and Small Scale Gold Mining (ASGM) | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What, if any, activities have AusAID supported or undertaken in regard to ASGM since 2000?</p> | <ul style="list-style-type: none"> • AusAID |

| Sector – Intentional Use – Dental Amalgam | |
|--|---|
| Question/Data Gap | Stakeholders |
| <p>What is the Australian situation in regard to dental amalgam:</p> <ul style="list-style-type: none"> • How much is used? • How many dental practitioners have mercury traps? • Who supplies dental amalgam to the Australian dental industry - national and/or overseas suppliers? • How is waste dental amalgam managed? Collection, transport, storage? • Who receives the waste dental amalgam? • What are current State and Territory requirements for waste dental amalgam management? <p>Is there an Australian Government position on the use of dental amalgam?</p> <p>Do the States and Territories have a role/stake in this?</p> | <ul style="list-style-type: none"> • DOHA • Australian Dental Association • States and Territories |

| Sector – Intentional Use – Lamps containing mercury | |
|--|--|
| Question/Data Gap | Stakeholders |
| How much mercury is imported into Australia in lamps containing mercury (such as fluorescents, CFLs, etc)? | <ul style="list-style-type: none"> • Lighting Council Australia |

| Sector – Intentional Use – Medical Equipment | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What are the current regulatory arrangements in regard to mercury, if any? (apparently none – note Australian Regulatory Guidelines for Medical Devices (ARGMD) released by TGA in April 2010)</p> <p>How widespread is the use of medical equipment containing mercury in Australia?</p> <p>Specifically, which types of equipment still contain mercury?</p> <p>Are there any types of medical equipment which contain mercury because there is no substitute?</p> <p>Is there an incentive within the sector to move away from mercury containing equipment?</p> <p>Are there medical facilities that have their own policies in place on the purchase of equipment containing mercury?</p> | <ul style="list-style-type: none"> • DOHA • Therapeutic Goods Administration • Australian Medical Association |

| | |
|--|--|
| Is there an Australian Government position on the use of medical equipment containing mercury? | |
|--|--|

| Sector – Intentional Use – Therapeutic goods | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What are the current regulatory arrangements in regard to mercury, if any?</p> <p>How widespread is the use of mercury in Australia in therapeutic goods?</p> <p>Specifically, which therapeutic products still contain mercury (such as skin lightening lotions)? Are any manufactured in Australia? If imported, from where?</p> <p>Are there any types of therapeutic goods which contain mercury because there is no substitute?</p> <p>Is there an Australian Government position on the use of mercury in therapeutic goods?</p> | <ul style="list-style-type: none"> • DOHA • Therapeutic Goods Administration • ACCORD • Australian Medical Association |

| Sector – Intentional Use – Medical vaccines | |
|--|--|
| Question/Data Gap | Stakeholders |
| <p>How widespread is the use of mercury in medical vaccines, and in other medicines?</p> <p>What medical conditions are the vaccines and other medicines used for? Are there effective alternative medicines?</p> <p>Is there an Australian Government position on the use of mercury in medical vaccines and other medicines?</p> | <ul style="list-style-type: none"> • DOHA • Therapeutic Goods Administration • Australian Medical Association |

| Sector – Intentional Use – Agvet Products | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>How widespread is the use of mercury in agvet products, including pesticides and fungicides?</p> <ul style="list-style-type: none"> ○ What is the purpose of mercury in a intended product? ○ Are products manufactured in Australia? ○ What products are imported into Australia? <p>Is there an Australian Government position on the use of mercury in agvet products?</p> <p>Are there alternatives to mercury in these products?</p> | <ul style="list-style-type: none"> • DAFF • APVMA • Animal Health Alliance • PACIA • Croplife |

| Sector – Intentional Use – Paint | |
|---|---|
| Question/Data Gap | Stakeholders |
| <p>Is mercury still used in paint manufacture in Australia?</p> <p>Do companies import paint and does the paint contain mercury? Where does the overseas manufactured paint come from?</p> <p>Is there an Australian Government position on the use of mercury in agvet vaccines?</p> <p>Are there alternatives to mercury in these products?</p> | <ul style="list-style-type: none"> • Australian Paint Manufacturers Federation |

| Sector – Intentional Use – Switches and relays | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>To what extent is mercury still used in switches and relays?</p> <p>Does Australian manufacture switches and relays? If so, is mercury used, who and where are the manufacturers?</p> <p>Are there alternatives to the use of mercury in switches and relays?</p> <p>If mercury is used in Australian manufacturing in switches and relays – are there any mercury-related licensing requirements applied by the States and Territories?</p> | <ul style="list-style-type: none"> • Australian Electrical and Electronic Manufacturers Association |

| Sector – Unintentional emission – coal combustion in power stations | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What technologies are currently used in Australian coal-fired power stations – both black and brown – to capture mercury emissions?</p> <p>How effective are they? How much mercury is recovered and how much escapes to atmosphere?</p> <p>What other measures are available? What are their costs, effectiveness and technical feasibility?</p> <p>What is currently done with mercury captured from power stations?</p> | <ul style="list-style-type: none"> • DRET • National Generators Forum • Australian Coal Association |

| Sector – Unintentional emission – coal combustion at aluminium smelters and cement production facilities | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What technologies are currently used at these facilities to capture mercury emissions?</p> <p>What other measures are available? What are their costs, effectiveness and technical feasibility?</p> <p>What is currently done with mercury captured from coal combustion at these facilities?</p> <p>What is the policy position of the industry on the control of mercury emissions? Is there an R&D policy on improving mercury capture?</p> | <ul style="list-style-type: none"> • DRET • Australian Aluminium Association • Cement Industry Federation |

| Sector – Unintentional emission – gold production | |
|--|---|
| Question/Data Gap | Stakeholders |
| <p>What technologies are currently used at these facilities to capture mercury emissions?</p> <p>What other measures are available? What are their costs, effectiveness and technical feasibility?</p> <p>What is currently done with mercury captured at these facilities?</p> <p>What is the policy position of the industry on the control of mercury emissions? Is there an R&D policy on improving mercury capture?</p> | <ul style="list-style-type: none"> • DRET • Minerals Council of Australia |

| Sector – Unintentional emission – copper, zinc, lead and silver smelting, and primary ferrous metal production | |
|--|---|
| Question/Data Gap | Stakeholders |
| <p>What technologies are currently used at these facilities to capture mercury emissions?</p> <p>What other measures are available? What are their costs, effectiveness and technical feasibility?</p> <p>What is currently done with mercury captured at these facilities?</p> <p>What is the policy position of the industry on the control of mercury emissions? Is there an R&D policy on improving mercury capture?</p> | <ul style="list-style-type: none"> • DRET • Minerals Council of Australia |

| Sector – Unintentional emission – biomedical waste incineration | |
|---|--|
| Question/Data Gap | Stakeholders |
| <p>What are current arrangements/requirements regarding incineration of biomedical waste?</p> <p>Who services the industry for incineration of biomedical waste? - <i>(a followup with the suppliers - what mercury-related licensing requirements are applied by the States and Territories?)</i></p> <p>What are the technical options to reduce mercury emissions from incineration of biomedical waste?</p> | <ul style="list-style-type: none"> • DOHA • Therapeutic Goods Administration • Australian Medical Association • States and Territories |

| Sector – Unintentional emission – crematoria | |
|--|--|
| Question/Data Gap | Stakeholders |
| <p>What are the technical options for reducing mercury emissions, such as mercury filters? What are their costs and effectiveness?</p> <p>What mercury-related licensing requirements are applied by the States and Territories?</p> | <ul style="list-style-type: none"> • Australian Cemeteries and Crematoria Association • States and Territories |

| Sector – Storage | |
|---|---|
| Question/Data Gap | Stakeholders |
| <p>Is there any storage of elemental mercury currently in Australia?</p> <p>How do mercury recyclers currently store their mercury?</p> | <ul style="list-style-type: none"> • Australian Council of Recyclers |

| Sector – Regulation | |
|---|--------------|
| Question/Data Gap | Stakeholders |
| <p>What regulation would be required to enable the following:</p> <ul style="list-style-type: none"> • Arrangements for labelling for products containing mercury? • Requirements for atmospheric emissions limits? | |