



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

TGA International [REDACTED]

Sent by [REDACTED]

09/12/2010 04:23 PM

[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,
[REDACTED]

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]

11/11/2010
02:14 PM

To [REDACTED]@environment.gov.au>
cc [REDACTED]@environment.gov.au>, [REDACTED]@environment.gov.au>

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,
[REDACTED]

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

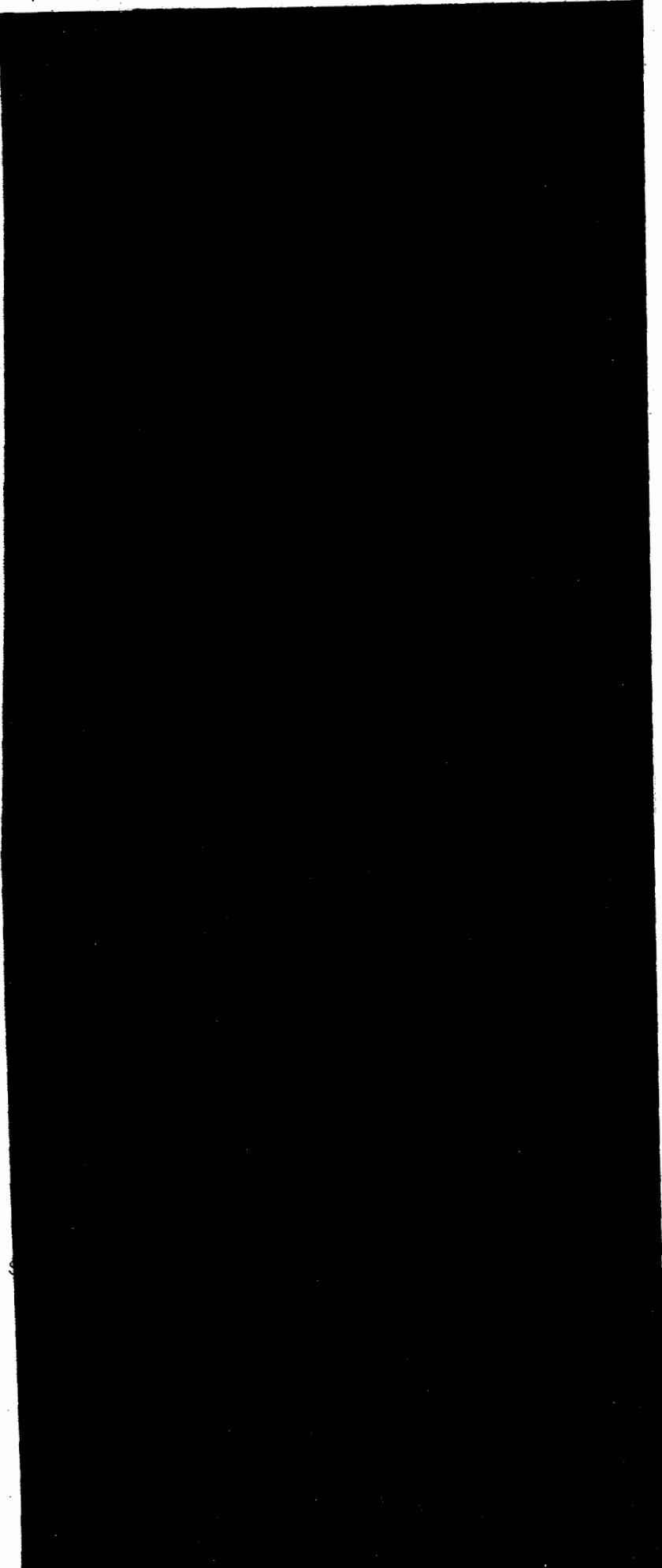
E-mail: tga.international@tga.gov.au



- Mercury in therapeutic products - Response for UNEP INC Oct 2010.DOCX



30/07/2010 01:42 PM



Dear Colleagues

Following up from the UDC - Mercury LBI meeting on Friday 23 July, we would like to request for you 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]
[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

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

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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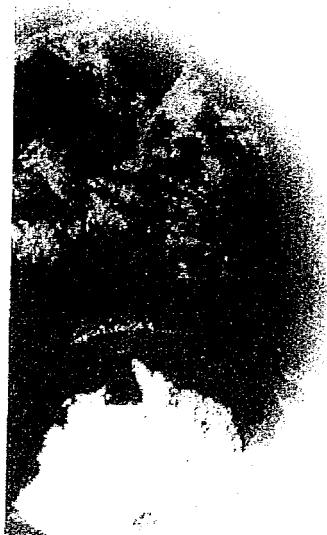
[REDACTED]



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

TABLE OF CONTENTS

REVISION HISTORY	2
NOTE FOR VIEWING THIS DOCUMENT	2
1 INTRODUCTION	3
2 CURRENT REGULATORY ARRANGEMENTS WITH REGARD TO MERCURY IN MEDICINES	3
2.1 SCHEDULING OF MERCURY-CONTAINING MEDICINES	4
3 USE OF MERCURY IN THERAPEUTIC PRODUCTS	4
3.1 NATURE OF MERCURY COMPOUNDS IN THERAPEUTIC GOODS	5
3.2 PRESCRIPTION AND NON-PRESCRIPTION MEDICINES	5
3.3 COMPLEMENTARY MEDICINES	5
4 USE OF MERCURY IN VACCINES	9
5 USE OF MERCURY IN MEDICAL EQUIPMENT	11
APPENDIX 1. IDENTIFIED DATA GAPS TO BE ADDRESSED FOR INC 2	15

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.frl.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/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/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 MERCROCHROME solution merbromin paint (50 ml bottle)	Weak disinfectant for skin infections	Biotech Pharmaceuticals Pty Ltd	Australia	Merbromin	
21265	ORION MERCROCHROME solution 10% merbromin paint (15 ml bottle)	General antiseptic, topical treatment for local infections	Orion Laboratories Pty Ltd	Australia	Merbromin	
21263	ORION MERCROCHROME 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	BLEPIIAMIDE 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 MERCUCROCHROME 1% solution (50, 100, 500 mL bottles)	Antiseptic	Biotech Pharmaceuticals Pty Ltd	Australia	Merbromin	
19661	CHIORSIG 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	Traumeel 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 antplex	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_stam%20_091009.pdf](http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/2723D54E78BF5739CA2576400027E1E9/$File/ATAGI_Thio_stam%20_091009.pdf)

Table 4 Vaccines containing mercury (as thiomersal)

ARTG No.	Product	Sponsor	Country of manufacture	Quantity ^a
143423	EMERPLU 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 Surgical 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	[REDACTED]
143117	Dental alloy – Dental amalgam, alloy	SDI Ltd	Australia	[REDACTED]
146286	Dental amalgam, capsule	Henry Schein Halas	Switzerland	[REDACTED]
161552 ^b	Dental amalgam, alloy	SDI Ltd	Australia	[REDACTED]

^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	[REDACTED]
144229	Lubricant	Allied Master Chemists of Australia Ltd	New Zealand	[REDACTED]

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 • Fluorecycle • 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
How will we be able to detect products containing mercury?	<ul style="list-style-type: none"> • Dr Peter Nelson

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

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
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)	<ul style="list-style-type: none"> • DOHA • Therapeutic Goods Administration • Australian Medical Association
How widespread is the use of medical equipment containing mercury in Australia?	
Specifically, which types of equipment still contain mercury?	
Are there any types of medical equipment which contain mercury because there is no substitute?	
Is there an incentive within the sector to move away from mercury containing equipment?	
Are there medical facilities that have their own policies in place on the purchase of equipment containing mercury?	

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>	<p>• Australian Paint Manufacturers Federation</p>

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>	<p>• Australian Electrical and Electronic Manufacturers Association</p>

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>	<p>• DRET</p> <p>• National Generators Forum</p> <p>• Australian Coal Association</p>

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	
<p>Question/Data Gap</p> <p>What are current arrangements/requirements regarding incineration of biomedical waste? 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> What are the technical options to reduce mercury emissions from incineration of biomedical waste?</p>	<p>Stakeholders</p> <ul style="list-style-type: none"> DOHA Therapeutic Goods Administration Australian Medical Association States and Territories

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

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

Sector – Regulation	
<p>Question/Data Gap</p> <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? 	<p>Stakeholders</p>