SENATE STANDING COMMITTEE

FOR THE

SCRUTINY OF BILLS

SECOND REPORT

OF

2009

11 March 2009

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MEMBERS OF THE COMMITTEE

Senator the Hon H Coonan (Chair)
Senator M Bishop (Deputy Chair)
Senator D Cameron
Senator J Collins
Senator R Siewert
Senator the Hon J Troeth

TERMS OF REFERENCE

Extract from **Standing Order 24**

(1) (a) At the commencement of each Parliament, a Standing Committee for the Scrutiny of Bills shall be appointed to report, in respect of the clauses of bills introduced into the Senate, and in respect of Acts of the Parliament, whether such bills or Acts, by express words or otherwise:

(i) trespass unduly on personal rights and liberties;

(ii) make rights, liberties or obligations unduly dependent upon insufficiently defined administrative powers;

(iii) make rights, liberties or obligations unduly dependent upon non-reviewable decisions;

(iv) inappropriately delegate legislative powers; or

(v) insufficiently subject the exercise of legislative power to parliamentary scrutiny.

(b) The Committee, for the purpose of reporting upon the clauses of a bill when the bill has been introduced into the Senate, may consider any proposed law or other document or information available to it, notwithstanding that such proposed law, document or information has not been presented to the Senate.

SENATE STANDING COMMITTEE FOR THE SCRUTINY OF BILLS

SECOND REPORT OF 2009

The Committee presents its Second Report of 2009 to the Senate.

The Committee draws the attention of the Senate to clauses of the following bills which contain provisions that the Committee considers may fall within principles 1(a)(i) to 1(a)(v) of Standing Order 24:

Aviation Legislation Amendment (2008 Measures No. 2) Bill 2008

Customs Amendment (Enhanced Border Controls and Other Measures) Bill 2008

Disability Discrimination and Other Human Rights Legislation Amendment Bill 2008

Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008

Aviation Legislation Amendment (2008 Measures No. 2) Bill 2008

Introduction

The Committee dealt with this bill in *Alert Digest No. 1 of 2009*. The Minister for Infrastructure, Transport, Regional Development and Local Government responded to the Committee's comments in a letter received on 10 March 2009. A copy of the letter is attached to this report.

Extract from Alert Digest No. 1 of 2009

Introduced into the House of Representatives on 3 December 2008
Portfolio: Infrastructure, Transport, Regional Development and Local Government

Background

This bill amends the *Aviation Transport Security Act 2004*, the *Civil Aviation Act 1988* and the *Transport Safety Investigation Act 2003* to further strengthen Australia's aviation security and safety.

The bill amends the *Aviation Transport Security Act 2004* to:

- broaden the existing information collection power under that Act so that the Secretary of the Department can require aviation industry participants to provide aviation security information if the Secretary believes, on reasonable grounds, that a participant has such information (and provides for penalties for failure to provide such information); and

- allow the Secretary to delegate his/her powers and functions under that Act to another agency head, where that other agency's functions and responsibilities relate to national security matters, and allows the agency head to sub-delegate these powers and functions to a Senior Executive Service employee, or acting Senior Executive Service employee of the relevant agency.

The bill amends the *Civil Aviation Act 1998* to allow for copying and disclosure of aircraft Cockpit Voice Recorder information for testing and maintenance purposes, subject to certain conditions.

The bill amends the *Transport Safety Investigation Act 2003* to:

- provide changes to penalties for offences for failing to report prescribed aviation, marine and rail accidents/incidents in accordance with Part 3 of that Act; and

- allows the Executive Director of Transport Safety Investigation to require further information from the industry in relation to transport safety matters after receiving an initial report.

The bill also contains application and savings provisions.

Regulations – incorporating material as in force from time to time Schedule 1, item 13, new subsection 3(2)

Proposed new subsection 3(2) of the *Transport Safety Investigation Act 2003*, to be inserted by item 13 of Schedule 1, would permit regulations made for the purposes of the definition of 'immediately reportable matter' or 'routinely reportable matter' to prescribe the matter 'by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or writing as in force from time to time'. The provision, therefore, seeks to delegate this aspect of legislative power.

The Committee notes that the explanatory memorandum states (at paragraph 48) that, in providing the definitions of the above matters in regulations, 'it is necessary to refer to other legislative instruments and industry manuals and standards which define certain technical terms', and that, if those other documents are changed, the regulations ought to be amended to reflect those changes.

However, it appears (judging by the example given in paragraph 49 of the explanatory memorandum) that such changes do not often occur. The Committee **seeks the Minister's advice** as to whether more information could be provided about the extent of the difficulty which the Transport Safety Investigation Act poses in its current form in relation to these matters; the rationale for why such a delegation of legislative power might be regarded as appropriate in these circumstances; and whether some limit might be included in the bill as to the scope of matters which may be applied, adopted or incorporated in the regulations.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to delegate legislative powers inappropriately, in breach of principle 1(a)(v) of the Committee's terms of reference.

Relevant extract from the response from the Minister

The Committee has requested that I provide further information about item 13 of the Bill which will allow 'regulations to be made for the purposes of the definition of ***immediately reportable matter*** or ***routine reportable matter*** which may prescribe the matter by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or writing as in force from time to time.'

Immediately reportable matters (IRMs) and ***routine reportable matters*** (RRMs) are the reportable accidents and incidents detailed in the Transport Safety Investigation Regulations 2003 (TSI Regulations). The problem of not being able to define them by reference to instruments and writing 'as in force from time to time' is broader than the example the Committee referred to in paragraph 49 of the Explanatory Memorandum. There are a number of instruments and manuals referred to in the Regulations but presently they can only be incorporated as the versions in force at the time the TSI Regulations came into effect on 1 July 2003.

Examples include International Civil Aviation Organization documentation, the Designated Airspace Handbook, the Manual of Air Traffic and the Code of Practice for the Defined Interstate Rail Network. These documents are referred to because they incorporate technical terms and operational parameters relevant for defining specific accidents and incidents. Documents like these are regularly reviewed and updated. In this context it is important that terms in the TSI Regulations retain the same meaning as those in the technical documents used by the transport industries.

The power to prescribe reportable matters by reference to other instruments and writing is not being used to impose unexpected requirements on industry. In this context the government believes the amendment is appropriate and no further limit should be included, particularly given the scope of the problem that it is trying to address. Further, I note that the provision proposed in item 13 of the Bill is not

inconsistent with subsection 98(3A) of the *Civil Aviation Act 1988* (CA Act) for the purpose of making regulations under that Act. Similar to the TSI Regulations, regulations made under the CA Act need to address technical matters in the aviation industry that are incorporated through other instruments or documents used by the industry.

I trust this has clarified the matter the Committee has raised. I acknowledge that the Committee is giving careful consideration to the Aviation Legislation Amendment (2008 Measures No.2) Bill 2008 and I look forward to hearing the outcome.

The Committee thanks the Minister for this comprehensive response, but notes that it would have been helpful if this information had been included in the explanatory memorandum.

Customs Amendment (Enhanced Border Controls and Other Measures) Bill 2008

Introduction

The Committee dealt with this bill in *Alert Digest No. 1 of 2009*. The Minister for Home Affairs responded to the Committee's comments in a letter dated 20 February 2008. A copy of the letter is attached to this report.

Extract from Alert Digest No. 1 of 2009

Introduced into the House of Representatives on 3 December 2008
Portfolio: Home Affairs

Background

This bill amends the *Customs Act 1901* and the *Financial Transaction Reports Act 1988* to ensure that the Australian Customs Service can effectively perform its operational law enforcement and regulatory roles/functions.

Schedule 1 amends arrival reporting requirements and stores/prohibited goods reporting requirements to also exclude Saturdays from the reporting period.

Schedule 2 requires an infringement notice to state that if a person pays to the CEO the penalty specified in the notice and – in the case of an alleged offence against section 243T of the Customs Act – any unpaid duty or any unrepaid refund or drawback of duty within 28 days of service of the notice, the person cannot be prosecuted for the alleged offence and will not be regarded as having been convicted of the offence.

Schedule 3 provides an exception to the offence of failing to make a cargo report.

Schedule 4 inserts new provisions, including offences, to deal with missing goods and goods delivered into home consumption without authority.

Schedule 5 harmonises the boarding powers with the United Nations Convention of the Law of the Sea.

Schedule 6 amends the impending arrival reporting requirements in relation to pleasure craft.

Schedule 7 clarifies the types of devices that can be used to stop or impede a ship.

Schedule 8 inserts a new circumstance in which the commander of a Commonwealth aircraft can request the pilot of another aircraft to land.

Schedule 9 extends the regime for the storage or taking into custody of prohibited weapons to all prohibited imports; and extends the power to seize goods without a warrant to 'unaccounted for' goods on board a ship.

Schedule 10 provides for arrest powers in the Customs Act to be consistent with those currently contained in the *Crimes Act 1914*.

Schedule 11 makes a technical amendment to the matters that must be included in a search or seizure warrant.

Schedule 12 inserts a new offence for obstructing or interfering with Customs equipment.

Schedule 13 extends the power to moor a Customs vessel to man-made structures.

Schedule 14 requires the owner or operator of a port or port facility to facilitate the boarding of Customs officials to conduct Customs and Immigration clearance of the ship and crew, and to verify information by the ship's master or the ship's agent prior to arrival.

Schedule 15 updates the wording in section 58 of the Customs Act.

Schedule 16 extends the circumstances in which Customs officers may enter and remain upon certain areas.

Schedule 17 extends the matters that can be authorised in a search or seizure warrant and the powers that can be exercised by Customs officers and persons assisting when executing a warrant.

The bill also contains application provisions.

Arrest without warrant
Schedule 10, item 2, new section 210

Proposed new section 210 of the *Customs Act 1901*, to be inserted by item 2 of Schedule 10, makes extensive provision for Customs officers and police officers to make arrests without a warrant. The Committee notes that the explanatory memorandum states (at paragraph 161) that the purpose of this amendment is to make the arrest powers in the Customs Act consistent with those contained in the *Crimes Act 1914*. Nevertheless, the Committee **seeks the Minister's clarification** in relation to whether making the arrest powers in the Customs Act consistent with those in the Crimes Act includes any extension of the current powers of Customs officers and, if so, the justification for such an extension.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Minister

The Committee has sought clarification in relation to whether making the arrest powers in the *Customs Act 1901* (the Customs Act) consistent with those in the Crimes Act includes any extension of the current powers of Customs officers and, if so, the justification for such an extension.

Currently, section 210 of the Customs Act provides that an officer of Customs or police may arrest without a warrant any person that the officer has reasonable grounds to believe is guilty of an offence listed in subsection 210(1).

Customs and Border Protection performs a significant border protection and counter terrorism role. To facilitate this function, Customs officers may exercise a power of arrest in relation to specified offences against the Customs Act. However, the current breadth of offences for which Customs officers may exercise a power of arrest pursuant to section 210 of the Customs Act is not sufficient and therefore the proposed power to arrest without warrant is required.

The list of offences is proposed to be extended to offences against subsection 33(1) or 33(5) of the Customs Act. The remaining offences are not being changed. Subsection 33(1) provides that it is an offence to intentionally move, alter or interfere with goods that are subject to the control of Customs where the movement, alteration or interference is not authorised. Subsection 33(5) contains intentionally

directing or permitting another person to move, alter or interfere such goods without authority. These offences are punishable by penalty of up to $550,000.

The potential ramifications of persons committing this offence are relevant to Customs and Border Protection's border protection and counter terrorism functions. In order to immediately respond to individuals who are breaching sections 33(1) and (5), it is proposed to expand the power of arrest to include these offences.

Whilst section 210 allows officers of Customs and police to arrest people, section 210 does not contain a number of safeguards and other provisions which are contained in the *Crimes Act 1914* (the Crimes Act).

As well as introducing the safeguards, the proposed amendments will allow an officer of Customs to arrest a person whom he or she believes on reasonable grounds has escaped from lawful custody to which the person is still liable under section 210 (proposed subsection 210(4) refers). The power to arrest a person who has escaped lawful custody will allow a Customs officer to re-apprehend a person who has escaped. The circumstances in which this may occur are set out in more detail in relation to the Committee's second query.

The proposed amendments will also allow an officer of Customs to conduct a frisk search or an ordinary search of a person who has been arrested (proposed sections 211 and 211A refer).

A frisk search can only be conducted if the officer suspects on reasonable grounds that it is prudent to do so in order to ascertain whether the person is carrying anything that would present a danger to a person or that could be used to assist a person to escape from lawful custody (a seizable item). Any seizable items found can be seized. This will reduce the risk of harm to officers of Customs and the person who has been arrested.

An ordinary search can only be conducted if the officer suspects on reasonable grounds that the person is carrying evidential material or a seizable item. The evidential material or seizable item can be seized. Again this will reduce the risk of harm to officers of Customs and the person who has been arrested. It will also reduce the risk of evidence being destroyed.

The proposed amendments will also allow an officer of Customs or police to request a person arrested to provide his or her name and/or address to the officer if the person's name and/or address are unknown to the officer.

Customs and Border Protection requires this information in order to lay charges and to conduct background checks to evaluate any potential risks to officers and to other people, including whether to recommend opposing bail.

The Committee thanks the Minister for this comprehensive response.

Retrospective application
Schedule 10, subitem 4(3)

Subitem 4(3) of Schedule 10 provides that '(s)ubsections 210(3) and (4) of the *Customs Act 1901* as in force after the commencement of this Schedule apply in relation to a person arrested under section 210 of that Act before the commencement of this Schedule as if he or she had been arrested under that section after that commencement'.

As a matter of practice, the Committee draws attention to any bill which seeks to have retrospective impact and will comment adversely where such a bill has a detrimental effect on people. The Committee notes that the explanatory memorandum states (at paragraph 192) that subsection 210(3) relates to the power of a Customs officer to release a person arrested if there are 'no longer reasonable grounds to detain the person'. Therefore, the possible retrospective application of this subsection is clearly beneficial to any person who has been arrested pursuant to it.

However, the explanatory memorandum further notes (at paragraph 192) that subsection 210(4) relates to 'the power to arrest [without a warrant] a person who is believed to have escaped lawful custody', but gives no explanation for the reason for that new subsection to apply in relation to a person arrested before it has commenced. The Committee **seeks the Minister's advice** as to the reason for this retrospective application.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Minister

> The Committee has also sought advice as to the reason for the retrospective application of proposed subsection 210(4) of the Customs Act.
>
> Proposed subsection 210(4) and the application provision in item 4(3) of Schedule 10 to the Bill will allow a Customs officer to arrest a person who has escaped after being arrested under section 210 even if the initial arrest occurred prior to the commencement of the amendments.

This secondary power of arrest is most likely to be required if a person escapes from Customs and Border Protection custody. Given the relatively small time that an officer of Customs typically holds a person in custody (this time usually being the time that it takes to deliver the arrested person to the custody of a police officer or taken before a magistrate or bail justice) it is anticipated this power will rarely be used. Should that person be held in custody pending a court appearance and escape lawful custody, that person may be arrested for offences under the Crimes Act or state offences.

Where a person escapes Customs and Border Protection lawful custody, it is proposed that officers of Customs will be given the power to re-apprehend the person. Under the application provision in item 4(3) of Schedule 10 that re-apprehension will be able to occur whether or not the initial arrest occurred before or after the amendments commence. In my view it is not unreasonable that officers of Customs be given the power to re-apprehend a person who has escaped lawful detention even if the initial arrest occurred prior to the amendments occurring.

Thank you for the opportunity to comment on these aspects of the Bill.

The Committee thanks the Minister for this response.

Disability Discrimination and Other Human Rights Legislation Amendment Bill 2008

Introduction

The Committee dealt with this bill in *Alert Digest No. 1 of 2009*. The Attorney-General responded to the Committee's comments in a letter dated 24 February 2009. A copy of the letter is attached to this report.

Extract from Alert Digest No. 1 of 2009

Introduced into the House of Representatives on 3 December 2008
Portfolio: Attorney-General

Background

This bill amends the *Disability Discrimination Act 1992*, the *Age Discrimination Act 2004* and the *Human Rights and Equal Opportunity Act 1986* to:

- implement recommendations made by the Productivity Commission in 2004;
- implement a recommendation made by the House of Representatives Standing Committee on Legal and Constitutional Affairs in 2007 to remove the 'dominant purpose' test from the Age Discrimination Act to prevent discrimination on the basis of a person's age; and
- improve the general operation of human rights law in Australia.

The bill amends the *Disability Discrimination Act 1992* to:

- introduce an explicit and positive duty to make reasonable adjustments for people with disability;
- make the defence of unjustifiable hardship available in relation to all unlawful discrimination on the ground of disability, except harassment and victimisation;

- clarify matters to be considered when determining unjustifiable hardship;
- clarify that the onus of proving unjustifiable hardship falls on the person claiming it;
- clarify the definition of disability;
- replace the 'proportionality test' in the definition of indirect discrimination;
- clarify obligations regarding carers, assistants, assistance animals and disability aids; and
- shift the onus of proving the reasonableness of a requirement or condition in the context of indirect discrimination from the person with disability to the respondent.

The bill amends the *Human Rights and Equal Opportunity Commission Act 1986* to:

- formally change the name of the Human Rights and Equal Opportunity Commission to the Australian Human Rights Commission;
- extend the period within which a person can take a terminated complaint to the Federal or Federal Magistrates Court from 28 days to 60 days; and
- improve the efficiency of the complaints handling process.

The bill also contains application provisions.

Retrospective application
Schedule 3, items 130, 148 and 153

Item 130 of Schedule 3 provides that the amendment made by item 129 'applies in relation to complaints made to the [Human Rights] Commission before, on or after the commencement of this Part'. Similarly, item 148 of Schedule 3 provides that the amendment made by item 147 'applies in relation to complaints made to the [Human Rights] Commission before, on or after the commencement of this Part' and item 153 of Schedule 3 provides that the amendment made by item 152 'applies in relation to complaints made to the President [of the Human Rights Commission] before, on or after the commencement of this Part'.

As a matter of practice, the Committee draws attention to any bill which seeks to have retrospective impact and will comment adversely where such a bill has a detrimental effect on people. The Committee notes that the explanatory memorandum (at paragraphs 157, 164 and 171 respectively) merely repeats the substance of the three items, and does not explain whether the retrospective application of the three sets of amendments will adversely affect any person. Therefore, the Committee **seeks the Minister's advice** as to the effect of these application provisions.

Pending the Attorney-General's advice, the Committee draws Senators' attention to the provisions, as they may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Attorney-General

Items 130, 148 and 153 provide for the application of the amendments to the *Human Rights and Equal Opportunity Act 1986* made by items 129, 147 and 152 of Schedule 3 respectively. They provide that the amendments in the latter three items apply in relation to complaints to the Commission whether those complaints were made before or after the commencement of the Part.

At present, the *Human Rights and Equal Opportunity Act 1986* provides for the formal finalisation of complaints of unlawful discrimination (dealt with generally under Part IIB Division 1) when they are 'terminated' or 'withdrawn'. Both are formal actions. When a matter is terminated by the Commission this permits a complainant to directly take their complaint to a court to seek resolution.

In addition, for complaints relating to human rights (under Part II Division 3) or equal opportunity in employment (under Part II Division 4), the Commission has power not to inquire into, or discontinue an inquiry into a complaint for various reasons including, in paragraphs 20(2)(b) and 32(3)(b), if satisfied that the person aggrieved does not desire the inquiry to be held or continued.

The amendments in items 129 and 147 of Schedule 3 will allow the Commission not to inquire or to discontinue an inquiry into complaints relating to human rights and equal opportunity in employment, if the Commission is satisfied that the complaint has been settled or resolved.

The President of the Commission can terminate complaints of unlawful discrimination. The amendment in Item 152 of Schedule 3 of the Bill would allow the President, in the same terms as already provided to the Commission in paragraphs 20(2)(b) and 32(2)(b), not to inquire or to discontinue an inquiry if satisfied that the person aggrieved does not desire the inquiry to be held or

continued. The item would also allow the President not to inquire or discontinue an inquiry, if satisfied that the complaint has been settled or resolved.

The Commission's obligation to inquire into a complaint relating to human rights under section 11(1)(f), or concerning discrimination in employment under s 31(b), ceases if one of the grounds for not inquiring are satisfied including if the Commission is satisfied that the aggrieved person does not wish them to commence an inquiry or continue it ─ or the complaint is terminated or withdrawn. But there is no specific authority not to proceed with an inquiry in regard to complaints received that are settled or otherwise resolved.

The provisions of items 130, 148 and 153 provide for this power not to inquire or discontinue an inquiry of a matter that is settled or resolved, to be applied in relation to existing, as well as new, complaints. The amendments thus provide a mechanism for finalisation of such matters. This will end the Commission's obligation to inquire into complaints that have already been settled or resolved without the need for a complainant to withdraw his or her complaint after it has been settled or resolved.

The application of this power to existing complaints will not trespass unduly on personal rights and liberties. It will only apply to complaints that are no longer being pursued by the complainants because they are already resolved or settled; or in the case of discrimination matters, also if the President is satisfied that the person does not wish the President to further inquire. Complainants are not precluded from making a further complaint relevant to the same matter should the settlement or resolution reached, not continue.

I trust this explanation responds to the Committee's concern.

The Committee thanks the Attorney-General for this response, but notes that it would have been helpful if this explanation had been included in the explanatory memorandum.

Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008

Introduction

The Committee dealt with this bill in *Alert Digest No. 1 of 2009*. The Parliamentary Secretary to the Minister for Health and Ageing responded to the Committee's comments in a letter dated 11 February 2009. A copy of the letter is attached to this report.

Extract from Alert Digest No. 1 of 2009

Introduced into the Senate on 3 December 2008
Portfolio: Health and Ageing

Background

This bill amends the *Therapeutic Goods Act 1989* to:

- allow the Minister to exempt medical devices from the operation of that Act so that they can be lawfully stockpiled for use in a health emergency;
- reformulate the test of whether a person is a 'fit and proper person' to hold a manufacturing licence or a medical device conformity assessment certificate;
- adopt the European Pharmacopoeia and United States Pharmacopeia as additional default standards under the Therapeutic Goods Act;
- provide public access to a much wider range of information held by the Therapeutic Goods Administration;
- clarify the operation of the advertising provisions to ensure that controls over restricted representations and prohibited representations apply to advertisements in all media; and
- amend penalty provisions across the Therapeutic Goods Act to align them with current policy on how these are formulated.

The bill also contains application, savings and transitional provisions.

Delegation of legislative power
Schedule 1, item 2, new subsection 41GS(1)

Proposed new subsection 41GS(1) of the Therapeutic Goods Act, to be inserted by item 2 of Schedule 1, would give the Minister an unfettered discretion to exempt specified kinds of medical devices from the operation of various parts of the Act. The Minister's exercise of this discretion is limited to the extent that the Minister must be satisfied that it is in the national interest for such an exemption to be made (proposed new subsection 41GS(2)), but there is no forum in which the fact of the Minister's satisfaction as to the national interest can be tested.

The only check on the exercise of the Minister's discretion is that, under proposed new subsection 41GW(2), the Minister must table particulars of an exemption – made to allow medical devices to be supplied because of an actual threat to public health caused by an emergency that has occurred – in both Houses of the Parliament within five sitting days of the exemption being made. In addition, the Secretary must cause a notice setting out the particulars of such an exemption to be published in the Commonwealth Gazette within five working days after the day on which it is made. Therefore, it would appear that proposed new subsection 41GS(1) delegates legislative power to the Minister, while subjecting the exercise of that power to only a limited scrutiny. The Committee **leaves for the Senate as a whole** the question of whether this delegation of legislative power is appropriate, and whether the level of parliamentary scrutiny is sufficient in the circumstances**.**

In the circumstances, the Committee makes no further comment on this provision.

Relevant extract from the response from the Parliamentary Secretary

As Parliamentary Secretary to the Minister for Health and Ageing with portfolio responsibility for the TGA, I am responding on behalf of the Minister.

The response to specific comments by the Committee in relation to the relevant provisions in the Bill is attached.

Delegation of legislative power/exemption from the Legislative Instruments Act

The Committee commented that new subsection 41GS(1) would give the Minister unfettered discretion to exempt specified kinds of medical devices from the operation of various parts of the *Therapeutic Goods Act 1989.*

However, the Minister can only make such an exemption if she or he is satisfied that it is in the national interest to do so, and the Minister's powers may only be delegated to the Secretary of the Department of Health and Ageing.

In practice the Minister will be making decisions on exemptions based on advice from an expert group including the Chief Medical Officer and members from the Office of Health Protection, the Office of Chemical Safety and the Australian Radiation Protection and Nuclear Safety Authority, with access to advice from security and intelligence services.

In relation to emerging infectious diseases, the Department also maintains close links with international organisations, such as the Centres for Disease Control and Prevention in the USA and the World Health Organisation. These organisations have disease surveillance and intelligence gathering mechanisms that provide early warnings about potential infectious threats.

The Committee thanks the Parliamentary Secretary for this response.

Legislative Instruments Act—exemption
Schedule 1, item 2, new subsection 41GS(6)

Proposed new subsection 41GS(6) of the Therapeutic Goods Act, to be inserted by item 2 of Schedule 1, provides that a Ministerial exemption of specified kinds of medical devices under subsection (1) of that section 'is not a legislative instrument'.

As outlined in Drafting Direction No. 3.8, where a provision specifies that an instrument is *not* a legislative instrument, the Committee would expect the explanatory memorandum to explain whether the provision is merely declaratory (and included for the avoidance of doubt) or expresses a policy intention to exempt an instrument (which *is* legislative in character) from the usual tabling and disallowance regime set out in the *Legislative Instruments Act 2003.* Where the provision is a substantive exemption, the Committee would expect to see a full explanation justifying the need for the provision.

In this case, the explanatory memorandum (at page 4) states that the exemption referred to 'is not a legislative instrument within the meaning of the *Legislative Instruments Act 2003*' and that subsection (6) 'explains rather than creates the exemption' from registration on the Federal Register of Legislative Instruments or from parliamentary scrutiny.

The Committee considers that the statement in the explanatory memorandum is open to question, because, for one thing, a Ministerial exemption under new subsection 41GS(1) appears to change the law with respect to the types of medical devices to which it refers; and, in addition, existing Ministerial emergency exemptions for therapeutic goods, which may be made under section 18A, are stated in current subsection 18A(9A) of the Therapeutic Goods Act to be 'disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*' (and therefore subject to parliamentary scrutiny and possible disallowance). Further, the explanatory memorandum notes (at page 1) that the amendments in the bill relating to exemptions for specified kinds of medical devices 'largely mirror the exemption provisions that currently apply to therapeutic goods, other than medical devices'. The Committee, therefore, **seeks the Minister's advice** about whether this apparent inconsistency can be resolved.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to insufficiently subject the exercise of legislative power to parliamentary scrutiny, in breach of principle 1(a)(v) of the Committee's terms of reference.

Legislative Instruments Act—exemption
Schedule 2, item 1, new subsection 18A(9A)

Proposed new subsection 18A(9A) of the Therapeutic Goods Act, to be inserted by item 1 of Schedule 2, provides that an emergency Ministerial exemption of specified kinds of therapeutic goods under subsection (1) of that section 'is not a legislative instrument'. The Committee notes that the explanatory memorandum states (at page 10) that the purpose of new subsection 18A(9A) is 'to explain, for the benefit of readers, that an exemption made under subsection (1) is not a legislative instrument. As the exemption is not a legislative instrument within the meaning of the *Legislative Instruments Act 2003*, it is not subject to requirements of that Act such as registration or parliamentary scrutiny. This subsection explains rather than creates the exemption'.

This statement is open to question, because subsection 18A(9A), as currently in force, provides that an exemption under subsection (1), and a revocation or variation of such an exemption under subsection (8), 'are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*'. Since the bill seeks to amend only subsection 18A(9A) of the Therapeutic Goods Act, it is difficult to see how an exemption under subsection 18A(1) can change from being a legislative instrument to a non-legislative instrument. The Committee **seeks the Minister's advice** about whether this apparent inconsistency can be resolved.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to insufficiently subject the exercise of legislative power to parliamentary scrutiny, in breach of principle 1(a)(v) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

The Bill would insert new subsections 41GS(6) and 18A(9A) stating that exemptions made by the Minister relating to the stockpiling of medical devices and medicines respectively are not legislative instruments.

Under the Office of Parliamentary Counsel's Drafting Direction the draft Bill was referred to other relevant agencies for comment and clearance. Consistent with Drafting Direction No. 3.8 the Office of Legislative Drafting and Publishing (OLDP) in the Attorney-General's Department was asked for advice on the applicability of the *Legislative Instruments Act* 2003 to the exemptions to be made under sections 41GS and 18A.

Section 5 of the Legislative Instruments Act sets out a general definition of what is a legislative instrument, subject to other provisions of that Act. Under paragraph 5(2)(a)

> "an instrument is taken to be of a legislative character if... it determines the law or alters the content of the law, rather than applying the law in a particular case;"

OLDP advised that in its view the exemptions had the effect of applying the law to a particular case, whether the case was an individual item or a class of items. According to the OLDP:

> "The exemption does not make or alter the law. It relies on the rules that are set out in the Act and records the decision in which those rules are applied to the particular case. This view would be supported further if the exemption

power included some objective criteria for the rule maker to consider in deciding whether to grant an exemption."

As noted above, the Minister in making a decision on an exemption must be satisfied that the exemption is necessary for the national interest. It is expected that only a limited range or classes of medical devices will be the subject of an exemption, which will be for a fixed period and will be subject to conditions relating to the quantity of the devices (not to all devices of the same kind), the source of those devices, and the persons or class of persons who may import, manufacture, supply or export those goods. Only those manufacturers, suppliers or importers that are specified in the exemption may legally deal with those exempt devices.

As a result the Government does not consider that the exemptions "determine or alter the content of the law", and as a result proposed new subsections 41GS(6) and 18A(9A) do not operate to create an exemption from the Legislative Instruments Act.

The Committee has also drawn attention to the inconsistency between the current subsection 18(9A) of the Act, which provides that an exemption covered by paragraph 18A(2)(a) of the Act is a disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901,* and the proposed new subsections 41GS(6) and 18A(9A). (The effect of paragraph 6(d) of the Legislative Instruments Act is that the exemption is taken to be a legislative instrument because it is a disallowable instrument.)

Regardless of the intention of the Parliament in providing in 2003 that paragraph 18A(2)(a) exemptions should be disallowable, the Government now believes, on the basis of advice provided to the previous Government in 2007, that there are strong national security reasons why exemptions should not be made public. These reasons were set out in the Explanatory Memorandum.

The Committee thanks the Parliamentary Secretary for this response, but notes that it would have been helpful if this fuller explanation had been included in the explanatory memorandum.

Strict liability
Schedule 1, item 35, new subsection 41MNB(6)

Proposed new subsection 41MNB(6) of the Therapeutic Goods Act, to be inserted by item 35 of Schedule 1, provides that an offence against proposed new subsection 41MNB(5) (breaching a condition of an exemption relating to a device) 'is an offence of strict liability'.

The Committee will generally draw to Senators' attention provisions which create strict liability offences. Where a bill creates such an offence, the Committee considers that the reasons for its imposition should be set out in the explanatory memorandum which accompanies the bill.

The Committee notes that the explanatory memorandum, when discussing new section 41MNB as a whole (at pages 7-8), does not refer to the *Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers*, and seeks to justify the imposition of strict liability in this instance on the ground that it 'will support the integrity of the exemption mechanism by ensuring that persons involved in the storage and supply of these devices comply with the relevant conditions attached to the exemption'.

The Committee does not consider that this is an adequate explanation for the imposition of strict liability in these circumstances and **seeks the Minister's advice** whether the recommendations in the *Guide* were considered in the drafting of this provision, and whether a fuller explanation can be provided as to the reasons why strict liability is considered appropriate in the circumstances.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

> The proposed new section 41MNB relating to breaches of the conditions of an exemption under proposed new section 41GS is based on elements within existing section 22 relating to breaches of a condition of exemption under existing section 18A, which include a strict liability offence.

It is important that conditions imposed on an exemption under proposed new section 41GT are adhered to: they are the mechanism to ensure appropriate storage, record-keeping, access to and supply of exempt devices.

Under new section 41GV the Minister must take reasonable steps to inform the persons or class of person who may import, manufacture, supply or export those devices of the exemption and any variation or revocation of the exemption. It is highly unlikely that any other person will have access to devices covered by the exemption, and thus be in a position to breach the condition of any exemption.

Imposing strict liability on the subsection 41MNB(5) offence of breaching a condition of exemption removes the need for the prosecution to prove an intent to breach a condition of exemption. It is intended to provide an effective deterrent to breaches of the conditions of exemption by ensuring that persons who are involved in the import, manufacture, storage, and supply of these devices comply with the conditions.

In the unlikely event that an importer, supplier or manufacturer mistakenly takes an action that breaches the conditions imposed under section 41GT, the Criminal Code provides a defence of an honest and reasonable mistake of fact.

The Committee thanks the Parliamentary Secretary for this comprehensive response, but again notes that it would have been helpful if this fuller explanation had been included in the explanatory memorandum.

Retrospective application
Schedule 3, subitems 23(2), 23(5), 23(6) and 23(9)

Subitems 23(2), 23(5), 23(6) and 23(9) of Schedule 3 apply the amendments of sections 40 and 41, 41EJ, 41ET and subsection 41JA(1C) of the Therapeutic Goods Act, to be made by Schedule 3 to licences granted and certificates issued 'before, on or after the commencement' of item 23. The Committee notes that the explanatory memorandum does not indicate whether the retrospective application in these circumstances will adversely affect any person other than the Commonwealth. Therefore, the Committee **seeks the Minister's advice** as to whether these amendments will have an adverse effect on any individual.

Pending the Minister's advice, the Committee draws Senators' attention to these provisions, as they may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

The Committee questioned the impact on persons, other than the Commonwealth, of the application of the amendments to the "fit and proper person test" retrospectively through sub-items 23(2), (5), (6) and (9).

The amendments proposed under this Schedule will replace a very wide and ill-defined test of fitness and propriety to hold manufacturing licences and similar permissions with a much narrower and more objective test.

The sub-items require the Secretary, in considering the continued fitness and propriety of a holder of a licence granted before the Bill comes into effect, to apply the new narrower test.

As a result there will be no adverse effect on any person.

Interested parties have been consulted on the proposed changes to the test and are supportive of the changes.

The Committee thanks the Parliamentary Secretary for this response.

Delegation of legislative power
Schedule 4, item 14, subparagraph 10(2)(a)(iv)

Subparagraph 10(2)(a)(iv) of the Therapeutic Goods Act, to be amended by item 14 of Schedule 4, will provide that a Ministerial order 'establishing a standard for therapeutic goods may: (a) be specified by reference to: … (iv) a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary'.

Current section 12 of the Therapeutic Goods Act provides that '(s)tandards under section 10 and orders revoking, varying or modifying standards of that kind are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*' and would now, by virtue of current subparagraph 6(d)(i) of the *Legislative Instruments Act 2003*, be regarded as legislative instruments for the purposes of the *Legislative Instruments Act 2003*.

These two provisions must be read in conjunction with items 1, 4 and 10 of Schedule 4, which provide definitions of, respectively, 'British Pharmacopoeia', 'European Pharmacopoeia' and 'United States Pharmacopoeia-National Formulary'. In each case, the definition refers to the publication of each respective Pharmacopeia as in force immediately before the commencement of the current bill. However, the definitions go on to provide that 'if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, [the relevant publication] includes those additions or amendments, or those new editions, from the effective date' published by the respective publishers of the Pharmacopoeias.

It therefore appears that the Ministerial order adopts each of the respective Pharmacopoeias as in force from time to time, with the result that the legislative power to make standards for therapeutic goods has been delegated, to some extent, to the British Pharmacopoeia, the European Pharmacopoeia and the United States Pharmacopoeia-National Formulary. However, the Committee **leaves for the Senate as a whole** the question of whether this delegation of legislative power is appropriate in the circumstances.

Relevant extract from the response from the Parliamentary Secretary

> The Committee drew attention to the fact that various items in Schedule 4 will allow the Minister to determine standards by reference to the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia - National Formulary "as in force from time to time".
>
> Under current arrangements new editions of the British Pharmacopoeia are only applicable after they have been specified by the Minister in the Gazette. As a result there can be a lag between when the British Pharmacopoeia comes into force in the United Kingdom and when it is adopted in Australia. This time lag is a source of potential confusion for persons dealing in therapeutic goods, who are accustomed to

complying with the British Pharmacopoeia in other countries as soon as it comes into force.

The proposed amendments in Schedule 4 will result in the three major pharmacopoeias applying in Australia as soon as they come into force in their "home jurisdiction". This will eliminate confusion for manufacturers, importers and others, and is strongly supported by industry.

The Committee thanks the Parliamentary Secretary for this response.

Excluding merits review
Schedule 4, item 15, new subsection 13(6)

Proposed new subsection 13(6) of the Therapeutic Goods Act, to be inserted by item 15 of Schedule 4, provides that a Ministerial order determining that a particular standard is not applicable to certain goods under proposed new subsection 13(5) 'is not a legislative instrument'. The Committee notes that the explanatory memorandum states (at page 19) that '(a)s the exemption is not a legislative instrument within the meaning of the *Legislative Instruments Act 2003*, it is not subject to requirements of that Act such as registration or Parliamentary scrutiny. This subsection explains rather than creates the exemption'.

Since the Ministerial order is not legislative in character, it may be assumed that the Minister's decision to make the order is an administrative decision. If that is correct, the Committee **seeks the Minister's advice** as to why that decision is not subject to merits review under the *Administrative Appeals Tribunal Act 1975*, when so many other decisions of the Secretary to the Department, and of the Minister, are reviewable under section 60 of the Therapeutic Goods Act.

Pending the Minister's advice, the Committee draws Senators' attention to the provision, as it may be considered to make rights, liberties or obligations unduly dependent upon non-reviewable decisions, in breach of principle 1(a)(iii) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

The Committee drew attention to the fact that a Ministerial order under proposed new subsection 13(5) is not a legislative instrument, and questioned why as an administrative decision it was not subject to review under section 60 of the Act or by the Administrative Appeals Tribunal.

The effect of an order under subsection 13(5) will be to exempt persons dealing with therapeutic goods that are a mixture of ingredients or components from complying with a standard that applies to only some of the ingredients or components.

Such an order will not have a detrimental effect or impose an obligation on any person. Indeed, it will confer a benefit in that in the absence of such an order a person dealing in such goods and not complying with a standard applicable to only some of the ingredients would potentially be committing an offence under section 14 of the Act.

In these circumstances the Government does not consider that merits review is applicable.

The Committee thanks the Parliamentary Secretary for this response.

Senator the Hon Helen Coonan
Chair

The Hon Anthony Albanese MP
Minister for Infrastructure,
Transport, Regional Development
and Local Government
Leader of the House

Reference: 00885-2009

Senator the Hon Helen Coonan
Chair
Standing Committee for the Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Senator Coonan Helen,

Thank you for the letter dated 5 February 2009 from the Senate Standing Committee for the Scrutiny of Bills about the Aviation Legislation Amendment (2008 Measures No.2) Bill 2008. The Committee has requested that I provide further information about item 13 of the Bill which will allow 'regulations to be made for the purposes of the definition of ***immediately reportable matter*** or ***routine reportable matter*** which may prescribe the matter by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or writing as in force from time to time.'

Immediately reportable matters (IRMs) and ***routine reportable matters*** (RRMs) are the reportable accidents and incidents detailed in the Transport Safety Investigation Regulations 2003 (TSI Regulations). The problem of not being able to define them by reference to instruments and writing 'as in force from time to time' is broader than the example the Committee referred to in paragraph 49 of the Explanatory Memorandum. There are a number of instruments and manuals referred to in the Regulations but presently they can only be incorporated as the versions in force at the time the TSI Regulations came into effect on 1 July 2003.

Examples include International Civil Aviation Organization documentation, the Designated Airspace Handbook, the Manual of Air Traffic and the Code of Practice for the Defined Interstate Rail Network. These documents are referred to because they incorporate technical terms and operational parameters relevant for defining specific accidents and incidents. Documents like these are regularly reviewed and updated. In this context it is important that terms in the TSI Regulations retain the same meaning as those in the technical documents used by the transport industries.

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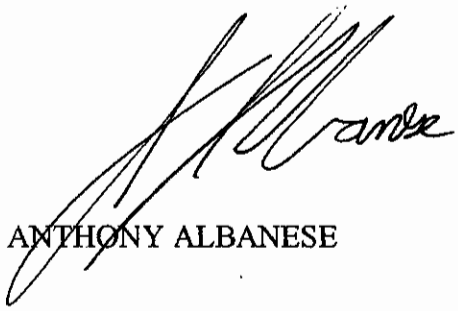
The power to prescribe reportable matters by reference to other instruments and writing is not being used to impose unexpected requirements on industry. In this context the Government believes the amendment is appropriate and no further limit should be included, particularly given the scope of the problem that it is trying to address. Further, I note that the provision proposed in item 13 of the Bill is not inconsistent with subsection 98(3A) of the *Civil Aviation Act 1988* (CA Act) for the purpose of making regulations under that Act. Similar to the TSI Regulations, regulations made under the CA Act need to address technical matters in the aviation industry that are incorporated through other instruments or documents used by the industry.

I trust this has clarified the matter the Committee has raised. I acknowledge that the Committee is giving careful consideration to the Aviation Legislation Amendment (2008 Measures No.2) Bill 2008 and I look forward to hearing the outcome.

Yours sincerely



ANTHONY ALBANESE

THE HON BOB DEBUS MP
Minister for Home Affairs

Ministerial No. 96926

20 FEB 2009

Senator the Hon Helen Coonan
Chair
Senate Standing Committee for the
Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Senator Coonan

I refer to the letter from the Secretary of the Senate Standing Committee for the Scrutiny of Bills (the Committee) of 5 February 2009.

The letter referred to *Alert Digest No. 1 of 2009* concerning the Customs Amendment (Enhanced Border Controls and Other Measures) Bill 2008 (the Bill).

Arrest without warrant - Schedule 10, item 2, new section 210

The Committee has sought clarification in relation to whether making the arrest powers in the *Customs Act 1901* (the Customs Act) consistent with those in the Crimes Act includes any extension of the current powers of Customs officers and, if so, the justification for such an extension.

Currently, section 210 of the Customs Act provides that an officer of Customs or police may arrest without a warrant any person that the officer has reasonable grounds to believe is guilty of an offence listed in subsection 210(1).

Customs and Border Protection performs a significant border protection and counter terrorism role. To facilitate this function, Customs officers may exercise a power of arrest in relation to specified offences against the Customs Act. However, the current breadth of offences for which Customs officers may exercise a power of arrest pursuant to section 210 of the Customs Act is not sufficient and therefore the proposed power to arrest without warrant is required.

The list of offences is proposed to be extended to offences against subsection 33(1) or 33(5) of the Customs Act. The remaining offences are not being changed. Subsection 33(1) provides that it is an offence to intentionally move, alter or interfere with goods that are subject to the control of Customs where the movement, alteration or interference is not authorised. Subsection 33(5) contains intentionally directing or permitting another person to move, alter or interfere such goods without authority. These offences are punishable by penalty of up to $550,000.

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The potential ramifications of persons committing this offence are relevant to Customs and Border Protection's border protection and counter terrorism functions. In order to immediately respond to individuals who are breaching sections 33(1) and (5), it is proposed to expand the power of arrest to include these offences.

Whilst section 210 allows officers of Customs and police to arrest people, section 210 does not contain a number of safeguards and other provisions which are contained in the *Crimes Act 1914* (the Crimes Act).

As well as introducing the safeguards, the proposed amendments will allow an officer of Customs to arrest a person whom he or she believes on reasonable grounds has escaped from lawful custody to which the person is still liable under section 210 (proposed subsection 210(4) refers). The power to arrest a person who has escaped lawful custody will allow a Customs officer to re-apprehend a person who has escaped. The circumstances in which this may occur are set out in more detail in relation to the Committee's second query.

The proposed amendments will also allow an officer of Customs to conduct a frisk search or an ordinary search of a person who has been arrested (proposed sections 211 and 211A refer).

A frisk search can only be conducted if the officer suspects on reasonable grounds that it is prudent to do so in order to ascertain whether the person is carrying anything that would present a danger to a person or that could be used to assist a person to escape from lawful custody (a seizable item). Any seizable items found can be seized. This will reduce the risk of harm to officers of Customs and the person who has been arrested.

An ordinary search can only be conducted if the officer suspects on reasonable grounds that the person is carrying evidential material or a seizable item. The evidential material or seizable item can be seized. Again this will reduce the risk of harm to officers of Customs and the person who has been arrested. It will also reduce the risk of evidence being destroyed.

The proposed amendments will also allow an officer of Customs or police to request a person arrested to provide his or her name and/or address to the officer if the person's name and/or address are unknown to the officer.

Customs and Border Protection requires this information in order to lay charges and to conduct background checks to evaluate any potential risks to officers and to other people, including whether to recommend opposing bail.

Retrospective application - Schedule 10, sub-item 4(3)

The Committee has also sought advice as to the reason for the retrospective application of proposed subsection 210(4) of the Customs Act.

Proposed subsection 210(4) and the application provision in item 4(3) of Schedule 10 to the Bill will allow a Customs officer to arrest a person who has escaped after being arrested under section 210 even if the initial arrest occurred prior to the commencement of the amendments.

This secondary power of arrest is most likely to be required if a person escapes from Customs and Border Protection custody. Given the relatively small time that an officer of Customs typically holds a person in custody (this time usually being the time that it takes to deliver the arrested person to the custody of a police officer or taken before a magistrate or bail justice) it is anticipated this power will rarely be used. Should that person be held in custody pending a court appearance and escape lawful custody, that person may be arrested for offences under the Crimes Act or state offences.

Where a person escapes Customs and Border Protection lawful custody, it is proposed that officers of Customs will be given the power to re-apprehend the person. Under the application provision in item 4(3) of Schedule 10 that re-apprehension will be able to occur whether or not the initial arrest occurred before or after the amendments commence. In my view it is not unreasonable that officers of Customs be given the power to re-apprehend a person who has escaped lawful detention even if the initial arrest occurred prior to the amendments occurring.

Thank you for the opportunity to comment on these aspects of the Bill.

Yours sincerely

Bob Debus

ATTORNEY-GENERAL
THE HON ROBERT McCLELLAND MP

08/25472 MC09/1382

Senator, the Hon Helen Coonan
Chair, Senate Standing Committee
for the Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Senator Coonan

I refer to Scrutiny of Bills *Alert Digest No. 1 of 2009* (4 February 2009) in which the Committee drew attention to items 130, 148 and 153 of Schedule 3 of the Disability Discrimination and Other Human Rights Legislation Amendment Bill 2008 and sought my advice on those provisions.

Items 130, 148 and 153 provide for the application of the amendments to the *Human Rights and Equal Opportunity Act 1986* made by items 129, 147 and 152 of Schedule 3 respectively. They provide that the amendments in the latter three items apply in relation to complaints to the Commission whether those complaints were made before or after the commencement of the Part.

At present, the *Human Rights and Equal Opportunity Act 1986* provides for the formal finalisation of complaints of unlawful discrimination (dealt with generally under Part IIB Division 1) when they are 'terminated' or 'withdrawn'. Both are formal actions. When a matter is terminated by the Commission this permits a complainant to directly take their complaint to a court to seek resolution.

In addition, for complaints relating to human rights (under Part II Division 3) or equal opportunity in employment (under Part II Division 4), the Commission has power not to inquire into, or discontinue an inquiry into a complaint for various reasons including, in paragraphs 20(2)(b) and 32(3)(b), if satisfied that the person aggrieved does not desire the inquiry to be held or continued.

The amendments in items 129 and 147 of Schedule 3 will allow the Commission not to inquire or to discontinue an inquiry into complaints relating to human rights and equal opportunity in employment, if the Commission is satisfied that the complaint has been settled or resolved.

The President of the Commission can terminate complaints of unlawful discrimination. The amendment in Item 152 of Schedule 3 of the Bill would allow the President, in the same terms as already provided to the Commission in paragraphs 20(2)(b) and 32(2)(b), not to inquire or to discontinue an inquiry if satisfied that the person aggrieved does not desire the inquiry to be held or continued. The item would also allow the President not to inquire or discontinue an inquiry, if satisfied that the complaint has been settled or resolved.

The Commission's obligation to inquire into a complaint relating to human rights under section 11(1)(f), or concerning discrimination in employment under s 31(b), ceases if one of the grounds for not inquiring are satisfied including if the Commission is satisfied that the aggrieved person does not wish them to commence an inquiry or continue it – or the complaint is terminated or withdrawn. But there is no specific authority not to proceed with an inquiry in regard to complaints received that are settled or otherwise resolved.

The provisions of items 130, 148 and 153 provide for this power not to inquire or discontinue an inquiry of a matter that is settled or resolved, to be applied in relation to existing, as well as new, complaints. The amendments thus provide a mechanism for finalisation of such matters. This will end the Commission's obligation to inquire into complaints that have already been settled or resolved without the need for a complainant to withdraw his or her complaint after it has been settled or resolved.

The application of this power to existing complaints will not trespass unduly on personal rights and liberties. It will only apply to complaints that are no longer being pursued by the complainants because they are already resolved or settled; or in the case of discrimination matters, also if the President is satisfied that the person does not wish the President to further inquire. Complainants are not precluded from making a further complaint relevant to the same matter should the settlement or resolution reached, not continue.

I trust this explanation responds to the Committee's concern.

Yours sincerely

Robert McClelland

Senator the Hon Jan McLucas
Parliamentary Secretary to the Minister for Health and Ageing

Senator the Hon Helen Coonan
Chair
Scrutiny of Bills Committee
Parliament House
Canberra ACT 2600

Dear ~~Senator~~ Coonan Helen

Thank you for your letter of 5 February 2009 to the Minister for Health and Ageing regarding the comments of the Scrutiny of Bills Committee (the Committee) contained in the Scrutiny of Bills *Alert Digest No. 1 of 2009* concerning the Therapeutic Goods Amendment (Medical Devices and other Measures) Bill 2009 (the Bill). As Parliamentary Secretary to the Minister for Health and Ageing with portfolio responsibility for the TGA, I am responding on behalf of the Minister.

The response to specific comments by the Committee in relation to the relevant provisions in the Bill is attached

Yours sincerely

Jan McLucas.

Jan McLucas

11 FEB 2009

Response to the Scrutiny of Bills Committee Report on the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008*

Delegation of legislative power/exemption from the Legislative Instruments Act
Schedule 1, Item2, new subsections 41GS(1) and 41GS(6) and Schedule 2, Item 1, new subsection 18A(9A)

The Committee commented that new subsection 41GS(1) would give the Minister unfettered discretion to exempt specified kinds of medical devices from the operation of various parts of the *Therapeutic Goods Act 1989.*

However, the Minister can only make such an exemption if she or he is satisfied that it is in the national interest to do so, and the Minister's powers may only be delegated to the Secretary of the Department of Health and Ageing.

In practice the Minister will be making decisions on exemptions based on advice from an expert group including the Chief Medical Officer and members from the Office of Health Protection, the Office of Chemical Safety and the Australian Radiation Protection and Nuclear Safety Authority, with access to advice from security and intelligence services.

In relation to emerging infectious diseases, the Department also maintains close links with international organisations, such as the Centres for Disease Control and Prevention in the USA and the World Health Organisation. These organisations have disease surveillance and intelligence gathering mechanisms that provide early warnings about potential infectious threats.

The Bill would insert new subsections 41GS(6) and 18A(9A) stating that exemptions made by the Minister relating to the stockpiling of medical devices and medicines respectively are not legislative instruments.

Under the Office of Parliamentary Counsel's Drafting Direction the draft Bill was referred to other relevant agencies for comment and clearance. Consistent with Drafting Direction No. 3.8 the Office of Legislative Drafting and Publishing (OLDP) in the Attorney-General's Department was asked for advice on the applicability of the *Legislative Instruments Act 2003* to the exemptions to be made under sections 41GS and 18A.

Section 5 of the Legislative Instruments Act sets out a general definition of what is a legislative instrument, subject to other provisions of that Act. Under paragraph 5(2)(a)

> "an instrument is taken to be of a legislative character if... it determines the law or alters the content of the law, rather than applying the law in a particular case;".

OLDP advised that in its view the exemptions had the effect of applying the law to a particular case, whether the case was an individual item or a class of items. According to the OLDP:

> "The exemption does not make or alter the law. It relies on the rules that are set out in the Act and records the decision in which those rules are applied to the particular case. This view would be supported further if the exemption power included some objective criteria for the rule maker to consider in deciding whether to grant an exemption."

As noted above, the Minister in making a decision on an exemption must be satisfied that the exemption is necessary for the national interest. It is expected that only a limited range or classes of medical devices will be the subject of an exemption, which will be for a fixed period and will be subject to conditions relating to the quantity of the devices (not to all devices of the same kind), the source of those devices, and the persons or class of persons who may import, manufacture, supply or export those goods. Only those manufacturers, suppliers or importers that are specified in the exemption may legally deal with those exempt devices.

As a result the Government does not consider that the exemptions "determine or alter the content of the law", and as a result proposed new subsections 41GS(6) and 18A(9A) do not operate to create an exemption from the Legislative Instruments Act.

The Committee has also drawn attention to the inconsistency between the current subsection 18(9A) of the Act, which provides that an exemption covered by paragraph 18A(2)(a) of the Act is a disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*, and the proposed new subsections 41GS(6) and 18A(9A). (The effect of paragraph 6(d) of the Legislative Instruments Act is that the exemption is taken to be a legislative instrument because it is a disallowable instrument.)

Regardless of the intention of the Parliament in providing in 2003 that paragraph 18A(2)(a) exemptions should be disallowable, the Government now believes, on the basis of advice provided to the previous Government in 2007, that there are strong national security reasons why exemptions should not be made public. These reasons were set out in the Explanatory Memorandum.

Strict liability
Schedule 1, Item 35, new subsection 41MNB(6)
The Committee has questioned the application of strict liability to the offence created by subsection 41MNB(5).

The proposed new section 41MNB relating to breaches of the conditions of an exemption under proposed new section 41GS is based on elements within existing section 22 relating to breaches of a condition of exemption under existing section 18A, which include a strict liability offence.

It is important that conditions imposed on an exemption under proposed new section 41GT are adhered to: they are the mechanism to ensure appropriate storage, record-keeping, access to and supply of exempt devices.

Under new section 41GV the Minister must take reasonable steps to inform the persons or class of person who may import, manufacture, supply or export those devices of the exemption and any variation or revocation of the exemption. It is highly unlikely that any other person will have access to devices covered by the exemption, and thus be in a position to breach the condition of any exemption.

Imposing strict liability on the subsection 41MNB(5) offence of breaching a condition of exemption removes the need for the prosecution to prove an intent to breach a condition of exemption. It is intended to provide an effective deterrent to breaches of the conditions of exemption by ensuring that persons who are involved in the import, manufacture, storage, and supply of these devices comply with the conditions.

In the unlikely event that an importer, supplier or manufacturer mistakenly takes an action that breaches the conditions imposed under section 41GT, the Criminal Code provides a defence of an honest and reasonable mistake of fact.

Retrospective application
Schedule 3, sub-items 23(2), 23(5), 23(6) and 23(9)
The Committee questioned the impact on persons, other than the Commonwealth, of the application of the amendments to the "fit and proper person test" retrospectively through sub-items 23(2), (5), (6) and (9).

The amendments proposed under this Schedule will replace a very wide and ill-defined test of fitness and propriety to hold manufacturing licences and similar permissions with a much narrower and more objective test.

The sub-items require the Secretary, in considering the continued fitness and propriety of a holder of a licence granted before the Bill comes into effect, to apply the new narrower test.

As a result there will be no adverse effect on any person.

Interested parties have been consulted on the proposed changes to the test and are supportive of the changes.

Delegation of legislative power
Schedule 4, Item 14, subparagraph 10(2)(a)(iv)
The Committee drew attention to the fact that various items in Schedule 4 will allow the Minister to determine standards by reference to the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia – National Formulary "as in force from time to time".

Under current arrangements new editions of the British Pharmacopoeia are only applicable after they have been specified by the Minister in the Gazette. As a result there can be a lag between when the British Pharmacopoeia comes into force in the United Kingdom and when it is adopted in Australia. This time lag is a source of potential confusion for persons dealing in therapeutic goods, who are accustomed to complying with the British Pharmacopoeia in other countries as soon as it comes into force.

The proposed amendments in Schedule 4 will result in the three major pharmacopoeias applying in Australia as soon as they come into force in their "home jurisdiction". This will eliminate confusion for manufacturers, importers and others, and is strongly supported by industry.

Excluding merits review
Schedule 4, Item 15, new subsection 13(6)
The Committee drew attention to the fact that a Ministerial order under proposed new subsection 13(5) is not a legislative instrument, and questioned why as an administrative decision it was not subject to review under section 60 of the Act or by the Administrative Appeals Tribunal.

The effect of an order under subsection 13(5) will be to exempt persons dealing with therapeutic goods that are a mixture of ingredients or components from complying with a standard that applies to only some of the ingredients or components.

Such an order will not have a detrimental effect or impose an obligation on any person. Indeed, it will confer a benefit in that in the absence of such an order a person dealing in such goods and not complying with a standard applicable to only some of the ingredients would potentially be committing an offence under section 14 of the Act.

In these circumstances the Government does not consider that merits review is applicable.