Ian Holland
Secretary, Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House Canberra ACT 2600

Dear Mr. Holland

Re: Inquiry into the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013

Thank you for your letter dated 5 April 2013 inviting me to make a submission addressing issues that may be of relevance to me in relation to this Bill. I appreciate the opportunity. I have attached a summary of my views including my concerns with particular provisions.

I have detailed major concerns I have with respect to the proposed amendments at Schedules 3, 5, 7, 9, 13 and 16. I have made some minor comments on the amendments proposed by the other schedules.

In addition I have taken this opportunity of suggesting two further amendments of substance and relevance to the Therapeutic Goods Act 1989 to enhance the operation of the Act and make it more responsive and relevant for the health and safety of all Australians.

Yours sincerely,

Doug Kentwell
Managing Director 6 May 2013

ATTACHMENT

THERAPEUTIC GOODS AMENDMENT (2013 MEASURES NO. 1) BILL 2013

SUBMISSION TO THE SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS – LEGISLATION COMMITTEE

Schedule 5 – Evaluation and registration of therapeutic goods
Schedule 9 – Review of decisions

At the outset I wish to address particular amendments in Schedules 5 and 9 that are identified as appearing "*to engage article 14(1) of the International Covenant on civil and political Rights (the ICCR)"*. I do not accept the rationale advanced to justify the exclusion of merits review of a decision under section 25AA approving the Product Information (PI). This is expressed in the Explanatory Memorandum (EM) as part of the proposed amendments to "*clarify the source of the power for the*

Secretary to approve product information under section 25AA of the Act." In my view such an amendment is not of a minor technical nature. Second, I find recognition of the ICCR enlightening given past experience. This latter aspect is covered in "Proposed new provision for consideration by the Parliament" below.

The Explanatory Memorandum (EM) describes Item 10 of Schedule 5 as removing the right to merits review by the Minister and subsequently, by the Administrative Appeals Tribunal (the AAT), in relation to a decision of the Secretary to approve or vary the Product Information (PI) for a medicine (subsections 25AA(1) and (4) of the Act refer).

The EM then proceeds to explain that the removal of merits review rights in these instances is considered to be necessary because a decision to approve, or to approve a variation to, the PI is an integral part of the decision by the Secretary to register the medicine to which the PI relates or to approve a variation to that medicine's entry in the Register (underlining mine). However, it then proceeds to state the opposite in the next paragraph by saying "*The Bill clarifies that the approval by the Secretary of PI for a medicine is a separate decision to the Secretary's decision approving its registration.....*"(underlining mine). In an attempt to reconcile both these assertions the EM concludes:

"As the PI approved by the Secretary will reflect the decision of the registration or variation decision of the Secretary (which is amenable to review) any concerns with the PI can effectively be addressed through a review of the registration or variation decision."

These proposed amendments will effectively replace the current practice of a one stage approval process for medicines with a two stage process, first the medicine itself (which is subject to merits review under section 60) and then the PI which will not be subject to merits review. This would be introduced by virtue of proposed section 25AAA(3)(b) which provides that:

"(3) The notice must set out the decision, and inform the applicant that the goods will not be included in the Register unless and until:

(b) if the goods are restricted medicine or the goods are medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph 25(1)(da)(ii) – product information is approved, under Section 25AA, in relation to the medicine."

Subparagraph 25(1)(da)(ii) provides:

"*25(1) If an application is made for the registration of therapeutic goods in relation to a person in accordance with section 23, the Secretary must evaluate the goods for registration having regard to:*

(d) whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established; and

(ii) the applicant is applying for the registration of medicine (other than restricted medicine) and the applicant has been given a notice in writing by the Secretary requiring the applicant to give to the

Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine."

The current approval provisions for the PI under section 25AA, "Approved product information for medicine" predicate that the Secretary will include the medicine in the Register prior to the PI being approved under that section as follows:

"25AA(1) If:
(b) an applicant for the registration of medicine (other than restricted medicine) is given a notice of the kind referred to in subparagraph 25(1)(da)(ii) and the Secretary includes the medicine in the Register in relation to the applicant under subparagraph 25(4)(d)(ii);

The product information that is approved under this section in relation to the medicine is the product information referred to in subparagraph 25(4)(d)(ia)."

The apparent reason as to why the EM claims that the approval by the Secretary of the PI for a medicine is a separate decision to the Secretary's decision approving its registration is merely because the approval of the medicine and the PI are governed by two separate provisions in the Act, section 25 and section 25AA, respectively. However, in practice the PI is developed and finalised as part of the primary decision-making under section 25 (refer to the TGA guideline "Transitional prescription medicine streamlined submission process, Version 1.5, January 2011, 4.8.4 Review and Decision").

The net effect of such an amendment is of major concern. It will mean that goods will not be included in the Register and therefore cannot be supplied (except if exempt or excluded under the Act) until the separate approval of the PI occurs. <u>This separate approval will not be subject to merits review.</u>

The PI is defined at Section 3 of the Act as "*information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods."*

There are numerous examples of decision-making where the ADEC or ACPM has recommended approval subject to the satisfactory finalisation of the PI. In negotiating a PI there is often disagreement about the nature and extent of the science in relation to the usefulness and limitations of the goods. There are other instances where the medicine has been approved on appeal by the Delegate of the Minister and the relevant evaluation unit head who initially rejected the application as Delegate of the Secretary has been reluctant to finalise the PI because his/her initial decision was overturned by the Delegate of the Minister under section 60. The bottom line is that this amendment:

- appears to be contrary to the Administrative Review Council's guideline "What decisions should be subject to merit review?" 1999, in that it is a substantive decision that will, or is likely to, affect the interests of a person;
- may unnecessarily force sponsors into the Federal Court where they disagree with the contents of the PI required by the TGA;

- will enable the Secretary another bite at the cherry so to speak to reject an application via the PI process even though the decision to reject may have been upheld on appeal in circumstances where the Delegate of the Minister has no power to intervene.

At present the negotiation and approval of the PI is part of the decision-making process under Part 3 of the Act and as such has always been included within the ambit of merits review under Section 60. It is therefore difficult to understand the policy drivers to exclude the PI from merits review other than to provide the regulator with a power to reject an application or to ensure a PI, and in turn an AusPAR, is more reflective of the regulator's views in comparison to the sponsor's views. This would appear to be a retrograde step in the context of open and transparent decision-making.

PROPOSED NEW PROVISION FOR CONSIDERATION BY THE PARLIAMENT

It was enlightening to note the recognition given to the ICCR. It is normally presumed that the administration of Commonwealth laws will be cognisant of the relevant duties and obligations under Treaties to which Australia is a signatory, particularly those relating to civil and political rights. However this is not always the case.

A case that went before the AAT but was not reported as it was withdrawn by the sponsor because of the poor cost-benefit of pursuing it any further centred on an orphan drug (ie. small patient population – no commercial benefit). Current treatment for the debilitating disease was weekly infusion. A competitor company developed an alternate therapy in the form of a tablet. The application for approval was rejected by the TGA Delegate essentially because the tablet was not as efficacious as the infusion and there was doubt that patients could be effectively monitored on the tablet to detect any deterioration in their condition so as to be switched back to infusion.

One of the grounds that the Applicant, the sponsor, relied upon in its Statement of Facts and Contentions (SFC) was that it was a fundamental human right to choose between an invasive versus non-invasive therapy (setting aside all the other arguments which included the greater cost of the infusion treatment). The Respondent, the TGA, responded in its SFC words to the effect that human rights had no place under the Therapeutic Goods Act 1989. To give the TGA the benefit of the doubt this could have been interpreted to mean that there is no reference to relevant human rights obligations in the Act.

Because of the opportunity afforded to me by the committee I therefore propose, in the context of this Bill, a simple amendment to the Act to put beyond doubt that the Act is administered in accordance with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. An appropriate amendment of section 4, "Objects of Act" would appear to be suitable.

Schedule 1 – Advertising

This proposed amendment is aimed at ensuring references to advertising includes a reference to the Code. However, elements of the Code can be subject to very broad interpretation. The Code

therefore either needs substantial revision to eliminate doubt and uncertainty or the development of an annotated version to clearly guide the industry.

Schedule 2 – Obtaining information etc.

This series of proposed amendments is designed to tighten up the information gathering powers of the Secretary and the relevant offence provisions. No major issue of concern is evident.

Schedule 3 – Goods that are not therapeutic goods

This proposed amendment could be interpreted as a de-facto form of cancellation from the Register – however, merits review of such decisions is included. I have concerns about the possible consequences, eg. EM states that "*Inclusion of goods in a subsection 7AA(1) determination would mean that, regardless of whether suppliers of the goods claimed that using the goods provided a therapeutic benefit or not, such items would be excluded from the definition of therapeutic goods and thus would be outside the scope of the legislation."*

At present the provisions of section 7 allow the Secretary to declare therapeutic goods not to be therapeutic goods. Such Orders titled Therapeutic Goods (Excluded Goods) Orders normally apply to classes of therapeutic goods. The Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, for example, also declares therapeutic goods not to be therapeutic goods when used, advertised, or presented for supply in a particular way. If excluded by such an order there appears to be no encumbrance on the continuing presentation and therapeutic claims of such goods.

However, the proposed amendment now provides two additional mechanisms to declare goods to be excluded goods or not to be therapeutic goods, one for the Minister and an additional one for the Secretary, respectively.

New section 7AA provides that the Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7) are excluded goods for the purposes of the Act. There are two issues with the design of this particular amendment:

- Why is this provision needed if Section 7 gives a similar power to the Secretary?

- Why is such a power vested in the Minister subordinate to the power already vested in the Secretary under Section 7?

One of the obvious reasons is that such a determination by the Minister is to be in the form of a disallowable instrument which must be tabled in the Parliament. Unlike a decision by the Secretary under existing section 7(1) or the proposed new section 9F it will not be subject to merits review under section 60. This provides the regulator with the option of utilising this mechanism if fearful of defeat via merits review. This is of major concern when considering the proposed new powers for the Secretary.

New section 9F provides that the Secretary may remove the entry of goods in the Register if satisfied that the goods are not therapeutic goods. The procedures for removal generally mirror the existing procedures at sub-sections 30(3)and (4), "Cancellation of registration or listing". However these existing provisions represent, apart from the criminal and civil offence regime in the Act, the ultimate sanctions that can be imposed on a sponsor for breaching any of the provisions at Subsection 30(2)(a) to (f), eg. it appears that the quality, safety or efficacy of the goods is unacceptable. It also appears that similar to section 30 this power includes the removal of individual goods not just classes of goods. There are three issues with the design of this particular amendment:

- Contrary to the similar provisions at section 30 this amendment prescribes no such "offence" criteria on which the Secretary needs to base her decision;

- Proposed new subsection 9F(6) provides that the removal has effect on the day specified in the notice under subsection (2) in relation to the goods, being a day not earlier than the day on which the notice is given to the person. This appears contrary to the rationale advanced at Schedule 12 to provide more certainty for sponsors in relation to the time available,ie. at least 20 working days instead of "such later day as specified in the notice", to put in place the necessary measures in order to remove goods from the market place etc where the Secretary has cancelled the registration or listing of a good from the Register. If such an amendment is considered necessary where it is in the form of a sanction under section 30, then surely a similar period of time should be afforded to sponsors where the decision may not be sanctioned related;

- Proposed new subsection 9F(7) provides that if the Secretary removes an entry of goods from the Register the Secretary must, as soon as practicable after the removal, cause to be published on the Department's website a notice setting out particulars of the removal. It is noted and welcomed that Schedule 3 at 8, provides for such a decision of the Secretary to be subject to merits review under Section 60. Consequently the provision needs to include the requirement that where the Secretary's decision is overturned on appeal that an appropriate notice setting out particulars of the outcome of the appeal and reinstatement of the good on the Register is also published on the Department's website.

In seeking to understand the policy drivers for this amendment the EM explains as follows:

First, in relation to the amendments providing the Minister with the relevant power:

"*This new power will allow the Minister to respond flexibly, on a case by case basis, to ensure the Therapeutic Goods Administration is not involved in the regulation of products for which there is no public health focus or for which there may be sound public policy reasons for their not being regulated under the therapeutic goods legislation."*

Second, in relation to why existing section 7 is deficient in this regard:

"*However, the Secretary may only exercise these powers (ie. under Section 7) to declare a product* ***not*** *to be a therapeutic good if satisfied that the product is not, in fact, a therapeutic good. As such, section 7 would not provide a basis for excluding from the regulatory scheme in the Act products which come within the scope of the definition of therapeutic goods in subsection 3(1) of the Act or where there may be some certainty as to their characterisation.*

The power for the Minister under new section 7A of the Act will not require the minister to come to a view that a product is not in fact therapeutic goods for it to be included in a determination."

This justification is difficult to understand given that section 7 is expressed to specifically apply to goods that are/are not therapeutic goods and provides for the Secretary to declare that particular goods or classes of goods are or are not, for the purposes of the Act, therapeutic goods.

For example, the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, made pursuant to section 7, expressly states that:

"*4. For the purpose of the Therapeutic Goods Act 1989 and subject to section 5 of this Order, the following goods, being goods intended for use in humans, are declared not to be therapeutic goods:*

5 For the purposes of the Therapeutic Goods Act 1989, the goods specified in column 2 in an item in the following Table 1, being goods that:

a. Are intended for use in humans, and
b. Are used, advertised, or presented for supply in the way specified in column 3,

are declared not to be therapeutic goods."

Consequently it begs the question as to why, notwithstanding the manner in which the EM describes the justification, such an additional power is necessary other than to provide an alternative mechanism more insulated from scrutiny than sponsor initiated merits review. In these circumstances the EM is certainly not reassuring when it proclaims that "*It is important therefore for product suppliers as well as the public that there is as much clarity as possible about which goods are covered by the regulatory scheme."*

In relation to the issue of clarity for product suppliers and the public I now turn to the policy driver for proposed new section 9F. This section provides for the Secretary to remove the entry of goods from the Register if she is satisfied that they are not therapeutic goods. However, the EM states that this power is to be distinguished from a similar power at section 30. However, in sharp contrast to section 30 there is no criteria in new section 9F to bind the Secretary as to the circumstances in which removal should occur, ie. as to why the goods should no longer be therapeutic goods. Apart from the extrinsic aid of the EM and the Second Reading Speech there is little to guide the aggrieved sponsor and the merits review process, for example, should an appeal be warranted.

Many sponsors of goods which claim a 'therapeutic use' seek to include such goods on the Register to benefit from the TGA's regulatory stamp of approval for marketing purposes. Many of these products as the EM suggests, whether medicines or medical devices, are categorised as natural or alternative therapies. There would appear to be no reason why the proposed new section 9F cannot

prescribe the circumstances or criteria within which the Secretary would determine that the goods are not therapeutic goods.

Schedule 4 – Restricted representations and prohibited representations

With one qualification, this appears to be a reasonable amendment enabling the Secretary to impose conditions on the use of a restricted or prohibited representation in advertising. The use of a restricted or prohibited representation in advertising is governed primarily by Section 42DK of the Act and the Code. Schedule 1 of this Bill contains a number of amendments designed to put beyond doubt that in those instances where regulatory action in relation to therapeutic goods is predicated on whether or not the goods comply with advertising requirements, those requirements include applicable provisions of the Therapeutic Goods Advertising Code, made by the Minister under section 42BAA of the Act. As parts of the Code are capable of broad interpretation it is important that any conditions imposed by the Secretary under this provision are not inconsistent with the Code. Perhaps the amendments proposed under Schedule 1 for advertising should therefore also include recognition of new section 42DK(3) which provides for conditions to be imposed.

Schedule 5 – Evaluation and registration of therapeutic goods

(Please refer to the above.)

Schedule 6 – Conditions of registration or listing

The EM explains the purpose of this amendment as enabling new conditions of registration or listing or a variation to registration or listing, to commence earlier than the current 28 days after the notice of the new or varied condition is given to the sponsor, <u>where the sponsor has requested the new or varied condition</u> (underlining mine). The EM explains that the current 28 day restriction precludes the Secretary from responding flexibly to requests by sponsors.

However, the EM then proceeds to state as follows:

"*The item also allows the removal of existing conditions to commence on the day specified in the notice, rather than after 28 days, <u>regardless of whether the change was requested by the sponsor</u>* (underlining mine)."

The EM then explains:

"*Allowing for the removal of a condition earlier than 28 days from the date of notice in both cases – ie. where a person has requested it, and where the Secretary has removed a condition on her own initiative – reflects that, in either situation, there will be expected to be a benefit to the sponsor in terms of a reduction in their regulatory burden through the removal of the condition."*

This claim would only be true where the condition imposes a regulatory burden. However, it is feasible for some conditions to impose a benefit which would be lost if the condition were removed. In addition, no adequate justification has been advanced as to why the existing 28 day period should

be varied to a lesser period of time unilaterally by the Secretary without the sponsor's concurrence. Because of the potential implications of such a decision by the Secretary the sponsor needs to be afforded sufficient notice to prepare for the changed conditions of registration.

Given the rationale advanced for the amendment this provision therefore requires qualification that an earlier commencement date than 28 days should only occur upon the sponsor's agreement whether the change was requested by the sponsor or initiated by the Secretary.

Schedule 7 – Presentation

This introduces a new power for the Secretary at paragraph 30(2)(aa) to cancel the registration or listing of the goods where it appears that the presentation of registered goods is not acceptable or the presentation of listed goods is unacceptable. This raises a key issue of interpretation for registered goods as "presentation" can embrace many elements. Listed goods, although of lower risk and therefore subject to less pre-market scrutiny than registered goods, appear to benefit, according to the EM, from provisions in both the Act and Regulations that prescribe in detail the circumstances in which presentation would be unacceptable (ie. subsection 3(5) and regulation 3A). Presumably this view is supported by the term "unacceptable" instead of "not acceptable" at subsections 3(5) and 3(5)(e) and the prescribed cases at regulation 3A(1) and (2).

The EM reinforces this by stating that:

"It is important to note the distinction between the presentation of listed therapeutic goods being 'unacceptable' and the presentation of registered goods not being 'acceptable', in new paragraph 30(2)(aa).....In relation to the presentation of listed therapeutic goods being 'unacceptable', this is intended to refer to the meaning of 'unacceptable presentation' as described in subsection 3(5) of the Act."

However, the EM goes on to explain that:

"In relation to registered goods, whether the presentation of such goods is 'not acceptable' can encompass a range of factors that might go beyond the scope of the definition of 'unacceptable presentation' in subsection 3(5) of the Act. For example, the presentation of registered goods may cover matters such as the consumer medicine information for the goods."

This explanation raises concerns. It would appear that the policy intent is for the more specific guidance of subsection 3(5) and regulation 3A to apply to only to listed medicines. However, the EM has described subsection 3(5) as an inadequate benchmark for registered medicines. In addition, Regulation 3AA, "*Unacceptable presentation of therapeutic goods – prescribed class of medicine*" which is made pursuant to the power at paragraph 3(5)(ca) of the Act (ie. for listed medicines) at regulation 3AA(a) specifically excludes prescription or registered medicines as follows:

"For paragraph 3(5)(ca) of the Act , a prescribed class of medicine is medicine for supply in Australia that is not:

(a) a product of a kind mentioned in Part 1 of Schedule 10"

Part 1 of Schedule 10 cover products evaluated by the Office of Medicines Authorisation of prescription and other medicines.

The bottom line is that if legislative guidance is afforded to goods that are subject to less regulatory scrutiny such as low risk listed medicines by what justification should those higher risk registered goods not be afforded similar guidance. For registered goods the "*range of factors that might go beyond the scope of the definition of 'unacceptable presentation'*" in my view should not be open-ended but codified at least to the same extent as it has for listed goods.

Schedule 8 – Consent to the import, supply or export of goods

This represents a constructive initiative to provide a right of merits review in relation to a decision by the Secretary imposing conditions on any granting of consent under Sections 14 or 14A of the Act to the importing into, supplying in or exporting from, Australia, of therapeutic goods that do not comply with an applicable standard.

Schedule 9 – Review of decisions

This proposed amendment to section 60 is consequential to the proposed amendments at Schedules 5 and 6. Please refer to my comments in relation to those amendments above.

Schedule 10 – Kits

This is a welcome amendment to remove an anomaly in the legislation whereby a "kit" was defined as including more than one therapeutic good thus excluding the benefits of the legislative scheme for a "kit" that comprised only one therapeutic good. This will allow greater flexibility for sponsors of kits and is given effect by the introduction of a new subsection 7B(1) to the Act.

Schedule 11 – False or misleading statements

This amendment appears satisfactory with the exception that the proposed penalty levels are higher than the relevant Commonwealth benchmarks. The general rationale advanced for this is in the EM appears to be that it serves an important role in deterring and addressing conduct that endangers public health. My only comment on this is that the therapeutics industry in Australia does not, from my experience, wilfully and knowingly engage in conduct that would endanger public health.

Schedule 12 – Notice of cancellation of registration or listing

This is a welcome initiative which will provide more certainty for sponsors in relation to the time available, ie. at least 20 working days instead of "such later day as specified in the notice", to put in place the necessary measures in order to remove goods from the market place etc where the Secretary has cancelled the registration or listing of a good from the Register, other than those circumstances where failure to cancel would create an imminent risk of death, serious illness or serious injury (ie. paragraph 30(1)(a) of the Act).

Schedule 13 – Publication

There are two major proposed amendments under this schedule. Both are of concern. The first is to require the Secretary to publish in the Gazette or on the Department's website a notice setting out particulars of the cancellation of any registered or listed therapeutic goods from the Register under section 30. The second amends section 60 to clarify when the 90 day period commences in which a request for merits review of an initial decision must be made by a person who is not a sponsor of a therapeutic good, (according to the EM).

Publication of cancellations under Section 30.

The proposed amendment provides at new subsection 30B that if the Secretary cancels the registration or listing of therapeutic goods under section 30, the Secretary must, as soon as practicable after the cancellation, cause to be published in the Gazette, or on the Department's website, a notice setting out particulars of the cancellation.

This amendment appears reasonable for those cancellations made under subsection 30(1), ie. where failure to cancel would create an imminent risk of death, serious illness or serious injury. However, in all other cases which comprise the most numerous, and which come under subsection 30(2), there is a process that must be followed prior to any decision to cancel. This decision is subject to merits review under section 60.

Notwithstanding such an appeal being lodged the decision takes effect under subsection 30(5) (unless stayed by the Federal Court upon application by the sponsor). However, if an appeal is upheld any public health or commercial damage to the sponsor caused by publication of the cancellation needs to be redressed by an equivalent publication explaining the reasons for the decision being quashed on appeal. Consequently an additional amendment is required to ensure this occurs. Such an amendment also needs to apply to the publication provisions relating to cancellation from the Register under sections 32GE and 41GP.

This is keeping with the views of the Australian Law Reform Commission as follows:

"Those accused of breaches of the law are entitled to public recognition of the fact that allegations against them have been discontinued or charges against them have been dismissed to the same extent to which those investigations or charges were publicised. This affords them some vindication of their denial of the charges and balances the public record."
(Report of the Australian Law Reform Commission, "Principled Regulation, Federal Civil and Administrative Penalties in Australia", Dec. 2002, para. 16.127)

Further to the above a suitable provision needs to be included in the Act for an appropriate public correction and explanation by the TGA for any decision under the Act that has been published and then overturned either by the Minister, a Court or Tribunal.

Amendment of section 60 to clarify when the 90 day appeal period commences

The legislative deadline for an appeal under section 60 is strict – there is no provision for consideration of a late application as there is under the Administrative Appeals Tribunal Act 1975.

First, there would appear to be an inconsistency between the EM and the proposed amendment. The opening paragraph of the EM describes the amendment as applying only to a person who is not a sponsor of therapeutic goods. However, both the proposed amendment and the following paragraphs of the EM do not appear to reflect this so the following comments are based on the proposed amendment only.

The proposed amendment at new subsection 60(2)(b) provides:

"(2) A person whose interests are affected by an initial decision may, by notice in writing given to the Minister

- *(a) if this Act requires the person to be given notice in writing of the decision, or of particulars of the decision – within 90 days after the notice is given to the person; or*
- *(b) otherwise – within 90 days after the earlier of:*
- *(i) notice of the decision, or of particulars of the decision, being published in the Gazette or on the Department's website; and*
- *(ii) the decision first coming to the person's notice;*

request the Minister to reconsider the decision." (underlining mine)

The current provision only refers to in subparagraph (a), after the particulars are so notified, and subparagraph (b)(ii), the decision first coming to the persons notice.

My view is that these particular amendments pose more potential problems than the policy justifications advanced for their introduction.

The first provision underlined at (a) above has been justified in the EM on the basis that this is designed to avoid situations where a person may argue years later that they have a right to seek review because they had only just became aware of the initial decision. This raises questions about the nature and extent of the evidence to prove that notice was 'given' rather than 'first coming to the persons notice'. Section 28A of the Acts Interpretation Act 1901 provides guidance in that "give" is by delivering it to the person personally, or by leaving it at, or sending it by pre-paid post to, the address of the place of residence or business of the person last known to the person serving the document, or for a body corporate, by leaving it at, or sending it by pre-paid post to the head office, a registered office or a principal office of the body corporate. In addition, it is not clear as to where electronic communications, such as email, fit into this scenario or the TGA's intentions.

Whilst the Act requires all sponsors to have a legal presence in Australia sometimes this can amount to just the legal requirements for the establishment of a company and the engagement of an agent or single employee, particularly for a new start-up biotech company or a new multinational entering the Australian market. In these circumstances the address for notices could be merely a PO Box and email address.

If such an amendment were to proceed I would suggest that an appropriate definition of 'given' including clarification of the term in the context of electronic communication mediums be inserted into the interpretation provisions at section 3 of the Act so as to alleviate any uncertainty.

The second provision underlined at (b)(ii) poses additional complications in that a decision could be made and then notified to a person belatedly, thus eroding the 90 day appeal period, in circumstances where the TGA has unbeknown to the person published the decision previously on the Departmental website. In my view, given there is no provision for a late application to appeal under section 60, the critical factor should be when the decision first comes to the person's notice not publication in the Gazette or on the Department's website. Consequently the proposed amendment could still recognise this form of publication but should preserve the current principle of when the decision first comes to the person's notice.

Schedule 14 – Public notification and recovery

The amendments proposed by this schedule are designed to broaden the dissemination of information requirements the Secretary may impose on a sponsor or supplier. This relates to the public notification and/or recovery of therapeutic goods including medical devices.

In relation to the public notification elements I refer to my comments in relation to the amendments at schedule 13 on the publication of cancellations under section 30.

Schedule 15 – failure to comply with requirements to provide information etc.

This schedule amends subsection 30(2) to allow the Secretary to cancel the registration or listing of a product where the sponsor of the goods has failed to respond to a notice to provide information or documents issued under section 31 within 14 days after the date specified in the notice for production of the material.

Apart from the civil and criminal penalty regimes in the Act, cancellation of a therapeutic good from the Register is generally regarded as the most severe sanction that can be imposed on a sponsor. My only concern with this proposed amendment is that the various timeframes in the legislation, eg 20 working days and in this case 14 calendar days do not appear to bear any relationship to industry dynamics. For example, most prescription medicines are sponsored by multi-national drug companies who need to have serious regulatory matters cleared through their head or global offices in the EU or the US. Often extensions of time need to be sought by the Australian sponsors because of unforeseen delays at head office. My general inclination is for timeframes in the Act to be more liberal to accommodate this.

Schedule 16 – Information

This is a curious amendment because there is no explanation advanced as to why the current provisions, which achieve the same result, are inadequate. The only change, to enable the TGA to obtain "*such information as will allow the determination of the application*" under sections 9D and

23 is the addition of a legislative instrument as an optional vehicle to the current "*form approved, in writing, by the Secretary".*

The EM explains that "*it is important that the Secretary is able to specify the kinds of information that must accompany section 23 applications for the various types of therapeutic goods."* The current forms approved by the Secretary do just this. The Transitional prescription medicine streamlined submission process guideline (V1.5 January 2011) at 4.2.5.3 "Certification by sponsor" states that the "*TGA's requirements for an effective submission are established through legislative instruments made under s.23.*" There is a link to the TGA web-page that lists two "legislative instruments" dated 14 January 2011. One therefore needs to question why a legislative instrument is now needed given that section 23 has been in the Act since its inception in 1989.

One indicator may be the growing dissatisfaction in some sectors of the industry of the way in which the initial application process under sections 9D and 23 is now being administered. The prescription medicine streamlined submission process includes an up-front vetting process whereby submissions are initially considered against the TGA regulatory requirements. This attracts an application fee which is non-refundable if the submission is deemed to be "not effective". The TGA maintains that there is no right of appeal under section 60 against rejection of a submission that is not effective. Consequently the industry suspects that this amounts to a mini evaluation with the object of rejecting up-front any applications that may ultimately be rejected after a full evaluation and thus attract appeal rights under section 60.

Part 4.3.5.2 of the guidelines covers "TGA regulatory requirements" that sponsors must abide by. These include those set out in legislative instruments made under section 23 of the Act which encompass:

- Pre-submission planning form
- Application for the registration, or to vary the conditions of registration, of prescription medicines or the eBS electronic equivalent
- Transitional draft Common Technical Document (CTD) Module 1 Administrative Information and prescribing Information for Australia
- EU CTD format documents adopted by Australia
- Transitional mandatory requirements for an effective submission
- Australian regulatory guidelines for prescription medicines (ARGPM).

Some sponsors claim that they have had submissions deemed to be not effective notwithstanding that all regulatory requirements had been fully met in circumstances where the reason advanced for the TGA's decision was, in their view, inadequate. However, because the TGA claims that there is no right to appeal such "decisions" under section 60 the sponsors have no formal recourse other than to challenge the legality of this policy in the Federal Court which they are loathe to do. If the sponsor wishes to proceed with the submission they must lodge a new pre-submission planning form and potentially a new submission dossier and pay another application fee. It may well be that this proposed amendment has been prompted by TGA fears that a legal challenge may be forthcoming and that bolstering the legislation in this manner may afford the regulator additional protection.

PROPOSED NEW PROVISION FOR CONSIDERATION BY THE PARLIAMENT

As I mentioned above in relation to the amendments proposed by schedules 5 and 9 this "policy" of the TGA that such decisions are not subject to merits review appears to be contrary to the Administrative Review Council's guideline "What decisions should be subject to merit review?" 1999, in that it is clearly a substantive decision that will, or is likely to, affect the interests of a person.

To put this matter beyond doubt I recommend that appropriate amendments be made to sections 23 and 60 to ensure that a right of appeal under section 60 is available where an application under section 23 is deemed to be "not effective".