Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Mr Elton Humphery
Secretary
Senate Community Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Mr Humphery

Thank you for your e-mail of 16 July 2009 regarding the Committee's recent hearings on the Therapeutic Goods Amendment (2009 Measures No 2) Bill 2009 and seeking a response to a series of questions from the ACCORD submission to the committee.

I attach a response to those questions, and additional information in relation to several other matters that I undertook to provide during the Department's evidence.

Yours sincerely

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1. RESPONSE TO QUESTIONS RAISED IN ACCORD SUBMISSION (Senator Moore, Hansard CA 40)

a) Is the proposal to house *chemicals scheduling* within a non-chemical regulator, the Therapeutic Goods Administration under the *Therapeutic Goods Act* legally valid?

First, the Commonwealth has considered the constitutional position carefully and is confident that the legislative framework underlying the policy is valid.

Second, the question overlooks the fact that;

- the *Therapeutic Goods Act 1989* (the Act) has as one of its objectives "to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia" (paragraph 4(1)(b) (and a "poison" is then defined as including anything included in the Poisons Standard); and

- the current scheduling arrangements for medicines and poisons are included in the Act.

The Federal Court considered the current scheduling provisions (which include chemicals) in some detail in the *Roche* case (Roche Products Pty Limited v National Drugs and Poisons Schedule Committee [2007] FCA 1352) and no questions were raised as to the constitutional validity of the provisions.

Third, the question assumes that the amendments confer power upon the TGA to make chemical scheduling decisions. This is not correct: the amendments in the bill confer power upon the Secretary of the Department, not upon the TGA. The Secretary for administrative convenience may delegate her power to any officer in the Department: at this point it is envisaged that scheduling decisions on medicines will be delegated to the TGA; and decisions on chemicals will be delegated to the Office of Chemical Safety.

b) What are the broader consequences of the new power for the Department Secretary's decisions on scheduling to automatically become a legislative instrument?

Under current arrangements the decisions of the National Drugs and Poisons Schedule Committee to amend the Poisons Standard are legislative in character. As a legislative instrument the Poisons Standard is subject to certain requirements of the *Legislative Instruments Act 2003*. However, it is not subject to Parliamentary disallowance as it is utilised by the States and Territories for regulatory enforcement purposes.

The amendments in the Bill simply confer the power to amend the Poisons Standard on the Secretary (rather than the National Drugs and Poisons Scheduling Committee) and retain the Poisons Standard as a non-disallowable legislative instrument.

The Department is unaware of any broader consequences.

c) Is it appropriate that such decisions are not subject to merits review?

Under current arrangements scheduling decisions are not subject to merits review. As a general principle, decisions to make or amend legislative instruments are not subject to merits review.
The Poisons Standard is a legislative instrument because it sets out the law as it applies generally to persons dealing with particular scheduled substances and not just to the applicant who sought the amendment to the Poisons Standard.

Making decisions to include a substance in the Standard merits-reviewable would pose some legal challenges.

It would also significantly delay adoption of amendments to the Standard by States and Territories – they would be unwilling to adopt changes to the Standard until appeal rights had been exhausted, thus delaying access to market for new substances, contrary to the intention of the Galbally Review recommendation.

It should also be noted that if merits review was extended to scheduling decisions, any party whose interests were affected by a decision could apply for merits review. This is likely to include any party that made a submission to a scheduling advisory committee, including public interest advocacy groups, as well as the original applicant.

Making scheduling decisions merits reviewable may also impact on the high level of scheduling uniformity across Australia.

d) Is it appropriate for the Department Secretary to be granted the power to circumvent the new Scheduling Committees to seek advice from "any party"?

It is important to note that the Committees are advisory, not decision-making. There is thus no question of them being "circumvented".

The power under subsection 52E(4) to seek advice from any source is intended to allow the Secretary to access appropriate and relevant sources of information that may not have been available to the advisory committees. For example:

- an application for down-scheduling of a medicine is received and referred to and considered by the Advisory Committee on Medicines Scheduling, which provides advice to the Secretary;
- after that advice has been provided the Secretary becomes aware that an NHMRC-funded research project has been carrying out a meta-analysis of the impacts of long-term exposure to the medicine;
- the Secretary can seek advice from the researcher.

e) Can a legally legitimate industry cost-recovery process be established for *chemicals scheduling* from these arrangements? For example, while the TGA regulates medicines and can readily apply service charges to those therapeutic product categories under its regulatory oversight, can the agency legitimately levy fees or service charges against chemical introducers for non-therapeutic chemical substances?

This is essentially another version of question (a), and the answer is the same: the Act can be amended to impose fees and charges for any activity carried out under it.

f) What is the justification for transferring the funding of these previously Budget-funded functions to cost recovery from industry, considering the net public benefit produced by the system?

The Galbally Review recommended that the costs of operating the scheduling committees should be fully recovered.

All regulatory activity produces public benefit. But the activities that are regulated produce considerable private benefits. If these activities were not conducted there would be no cost of regulation. Successive Governments have taken the view that regulatory activities should be funded by cost recovery from the regulated industries.

g) What is the intended fee structure for the proposed cost-recovery arrangements?

These will be set out in the draft Cost Recovery Impact Statement to be made available for public comment later in 2009.

h) Why does the Bill specify one aspect of the membership of the proposed Advisory Committee on Chemicals Scheduling - namely, that each state and territory can nominate a representative (see 52C(3)) - but remain silent on other key member bodies with both a role and expertise in chemicals regulation for public health - NICNAS, APVMA and the federal Department of Health & Ageing's Office of Chemical Safety and Environmental Health? What mechanisms will be in place to ensure that the states and territories nominate members with appropriate expertise to ensure the scientific integrity of the Advisory Committee's decisions?

The States and Territories are identified in the legislation as they are enduring entities. (They are identified in the current provisions within the Act.)

It will be a matter for State and Territory governments to nominate appropriate members of the committees.

Provisions for other members of the advisory committees will be included in the regulations, as currently is the case.

i) How will the new arrangements, under Australia's medicines regulator, the TGA, deal with emerging local and international policy issues specifically related to chemicals? This includes, nanotechnology, the Globally Harmonised Scheme for Classification & Labelling of Chemicals, the recent proposal of the Environment Protection & Heritage Council for a national Environmental Chemicals Bureau and the soon-to-be-established COAG Standing Committee on Chemicals.

As observed under the answer to question (a) above, the Act confers power upon the Secretary, not the TGA. The Office of Chemical Safety will continue to be responsible for dealing with these issues as they relate to chemicals.

j) Is it appropriate that the National Coordinating Committee on Therapeutic Goods has oversight of *chemicals scheduling* when the membership of this group does not reflect either input or expertise from chemical regulators or the chemicals industry?

The NCCTG, as a sub-committee of AHMAC, includes State and Territory members responsible for the administration of the various State and Territory drugs and controlled substances Acts, which cover both medicines and chemicals. As a jurisdictional committee it is not appropriate to include representation from industry.

k) Have administrative arrangements that could more appropriately separate *chemicals scheduling* from medicines scheduling been adequately investigated (or indeed investigated at all) with the states and territories?

The administrative arrangements for scheduling were extensively investigated by the Galbally Review.

In implementing the Galbally Review recommendations the State and Territories have consistently stated that their agreement to reform in this area is conditional on:

- a single standard covering medicines and chemicals;
- a single scheduling policy framework covering medicines and chemicals; and
- a single secretariat providing services and support to both the medicines and chemicals scheduling advisory committees.

Against this background there is little scope at this time for greater separation of the medicines and chemicals scheduling process than that set out in the Bill.

2. DETAILS OF CONSULTATION PROCESS FOR RASML (Senator Siewert, Hansard CA37)

Appendix 1 of the Required Advisory Statements for Medicine Labels (RASML) (http://www.tga.gov.au/meds/rasml.pdf) sets out the current process for consultation on changes to the document.

If a change may be required because of the potential rescheduling of a substance, the TGA uses the National Drugs and Poisons Schedule Committee consultation process. Interested parties have the opportunity to comment on proposed statements and their application to particular substances through the NDPSC's Pre-Meeting Gazettal process. Changes recommended by the NDPSC and decided by the relevant TGA Delegate will be gazetted and published on the TGA's web site.

The process for change in other circumstances involves consideration of a "Proposal to Amend" submitted using a form on the TGA website. Proposals are published on the TGA web site and peak bodies are contacted directly and invited to comment. The period for comments is 4 weeks from the date of publication on the TGA web site, unless otherwise specified in the web site information.

A decision is made by the TGA after taking into account advice from the expert committee and all comments. All decisions to change the RASML document are gazetted (including text

of the change). All decisions (including a decision not to change) and reasons for them are published on the TGA web site.

An abbreviated process (excluding the consultation phase) applies where an advisory statement is required in respect of a new substance (i.e. where there are no goods containing the substance included in the Australian Register of Therapeutic Goods). This is appropriate:

- because there are no existing products that will be affected;
- to avoid delays in the approval process for new substances;
- because the sponsor of the new substance application will be involved in the approval process and therefore aware of the requirement for the advisory statement

The need for advisory statements will be considered as part of the evaluation of the product.

3. FEES AND CHARGES RELATING TO LISTING COMPLEMENTARY MEDICINES (Senator Boyce, Hansard CA 40)

The following fees and charges took effect on 10 July 2009:

Listed medicines		**Fee $**
Application fee		640
Processing fee (variation to an existing listing)		320
Annual charge		810
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		**Fee $**
New Listable Medicines Substance	1-50	8,190
	51-250	10,500
	251-500	14,400
	501-1000	19,100
	1001-2000	28,700
	2001-3000	38,300
	>3000	57,300
Assessment of safety information or documents submitted pursuant to Section 31 of the Therapeutic Goods Act 1989		6,240

Listed medicines - export only	
Application fee	640
Processing fee (variation to an existing listing)	320

Listed medicines - export certificates	**Fee $**
Certificate of Pharmaceutical Product	130
Certificate of Listed Product	130
Certificate of Exempt Product	130