EDITED SUBMISSIONS RECEIVED IN RESPONSE TO THE NOTICE INVITING FURTHER SUBMISSIONS IN RELATION TO DELEGATE'S INTERIM DECISIONS ON RECOMMENDATIONS FROM THE:

Joint Meeting of the Advisory Committees on Medicines & Chemicals Scheduling – 8 December 2010 (ACCS-ACMS#1); and
Meeting of the Advisory Committee on Medicines Scheduling – 9 December 2010 (ACMS #1)

Regulation 42ZCZQ, Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary of the Department of Health and Ageing publishes herein all public submissions made in response to the invitation contained in the February 2011 Reasons for delegate's interim decisions (accessible at www.tga.gov.au/regulation/scheduling-decisions.htm).

This call for further submissions (as required under subsection 42ZCZP of the Regulations), invited comments from the applicant and parties who made a valid submission in response to the original invitation for comment (published on 29 September 2010 at www.tga.gov.au/regulation/scheduling-adv-com.htm) on the interim decision. The closing date for these further submissions was 2 March 2011.

In accordance with the requirements of subsection 42ZCZQ of the Regulations these further submissions have been edited to remove information that the delegate considers to be confidential.

As advised in the notice inviting public comments, it was up to the person making the submission to highlight any information which they wished to request be considered as confidential. Material claimed to be commercial-in-confidence has been considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/regulation/scheduling-policy-framework.htm.

Discrete submissions have been grouped by item. However, a number of applicants provided submissions that related to multiple items. These submissions on multiple items have been separately grouped.

LIST OF SUBMISSIONS

1. SUBMISSIONS ON INTERIM DECISIONS ARISING FROM RECOMMENDATIONS BY ACCS-ACMS#1

Only one submission was received. This was a submission relating to multiple items (triclosan, laureth carboxylic acid and sodium lauryl sulfate).

2. SUBMISSIONS ON INTERIM DECISIONS ARISING FROM RECOMMENDATIONS BY ACMS#1

The delegate noted that only one submission was received following the publication of the interim decision on diclofenac. The submission was not considered a further submission under Regulation 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations) as the party did not provide a submission in response to the original invitation for the making of submissions under subregulation 42ZCZK(1) of the Regulations.

In this instance the delegate considered it appropriate to include this submission in the scheduling consideration. However, the future consideration of this kind of submission will be determined on a case by case basis.

[redacted]

21 February 2011

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the Delegate's Interim Decision under subsection 42ZCZP of the Therapeutic Goods Regulations 1990

We refer to the notice published on 16 February 2011 of the Delegate's interim decisions under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989.*

[redacted] provided comments on **laureth carboxylic acid, sodium lauryl sulphate (SLS) and triclosan** for consideration at the joint meeting of the ACMS and ACCS held in October 2010.

[redacted] has reviewed the Interim Decisions & Reasons for Decisions by the Delegate of the Secretary to the Department of Health and Ageing. While the interim decisions relating to the above mentioned chemical substances do not coincide exactly to our pre-meeting submissions, we believe that they are pragmatic and acceptable to [redacted] We therefore support the Delegate's interim decisions.

We look forward to further advice from the ACMS and ACCS. Should the Committees require any additional information from [redacted] at this stage please do not hesitate to contact me on [redacted]

Yours faithfully

[redacted]

[redacted]

XXXXX

The Delegate
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

2 March, 2011

To the Delegate

Item 2.1.2 Diclofenac

XXXXX would like to express concerns regarding the interim decision reached in relation to the scheduling of diclofenac, published on 16 February 2011 on the TGA's website http://tga.health.gov.au/regulation/scheduling-decisions-1102.htm.

Public comment was invited under Regulation 42ZCZK, *Therapeutic Goods Regulations 1990* by a notice published on the TGA's website on 29 September 2010 for a Meeting of the Advisory Committee on Medicines Scheduling (date to be advised) and Joint Meeting of the Advisory Committees on Medicines & Chemicals Scheduling (date to be advised)

It is noted that in this notice, the item was listed on the agenda as follows:

> 1.2 Diclofenac – proposal to include preparations containing 3 per cent or more of diclofenac for the treatment of solar keratoses in Schedule 4

The matter was apparently considered at the December 2010 meeting of the ACMS. However the committee's recommendations and the resulting interim decision has resulted in all dermal preparations containing diclofenac greater than 1% to be reclassified as Schedule 4, as shown by the proposed amendment to the Schedule 4 entry for diclofenac:

> DICLOFENAC except:
> (a) when included in Schedule 2 or 3; or
> (b) in preparations for dermal use unless:
> (i) for the treatment of solar keratosis; or
> (ii) containing more than 1 per cent of diclofenac.

The initial proposal had minimal impact to the sponsor, and for this reason we chose not to provide a pre-meeting submission in response to the notice of 29 September 2010. However the interim decision reached is quite different from that envisaged in the notice and it has significant impact to the sponsor in relation to XXXXX.

However according to the Notice under subsection 42ZCZP of the Therapeutic Goods Regulations 1990, (under which the interim decision was published) submissions from the sponsor need not be considered by the Delegate if the sponsor had not made a valid submission in response to the original invitation. The sponsor believes this policy lacks procedural fairness when the outcome differs substantially from the proposal outlined in the initial invitation for comment and hence affects a significantly different groups of products (as is the case here).

The sponsor agrees that products for the treatment of solar keratoses are appropriate in Schedule 4, as was envisaged in the original issue raised for the consideration of the ACMS, due to the nature of the condition to be treated. However the sponsor does not believe that all dermal preparations containing greater than 1% diclofenac should be classed as Schedule 4.

Dermal preparations containing diclofenac for relief of pain and inflammation have been available since 2000, as unscheduled medicines. While in Australia, the highest strength remains at 1%, XXXXX.

Scheduling of topical diclofenac worldwide indicates

In previous applications for rescheduling in February 1997 and February 2000, the sponsor had adequately addressed issues under Section 52E, in relations to:

(a) Toxicity and safety of diclofenac: Minimal absorption is expected from a dermal preparation when used on intact skin. Systemic absorption from dermally applied diclofenac is around 7% and is well below systemic strengths of diclofenac currently available as OTC medicines.
(b) Risks and benefits associated with diclofenac: Dermal preparations of diclofenac offer consumers an alternative treatment option when systemic preparations may not be appropriate or suitable. XXXXX
(c) Potential hazards associated with diclofenac: Systemic absorption is around 7% from a dermal preparation, safety risks are low.
(d) Extent and patterns of use of diclofenac: As with all NSAIDs, use is limited to short term treatment.
(e) Dosage and formulation of diclofenac: New dosage and formulations of diclofenac will be appropriately evaluated by the TGA, at which time both safety and efficacy will also be evaluated.
(f) Need for access to diclofenac: Dermal preparations of diclofenac offer an important treatment option for patients who do not require (or cannot use) systemic preparations, thereby reducing their exposure to the drug.
(g) Potential for abuse of diclofenac: Potential for abuse is low.
(h) Purposes for which a substance is to be used: Dermal preparations of diclofenac marketed by the sponsor will be solely for the relief of pain and inflammation, and will exclude solar keratoses.

Therefore, in light of the low risk to public health and safety, the sponsor strongly believes that dermal preparations of diclofenac at any strength, for the treatment of pain and inflammation, should remain exempt from scheduling.

The sponsor requests the Delegate to reconsider the interim decision, either by

1) accepting an alternative wording to the amendment:
   DICLOFENAC except:
   (a) when included in Schedule 2 or 3; or
   (b) in preparations for dermal use unless:
      (i) for the treatment of solar keratosis; **and**

(ii) containing more than 1 per cent of diclofenac

or

2) deferring the decision so that a formal submission from the sponsor can be considered by the Advisory Committee on Medicine Scheduling

Yours sincerely,

XXXXX