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Consumer Healthcare
Products Australia

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ABN 55 082 798 952

Suite 1, Level 2
35 Chandos Street
St Leonards NSW 2065

+61 2 9922 5111
PO Box 209, St Leonards NSW 1590

info@chpaustralia.com.au
www.chpaustralia.com au

4 July 2019

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment

We refer to the notice inviting further comment under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990* and would like to provide comment on the Delegate's Interim Decisions arising from the March 2019 meeting of the ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

CHP Australia (Consumer Healthcare Products Australia) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. CHP Australia also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. CHP Australia has considered the Delegate's Interim Decisions and Reasons for Decisions and would like to comment on the following scheduling proposals:

Item 1.1 – Interim decision in relation to cetirizine

CHP Australia does not support the Delegate's interim decision on cetirizine.

In our view, the Delegate's reasons for not amending the scheduling to allow a proposed exempt pack size of 20 dosage units, are not persuasive or evidence based, for the reasons outlined below:

- CHP Australia does not agree that increasing the general sales level pack size to 20 dosage units (20 days' supply) may delay a person seeking advice in a pharmacy or delay best practice treatment. Most consumers who purchase medicines in a general sales outlet are repeat purchasers

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who are familiar with the medicine and buy for convenience. These purchasers are not, at the time of purchase, necessarily seeking advice.

- Although other allergy treatment options exist, such as intranasal corticosteroids, some allergy sufferers prefer treatment options that can be used intermittently and flexibly for symptom relief (such as cetirizine), so that they do not need to use nasal sprays when they are feeling well. See https://www.allergy.org.au/patients/allergic-rhinitis-hay-fever-and-sinusitis/allergic-rhinitis-or-hay-fever. For these consumers, there is no evidence that the presence of a 20-day pack size in a general sales outlet will adversely impact quality use of medicines or best practice treatment of seasonal allergic rhinitis.
- Allergy sufferers will generally seek medical advice or pharmacist advice when they need to do so, and there is no evidence that the pack size that is purchased has any bearing on when they will seek advice.
- CHP Australia is not aware of any safety concerns with the availability of the currently available unscheduled 10-day supply of cetirizine. There is no evidence that people misuse the product by taking higher doses (that would lead to increased risk of sedation).
- While Cetirizine is not entirely devoid of CNS activity, it is incorrect to conclude that it's *in contrast to* other second-generation antihistamines. At the 10mg daily dose cetirizine is still considered "non-sedating" in many parts of the world and considered to be similar to other second-generation antihistamines.
- CHP Australia does not believe that there is a negative impact on public health should a 20-day pack size of cetirizine become available in a general sales outlet.

Item 1.4 – Interim decision in relation to mometasone

CHP Australia does not support the Delegate's decision in relation to mometasone and is concerned that the new proposed entry directly conflicts with recent decisions to remove actuation limits from other intranasal corticosteroids (so that they aligned with the (then) current Schedule 2 mometasone entry). CHP Australia believes that the decision to introduce an actuation limit is an error that should be corrected.

- CHP Australia believes that mometasone for dermal use containing 0.1% or less of mometasone, in packs containing 15g or less, substantially meets the Schedule 3 scheduling factors.

- The medicine is substantially safe with pharmacist intervention – noting that pharmacists currently intervene in the supply of lower potency dermal corticosteroids, which have very similar precautions and contraindications to higher potency corticosteroids.
- In relation to intranasal mometasone and the introduction of a limit on the number of actuations, CHP Australia believes that this is an error that should be addressed.
- It should be noted that the update to the Poisons Standard dated 1 February 2019 removed the actuation limit of 200 actuations or less from the entry for budesonide in aqueous nasal sprays (see the Final Decision here: https://www.tga.gov.au/book-page/12-budesonide-0).
- Similarly, a decision was made to remove the actuation limit for fluticasone, and this was included in the 1 October 2018 update to the Poisons Standard, (see the Final Decision here: https://www.tga.gov.au/book-page/13-fluticasone-0).
- Both decisions (for budesonide and fluticasone) and the corresponding updates to the Poisons Standard were made to align both intranasal corticosteroid entries with that of intranasal mometasone, which does not have an actuation limit.
- CHP Australia finds it very concerning that the Delegate is now seeking to include an actuation limit for mometasone, which directly contradicts the final decisions made in September 2018 and June 2018 and Poisons Standard updates of 1 October 2018 and 1 February 2019.
- When deciding to remove the actuation limit for fluticasone, the Delegate's interim decisions stated that "*There is no difference in the risks of the substance by allowing more doses per pack*[1]." Similarly, for budesonide, the Delegate stated that "*Removing the actuation limit will allow new larger pack sizes and provide a longer duration of treatment*"; "*This change to the scheduling of budesonide in the Poisons Standard will align the Schedule 2 entry with other intranasal corticosteroids*" and "*Making budesonide available in a larger pack size is unlikely to impact the risk-benefit profile significantly*[2]".
- CHP Australia is very concerned that within the space of a year, two inconsistent scheduling decisions have been made. Consistent, non-arbitrary decision making is important for industry.

[1] https://www.tga.gov.au/book-page/13-fluticasone
[2] https://www.tga.gov.au/book-page/12-budesonide

- CHP Australia requests removal of the actuation limit for intranasal mometasone as we do not believe that there ought to be a limit introduced for mometasone after it has already been decided that similar limits are not needed for other equivalent intranasal corticosteroids.

Item 1.5 – Interim decision in relation to modified release paracetamol.

CHP Australia believes that the current Schedule 2 entry for modified release paracetamol is appropriate and does not support the Delegate's interim decision to up-schedule modified release paracetamol to Schedule 3.

CHP Australia acknowledges (and supports) the Delegate's decision to maintain the Appendix H entry for Schedule 3 paracetamol.

We are, however, concerned with the inadequate transition timeframe that has been proposed by the Delegate.

A "switch effective" date of 1 October 2019 leaves sponsors and retailers with only 3 months transition, in which time it is impossible for sponsors to complete the necessary regulatory changes involved in being ready to supply an approved Schedule 3 product.

The following changes are needed, to enable supply of a compliant S3 product:

- Prepare and sign off new artwork (in-house)
- Prepare and sign off new Product Information and Consumer Medicine Information (in-house)
- Submit these changes to the TGA
- Allow 9 months (average) for TGA approval of a C3 application
- After approval, organise with production planning / supply chain for stock with revised labelling to be produced and distributed (some sponsors may undertake some of these steps at overseas sites)
- Apply to States and Territories for labelling exemptions to continue supplying S2 stock, in order to avoid costly and unnecessary write-offs of existing products (as we have done with previous re-scheduling exercises of this nature, CHP Australia will work with the States and Territories to arrange exemptions on behalf of all affected sponsors)

Clearly, it is not possible for S3 labelled product to be produced and be available to pharmacists within 3 months.

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We would like to bring to the Delegate's attention that comparable changes to products and labelling have had more generous transition times allowed, to accommodate the requirement for regulatory changes. Examples are:

- The 2009 up-scheduling of codeine containing analgesics and cold & flu medicines from Schedule 2 to Schedule 3, which had an 11-month transition timeframe;
- The 2017 up-scheduling of codeine containing analgesics and cold & flu medicines from Schedule 3/Schedule 2 to Schedule 4, which had a transition timeframe of more than 12 months
- The TGA allows 18 months transition for updates to RASML warning statements on labelling
- The TGA allowed a generous transition for recent re-writing of PI documents when the templates were updated

CHP Australia also understands that due to sales volumes and popularity of modified release paracetamol among consumers, pharmacists will be carrying large volumes of stock of S2 modified release paracetamol, and inadequate provisions for implementation of the up-schedule to Schedule 3 will mean that there will be a significant business impact, on pharmacies as well as the sponsors.

The costs of recalling or re-working stock are significant, and CHP Australia believes that it is unreasonable to impose a significant operational and financial burden on pharmacy and sponsors, where there is no urgent public health issue that needs to be addressed and where the up-scheduling is being made on the basis of the potential for harm from inappropriate use[3] rather than a documented critical urgency.

With all these factors in mind, CHP Australia requests that a "switch effective" date of no earlier than 1 October 2020 be applied.

Kind Regards

Steve Scarff
Regulatory and Legal Director

M 0404 900 566
E steve.scarff@chpaustralia.com.au

[3] https://www.tga.gov.au/book-page/15-interim-decision-relation-paracetamol-modified-release