[redacted]

'Proposed Amendments to the Poisons Standard (Medicines/Chemicals)

Dear Sir/Madam,

I wish to submit the following comments on the 'Proposed Amendments to the Poisons Standard (Medicines/Chemicals)

Consultation: Proposed amendments to the Poisons Standard - ACMS and ACCS, November 2019

Amendment to Paracetamol Schedules 2 and 4 Scheduling:

Yours Sincerely,

Ronald Peter Batagol, PhC,FSHP,Advancing Practice Adv.PP(II) pharmacist,

ACIS, AGIA,Dip.Jnl, Certif.Criminology& Forensic Psychology,

Senior Hospital Pharmacist, Obstetric Medicines and Medication Safety Consultant,

Specialist Advisor to contribute to TGA's Regulatory Functions.(Appointed January 2017)

MY SUBMISSION IS AS FOLLOWS:

With respect to the proposed changes, I note that:

"Scheduling decisions involve a risk-benefit consideration in the context of protecting public health. This risk-benefit consideration takes into account factors such as those set out in **section 52E of the Therapeutic Goods Act 1989** (CTH) , including: the toxicity of the substance".

-namely, section 52E of the Therapeutic Goods Act 1989, specifically states that:

The Secretary needs to take certain matters into account in exercising powers, as follows:

(1) In exercising a power under subsection 52D(2), the Secretary must take the following matters into account (where relevant):

(a) the risks and benefits of the use of a substance;

(b) the purposes for which a substance is to be used and the extent of use of a substance;

(c) the toxicity of a substance;

(d) the dosage, formulation, labelling, packaging and presentation of a substance;

(e) the potential for abuse of a substance;

(f) any other matters that the Secretary considers necessary to protect public health.

MY COMMENT:I believe that all these requirements are complied with by the Secretary, in the detail supplied regarding the suggested amendments.

(2) In exercising a power under subsection 52D(2), the Secretary must comply with any guidelines of:

(a) the Australian Health Ministers' Advisory Council; and

(b) the subcommittee of the Council known as the National Coordinating Committee on Therapeutic Goods (or any replacement subcommittee);

notified to the Secretary for the purposes of this section.

(3) In exercising a power under subsection 52D(2), the Secretary must have regard to any recommendations or advice of the Advisory Committee on Medicines Scheduling or the Advisory Committee on Chemicals Scheduling.

MY COMMENT:I believe that all these requirements are and will be, complied with by the Secretary, in the detail supplied regarding the suggested amendments, and the subsequent deliberation by the Advisory Committee on Medicines Scheduling.

THE PROPOSED CHANGES ARE AS FOLLOWS:

1.Schedule 4 - Amend Entry for PARACETAMOL, by

adding a section (i) stating:

"in liquid preparations for oral use except when in Schedule 2".

AND

2. Schedule 2 - Amend Entry for PARACETAMOL, by

Adding a section (a) stating:

(a)liquid preparations for oral use containing no greater than 50 mg per mL of paracetamol in 100 mL with a maximum of 50 g paracetamol per container;

I note the following reasons for the proposed changes:

- **The paracetamol entries in Schedules 2, 3 and 4 of the Poisons Standard aim to minimise the risk of accidental poisoning by limiting the total dose in a pack. However, there is no limit on the amount of paracetamol that can be supplied in the liquid form in Schedule 2.**
- **A product containing large quantities of paracetamol, particularly in liquid form, carries a potential for significant human toxicity (including delayed irreversible hepatotoxicity) if the product is accidently ingested or deliberately misused.**
- **In view of the known risks of paracetamol toxicity to humans (the acute toxic effects include hepatic and renal tubular necrosis) and in the interests of public health, it is appropriate to limit the volume or maximum paracetamol mass in Schedule 2 paracetamol liquid preparations.**

MY COMMENTS:

In the Royal Childrens Hospital, Melbourne "Paracetamol Poisoning" document, the Syrup form of Paracetamol is included amongst the potential sources of poisoning, through overdosage:

1. Royal Childrens Hospital Melbourne

Paracetamol poisoning

As stated at: https://www.rch.org.au/clinicalguide/guideline_index/Paracetamol_poisoning/

Paracetamol is the most widely used over-the-counter analgesic agent in the world. It is involved in a large proportion of accidental paediatric exposures and deliberate self-poisonings. It is the leading pharmaceutical agent responsible for calls to poisons information centres in Australia and New Zealand. Hepatic failure and death are uncommon outcomes, although paracetamol remains the most important single cause of acute fulminant hepatic failure in Western countries.

AND

:Stated or likely dose taken

Presented as syrup, immediate or modified- release tablets

If possible determine the exact name and tablet size.

2. From: The Sydney Children's Hospital Network

Guideline No: 2014-9041 v2 Guideline:

MANAGEMENT PRACTICE GUIDELINE

Guideline No: 2014-9041 v2 Guideline: Paracetamol Overdose - Assessment and Management Date of Publishing: 14 May 2018 3:39 PM Date of Printing: Page 7 of 11 K:\CHW P&P\ePolicy\Jul 17\Paracetamol Overdose.docx This Guideline may be varied, withdrawn or replaced at any time. **Paediatric (< 6 years) liquid paracetamol ingestion In children suspected of ingesting > 200 mg/kg, measure serum paracetamol level at least 2 hours post-ingestion:**

• If the concentration 2-4 hours after ingestion is < 150 mg/L (1000 micromol/L), acetylcysteine is not required. • If the 2 hour concentration is > 150 mg/L (1000 micromol/L), measure again at 4 hours postingestion. If the 4 hour concentration is still > 150 mg/L (1000 micromol/L), commence acetylcysteine infusion as per the paracetamol nomogram. • For children presenting later than 4 hours post ingestion or ≥ 6 years, treat as per the Acute Ingestion Management Flow-chart

3..Writing in "The Conversation" on 2nd. September Rose Cairns,Lecturer in Pharmacy, University of Sydney,

in an article entitled: , *"Australia has a paracetamol poisoning problem. This is what we should be doing to reduce harm"*, she discussed a concerning increase in paracetamol poisonings, and resulting liver damage, in Australia over the last decade.

In fact, paracetamol is actually the number one pharmaceutical Australian poisons centres receive calls about.

Paracetamol is safe if used appropriately, at a maximum of *four grams per day in adults* (equivalent to eight 500mg tablets, or six 665mg modified release tablets).

However when this dose is exceeded, there is a potential for harm. And the bigger the dose, the greater the risk.

It's time to consider restrictions, including reducing pack sizes and changing the way paracetamol is sold.

The article she refers to was pulished in the Medical Journal of Australia 2nd. September, 2019:

"Paracetamol poisoning-related hospital admissions and deaths in Australia, 2004–2017": Cairns R et.al.,

Med J Aust 2019; 211 (5): 218-223. || doi: 10.5694/mja2.50296

At:https://www.mja.com.au/journal/2019/211/5/paracetamol-poisoning-related-hospital-admissions-and-deaths-australia-2004-2017

The Study was a retrospective analysis of data on paracetamol-related exposures, hospital admissions, and deaths from the Australian Institute of Health and Welfare National Hospital Morbidity Database (NHMD; 2007–08 to 2016–17), the New South Wales Poisons Information Centre (NSWPIC; 2004–2017), and the National Coronial Information System (NCIS; 2007–08 to 2016–17).

It is noted that paracetamol pack sizes have been restricted in the UK since 1998[8] to 8 g for non-pharmacy sales and to 16 g for pharmacy sales (formerly: 50 g). The approach appeared effective, as the number of large paracetamol-related overdoses, liver unit admissions, and suicide deaths in England and Wales subsequently declined.

It is also noted that " in 2009, the availability of non-prescription paracetamol was restricted in Germany to a maximum 10 g, and it can be purchased only in pharmacies. Most western European countries have similar restrictions

The authors also note that "In 2018, 14 of 21 surveyed European countries had pharmacy pack size restrictions (range, 8–30 g); most European countries do not permit non-pharmacy sales, and the rates of poisons centre calls regarding paracetamol are lower in these states".

Amongst the conclusions to the Study are the comments under **The implications, namely:**:

" Public health measures that restrict the availability of paracetamol, such as reducing non-prescription pack sizes, are needed to stem the increasing number of paracetamol overdoses":.

Clearly, there is an overall concern about the potential for poisoning arising from deliberate or accidental overdosing of Paracetamol.

Whilst the issues raised above from The Royal Childrens Hospital, Melbourne, The Sydney Childrens' Hospital Network and the published review and comments in "The Conversation" article by Cairns et.al. primarily deal with the overall picture, including adults and children, the important inclusion of the paediatric component is identified.

- **Therefore, I agree with the suggested proposal that "In view of the known risks of paracetamol toxicity to humans (the acute toxic effects include hepatic and renal tubular necrosis) and in the interests of public health, it is appropriate to limit the volume or maximum paracetamol mass in Schedule 2 paracetamol liquid preparations".**

In this context, I note that the requirements of the Poisons Standard June 2019, under sale or supply , state that *"A person, other than a pharmacist (or an assistant under the direction of a pharmacist) or a medical, dental or veterinary practitioner in the lawful practice of their professions, must not sell or supply a Schedule 2 poison unless licensed to do so".*

There is also a provision to allow premises from which the poison will be sold is more than 25 kilometres by the shortest practical route from the nearest pharmacy, to sell Schedule 2 Poisons.

- **To summarise, apart from this last provision for remote locations, I believe that , it is appropriate to limit the volume or maximum paracetamol mass in Schedule 2 paracetamol liquid preparations, as this will ensure that purchasers of paracetamol liquid preparations will have the benefit of a pharmacist's guidance on appropriate dosage and precautions, provided either directly or under the direction of that pharmacist.**

- **In this context, I emphasise the following points noted in the paper by Cairns et.al.:**

> ***"Paracetamol pack sizes have been restricted in the UK since 1998[8] to 8 g for non-pharmacy sales and to 16 g for pharmacy sales (formerly: 50 g). The approach appeared effective, as the number of large paracetamol-related overdoses, liver unit admissions, and suicide deaths in England and Wales subsequently declined.***
> ***It is also noted that " in 2009, the availability of non-prescription paracetamol was restricted in Germany to a maximum 10 g, and it can be purchased only in pharmacies. Most western European countries have similar restrictions."***
>
> **My Conclusuion:**

I believe Australia should review the current situation of Paracetamol availability, and work to bring it in line with what is the situation noted above in many regions overseas., by . In Schedule 2, amending the entry for PARACETAMOL, by :adding a section (a) stating:

(a)liquid preparations for oral use containing no greater than 50 mg per mL of paracetamol in 100 mL with a maximum of 50 g paracetamol per container;