BY EMAIL TO THE THERAPEUTIC GOODS ADMINISTRATION

Submission for public consultation on an application to amend Schedule 7 of the Poisons Standard re nicotine - comments on interim decision

Dear Sir or Madam,

I am exercising my right of comment on the application to amend the Poisons Schedule in relation to nicotine. I do not expect the decision to change, and so my comments will be brief.

Comments on recommendations

Having strongly supported a change to the Schedule as a key Tobacco Harm Reduction measure, I am of course very disappointed that the Committee has chosen to maintain the status quo, including the exemption from the probation of nicotine in "tobacco prepared and packed for smoking". I note the reasons given for rejecting the application are consistent with the standard orthodoxy of the more prominent public health and harm reduction advocates in Australia, especially the claims that not enough is known about the nature and long-term effects of Electronic Nicotine Delivery Systems (ENDS) and vaping on users and bystanders; the concern about "renormalisation" of smoking behaviours; and the claimed "gateway effect" of vaping take-up by young people leading to deadly tobacco smoking.

As I argued in my submission, these factors are not material to deciding on this application. The only real question is whether the proposed nicotine dosage, delivered by ENDS, is safe or not safe. The policy judgments that were made by the Committee are matters of wider public policy that are more appropriate for Parliament and other Commonwealth and State regulators and, in my view, ruling on them is *ultra vires* for this process.

But having ruled in these issues, the Committee and delegates need to ensure submissions are considered fairly and impartially, and that the **full weight** – for and against – of scientific and clinical evidence, and relevant overseas precedents and practice, are taken fully into account. My conclusion on reading the Interim Decision, and noting the procedural concerns raised below, is that evidence in favour of ENDS and vaping as safer and less risky access to nicotine, and considering safety and risks of nicotine separate to combustible tobacco nicotine delivery, has been either discounted or even ignored. That this apparent lack of impartiality produces a result counter-intuitive to leading overseas thinking – and not just the commonly-cited reports of Public Health England and the Royal College of Physicians – is not only disappointing, but unwise.

Given, however, the Committee and the TGA are determining that it is appropriate to decide on the basis of these issues, they should have been consistent in its overall treatment of nicotine delivery systems and prohibit access to nicotine completely. The exemptions for tobacco prepared and packed for smoking, and for clinically-approved nicotine delivery through patches and gums, therefore should be abolished to ensure this consistency. To penalise one delivery system while retaining all others, especially deadly combustible tobacco, is inconsistent and illogical to the point of being indefensible. That of course is impractical in reality, but in itself serves to highlight the logical inconsistencies in the Interim Decision.

This application outcome has made it clear that the only way that lawful access to nicotine via ENDS will be permitted will be via direct legislative intervention, including potentially an amendment to the Therapeutic Goods Act. That sort of *ad hoc* intervention is not necessarily good policy or regulatory practice, but if the scientific consideration process's impartiality and willingness to

consider disruptive innovations cannot be trusted, it may be necessary for Parliament and appropriate public policy-makers to resolve the situation.

Comments on process

I note that the Committee formed its view with reference to submissions and consultations as well as its own deliberations and expert opinion. I also understand that expert consultancy advice was commissioned and paid for by the TGA to assist the consideration of the application.

As part of finalising this application, it is in the public interest for the Committee, and the TGA, to disclose which individuals and organisations were directly consulted, and what interests they advocated or represented. It is also appropriate that the identity of the commissioned consultants or advisers, and their terms of engagement – including a project or tender brief and budget – are also disclosed. Any related declarations of conflict of interest by parties consulted also should be disclosed.

It is important that all parties, and the Australian public have confidence that the consideration of the application was fully impartial, and was free from bias. It is not possible to be assured of freedom from bias by releasing the Interim Decision alone.

Redactions

I especially want to express my great concern about the extremely heavy redaction of submissions, including my own.

In my case, I ticked the cover sheet box agreeing to the full publication of my submission. Indeed, I released it publicly myself in anticipation. I did not expect my submission to be so heavily redacted as to be almost unrecognisable even to me, in complete disregard of my expressed wishes.

As a general issue, who and what interests support or oppose a scheduling application should not be made secret or redacted, unless there are compelling confidentiality or commercial-in-confidence reasons for doing so. Parties making submissions should be prepared to stand by their submissions publicly. It appears, therefore, the current process for scheduling applications is too secretive, and thus dangerously counter-productive. The redacted submissions, shorn of not only the identities of the submitters but key elements of their submissions, makes it impossible for third parties to evaluate the quality of the submissions, and the motives and interests of the submitters.

When many submissions for and against would have been made by parties with well-known interests in, and opinions on, the issue, keeping them secret and redacting them is pointless at any rate, and not in the wider public interest.

I also note that I am aware that other some submitters' wishes for full publication were similarly ignored. This includes the major submission in support of the application, co-signed by 40 Australian and international experts: the names of all these highly-reputable authorities were redacted, as well as much of their argument. Looking at the redactions overall, it is hard to avoid the conclusion that the redactors exercised a deliberate or inadvertent bias in their excisions that favoured the decision, and evidence in its favour. I certainly request that my submission be reposted in its unredacted entirety, and hope that other redactions are removed if they were made contrary to the submitter's wishes.

Lastly, I note that I received no notification, as a submitter, of the publication of the interim decision, nor an invitation to make follow-up comment in accordance with TGA policy and procedure. This is discourteous to all those who took the trouble to submit, but with the excessive and capricious redactions to submissions it also leaves open the questioning of whether procedural fairness truly was honoured in this process.

I am happy for these comments to be published, and indeed would be disappointed if they are not. With that in mind, I advise that I intend to release them myself regardless, as I did my original submission.

While I believe the outcome of this process to be a retrograde step for Tobacco Harm Reduction in Australia, thank you for the opportunity to contribute to this important debate.

Yours sincerely,

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