

6 November 2009

Hon Peter Dunne
Associate Minister of Health
Parliament Buildings
WELLINGTON

Dear Minister

EACD recommendations in relation to pseudoephedrine and ephedrine

The Expert Advisory Committee on Drugs (the Committee) met on 17 June 2009 and 8 October 2009 to consider pseudoephedrine (PSE) and ephedrine (EPH) in accordance with section 4B of the Misuse of Drugs Act 1975 (MoDA). The minutes from these meetings are attached. The Committee met again on 5 November 2009 to confirm its final advice to you on the classification of PSE and EPH.

On 16 July 2009, my colleague Dr Stewart Jessamine wrote to you (in the capacity as Acting Chair of the Committee) outlining the Committee's preliminary view that:

- as PSE is the main precursor ingredient used to manufacture methamphetamine in New Zealand the harms of ongoing availability of PSE in New Zealand now outweigh the benefits
- both PSE and EPH should be reclassified as Class B2 controlled drugs under the MoDA
- PSE's current status as a registered medicine in New Zealand should be reviewed by Medsafe, with a view to 'delisting' it.

Since the Committee made its recommendation to you, I note that the Prime Minister's Chief Science Adviser, Professor Sir Peter Gluckman has reported to the Prime Minister on PSE and that his conclusions were largely similar to those of the Committee.

On 28 September 2009, the Cabinet Business Committee noted that the EACD had provided preliminary advice that PSE and EPH should be classified as Class B2 controlled drugs under the Misuse of Drugs Act 1975 and invited the Associate Minister of Health to report to the Cabinet Social Policy Committee by 30 November 2009, following the further advice from the EACD on the presumption for supply, with a view to progressing the reclassification of PSE/EPH.

In my letter of 16 July, I advised that before providing you with formal advice on this matter the Committee proposed to consult with the pharmaceutical industry and pharmacies to ensure that all relevant information was considered in its final advice given the significant regulatory impact on these stakeholders. However given that the Government has now decided to reclassify pseudoephedrine, the proposed EACD consultation with industry is now no longer needed and the Committee does not intend to undertake further work in this regard. I understand that the Ministry of Health will consult with representatives from industry for the Regulatory Impact Statement required for the report to the Cabinet Social Policy Committee.

Presumption for supply

You have also requested that the Committee provide further advice about the amount, level and quantity at and over which PSE/EPH might be presumed to be for supply.

At its meeting on 8 October 2009, the Committee considered the following options for the presumption for supply of pseudoephedrine and ephedrine:

- i Set the presumption for supply level for PSE and EPH at 5 grams
- ii Set the presumption for supply level for PSE and EPH at 10 grams
- iii Do not set a specific presumption for supply level for PSE or EPH, which would have the effect of both drugs being presumed to be for supply at and over a 'default' level of 56 grams

The Committee considered evidence presented in a Ministry of Health briefing paper (attached). The maximum period of supply on a prescription containing pseudoephedrine is one month, where the amount of pseudoephedrine per tablet is 60 milligrams (mg) and the Committee noted that it is unlikely long term prescriptions would be given for general cold and flu treatments.

Setting the presumption for supply at the 'default' level of 56 grams was considered unacceptable as it represents a large volume of PSE (or EPH) which could be used to manufacture a significant amount of methamphetamine thus creating potential for a large degree of harm.

The option of setting the presumption for supply at 5 grams was discussed. Packets containing PSE content exceeding 5 grams, sufficient for one month's supply, are currently available on the New Zealand market. It was therefore agreed that a presumption for supply of 5 grams would be too low.

There was consensus that the presumption for supply would be better represented by an upper limit less likely to capture legitimate consumers holding larger quantities of PSE or EPH, for example, international tourists and those with a large prescription from their medical professional. A consensus emerged that a presumption for supply of 10 grams would be more appropriate.

Review of pseudoephedrine as a medicine

The Cabinet Business Committee also directed Medsafe to review the status of PSE as a medicine with a view to delisting it. The Committee understands that Medsafe is aware of this request and, in accordance with the view expressed by the Prime Minister, has indicated that it will undertake this review once the change in the legislation has been in place for at least several months.

The Committee also wishes to advise that after the legislation has been enacted, the Minister of Health will need to determine which individual prescribers or class of prescribers will be authorised as well as where the medicines can be dispensed from and who can prescribe them. While there is currently debate about this it is expected that consultation undertaken for the Regulatory Impact Statement and by the Select Committee considering the legislative change will inform whether access should be limited to specialists, or available to GPs.

The Committee's confirmed advice is:

- pseudoephedrine (PSE) and ephedrine (EPH) should be reclassified as Schedule 2, Part 2 (Class B2) controlled drugs in the MoDA
- the presumption for supply level of PSE and EPH be set at 10 grams
- the status of PSE and EPH as registered medicines in New Zealand should be reviewed by Medsafe at some stage following the re-classification process should this still be necessary.

I would be pleased to discuss with you this advice or any issues arising.

Yours sincerely

Ashley Bloomfield (Dr)
Chair, Expert Advisory Committee on Drugs

cc Dr Janice Wilson, Deputy-Director General, Population Health