Australian Government

Department of Health

Committee Secretary
Standing Committee on Health
PO Box 6021
Parliament House
Canberra ACT 2600

Dear Committee Secretary

I am writing to bring to the Committee's attention to the details of the Managed Entry Scheme (MES) that was established under the recently expired Memorandum of Understating (MOU) agreed with Medicines Australia by the previous Government.

In evidence provided to the Committee during the hearing of 29 July 2014, Mr del Cuore (page 18 of Hansard) advised that:

> *"currently no company has accepted the managed entry scheme as has been proposed under the memorandum of understanding"*

I would like to advise the Committee that Mr Del Cuore's statement oversimplifies the use of the MES framework, and does not acknowledge that the scheme has been used, by both companies and the Pharmaceutical Benefits Advisory Committee (PBAC).

By way of background, the MES is a mechanism whereby the PBAC is able to recommend Pharmaceutical Benefits Scheme (PBS) subsidy for a medicine at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness (value for money) to support listing of the drug at a higher price.

Clauses 26 and 27 of the MOU stated that:

From 1 January 2011, the Commonwealth undertakes to introduce a mechanism whereby the PBAC may recommend PBS coverage at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness to support listing of the drug at a higher price. The PBAC will provide advice in relation to sources of uncertainty and specific evidence required to support a subsequent application.

It is agreed that the application of this mechanism will initially be restricted to submissions where the PBAC agrees that there is a clinical need for the intervention, and when:

- *the PBAC would not otherwise recommend the listing of the drug at the proposed price because the extent or value of the clinical effect is uncertain; and*

- *there is a randomised clinical trial (or comparable "fit-for-purpose" evidence), due to report within a reasonable timeframe, which the PBAC is satisfied will resolve the identified area of uncertainty.*

The parties note that this does not preclude use of other tools for managing uncertainty (e.g. risk-sharing agreements) where appropriate.

This provision provided an opportunity for both companies and the Government to expedite the listing of high cost medicines where there was a high and unmet clinical need, but only limited evidence to support the cost-effectiveness (value for money) of the medicine was collected by the sponsor at the time the first submission to the PBAC was lodged. The MES mechanism was intended to provide early access to patients to high value medicines, in parallel with the ongoing collection of data necessary to establish the value for money of the medicine.

Since 2011 the PBAC has considered around ten potential PBS listings which included a plan to collect additional evidence to support the listing. For some of these ten medicines the concept was proposed by the sponsor, others by the PBAC. It is important to note that both the Sponsors of medicines and the PBAC have sought to use this Managed Entry mechanism to try and facilitate listings on the PBS, and that this is over and above the other existing tools available to manage uncertainty, such as risk-sharing agreements and PBS restrictions.

It is also important to note that, the framework for the collection of evidence in a randomised controlled trial for a Managed Entry Scheme has not prevented either the PBAC or sponsors from exploring options designed to solve problems constructively, including by advancing proposals to use other available data, such as observational data or patient registries, in order to expedite a listing and provide quicker access for patients. The MOU was a starting point for promoting the use of Managed Entry, not a restriction on its application.

Given that the content of the companies' submissions to the PBAC is commercial-in-confidence, and the PBAC's minutes are, at the insistence of the pharmaceutical industry, not fully transparent to the public, it may be that Mr del Cuore was not fully aware of what his company's competitors may have proposed or agreed to.

I trust this information is of assistance.

Yours sincerely

Felicity McNeill
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Pharmaceutical Benefits Division

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