To whom it may concern,

Outlined below please find a submission from Novo Nordisk Pharmaceuticals Pty Ltd, to the Finance and Public Administration References Committee regarding the inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

Novo Nordisk is a global healthcare company with a head office in Denmark and affiliates or offices in 74 countries. In Australia, Novo Nordisk currently employs over 100 people and is a leader in diabetes care, with additional therapeutic portfolios in haemophilia management, growth hormone and women's healthcare.

Novo Nordisk believes that the recent Government decision to defer the listing of some medicines on the Pharmaceutical Benefits Scheme (PBS) despite a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC), and the decision to refer all medicines to Cabinet for approval, creates an additional unnecessary hurdle that is in direct contradiction to aspects of the central objectives of the National Medicines Policy[1], namely:

1. timely access to the medicines that Australians need, at a cost individuals and the community can afford; and

2. maintaining a responsible and viable medicines industry.

The existing PBAC health technology assessment process is specifically designed to interrogate all economic, societal, and clinical aspects of listing a new medicine on the PBS. This process is highly regarded as a key achievement for Australia. Novo Nordisk urges the Government to reverse this unnecessary deferral decision and takes this opportunity to provide comment on certain aspects of the *Terms of Reference* for this inquiry.

Terms of Reference

(a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;

- The PBAC operates a highly rigorous interrogative process for the health economic assessment of new medicines in Australia. The PBAC assessment follows very clear and strict guidelines and under the National Health Act, the PBAC is required to consider both the effectiveness and cost of a proposed drug and medicinal preparation. Therefore, if the PBAC recommends to the Minister for Health that a medicine should be subsidised by the Australian Government under the PBS, then the Australian public and taxpayer can be confident that the cost benefit ratio of a new medicine has been scrutinised and found to be beneficial for the Australian public by experts in the field. It is therefore unconscionable for the Government to ignore the expert advice of the PBAC and indefinitely defer the listing of a medicine on grounds of cost containment. Furthermore, there have been no clear guidelines as to which medicines are being deferred or how the decision process is being made nor are there any avenues for appeal. This is especially challenging when there is a fee of $119,500 which a pharmaceutical company must pay in order to submit a major application to the PBAC for review. This fee is paid in advance and in good faith and therefore comes with expectations that the legislated process will be

[1] National Medicines Policy 2000

followed by all parties in an open, equitable and transparent manner. It is clear that a fiscal decision is now taking precedence over the health needs of the Australian population.

(b) any consequences for patients of such deferrals;

- New and innovative medicines can offer significant benefits to patients. These benefits are scrutinised by experts on the PBAC and factor heavily in their decision to recommend a listing. The deferral of the listing of new medicines means that their clinical and economic advice is being largely ignored. Patients will not be given the opportunity to have access to potentially superior products. This places the optimal health of the patient at risk and may add to longer term health costs.

(c) any consequences for the pharmaceutical sector of such deferrals;

- The deferral of medicines with a positive PBAC recommendation has introduced significant uncertainty for Novo Nordisk in Australia. The launch of a new medicine requires significant investment by a pharmaceutical company – not only does Australian specific product need to be brought into the country but often additional staff need to be employed and educational material for both health care professionals and patients needs to be developed. Clinical trials with new medicines are approved in Australia by ethics committees with the expectation that the new medicine will be made available in a timely manner once approved. Prior to the announcement of deferrals, companies could commit to this additional investment once a positive PBAC recommendation was achieved. Without any certainty that a medicine will be listed on the PBS and with no clear guidance as to the timelines, then the ability of a company such as Novo Nordisk to make a medicine available is severely compromised. Continued investment in a relatively small market such as Australia is likely being questioned by members of the global pharmaceutical industry with the significant uncertainty that has resulted from these changes to the process. .

(d) any impacts on the future availability of medicines in the Australian market due to such deferrals;

- Novo Nordisk is a global company and is therefore also subject to international scrutiny by our parent company. If the listing of innovative medicines on the PBS becomes an unrealistic hurdle (i.e. indefinite deferrals despite proving that an innovative medicine is cost effective), then Novo Nordisk Australia may not be given the opportunity to even apply for PBS listing of new medicines. This clearly has an impact for patients, health care professionals and the broader community. Novo Nordisk contributes significantly to research and development in Australia – as just one example, the current clinical trial programme running in Australia will bring an investment of over $8million to Australia. Such programmes will be compromised should the uncertainty surrounding PBS listing remain. Moreover, the invaluable clinical experience Australian Investigators gain with new medicines as part of these clinical development programmes will likely suffer as a consequence.

(e) the criteria and advice used to determine medicines to be deferred;

- Novo Nordisk is not aware of any clear or transparent guidelines which have been implemented to determine which medicines are to be deferred.

(h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010;

- The Memorandum of Understanding between the Commonwealth of Australia and Medicines Australia signed in May 2010 was an example of collaboration and commitment from both the pharmaceutical industry and the Government to provide

savings to the PBS and at the same time provide a stable pricing policy environment. This MoU took considerable time to develop and come to an agreement with key input from industry and key Government stakeholders. The decision by the Government to defer the listing of medicines has introduced significant uncertainty into the pricing policy environment and therefore contradicts the intent of the Memorandum of Understanding.

The process of listing a pharmaceutical product on the PBS is rigorous, transparent and guarantees the availability of cost effective innovative medicines for the Australian public. We urge the Government to continue this fair process and reverse the indiscriminate deferral of medicines on the PBS.

Sincerely,

Mirella Daja
Director, Market Access
Novo Nordisk Australasia