

RESPONSE – NORTHERN TERRITORY GOVERNMENT:

**INQUIRY INTO THE GOVERNMENT'S ADMINISTRATION OF THE
PHARMACEUTICAL BENEFITS SCHEME**

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

The Northern Territory Government Department of Health (the Department) endorses the transparent processes followed by the PBAC in ensuring an expert and independent evaluation of submissions for PBS listing, and making evidence-based recommendations.

There is a delay in listing a given medicine on the PBS following affirmative recommendations from the PBAC. This has financial consequences for the Department and clinical implications for patients in the Northern Territory. Therefore, any measure to streamline the PBS listing of a given medicine following endorsement by the PBAC would be strongly supported.

b) Any consequences for patients of such deferrals

The Department currently has a policy to facilitate access to essential medicines where the cost of medicines would otherwise serve as a barrier. Under this arrangement, medicines that are deemed to be essential by medical specialists but are not covered by the Australian Government subsidy arrangements will have the costs met by the Department.

Where a medicine is initiated while it is still under consideration for PBS listing, the Department meets the full cost until such time as it is listed. In the rare event that an evidence-based therapeutic agent, supported by medical specialists and initiated for a client is not successful in gaining PBS listing, approval is sought from the Northern Territory Drugs and Therapeutics Committee for continuation of supply. This effectively provides a safety net for limiting the consequences to patients of such deferrals. However, patients are now required to attend public hospital pharmacies to access these medicines. This requirement fragments the persons medication supply and may result in the need for the patient to travel considerable distances. More often though, medicines supported by specialists will meet the PBAC evaluation criteria and gain a PBS listing. This means the Northern Territory Government funding is but an interim measure until such time as the patients are supported by the Commonwealth subsidy.

c) Any consequences for the pharmaceutical sector of such deferrals

The Department cannot comment specifically on the impact on the pharmaceutical industry, however, there are cost implications for the Department that needs consideration. The delay in PBS listing a product following an affirmative recommendation from the PBAC means the medicine is often funded by the Department. Understandably, this creates opportunity costs, where funds are diverted from other essential hospital services in order to fund medications.

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

While the Department is unable to comment on the magnitude of impact of deferral on Australian Markets, it seems intuitive that any delay in listing a medicine after it is endorsed by the PBAC is likely to create cost implications for those sectors that invest in the development of medicines. As such, it is possible that delays could serve as a deterrent to pharmaceutical companies marketing some medicines in Australia.

e) The criteria and advice used to determine medicines to be deferred

While the processes utilised by the PBAC in their evaluation and decision-making is transparent and the information is available in the public domain, the processes utilised by the Australian Government in deferring the listing once a positive recommendation is made by the PBAC is less clear. Accordingly, the Department is unable to comment on whether this process is appropriate or sufficient. As previously mentioned, deferral of a PBS listing has the potential to impact the Department and the patients it serves. A decision-making process with more transparency would be highly recommended by the Department.

f) The financial impact on the Commonwealth Budget of deferring the listing of medicines

In the immediate term, deferral of listing medicines on the PBS constitutes a shifting of cost from the Australian Government to the Northern Territory Department of Health. As cost could represent a significant barrier to access of some medicines, where clients are unable to meet the cost, these medicines are funded by the Department until they are PBS listed. For this interim period, until the Australian Government effectively subsidises the medicine, the cost is typically borne by the Department.

g) The consultation process prior to a deferral

At present the Department is unaware of any formal stakeholder consultation process being in place to inform decisions to defer a PBS listing of a medicine after a positive recommendation by the PBAC. This decision does have the potential for impact on the Department both from financial and patient care perspectives. As such, a transparent consultation process around the decision to defer a listing would be strongly recommended.

One suggested model for this to occur would be for the Australian Government to contact the Northern Territory Minister of Health in the event of a decision being made about deferral of listing. The Northern Territory Minister of Health may:

- Undertake prompt consultation with key stakeholders to evaluate the potential impact on client care and any budgetary considerations; and
- Make recommendation to the Commonwealth Minister of Health supporting or recommending against the decision to defer a listing

h) Compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010

The Department is unable to comment on the above MOU.

i) Any other related matter

Nil.