

July 15, 2011

Senator Scott Ryan,  
Chair,  
Senate Finance and Public Administration References Committee  
PO Box 6100  
Parliament House  
Canberra ACT 2600  
Email: [fpa.sen@aph.gov.au](mailto:fpa.sen@aph.gov.au)

Dear Senator Ryan,

**Re: Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS)**

I write in support of Medicines Australia's submission to the Finance and Public Administration References Committee in relation to the above inquiry.

Amgen endorses the sentiments and concerns expressed in MA's submission in relation to the adverse impact of the Government's change in the process for Cabinet approval of medicines for PBS listing, including the deferral of some medicines that have been recommended by the Pharmaceutical Benefits Advisory Committee.

For Amgen, the key concern is the uncertainty that this creates for our future pipeline. The impact of this type of uncertainty on our business is immeasurable.

It makes it impossible for us to plan adequately in terms of our workforce needs, our likely revenue base, our contribution to global performance, our clinical trials program, and results in the diminution of business confidence.

Amgen would like to make some brief comments in relation to terms of reference (a) and (h).

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

The PBAC process is an independent, rigorous and thorough examination of the qualities of every medicine seeking subsidy. In determining the suitability of medicines for subsidy by the Government, the PBAC considers the effectiveness, cost-effectiveness and clinical place of a product compared with other products already listed in the PBS for the same, or similar, indications.

Any medicine for which there is a positive PBAC recommendation is therefore value for money for Australian taxpayers and deserves to be listed on the PBS.

Companies are well acquainted with the PBAC process which has been operating around the cost effectiveness assessment for more than 17 years. The process itself is transparent in

terms of timeframes, what is required of companies and the outcomes of the PBAC decision making process. Positive PBAC recommendations have always achieved Ministerial (if under \$10m) or Cabinet approval, which has provided predictability and consistency for companies such as Amgen.

While Amgen's view is that the PBAC process may not adequately capture all the societal benefits of medicines, nevertheless, its judgement is based on analyzing data and rational decision making. It takes a science-based approach, which reflects one of Amgen's key values, and is well understood by a sector driven by science.

The requirement that all new listings (regardless of their net cost) be approved by Cabinet and the deferral of some medicines by Cabinet inappropriately brings the political process into a scientifically-based system; and undermines the transparency and predictability of the process.

It also changes the nature of the national formulary, the PBS. Since it began in 1948, the PBS has included all medicines meeting the listing requirements. The recent measure to defer some medicines is at odds with the long term approach of the PBS.

### **Term of reference (h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010**

From Amgen's perspective, the whole intent of the 4- year MOU signed last year was to provide business certainty and to deliver a range of initiatives to improve the listing process so that innovative medicines reach patients sooner. One of those initiatives involved a more certain timeframe for Cabinet approval.

Certainty around pricing ensures a sustainable PBS and money to fund new medicines. Initiatives to improve the listing process are important in the Australian context because of the unique features of the regulatory and reimbursement systems, particularly around the time that it takes to achieve reimbursement status.

The MOU between Medicines Australia and the Government gave us an opportunity to sell the benefits of the Australian environment to our head office.

The Government's actions around the Cabinet process undermine this certainty and potentially undo the positive impact of the listing improvements.

We trust that the Senate Committee will share our concerns about the adverse impacts of the Government's recent change to the Cabinet process.

Yours sincerely,

**Ian Thompson**  
**Managing Director**