Streamlining the Listing of New Medicines on the Pharmaceutical Benefits Scheme

The Access to Medicines Working Group has been exploring the capacity to further streamline and coordinate processes to reduce the time it takes to list a medicine on the Pharmaceutical Benefits Scheme (PBS).

As part of this exploration, the AMWG has met with the Therapeutic Goods Administration (TGA) to discuss the various ways in which the TGA and the Pharmaceutical Benefits Advisory Committee can increase the efficiency of their processes. These discussions included examining the possibility of aligning the medicine registration and PBS listing processes to allow parts of these areas to run concurrently.

During these discussions a number of areas have been identified where efficiencies in the registration of new medicines by the TGA can be made, while maintaining the integrity of the regulatory process. The AMWG has received 'in principle' agreement from the TGA on ways to decrease the time to have new medicines registered on the Australian Register of Therapeutic Goods.

The AMWG will work closely with the TGA on these identified areas, as there is agreement that this is the area where the greatest gains can initially be made.

AMWG will continue to examine ways to both leverage this improvement in regulatory time lines and also build improvements into the PBS process to facilitate earlier times to listing. Possible improvements in the PBS process that might be explored include the use of pre-submission meetings, improvements to the post-PBAC processes, and, possibly, earlier commencement of PBAC evaluation whilst TGA assessment is under way.

It should be noted that while every effort will be made to streamline the areas identified, all parties involved stress that this work will be conducted with absolute regard to maintaining high standards in relation to the assessment of efficacy, safety and cost-effectiveness in the processes of the registration and PBS listing of new medicines.

A working group consisting of AMWG members, the Pharmaceutical Evaluation Branch and the TGA will be convened to further discuss work in these areas. It is expected this group will provide a report to the Minister on its findings at a later date. As well as identifying areas where the time to listing could be improved, the AWMG will continue to receive updates on the streamlining work of the TGA, offering support as needed.