Fast track approval pathways

Before a new prescription medicine can be available for use in Australia, the TGA assesses it for safety, quality and efficacy.

There are three pathways the TGA can use to assess a prescription medicine: the standard pathway, the priority review pathway and the provisional approval pathway.

Priority review and provisional approval are pathways that fast track prescription medicines onto the market, making them available to patients sooner than they would be under the standard pathway.

Typically, a pharmaceutical company needs many years to collect evidence that confirms the safety, quality and efficacy of a medicine by running clinical trials and doing other research. It could also take up to eleven months for us to review this evidence through the standard pathway depending on the complexity of the medicine. In the meantime, some patients with serious, life-threatening conditions could need urgent access to the medicine, but not be able to access the medicine until it is approved.

For this reason, medicines for serious or life-threatening conditions are sometimes eligible to undergo a fast track process to make the medicine available to patients sooner than normal. The sponsor must apply and the medicine must meet criteria to use a fast track pathway. For example, the medicine must be a major advance over any similar medicines that are already approved for supply.

Fast track pathways can be used for both new medicines and new uses for already approved medicines.

Some medicines that have already been approved through a fast track pathway treat conditions like prostate cancer, skin cancer, and haemophilia.

Priority review

Under priority review we aim to finish our review of a medicine up to three months earlier.

We can complete these reviews faster because the approval process is more flexible. For example, under priority review we ask the pharmaceutical company questions about their application as they arise, rather than sending the questions as a group after we finish a round of assessment.

Priority review involves the same amount and type of evidence as the standard review process, and so has no impact on the level of safety, quality or efficacy of the medicine. Unlike provisional

medicines, a medicine approved under priority review will receive ongoing approval, identical to approval under the standard pathway.

The flexible approach we take on priority applications is much more resource intensive than the standard pathway. This is not a feasible option for all medicines, so the pathway is reserved only for medicines that treat serious and life-threatening conditions.

Provisional approval

We can give provisional approval to medicines which provide a promising treatment for a serious or life threatening condition. This makes the medicine available for a limited period while the pharmaceutical company completes final clinical trials.

Under the standard pathway, a medicine is not available until after all clinical trials have been completed, so this can make a medicine available up to two years earlier than normal.

In order to do this, the sponsor must apply and we must be satisfied that the benefit of earlier access for patients is greater than the risk of not yet having all of the supporting evidence that we usually require.

As a condition of provisional approval, the company must agree to continue clinical trials and submit comprehensive evidence for review. If they do not follow this plan or submit this evidence, we can cancel the approval.

When the limited provisional approval period is up, we review of all the evidence. If we find that the benefit of the medicine to patients outweighs the risks associated with its use, we give the medicine ongoing, full approval. If after the review, or at any other stage, we find the risks outweigh the benefits, we cancel the approval. If the medicine is cancelled, health professionals will discuss other treatment options with patients taking the medicine.

It is important to report side effects

While all medicines may have side effects, it is particularly important that you report to your doctor any issues you experience with a provisionally approved medicine.

Any issues should also be reported to us so we can build up the full picture of a new medicine's safety profile. You can ask your doctor to do that on your behalf.

One of the best ways to report is over the phone to an NPS Medicinewise pharmacist on 1300 134 237 as they can ask questions to get the best information and provide advice on how to manage the side effect. You can also report any issues directly to the TGA.

Other important information

Your doctor will give you information about medicines they prescribe, including if the medicine is provisionally approved. However, for more information you can also check the Consumer Medicines Information (CMI).

When looking at the CMI for provisional or priority medicines, you may notice a black triangle symbol (▼). This symbol is a reminder to report side effects. The black triangle does not mean that there are known problems with the medicine, only that the medicine is new, or being used in a new

way, and the TGA is seeking as much information as possible to get the full picture of its safety profile.

If you have concerns about any medicine you are taking, always consult your doctor.

Medicines subsidies through the PBS

Subsidies are determined and administered by a different section of the Department. For information on which medicines are subsidised by the Australian Government, consult the Pharmaceutical Benefits Scheme website.

URL: https://www.tga.gov.au/node/874702