PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Standing Committee on Health, Aged Care and Sport

Inquiry into approval process for new drugs and medical technologies in Australia

Written Question on Notice, 23 June 2021

PDR Number: IQ21-000122

Establishment of the National Registry for clinical trials

Written

Member: Trent Zimmerman

Question:

Clinical Trials
Has the Department done some work to establish a National Registry for clinical trials?

Answer:

The Australian Department of Health has a contract for services with the University of Sydney to manage the Australian New Zealand Clinical Trials Registry (ANZCTR), an online public registry of clinical trials being conducted in Australia, New Zealand and a range of other countries. It is one of the two main clinical trials registries used in Australia.

All Australian Governments recognise the need for innovation, streamlining and continuous improvement in the clinical trials sector. A review of the ANZCTR in 2018 raised the prospect of streamlining data reporting requirements to reduce the clinical trial reporting burden, support and improve governance, and achieve the registry's integration within a national 'One Stop Shop'. The proposal for the One Stop Shop has been further informed by expert advice and analysis and comprehensive literature reviews, underpinned by comprehensive sector engagement, that have provided key insights into successful approaches for improving the clinical trials environment.

The Australian Government has announced its intention to develop and establish a One Stop Shop for Clinical Trials and Human Research Approvals in collaboration with all jurisdictions, and a related National Clinical Trials Front Door (NCTFD). The Australian Commission on Safety and Quality in Health Care (ACSQHC) has been engaged to undertake national consultations on these initiatives. A project advisory group, chaired by Professor Ian Chubb, former Chief Scientist and clinical trial participant, will guide the consultation process. More information is available at: www.safetyandquality.gov.au/our-work/national-platform-health-and-medical-research.

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Department of Health

Standing Committee on Health, Aged Care and Sport

Inquiry into approval process for new drugs and medical technologies in Australia

Written Question on Notice, 23 June 2021

PDR Number: IQ21-000111

Medicines on the Pharmaceutical Benefits Scheme (PBS)

Written

Member: Trent Zimmerman

Question:

How long on average do medicines stay listed on the PBS?

Can you explain the process of updating the PBS?

Do medicines ever come off the PBS? If so, for what reason?

Answer:

As a long-running program, there are numerous medicines that have been listed on the PBS for decades. For example, amoxicillin 125mg/5ml powder for oral liquid was first listed on the PBS on 1 December 1974. Various brands of this medicine remain available.

A medicine generally stays on the PBS until the sponsor chooses to delist it or it no longer holds registration with the Therapeutic Goods Administration (TGA). As of July 2021 there were 905 PBS-subsidised drugs available in 2428 forms, marketed as 5401 brands. Hence collating statistics on the average time a medicine stays listed on the PBS would represent a substantive resource investment by the Department.

In order for a medicine to be included on the PBS, the sponsor (usually a pharmaceutical company) must lodge a submission with the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is required to give consideration to the safety, clinical effectiveness and cost-effectiveness of the medicine, including comparing it to alternative treatments, before making a recommendation on whether or not to list the medicine on the PBS.

Following a positive PBAC recommendation to list or amend the listing of a medicine on the PBS, further work is required, including:

- agreement on the subsidised rate for the medicine with the company responsible for the supply of the medicine in Australia (the sponsor)
- finalisation of the restriction wording, which sets out the circumstances for prescribing that apply for the medicine to be available for subsidy (for instance, eligible patients and conditions)
- submission of listing documents by the sponsor, including an assurance of supply
- agreement of the expected costs with the Department of Finance and approval by Government
- finalisation of a deed of agreement, if required, between the Commonwealth of Australia and the sponsor
- finalisation and distribution of the amended PBS Schedule under embargo to software vendors, Services Australia and others, to check and load data in their systems to give effect to the new listing
- execution and registration of required legislative instruments, and
- publication of the amended PBS schedule.

The PBAC does not generally consider submissions for listing of new brands of existing pharmaceutical items, unless they are biosimilar medicines. Applications for the listing of a new brand are received and assessed by the Department. If they meet the criteria for the New Brand pathway, they may progress to listing subject to determination by the Departmental delegate. If the criteria are not met, the submission is rejected by the Department and the company is advised to apply instead to the PBAC. Further information about the New Brand submission process is available at: www.pbs.gov.au/info/industry/listing/procedure-guidance/5-lodging-submissions/5-8-new-brand-of-existing-pharmactcl-item-sub.

From time to time, medicines are delisted from the PBS Schedule. This generally occurs at the request of the company responsible for the supply of the medicine in Australia. Reasons vary, but may include the listing of newer, more advanced alternatives or changes in clinical practice that reduce market share, supply issues, a material change in the cost of imported supply, that the medicine is now available without a prescription (over-the-counter), or it is discontinued for other commercial reasons.

When a sponsor submits a request to remove a medicine from the PBS Schedule, advice is often sought from the PBAC. In these instances, one of the matters which the PBAC provides advice on is whether the delist will result in an unmet clinical need for patients. If the PBAC notes the potential for an unmet clinical need, then it may ask the Department to investigate alternative arrangements.

Ultimately, pharmaceutical companies make their own decisions about whether they intend to delist a medicine from the PBS Schedule and cannot be compelled by the Government to keep supplying a medicine on the PBS.