

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Standing Committee on Health, Aged Care and Sport

Approval processes for new drugs and novel medical technologies in Australia

18 June 2021

PDR Number: IQ21-000123

The number of Pharmaceutical Benefits Advisory Committee (PBAC) applications that are rejected on their first go

Spoken

Hansard Page number: 21

Member: Trent Zimmerman

Question:

CHAIR: What proportion of PBAC applications are rejected on their first go?

Ms Platona: We're going to take exact numbers on notice, but it depends on the type of application. The type of application to the PBAC matters a great deal.

CHAIR: Could you provide some data on that, and also on what proportion of applications that have been rejected more than once are subsequently withdrawn altogether?

Ms Platona: Yes, we can.

Answer:

Q1. What proportion of PBAC applications are rejected on their first go?

From March 2020 to March 2021 PBAC meetings inclusive, 38 out of 132 (29 per cent) first time submissions received a not recommended outcome from the PBAC.

Q2. What proportion of applications that have been rejected more than once are subsequently withdrawn altogether?

From March 2020 to March 2021 PBAC meetings inclusive, there were 20 submissions received a second or subsequent not recommended outcome from the PBAC. Of these, 15 (75 per cent) have not been resubmitted for PBAC consideration to date.

A PBAC decision to not recommend PBS listing does not necessarily represent the PBAC's final views on the merits of a medicine. In general, it is the responsibility of the sponsor (usually a pharmaceutical company) to apply to the PBAC. Sponsors may resubmit addressing the concerns previously raised by the PBAC. Sponsors make their own decisions regarding their products and cannot be compelled to resubmit to the PBAC.