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Baker's dozen knock on PBS door

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A quarter of the PBAC-recommended submissions that have been marked by Health as still actively pursuing PBS listing are in the final stage awaiting a PBS berth, including two products that are supposed to be on a fast pricing pathway.

While the Government **listed five submissions on the PBS this month**, this still left 45 products waiting for a berth, of which 13 are in government processes.

Of these 13, two arrived in the final stage before PBS listing last month while nine have now been there for close to two months. One, Amgen's OTEZLA (apremilast), has been ready and waiting for a PBS berth since June 2022 – almost 15 months.

Recommended in May 2022 for severe chronic plaque psoriasis, Amgen moved quickly to secure the necessary arrangements for the listing, but once its submission reached government processes, it stopped dead.

Otezla is now likely to be the therapy that has spent the longest time in the final stage of pricing negotiations without achieving a PBS listing, although Boehringer Ingelheim's JARDIANCE (empagliflozin) is now almost four months in the final stage.

Two of the late-stage queue are supposedly on a fast pricing pathway, including MSD's KEYTRUDA (rolizumab), recommended for PBS listing for cervical cancer in November 2022, meaning it is now 10 months in pricing negotiations despite supposedly having a designated person to assist it along the pathway.

The other, AstraZeneca's ENHERTU (trastuzumab deruxtecan), is moving faster along Pr nended in March. It has been waiting for a PBS berth since mid-July.

Other new therapies are also stuck in pre-PBS purgatory, including Astellas' PADCEV (enfortumab vedotin), the company first applying for funding in March 2022 and taking three submissions to secure recommendation in urothelial cancer but still not listed on the PBS.

While the Department of Health has set itself a metric that says as long as 80 per cent of submissions are moved out of government processes in six months it has achieved its goal of timely access, most therapies take months to get to this stage – if they get there at all. Forty PBAC recommended submissions have been abandoned by sponsors in recent years.

The most recent sponsor to walk **away was Eli Lilly with VERZENIO (abemaciclib)**, although Lilly seems to be pursuing the matter with a new submission on the PBAC's November agenda.

Of the 45 submissions considered by Health to still be active, nine have their agreement to listing arrangements under consideration, including AstraZeneca's IMFINZI (durvalumab) for small cell lung cancer. Recommended in November 2020, the listing stalled but is now back on the PBAC agenda for November 2023 although the company has also recently lodged pricing documents, suggesting a deal has been done.

Also stalled in this stage is Novartis' COSENTYX (secukinumab), recommended in March 2022, and Eli Lilly's TALTZ (ixekizumab) recommended in November 2021.

Sponsors have lodged pricing documents for a further 11 therapies, including two recommended in November 2020 that are back on the 'use it or lose it' train after PBAC reconsideration, while four sponsors from the July PBAC meeting and two from May have submitted a notice of intent. Six sponsors from recent meetings are yet to move on their PBAC recommendations.