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PHARMA IN FOCUS

By Megan Brodie 16 April 2020

PBAC fees too high for little guy

The owner of Australia's largest independent pharmaceutical company says changes to PBAC fees mean small companies need to budget almost $2 million to make a submission for a medicine to be listed on the PBS, with no guarantee of success.

In a submission on new fees being introduced as part of PBS process improvements, Specialised Therapeutics Australia CEO Carlo Montagner said the proposed fee hikes due to take effect on 1 July presented "a major barrier" to PBS access for small, independent pharma companies like STA.

"These fee increases will mean the cost of submitting a major submission is now well in excess of $300,000 – irrespective of whether the application is successful," Montagner said.

"STA has estimated that the combination of fee increases, new fees for various processes and internal costs of submission preparation will mean that the real cost per submission is approaching $750,000.

"Considering that it typically takes several submissions to achieve a PBS listing, companies need to budget almost $2 million for a
single submission, with no predictability that the submission will be successful or commercially feasible if onerous listing conditions are mandated by the PBAC."

Montagner argues large, multinational companies are more able to bear the upfront cost of larger fees while for smaller companies, they "potentially mean the financial risk is simply too great, especially when the outcome of a PBAC submission is highly unpredictable".

The STA submission proposes companies like STA with annual revenues of less than $50 million be granted an exemption from paying new fees ‘upfront’ for at least the first two PBAC applications, instead paying back the cost in instalments after a successful PBS listing and earnings of more than $3 million a year.

Montagner says STA’s experience was that demonstrating statistically significantly improved survival data and furnishing positive funding recommendations from key overseas agencies did not guarantee success at PBAC.

In the past year, STA has twice submitted unsuccessfully for breast cancer drug Nerlynx and also twice for myeloma therapy Aplidin at a combined fee cost of almost $1 million. The outcome of its second Aplidin submission will be released next week.

He said the proposed fee hikes, such as the $238,230 fee for the facilitated resolution pathway and the $72,000 cost of an associated facilitated workshop, “appear exorbitant”and “seem disproportionate to the work input required by the Department of Health”.

STA supported a call by Medicines Australia for an independent audit of the proposed charges, with Montagner saying “more clarity is required”.

Montagner says while “there will always be risk when it comes to bringing new medicines to market”, “the reality is that with the new fees and increases to existing fees, pharmaceutical companies will be spending in excess of $3 million for every drug they try to list”.

“It’s a vast amount of money when there is no definitive predictor of listing success that a company can rely on to determine the degree of investment risk.”

Orphan drugs hardest hit

Montagner says orphan drug submissions will be particularly adversely impacted by the proposed fee hikes as their potential PBS revenue is insufficient to justify the multi-million dollar outlay required to submit them to the PBAC.

“I would like to propose that the first two PBAC submissions for orphan designated drugs are fee exempt, with a further minor submission included (if this

is required following an unsuccessful second major submission),” he says.

Montagner says when the full impact of the July 2020 PBAC fee increases is realised in two to three years, small Australian-owned companies like STA “will not be able to take on the financial burden and associated risk to bring these new medicines to Australia”.

“Ultimately, this means that patients will miss out, because the international drug development companies STA partners with to make these therapies available do not have an established presence in this region.

“Of most concern is that Australia will end up like New Zealand, where many companies no longer submit products for regulatory approval due to the low probability of achieving reimbursement.”