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PHARMA IN FOCUS

By Megan Brodie 14 May 2019

PBAC System Labelled ‘Broken’

Australia’s reimbursement process for listing new drugs is broken and Australia is now on the precipice of missing out on new drugs, Specialised Therapeutics Australia CEO Carlo Montagner has warned.

Companies spend millions of dollars and take years to get a new drug listed on the PBS, says Montagner, yet the system is not designed to handle complex new therapies, which include most cancer drugs.

“The system is broken,” Montagner, who is also the owner of STA, told Pharma in Focus. “Patients are denied access to new drugs sometimes for years as we try to understand what is required.”

With STA’s new breast cancer drug Nerlynx rejected by the PBAC in March and the company’s newest therapy Aplidin to be considered by PBAC in July, Montagner says these high cost new drugs face rejection at least once if not twice due to a failure in the PBAC evaluation process.

A meeting with PBAC chair Andrew Wilson following the rejection of Nerlynx highlighted the problem for Montagner, who said the committee had legitimate concerns which could have been addressed in the submission had the company known.

However, with pre-PBAC submission meetings held with the department of health, he said PBAC did not see Nerlynx before its March meeting and STA remained unaware of its concerns until the submission was rejected.

“There was a lack of understanding as to where [Nerlynx] had a place in therapy,” he said. “The TGA, FDA and EMA had all agreed on the analysis but the PBAC did

not.

“If we had the opportunity to hear these questions, we could have addressed them and I think they would have been satisfied with the responses. Instead we now have to reapply.”

The issues must now be addressed in a resubmission which cannot be heard before November.

“It’s frustrating we can’t have a dialogue with the PBAC prior to its meeting,” he said. “We don’t have any discussions with the committee as to what it requires until the drug is rejected.”

Montagner told Wilson Australia needed a model similar to the US system whereby an oncology committee considers an application for market access prior to FDA consideration.

He is now planning to meet with the incoming health minister after the election to relay his concerns regarding both PBAC and the need for greater harmonisation between the MSAC and PBAC processes. STA is currently on its seventh submission for its genome analysis product Oncotype DX.

“The key to cancer care is around diagnostics and the current National Medicines Policy is not designed for this,” he said. “It needs to adjust and to adjust quickly.”

Montagner warned Australia was “on the precipice of missing out on drugs” with rebates the only reason many companies accepted what were either among the lowest or the lowest price in the world for new therapies.

He said delays in access also needed to be addressed with first time major submissions taking on average two to three meetings before being positively recommended, and patients waiting years for new therapies.

“With Aplidin, patients don’t have two to three years to wait,” he said. “Patients are dying within six to nine months.”

STA successfully launched two cancer drugs onto the PBS under the Coalition but invariably battled its way through PBAC.

Chemotherapy nausea drug Akynzeo was twice rejected before being listed in

April 2016 and cancer drug Abraxane was rejected for breast cancer in 2015 before being resubmitted in breast and pancreatic cancer to the March 2019 meeting where it was positively recommended.