Channel 9 News: June 2019

The following news clip appeared on National Nine News. Click to view.

Pharma in Focus: 17 May, 2019

PHARMA IN FOCUS

By Megan Brodie 17 May 2019

Drugs to be Tracked End-to-End

Local pharma Specialised Therapeutics Australia (STA) has launched a tracking system that will enable real time monitoring of its drug products as they move through the supply chain, while also making the practice of vial sharing more difficult.

The company has adopted a Unique Product Identification (UPI) system that involves printing a 2D barcode on every drug product packaged and distributed,

beginning with STA's newest cancer drugs Nerlynx and Aplidin.

While the drugs have been registered by the TGA in the past six months, they are not yet listed on the PBS. Nerlynx was rejected by the PBAC in March and Aplidin is to be considered by the committee in July.

"The UPI system is expected to be rolled out across the company's entire portfolio by 2020," STA CEO Carlo Montagner said, describing his company as "an early pharmaceutical adopter" of the tracking system which is mandated in the US and Europe.

Montagner said the tracking system was designed to improve product integrity by minimising or eliminating dispensing errors and the chance of counterfeit products entering the supply chain, he said it would also prevent the vial sharing practice used in hospital pharmacies to prevent product wastage and save costs.

Montagner said it was common practice for pharmacy compounders to package intravenous cancer drugs for individual patients from multiple supply batches in order to minimise wastage, yet companies were paid per patient not by volume.

With 80 per cent of STA's cancer drugs used in a hospital setting, Montagner told Pharma in Focus this week the practice of vial sharing was a significant threat to both the company's earnings and patient safety because the vial used could not be identified.

"Without tracking technology, there has been poor visibility on the final destination of all batches produced," he said.

"Our new UPI model will ensure that we know exactly which vial any single patient has received from which batch. If there is a recall or any other problem, we can track every unit of product to the patient."

Montagner said it was inevitable a drug tracking system would be implemented industry-wide under federal government mandate in line with Europe and the US.

"I would call on the federal government and indeed, all pharmaceutical manufacturers to introduce similar measures to ensure the highest patient safety standards are adopted," Montagner said.

"We are proud to be Australian innovators but believe these measures must be

widely adopted by all pharma companies in this region to mitigate potential patient risks.

“Track and trace technologies enable us and our partners to ensure safe drug distribution chains, and to implement any product recalls as rapidly as possible. In the event of an urgent product recall, we can now quickly and effectively track every unit of product to ensure patient safety remains paramount.”

Pharma in Focus: 14 May, 2019

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.

Weekend Australian: 11 May, 2019

Weekend Australian

By Sarah-Jane Tasker 11 May 2019

Speed Up Cancer Funding, ALP Told

The head of Australian drug company Specialised Therapeutics, Carlo Montagner, has warned that Bill Shorten’s cancer policy will not hit its target unless he overhauls the process to reimburse lifesaving treatments and puts a time frame on listing recommended drugs.

Mr Montagner said while it was a great “catch cry” to say all cancer drugs recommended for reimbursement would be approved by a Labor government, the approval process needed reviewing because it was delaying access to much-needed treatments.

“What would be more reassuring would be if Bill Shorten gave an actual time frame and said if the Pharmaceutical Benefits Advisory Committee recommended a drug, he would list it in six months,” he said.

Mr Montagner also said Labor had work to do to reassure the industry, given the last time it was in government it installed a new measure that meant any drug that cost the government $20 million or more a year had to be approved by cabinet, which he said delayed drug listings.

The Opposition Leader, in his $2.3 billion cancer care package, promised that every drug recommended by independent experts would be listed on the Pharmaceutical Benefits Scheme. That promise has also been given by the Liberal Party.

“I place little weight on either government saying that as soon as the PBAC recommends a drug we will list it,” Mr Montagner said. “The complexity of the processes that are required for drug approval need to be resolved first before any government can say they will list a drug as soon as it is recommended. The recommendation part is what is really delaying access to these new lifesaving therapies.”

Mr Montagner said both major parties had underestimated the complexity of first the drug approval process and then the price negotiations that took place once a drug was approved for reimbursement.

“It is clear that the process doesn’t work for complex drugs and most cancer drugs are complex,” he said. “It is rare that the PBAC will approve a cancer drug the first time around.”

Mr Montagner’s call for an overhaul of the drug approval system comes as he waits for the PBS to green light reimbursement for a new drug for multiple myeloma, which costs about $8000 a month.

The drug, Aplidin, has been approved by the Therapeutic Goods Administration,

which is a world-first approval. The approval means Australian patients are the first globally to get access to this new therapy. Specialised Therapeutics is providing Aplidin to Australian patients via an exclusive licence arrangement with Spanish company PharmaMar. While the company awaits the outcome of its submission for a PBS listing, it is making the drug available in Australia through a compassionate access program.

Aplidin — which has been developed from "sea squirts" found 120m below the ocean's surface — is a new treatment option that can prolong the life of the patient. Mr Montagner said the drug was giving some patients an extra year of life. Since February, 60 Australian patients with multiple myeloma had been given the drug via the program.

"Myeloma is an aggressive disease and needs as many therapies as possible," he said. "Because Aplidin is marine derived it has this mechanism of action that is unique to the currently available drugs for multiple myeloma."

Australian Pharmacist: 1 May, 2019

AUSTRALIAN PHARMACIST

1 May 2019

Medicines Update: Nerlynx – Puma Biotechnology

A new medicine shown to significantly reduce the risk of cancer recurrence or

death in an aggressive form of breast cancer has been approved by the TGA for use in Australian patients. Nerlynx (neratinib) is an oral medication taken for 12 months by women with early stage HER2-positive (HER2+) breast cancer. It is indicated for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy.

The greatest benefit is seen in women who are hormone-receptor positive (HR+) and who initiate Nerlynx therapy within 12 months of completing trastuzumab based therapy. Their five-year risk of recurrence or death is reduced by 42% after completing 12 months of Nerlynx therapy.

Professor Arlene Chan AM, from the Breast Cancer Research Centre Western Australia, described the TGA approval of Nerlynx as ‘a huge step forward’, noting that women diagnosed with HER2+ breast cancer have a one-in-four chance of cancer recurrence even after surgery, chemotherapy and trastuzumab-based therapy.

Diarrhoea was the most common side effect of the medication, but evidence was being gathered that anti-diarrhoeal medications can substantially reduce these side effects.

A reimbursement application has been submitted to the Pharmaceutical Benefits Advisory Committee and is currently under evaluation.

3AW: 19 March, 2019

3AW

19 March 2019

Interview with Dr Richard de Boer, Oncologist, Peter MacCallum Cancer Centre

Interview with Dr Richard de Boer, oncologist, Peter MacCallum Cancer Centre. Mitchell says it has been discovered a drug is effective in reducing the chance of relapse of breast cancer. De Boer explains this drug has been approved by the TGA now but it is not yet on the PBS. De Boer states this drug is specifically for those with HER2-positive breast cancer. De Boer states this drug reduces the chances of HER2-positive breast cancer returning by 25%. He states Specialised Therapeutics, which is bringing this drug to Australia, has opened a scheme that will see the drugs given for free to patients until the drug is listed on the PBS. Mitchell says this drug looks very promising.

Herald Sun: 19 March, 2019

HERALD SUN (MELBOURNE)

By Aleks Devic 19 March 2019

Breast cancer hope: Regulator green-lights treatment

A NEW breast cancer wonder drug has been approved for use in Australia from today.

Women diagnosed with the aggressive HER2+ breast cancer have a one in four chance of relapse, even after surgery and chemotherapy. But test data has shown the drug, Nerlynx, reduces the five-year risk of death or recurrence in women with earlystage HER2+ by 42 per cent.

The Therapeutic Goods Administration has now approved use of the drug.

Pharmaceutical company Specialised Therapeutics is lobbying the federal government to put the drug, which in North America costs $200,000 for a full 12-month course of treatment, on the Pharmaceutical Benefits Scheme. But for the moment, the drug is available free via an access program. Specialised Therapeutics and the drug's developers, Puma Biotechnology Inc., will absorb the cost.

Nationally, it is predicted that 19,371 women will be diagnosed with breast cancer this year, and it is estimated that 20 per cent of all newly diagnosed women will have HER2+ early breast cancer. Oncologist Professor Arlene Chan, AM, from the Breast Cancer Research Centre Western Australia, said the drug would improve lives and dramatically cut relapse risks. Prof Chan, who was involved in trials of Nerlynx, said: "Those women who are spared an invasive relapse will be eternally grateful that they have received this drug."

Breast Cancer Network Australia chief executive officer Kirsten Pilatti said the drug provided patients with additional treatment options. "What we do know is the fear of the breast cancer returning is one of (patients') greatest fears," Ms Pilatti said. "Any treatment option that can reduce a woman's risk of recurrence is not just great from a cancer perspective but also from an emotional perspective," she said. "This is a great first step."

Women are being urged to consult their oncologist about whether the drug is a suitable treatment for them. And they are being reassured that it will not leave them out of pocket.

Kate Harper, who was diagnosed with the HER2+ breast cancer when her twin boys were aged just six, has begun treatment with Nerlynx. “I have two young children. I have got a lot to live for. I have always said I will do anything and everything I can to give myself a chance and my children a chance,” she said.

Doctors say the most common side effect of the drug is diarrhoea, which data suggests treatment can reduce.

West Australian: 19 March, 2019

The West Australian (Perth)

19 March 2019

Cancer Drug Nod

A new breast cancer wonder drug has been approved for use in Australia from today.

Women diagnosed with the aggressive HER2+ breast cancer have a one in four chance of relapse, even after surgery and chemotherapy. Nerlynx reduces the five-year risk of death or recurrence in women with early-stage HER2+ by 42 per cent.

For the moment the drug is available free via an access program.

Channel 9: 4 June, 2018

Channel 9

4 June 2018

Interview with Dr Penny Adams, Medical Expert

Interview with Dr Penny Adams, Medical Expert. There is a medical breakthrough for women with the most common form of early-stage breast cancer, with new research revealing that genetic testing could help them skip chemotherapy without affecting their chances of beating the disease. Adams says the study in women with early breast cancer has analysed the genetics of the cancer cells in a test called an Oncotype-DX, looking at 21 genes on the cancer cells and have ranked the cells into the risk of recurrence. Adams says in the past, women who are intermediate or high had gone on to have a chemotherapy. Adams says the research on 10,000 women shows that intermediate women do not benefit from Chemotherapy. Adams says the test costs US$4,000.

Adams says alternatives to Chemotherapy for intermediate patients include the removal of lumps or radiotherapy.

The Australian: 4 June, 2018

The Australian

4 June 2018

Breast Cancer Patients Can Skip Chemo: Study

CHICAGO: About 70 per cent of women with early-stage breast cancer and an intermediate risk of cancer recurrence can safely skip chemotherapy after their tumours have been removed, US researchers say.

“This is a major finding,” said Larry Norton, a breast cancer expert at Memorial Sloan Kettering Cancer Centre in New York, who helped organise the government-funded study more than a decade ago.

“It means that maybe 100,000 women in the United States alone do not require chemotherapy,” Dr Norton said.

The research, presented at the American Society of Clinical Oncology meeting in Chicago, studied how to treat women with early-stage breast cancer that responds to hormone therapy. Women were deemed to have a medium-level risk of the cancer returning based on a 21-gene panel known as Oncotype DX from Genomic Health. The test predicts the likelihood of cancer recurrence within 10 years. Those who score low on the test — from 0 to 10 — are already told to skip chemotherapy after their tumours are removed and they receive hormone therapy. Those who score high — 26 to 100 — receive both hormone therapy and chemotherapy.

The study, published in The New England Journal of Medicine, involved more than 10,000 women with breast cancer that had not spread to nearby lymph nodes and

whose tumours responded to hormone therapy and tested negative for the HER2 gene. Of those, 6711 scored in the intermediate range of 11-25, and were randomly assigned hormone therapy alone or hormone therapy plus chemotherapy. The study found that all women over 50 with this type of breast cancer could skip chemotherapy, a group that represented 85 per cent of the study's population. In addition, women 50 and younger who scored between 0 and 15 could be spared chemotherapy and its toxic side effects.

However, chemotherapy did offer some benefit to women aged 50 and younger who had a cancer recurrence score of 16-25. Steven Shak, chief scientific officer at Genomic Health, said about four in 10 women in the US with early-stage breast cancers were not tested for recurrence risk. He expected the study's results to change that practice.

"This is going to provide the highest level of evidence now for our test being indispensable in clinical practice," Dr Shak said.