Biotech Daily

Tuesday October 14, 2014

Daily news on ASX-listed biotechnology companies

Federal Government 'Action Plan For Australia's Future'

TGA To Accept 'Trusted' Regulation

Comment: Cochlear, Medicines Australia, Biotech Daily

Ausbiotech Welcomes Tax, Regulatory Changes

FEDERAL GOVERNMENT

In a series of media releases, the Federal Government said it had 'An Action Plan for Australia's Future' and an 'Industry Innovation and Competitiveness Agenda'.

The media releases from Prime Minister Tony Abbott and Industry Minister Ian Macfarlane said the Federal Government would "invest $188.5 million in Industry Growth Centres to pursue global excellence in areas of competitive strength".

The media release said there would be five centres including food and agriculture; mining equipment, technology and services; oil, gas and energy resources; advanced manufacturing; and medical technologies and pharmaceuticals.

The media releases said that through the medical technologies and pharmaceuticals centre, businesses might be assisted to identify new opportunities through linking with medical device and materials researchers to develop new biomedical devices and platform technologies to improve health outcomes and business profitability.

The Federal Government said it would invest $12 million to improve the focus on science, technology, engineering and mathematics subjects in primary and secondary schools across the country.

The media releases said that the Industry Innovation and Competitiveness Agenda was a central part of the Government's Economic Action Strategy "to build a strong, prosperous economy for a safe, secure Australia".

The Government said it had scrapped the carbon and mining taxes, cut more than 10,000 pieces of "unnecessary legislation and regulations", commenced the largest infrastructure construction program in Australian history and signed free trade agreements with Japan and Korea.

The Government said would "change the taxation treatment of employee share schemes to encourage start-ups to attract and retain employees and commercialize good ideas in Australia ... [and] reverse for all companies the changes made in 2009 to the taxing point for options".

The Government said it would reform the 457 visa program for skilled migrants, while improving program integrity to ensure that sponsored workers on 457 visas were a supplement to, and not a substitute for, the local workforce.

The Government said it would host a series of roundtables around Australia to consult with the business community, industry associations and peak bodies, as well as academia, on the policy directions outlined in the Competitiveness Agenda.

The Government said that its Competitiveness Agenda Report and fact sheets were available at www.industry.gov.au/growthcentres.

Wednesday October 15, 2014

FEDERAL GOVERNMENT

The Federal Government says Australia will not regulate a system, service or product approved by a trusted international standard without good reason.

In yesterday's launch of the 'Industry Innovation and Competitiveness Agenda - An action plan for a stronger Australia', the Federal Government said it would "adopt the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is good reason to do so".

"All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle," the Innovation and Competitiveness Agenda said.

"As a first step, the Government will enable Australian manufacturers of medical devices to register routine medical devices using conformity assessment certification from European notified bodies," the Agenda said.

“The regulation of industrial chemicals is another early priority for reform,” the Agenda said.

The Department of Prime Minister and Cabinet said the Government was “removing regulation that duplicates trusted overseas processes, except in cases where unique Australian regulations can be justified”.

The Government said that adoption of the principle that approval under a trusted international standard, would be sufficient unless there was a demonstrable reason not to would “reduce costs and delays for businesses, increase the supply of products into the Australian market and allow regulatory authorities to focus on higher priorities”.

“As a first step, the Therapeutic Goods Administration will enable Australian manufacturers to register routine medical devices using conformity assessment certification from European notified bodies,” the Government said. “Similarly, the National Industrial Chemicals Notification and Assessment Scheme will better utilise and increase its acceptance of international risk assessment materials from trusted overseas regulators.”

“To ensure a thorough review of all regulations, ministers will be asked to write to regulators in their portfolio and key business and other stakeholders seeking their views on each of their standards and risk assessment processes against this principle,” the Federal Government said.

“Separately, stakeholders can submit examples of unnecessary divergence from international standards at www.cuttingredtape.gov.au,” the Government said.

The Federal Government said that Australia’s chemicals regulatory arrangements were complex, involving about 140 pieces of legislation, multiple agencies and numerous regulatory decision makers at all government levels.

The Government said it intended to remove regulatory barriers to the introduction of lower-risk industrial chemicals already approved overseas, while allowing resources to be devoted to assessing higher risk industrial chemicals.

Yesterday, the Federal Government said the Agenda included $188.5 million for five Industry Growth Centres, one of which would be for medical technologies and pharmaceuticals, to assist businesses link with medical device and materials researchers to develop new biomedical devices and platform technologies (BD: Oct 14, 2014).

The Federal Government said it would invest $12 million to improve the focus on science, technology, engineering and mathematics subjects in primary and secondary schools; change the taxation treatment of employee share schemes to encourage start-ups to attract and retain employees; reverse changes made in 2009 to taxing options; and reform the 457 visa program for skilled migrants.

COCHLEAR

Cochlear chief executive officer Dr Chris Roberts told Biotech Daily that he welcomed Prime Minister Tony Abbott's Industry Innovation and Competitiveness Agenda.

"The Government's Action agenda contains some important changes to how medical systems will be regulated in Australia," Dr Roberts said.

"It adopts the principle that if a system or product is approved under a trusted international standard or risk assessment, then Australian regulators will also approve it unless there is a good reason not to do so," Dr Roberts said.

"This is a huge win for an export company like Cochlear that sells devices into dozens of countries around the world that require country of origin approval," Dr Roberts said.

In a Cochlear media release, Dr Roberts said that the Industry Innovation and Competitiveness Agenda would enhance his company's international competitiveness, cut red tape and improve export opportunities.

"The Agenda shows the Australian Government appreciates that business is critical to strong economic growth," Dr Roberts said.

"The government understands the benefits of linking science with industry, and delivering a highly-skilled workforce, Dr Roberts said.

"Changes to employee share schemes and 457 visa rules are also important in encouraging a smart Australia," Dr Roberts said.

"Today's Agenda will help grow our export capacity and streamline market access," Dr Roberts said.

"It means Cochlear is better placed to export its products, create jobs and improve health outcomes," Dr Roberts said.

Cochlear was up $2.17 or 3.1 percent to $71.29 with 450,796 shares traded.

MEDICINES AUSTRALIA

Medicines Australia chairman Dr Martin Cross also welcomed the Industry Innovation and Competitiveness Agenda and the announcement of five industry growth centres.

"Australia is uniquely placed to harness our competitive advantages, particularly in the medical technologies, pharmaceuticals and advanced manufacturing sectors," Dr Cross said.

"I am particularly encouraged by the Government's commitment to support growth in Australia's medical technologies, pharmaceuticals and advanced manufacturing sectors, when the global market for medicines and vaccines is projected to double over the next 10 years," Dr Cross said.

“We are not only conveniently located but we also have a world-class medical research infrastructure and a well-established reputation in the region for manufacturing safe, high-quality medicines and vaccines,” Dr Cross said.

“With the right policies in place, like those announced by the Government today, Australia could double its exports of medicines and vaccines products by 2024,” Dr Cross said.

“We could also double the level of investment Australia attracts in pharmaceutical [research and development] and clinical trials,” Dr Cross said.

“Government policies are amongst the strongest influencers of global company and local investment decisions,” Dr Cross said.

“We need a stable and business-friendly policy environment in Australia to encourage high-tech industries like the global pharmaceuticals sector to directly invest here for the long term,” Dr Cross said.

“Industry is looking forward to working with the Government to contribute tangibly to these centres,” Dr Cross said.

BIOTECH DAILY

Biotech Daily has long been a critic of the Australian Therapeutic Goods Administration and understands industry enthusiasm to subvert what has been often described as bizarre and chaotic decision-making, as well as its role in obfuscating real regulation.

While some might be glad to see no Australian regulation, Biotech Daily would rather an Australian regulator combining the clarity of the US Food and Drug Administration and the generally easier approval of the European Medicines Authority, both of which have their own problems.

In broad terms, we support the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements, unless it can be demonstrated that there is good reason to do so.

The rapid approval of the CSL influenza vaccine that caused a spate of paediatric febrile convulsions while not approving Acrux’s transdermal eostrogen already approved by the FDA and on sale in the US for four years are the two examples that leap to mind when considering the TGA and regulation, along with permitting generally untested non-efficacious, but as-safe-as-water, over-the-counter potions to take up valuable shelf space at pharmacies.

That said, the fact that a drug, device or diagnostic might be approved in Europe or the US and putting the onus of proof on the consumer or a competitor, that the product might not be suitable for Australia, is a concern.

Another concern is the call for “a thorough review of all regulations” with Ministers to write to regulators and stakeholders “seeking their views on each of their standards and risk assessment processes against this principle” and asking any interested party to submit examples of unnecessary divergence from international standards to a “cutting red tape” website.

This process could be an extraordinarily long bureaucratic process to allegedly cut red tape. The UK Government under Margaret Thatcher spent some GBP500 million to find GBP15 million of civil service ‘wastage’.

Biotech Daily is not certain how the $188.5 million for five Growth Centres, one of which would be for medical technologies and pharmaceuticals, compares to last year’s Labor election promise of $47.5 million for 19 Centres for Research Excellence or the other promises to implement $70 million of investments and reforms as its initial response to the McKeon Review, $4.2 million seed funding for four Integrated Health Research Networks, $5.8 million in Partnership Project grants and two NHMRC John Cade fellowships in mental health research (BD: Aug 20, 2013).

More importantly Biotech Daily believes our industry would be best served by rapid progress on the proposed $20 billion Medical Research Future Fund, de-coupling it from the controversial $7 Medicare co-payment and providing a significant commercialization component to enable the Australian development of any research discoveries.

David Langsam
Editor

AUSBIOTECH

Ausbiotech says it welcomes the restoration of the tax treatment of employee share schemes use of European certification for routine medical devices.

Ausbiotech chief executive officer Dr Anna Lavelle said her organization had advocated the changes announced in the Federal Government’s Industry Innovation and Competitiveness Agenda “for many years”.

“We are reassured to see the Government is listening to industry’s views about how to give Australian technology start-ups a fair go and for home-grown technology to be more internationally competitive,” Dr Lavelle said.

“The reversal of the [employee share scheme], altered in 2009, and the ability for Australian companies to rely on regulatory processes undertaken by European notified bodies are big wins for common sense,” Dr Lavelle said.

“Australian companies have for many years been frustrated by an inability to incentivize innovation employees with shares and options, and separately by a need to repeat expensive regulatory processes that do not increase safety but instead results in delays and unnecessary cost,” Dr Lavelle said.

Ausbiotech said that biotechnology was at the core of our country's promising sectors with three of eight relevant, medical technologies and pharmaceuticals, food and agribusiness, and advanced manufacturing, and recognized as growth sectors with competitive strength.

Ausbiotech said it "looks forward to further details on the plan to establish five Industry Growth Centres, three of which relate to biotechnology".

The industry organization said it welcomed the focus on the Government's $9.2 billion annual investment in research to get a better commercial return, in particular, strengthening intellectual property and improving tax and research funding arrangements to deliver incentives for the translation of research and for collaboration with industry, and the establishment of the Commonwealth Science Council.

Ausbiotech said it was hopeful that these steps are followed by further actions to support innovation, entrepreneurship and translation of research and looks forward to the Tax White Paper, which it is hoped will include a tax incentive for Australian innovation and manufacturing to be internationally competitive.