
Biotech News

Biotech & Health Fortnightly News

26 July 2005

Welcome

AAR Biotech News is a fortnightly news service to keep you on top of developments in this fast-moving industry. It is updated every other Tuesday, and subscribers are alerted on Wednesday.

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APVMA Guidelines for the Registration of Biological Agricultural Products

In brief: Senior Associate Caroline Ryan provides an overview of the APVMA's Guidelines for the Registration of Biological Agricultural Products that have been issued to assist Applicants in understanding the additional data requirements to be addressed when applying to register an agricultural chemical product with an active constituent that comprises or is derived from a living organism.

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Background

As reported in an earlier edition of [Biotech News](#), the Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is the Australian Government agency responsible for the assessment, registration and regulation of pesticides and veterinary medicines, up to and including the point of retail sale.

A number of products of biological origin are encompassed by the definition of *Agricultural Chemical Product* in the *Agricultural and Veterinary Chemicals Code (the Code)*, and are therefore subject to regulation by the APVMA. As biological products can have different properties to conventional chemical products, the APVMA has recently published separate [Guidelines for the Registration of Biological Agricultural Products \(the Guidelines\)](#) to assist Applicants in understanding the additional requirements to be addressed when applying to register a Biological Agricultural Product.

Biological Agricultural Products

The Guidelines define a Biological Agricultural Product as an agricultural chemical product with an active constituent that comprises or is derived from a living organism, with or without modification. This definition encompasses a number of chemicals that are commonly referred to by manufacturers as being 'herbal', 'organic' or 'botanical' products.

The Guidelines identifies the following 4 groups of Biological Agricultural Products as being subject to additional requirements.

Group 1 – Biologically Derived Chemicals (including pheromones, hormones, growth regulators, enzymes and vitamins).

Group 2 – Unpurified or Partially Purified Extracts (such as plant and some food product extracts, oils).

Group 3 – Microbial Agents (such as fungi, viruses, and bacteria).

Group 4 – Other Living Organisms (such as microscopic insects, plants and animals, including some organisms that have been genetically modified).

The Guidelines identifies the following as categories of products that are **not** considered to be Biological Agricultural Products.

Products categorised as conventional agricultural chemical products

Products where the active constituent is a biologically derived chemical that has direct toxicity to the target species and can be purified, fully identified and has a residue detection method applied, are not considered to be Biological Agricultural Products for the purpose of the Guidelines. An example of this category includes nicotine and strychnine-based products.

Exempt Products

Schedule 3 of the Code Regulations specifically exempts certain classes of products from registration. These include soil ameliorants, fertilisers and domestic disinfectants. More detailed information on what is considered to be an exempt product can be obtained directly from the APVMA.

Plant Growth Stimulating Products

Plant growth stimulating products that are not for pest control or specific growth regulation are dealt with under State and Territory regulation and are not administered by the APVMA. Products based on plant hormones are required to be registered with the APVMA.

Higher Plants

Higher plants are not required to be registered with the APVMA. However, certain categories of genes inserted in the genome of plants may require registration. For example, genes that code for the production of pesticidal substances are considered to be a pesticide and require regulatory approval and registration.

Data Requirements – Biological Agricultural Products

During the evaluation process for registration of a new product, the APVMA takes full account of the nature of the product on a case by case basis, including a review of the data supplied by the Applicant. This process requires the Applicant to supply data to the APVMA in relation to the following categories:

- a) Chemistry & Manufacture;
- b) Toxicology;
- c) Metabolism and Toxicokinetics;
- d) Residues;
- e) Overseas Trade Aspects;
- f) Occupational Health & Safety;
- g) Environmental Aspects;
- h) Efficacy and Safety; and
- i) Any Special Data Requirements.

Chapter 4 of the Guidelines discusses in detail the additional data requirements for Biological Agricultural

Products categorised in Group 1 and 2. This includes additional information such as the biological properties of the active constituent, and the likely biological effects arising from use of the Biological Agricultural Product.

Chapter 5 of the Guidelines discusses in detail the additional data requirements for Biological Agricultural Products categorised in Group 3 and 4. This Chapter includes important information such as what details are required to be given during the Application process for the purpose of identifying the active agent (being either a microbial agents or some other living organism).

Genetically Modified Products

The Guidelines recognise that products from any of the Groups outlined above can consist of or be derived from genetically modified organisms (**GMOs**). Products based on GMOs are identified in the Guidelines as having additional data requirements concerning genetic manipulation.

Applicants will be required to provide additional information on the following items:

1. the host organism;
2. the donor organism;
3. genetic engineering techniques used;
4. identity of the inserted or deleted gene segment;
5. information on the control region of the gene;
6. description of the new traits or characteristics that are intended to be expressed;
7. tests to evaluate genetic stability and exchange; and
8. environmental expression and toxicology tests.

In addition to complying with the requirements of the APVMA, such products are also likely to be subject to regulation by the Gene Technology Regulator under the *Gene Technology Act 2000* (Cth).

Conclusion

In most cases, before agricultural and veterinary chemical products can be sold, supplied, distributed or used in Australia, they must be registered by the APVMA. In many cases, such products are based on an active constituent that comprises or is derived from a living organism, and will therefore be required to meet additional data requirements during the Application process. The Guidelines have been issued by the APVMA to assist Applicants in understanding the additional requirements to be addressed when applying to register a Biological Agricultural Product.

The APVMA welcomes comments and suggestions for improvement on the usefulness of the Guidelines. Comments can be submitted to the Program Manager Pesticides, APVMA PO Box E240, Kingston, ACT, 2604.

For further information please contact Dr Trevor Davies on +61 2 9230 4007.

Regular intellectual property news from Australia and overseas.

- [India's patent law reforms draws in Merck](#)

India's patent law reforms draws in Merck

July 22 – India has recently made it illegal for unauthorised parties to manufacture patented drugs. Following a 20 year absence, Merck will now re-enter the Indian market via a wholly owned subsidiary, MSD Pharmaceuticals Private. Merck stated that the tightening of India's patent laws helped in its return and is considering the establishment of manufacturing and research units in the near future. India is the world's fourth largest producer of medicines by volume, but ranks 13th by market value.

[Source: Reuters]

Company news

Regular news within the Australian biotech industry.

- [BresaGen awarded BioInnovations SA grant](#)
- [Genesis buys into fertility testing](#)
- [Healthscope completes Nova acquisition](#)
- [Life Therapeutics bolsters US presence](#)
- [Progen cancer program backed by \\$3.4 million grant](#)

BresaGen awarded BioInnovations SA grant

July 19 – BresaGen has been awarded a AU\$200,000 BioInnovations SA Commercial Infrastructure Grant toward the purchase of an aseptic filling line to enable medium scale sterile filling for use with production of bacterially sourced peptides. BresaGen anticipates commissioning the equipment in the first quarter of 2006.

[Source: Company Announcement]

Genesis buys into fertility testing

July 18 – Genesis Biomedical has signed an agreement for the purchase of the private New Zealand based biotechnology company Manuatu Biotech Investments Limited. The agreement provides Genesis with access to fertility testing markets in which MBIL holds developmental proprietary technology in the form of test strips that measure hormone metabolites for both human females and other mammals. Genesis is currently considering appropriate capital raising in light of the recent acquisition and proposed four phase developmental process.

[Source: Company Announcement]

Healthscope completes Nova acquisition

July 25 - Healthscope has completed the compulsory acquisition of outstanding shares in Nova Health Limited following an unconditional off market bid by Healthscope on 30 May 2005. The bid was supported by the placement of approximately AU\$77.5 million in ordinary shares to institutional shareholders.

[Source: Company Announcement]

Life Therapeutics bolsters US presence

July 26 – Life Therapeutics will relocate two of its three business divisions from Sydney to Atlanta, US. The corporate office and both the diagnostics and bioprocess production divisions will be transferred to the US by the end of Q1 2006. Life Therapeutics cited recent US acquisitions and centralisation of the company's major activities to gain better access to US Food and Drug Administration resources as major impetus for the move. The Australian office will remain company headquarters.

[Source: Company Announcement]

Progen cancer program backed by \$3.4 million grant

July 25 – Progen Industries has announced that it intends to accept a AU\$3.39 million AusIndustry Commercial Ready grant to support its maturing cancer drug pipelines over the next three years. The funding will provide 50 per cent of the required budget to develop early stage compounds for entry into clinical trials. The new grant follows on from previous AusIndustry funding that aided in generating new angiogenesis mediating compounds and IP expanding Progen's portfolio to include 15 patent families and 24 issued patents.

[Source: Company Announcement]

Government news

Regular news from state and federal governments.

- [Commonwealth Government fast track flu vaccine](#)
- [Pfizer's Lipitor to remain at current price](#)

Commonwealth Government fast track flu vaccine

July 22 – The Commonwealth Government will provide CSL with AU\$4.93 million to fast track production of a pandemic influenza vaccine targeting the current H5N1 avian influenza strain. The funds enable CSL to expand current manufacturing capacities and to begin clinical trials of a prototype vaccine in September 2005 with a proposed registration date of August 2006. The funding is in addition to AU\$23.2 million provided to establish an independent World Health Organisation Collaborating Centre on influenza.

[Source: Federal Department of Health and Ageing]

Pfizer's Lipitor to remain at current price

July 20 – The Minister for Health and Ageing, Tony Abbott, has accepted the Pharmaceutical Benefits Advisory Committee's recommendation that atorvastatin (Pfizer Inc's product, Lipitor®), is more effective at lowering cholesterol than simvastatin, and therefore warrants a higher price for PBS subsidy. As a result, Lipitor® will not be affected by the 12.5 per cent price reduction that will affect other brands of cholesterol lowering medicines when the new generic brands of simvastatin are listed on the PBS from 1 August 2005. Almost one million Australians are prescribed Lipitor® to help manage their cholesterol levels.

[Source: Media Release]

Science news

Regular science news

- [UQ discovers emotive protein](#)
- [Protein regenerates brain and spinal cord](#)

UQ discovers emotive protein

July 18 – University of Queensland researchers have identified a protein involved in memory and other emotive functions. The researchers identified the protein within a section of the brain responsible for mediating emotions, the amygdala. Emotive based neurological disorders are thought to stem from changes in connective strength between cells within the amygdala. The protein itself was found to play a role in regulating information processing, and when blocked, increased strength between these cells. It is thought that the discovery may lead to the development of treatment strategies for numerous mental disorders such as post traumatic stress, anxiety and depression.

[Source: EurekAlert]

Protein regenerates brain and spinal cord

July 25 - Researchers at the University of Helsinki have discovered a KDI tripeptide that inhibits glutamate and has been shown to prevent permanent nerve cell death. When injected directly into the damaged area, KDI has been shown to increase synaptic function and neurite outgrowth between damaged neurones but does not regenerate new neurones. The study does not represent a cure but it is hoped to contribute to methods of reducing disease progression when incorporated into an effective drug.

[Source: BBC News]

International news

Biotechnology news from around the world.

- [Teva keen on Ivax acquisition](#)
- [PCRM claims Merck passed Vioxx on animal experiments](#)

Teva keen on Ivax acquisition

July 25 – Teva Pharmaceuticals has positioned itself to be the worlds biggest generic drug maker after reports that the company is seeking to acquire Ivax Corporation for US\$7.5 billion in cash and stock. Teva's US\$20 billion market capital is over three times that of Ivax with a value of US\$6 billion. In February 2005, Novartis entered a US\$8 billion deal to acquire Hexal and Eon Labs, placing it as the top generics company. If successful, the acquisition will significantly boost Teva's revenues as analysts state the companies combined would generate US\$8 billion in sales in 2005.

[Source: Reuters]

PCRM claims Merck passed Vioxx on animal experiments

July 14 – The US Physicians Committee for Responsible Medicine has filed a suit against Merck & Co alleging the company relied on positive animal safety results, while ignoring human trial data for the painkiller Vioxx. The suit claims Merck was aware of the limitations of animal testing data and, while ignoring more effective safety assessment methods, cited animal data to justify its safety and prolong sales of the drug. Vioxx was removed from the market following the VIGOR clinical trial that linked Vioxx to congestive heart failure. The case is believed to be the first time a US pharmaceutical company has been sued specifically for relying on animal tests.

[Source: Physicians Committee for Responsible Medicine]

Events

Please visit AAR Biotech News' online events section for information on the latest conferences.

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