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Federal Court overrules vet products regulator on generic registrations.

Federal Court finds APVMA interpretation of Confidential Commercial Information requirements to be erroneous.

Farmers to once again have access to new generic veterinary chemicals at favourable prices.

In the Federal Court today, Justice Stephen Rares handed down a decision in the case of Abbey Laboratories vs The Australian Pesticides and Veterinary Medicines Authority (APVMA) that restores the ability of registrants of generic veterinary medicines to request the APVMA to use all non-patented and unprotected information that it possesses in order to help satisfy itself as to the efficacy and safety of new generic products.

This system had been in place for more than twenty years and ensured Australian farmers and other users of animal health products had available to them new generics developed mostly by local companies, and kept the cost to the Australian community of veterinary medicines to the lowest level possible.

The APVMA took a decision in September 2014 to reinterpret its legislation (The Agvet Code) such that it claimed it could no longer use its knowledge of existing registered products and formulations in assessing new applications for registration. The APVMA claimed that it had legal advice to this effect but despite overwhelming legal opinion to the contrary, as well as the existence of a precedent in an earlier Federal Court case, the regulator refused to reconsider its position, or to release the details of the legal advice that it relied upon.

Mick Findlay, Director of Abbey Laboratories and a board member of the VMDA, said that 'Abbey was far from the only company affected by this APVMA decision' and that he had 'fought hard for the APVMA to listen to reason and reconsider, but to no avail'.

Jim Adams, President and Executive Director of the VMDA, said that virtually all of its members (large and small and including those in service roles such as regulatory consultants and laboratories), had been suffering unnecessarily for almost two years. He estimated that the total direct cost to his members could be measured in \$millions, and that the loss of future earnings that would continue for several years would be a significant multiple of those direct costs.

'Farmers are the most adversely affected group' he said, 'and they will have several years more of not seeing the savings that could have been generated by products that did not achieve registration in this period'.

Mr. Adams also commented that like Mr. Findlay, he 'could not understand the intransigence of the APVMA in respect of this issue despite our association trying again and again to achieve a resolution'.

'Hopefully now', he said, 'The APVMA will see and the Minister will ensure, that an immediate return to the status quo will be the only fair outcome for all parties, including our Australian industry and farmers'.

Contact: Jim Adams: vmda@vmda.com.au Tel: 0447 715 515.