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The Honourable Rick Wilson
Federal Member for O'Connor
As Chairman of the recently advertised pesticide enquiry

Dear Rick Wilson and fellow members of your committee

I am writing to you concerning the very difficult inefficiencies associated with getting our major products through the APVMA bureaucracy.

Jurox is a family owned veterinary pharmaceutical company located in the Maitland area. Our factory is a mid sized company developing products based on our own research. I refer you to our website https://www.jurox.com/au/

We employ over 160 people, most of these in the Hunter Valley, but have sales staff throughout Australia.

Our most successful product is an anaesthetic Alfaxan widely used in Australia and having a commanding position in veterinary practices here. We export that product to New Zealand where we have a sales and marketing operation as in USA and UK. We use agents in Canada, Japan, Korea, Taiwan and a number of countries in mainland Europe and South Africa.

Alfaxan is over 30% of our total revenue of some $60-70 million in 17/18. We have spent some 6+ years developing a suitable formulation which contains a preservative and is covered by intellectual property around the world. In the induction anaesthesia market in Australia, we account for over 85% of all inductions of anaesthesia in dogs and cats. It is very safe as a wide group of animals can be successfully anaesthetised using this product.

Our original discovery in 1998 was a way to solubilise alfaxalone the active ingredient in using cyclodextrin which got over a problem the originator had with their solubilisation procedure leading to anaphylactic shock death, thick ears etc. In Europe and America, Canada etc our product has to be used for a very limited period of time after broaching and the residue of the bottle thrown away. This causes a difficulty in expanding our markets. The new preserved product solved that problem and is now registered in Canada and after some intervention through the new Head of APVMA, registered in Australia as well. It was only 3-4 months behind the APVMA's approval date.

Whilst Australia was the third country after Canada and New Zealand to approve our preserved product, we still cannot ship to Canada at the date of writing this because of a broken procedure to get an Export Permit. This starts with a system where we must ask the APVMA to ask the TGA to

conduct an audit or a desk review on the new product. We offered an APVMA auditor and a senior auditor in the TGA, the option of completing this audit or review of our preserved product, which is made in an FDA, TGA, European MRA and Canadian approved facility at our plant in Rutherford. The APVMA auditor has completed his review, while we await TGA's stance. Until the TGA's stance is resolved, Jurox will not have a license issued to permit export.

Fortunately when the US approval of this product becomes a reality in 6 weeks time, we will not have to put up with this back and forth. We'll be able to ship directly to our operation in the US on known timelines. A number of countries in Europe will be approving our preserved alfaxan by 28 February and we should be on the market there in March or early April.

My Head of Quality, Anthony Walshe, confirmed to me on Wednesday afternoon that Michelle Wooster at the APVMA (new Acting Director of MQL) would call yesterday 8 February, to confirm APVMA decision and timelines for the MRA to be provided. The outcome of the conversation held on 9 February was that the APVMA would defer it decision to the TGA whether to issue the appropriate license. This effective means that there was no progression on this item between the two regulators, from initial discussions held on 7 December 2017. Meanwhile we have products sitting on our dock waiting to go to our distributors in Canada.

This is a ridiculous bureaucratic nightmare. As your members will possibly be aware, the TGA does not like having to be the lapdog to the APVMA in regard to audits for overseas exports. Why can the system not be simplified to allow us to deal with the TGA directly and to take their guidance?

My second beef, is our dealing as a company trying to develop export markets why do we have to go cap in hand to the APVMA and ask them to ask the TGA to carry out an audit for Europe and Canada to VICH guidelines (of course Australia operates on VICH guidelines which were current in 1997). They have never embraced the requirements for GMP up to the 2007 VICH guidelines and now there is a 2017 guideline in which we are given one year's grace to bring our operations up to this standard by TGA.

I'm sure part of this problem is that people think you don't need GMP to make pesticides in a tin shed and why should we do anything different for animal health products. Unfortunately the rest of the developed world look upon veterinary drugs as being very similar to human drugs. We need to have a TGA audit for our licences in Europe and Canada by the middle of this year. To do this we have request the APVMA to request TGA to have an audit. TGA will then send us a bill for over $50,000 to carry out that audit and tell us we must pay it before they'll bother to come and see us. We requested this audit to take place in February and now we're at 9 February and we have no answer from the TGA when this audit will take place.

Once we have the audit with the TGA we will have findings as everybody does, we will answer the findings to their satisfaction and then we'll wait some time before the APVMA decides to issue us with an MRA for Europe!

The third point I wish to make is we have a heart drug for dogs which is a generic of a Boehringer drug which has been off patent since August 2017. We have done the work required to produce a generic of the Bohringer drug. It was submitted to the regulator on 1 November 2016 and should have come out in September 2017. We have had no communication until we met up with the Head of the APVMA (Acting Head at that time) in November 2017. We requested he help us with our major product Alfaxan as it had gone into a black hole and also our Pimobendan product which should have been out by 15 August 2017.

We had not been given the courtesy of access to their efficacy and safety assessment report at that stage. We only received that in November 2017 after a request to have access. Unfortunately it has still has not been approved by the APVMA. Today one of our new competitors, the English company Dechra, announced that they are launching a first to market generic and we think this is unacceptable. They were quick to market in Europe as they knew the guidelines and the timelines. In Australia we understand from their European SPC package insert that they had a slightly faster uptake of drug. We justified that slightly faster uptake to the APVMA: What holds up our application? European regulators are well run and are obviously pragmatic and make no comment on Dechra's SPC about the slightly faster uptake for them. The risk adversity of the APVMA is frightening!

Please excuse my annoyance but we are trying to run a business. We are getting more and more export business but with one hand tied behind our back.

Thank you for taking the time to read this.

Yours sincerely

[redacted]

John O'Brien
Managing Director