

# Unlawful Conduct And Unnecessary Regulation

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The agricultural chemical company Imtrade has won a victory against the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the Federal Court with similarities to the Pan Pharmaceuticals case that led to the payment of \$55 million in damages. Like the Pan case, it involved regulatory overreach.

The case arose because Imtrade gave a fictitious name and address in China as the manufacturer of certain active constituents. The company says it did not want the information made available to its competitors and considered it irrelevant to the APVMA.

In early May the APVMA enlisted the Australian Federal Police to raid Imtrade's Perth premises and threatened criminal charges. Two weeks later the APVMA imposed a compulsory recall of the affected products, some 47 in total, and notified Imtrade that the products were no longer registered.

Imtrade appealed to the Administrative Appeals Tribunal (AAT), which promptly halted the recall. The APVMA then went to the Federal Court, which gave its decision on 12 September.

The APVMA argued it was entitled to treat Imtrade's approvals and registrations as invalid from the beginning because they were based on fraudulent information. That meant there was no need to go through the formal process of cancelling the approvals and registrations.

The court disagreed and ordered their reinstatement, finding that the APVMA had acted unlawfully by removing the products from the approved products register.

It said the false information had not been relied upon but was collected to comply with the regulations, and criticised the APVMA for resorting to "self help" rather than seeking remedies in the court. Even if there had been safety considerations, it said only a court could decide whether an administrative decision could be nullified in this manner.

It also referred to the rights of innocent third parties affected by the decision, as they were exposed to criminal liability, forfeiture, injunctions and search warrants. The APVMA already had the power, it said, to correct particulars as well as to suspend or cancel approvals and registrations with time for affected third parties to dispose of unapproved products.

The APVMA is indignant and would like to appeal, and still talking about criminal prosecutions. But as it stands, the law now says the regulator exceeded its authority and denied natural justice to a registrant. That exposes it to damages.

It is ironic that, while it took umbrage at the AAT halting the recall, that may have saved it from substantial damages. Imtrade's products were only off the market for two weeks.

The case raises many questions about the function of a regulator when those it regulates have no say in its governance yet provide its entire funding.

Chemical registrants are especially entitled to ask why they should foot the bill for unlawful conduct. The action against Imtrade is understood to have been at least partly motivated by retribution, in response to the company having bribed a couple of APVMA staff to accelerate consideration of its applications. The TGA's pursuit of Pan similarly had a personal aspect to it.

There was no imminent safety issue and trade was not threatened. Imtrade admits it lied, but lying to a government agency is hardly a hanging offence. Imagine if the taxation department took the same approach.

The case exposes major weaknesses in the APVMA's funding model. If it were to succeed in a prosecution of Imtrade, any fines would go to consolidated revenue. Yet if Imtrade were to win damages or costs, industry would foot the bill.

The main reason the APVMA is reluctant to appeal is financial. The organisation's income is down because drought has reduced revenue from the sales levy that generates more than 60% of its income. If public safety or trade had been genuinely at stake, that might well be a problem.

On the other hand, the prospect of paying for losing cases helps keep the APVMA civil. Veterinary pharmaceutical company Phibro found that commencing action in the AAT over a labelling dispute led to much greater willingness to negotiate.

What the case also highlights is the fact that Australia is cursed by unnecessary regulation and public servants who unreasonably enforce such regulations at public expense.

Intrade had a point in questioning why it should disclose details of its manufacturer. The information might be of value to competitors but crop chemical manufacturers are not inspected or licensed. Even if they were, it is difficult to see much benefit from the \$1.3m it costs to license animal health manufacturers.

The cost exceeds the benefit on various other APVMA activities too, which it does not appear to have noticed. Although industry feedback is now being sought on new funding options, the proposals are for indexation of levies and cost-recovery on manufacturer licensing. In other words, they aim to raise more money rather than regulate less.

Now might be a good time for a serious rethink of the regulator's purpose, whether it is achieving its purpose cost effectively, and whether industry should foot the bill for it all. Acting unlawfully and collecting information for no useful reason seem like obvious places to start.