PEER REVIEWED

Data Protection – An Industry Success Story for New Zealand Agriculture

Until recently, New Zealand had one of the worst data protection regimes for animal medicines in the developed world. This all changed in November 2016, when our Parliament passed a major law change to extend data protection. The law change was a result of more than 15 years of advocacy by Agcarm, with the resulting outcome being a significant win for animal medicine and crop protection manufacturers.

At first, the Government was not interested in extending data protection – reasoning that it would be anti-competitive to generic-based companies, and would lead to product price increases for farmers. The organisation which lobbies on behalf of its farmer members, Federated Farmers, also did not initially support a law change – believing that farmers would end up paying higher prices for essential animal health products.

Over a number of years, Agcarm lobbied industry and government to extend data protection, using case studies and comparing international agricultural trading competitor data protection levels. Agriculture's critical role to New Zealand's economy, and the need to incentivise less hazardous products, and provide new and innovative products to replace those no longer in use, or where resistance is occurring, were other drivers.

New Zealand growers and farmers were missing out on new technology due to the lack of protection on the data proving that a product works, is safe for people and the environment, and that residues in produce are within acceptable limits.

Farmers of minor species, such as goats, and growers of minor crops were especially limited by the lack of data protection. In the goat industry, the most commonly used veterinary medicines are drenches. The lack of protection meant that many anthelmintics had to be used 'off-label' – meaning that they were not tested or registered for goats.

Off-label use limits export trade as many overseas customers do not allow it. An increase in protection means products can be registered with a label claim and a maximum residue limit set for that species.

Animal health companies shelved plans to develop new uses, or launch products to treat new species, because of a lack of data protection. One example of a product that was not introduced to New Zealand was estimated to have potential sales of less than NZ$1 million a year. Because it was a new use of an existing compound, there was no data protection and could be quickly copied, so the company chose not to introduce it. This is because the cost of assembling the data package to market might cost more than NZ$500,000.

Manufacturers need to provide this information in order to get approval from New Zealand's two regulators: the Ministry for Primary Industries and the Environmental Protection Authority. The data package supplied in support of an application represents a significant investment – costing hundreds of thousands of dollars to assemble. Under the old regime, this data was either not protected from competitors, or was not protected for long enough to satisfy the return on such a significant investment. There was no protection for adding claims for minor crops to product labels. This saw industry grower groups having to fund a significant portion of the data generation themselves.

The research and development needed to register label claims requires trials (for residues and efficacy) to be carried out in New Zealand. Many close trading partners such as Australia, the USA and Canada have access to government funds, as well as longer data protection periods. This put New Zealand farmers at a disadvantage.

The upshot is that farmers and veterinarians miss out on new and better products.

The New Zealand Government eventually realised that to double primary industry exports – as it had set out to do – it would need to encourage innovative solutions for the agricultural sector. The ambitious target of increasing these exports from NZ$32 billion in 2013 to over NZ$64 billion by 2025 required some innovative measures for our primary industries. Data protection was an obvious solution as it would increase the availability of new and innovative animal health products for the agricultural sector, thus providing healthier and higher yielding livestock.

In late 2016, political parties eventually agreed to extend data protection to encourage businesses to register new and innovative products required by the New Zealand agricultural sector. There was only one exception – the Green Party – who maintained an entrenched view that longer protection would lead to the greater use of harmful chemicals on our farms. The party also claimed that it would not allow access to confidential information on animal medicine formulations. This was disregarded by the Government, who agreed that the law change would incentivise the registration of products with lower hazard classifications that are less harmful to our environment.

The Minister responsible for leading the changes was the Honourable Jo Goodhew, Minister for Food Safety. Agcarm met with Hon. Goodhew (and other political leaders) on several occasions to explain the need for the extension of data protection and the benefits that it would bring to agriculture in New Zealand. Her comment on the passing of the bill was that it was very important for the primary industry's productivity and international competitiveness that our farmers have access to effective agricultural compounds. The Government welcomed Agcarm members' commitment to ensuring extended data protection, and she looked forward to seeing the positive impacts that it would have on our country.

Allied industry groups also changed their view, as innovation became viewed as critical to the future growth in farming. A number of groups, such as the deer industry and Federated Farmers provided supportive submissions to the Primary Production Select Committee hearings on the new laws, which assisted in influencing decision-makers.

Summary of Changes			
		Previous provisions	**New provisions**
New Registrations	Innovative Trade Name Products	Five years' protection	10 years' protection
	Non-innovative Trade Name Products	No protection	Five years' protection
New Provisional Registrations	Innovative Trade Name Products	Five years' protection	Five years' protection. Can be extended up to a further 10 years if it is subject to a new registration of the same innovative trade name product.
	Non-innovative Trade Name Products	No protection	Five years' protection. Can be extended up to a further five years if it is subject to a new registration of the same non-innovative trade name product.
Variations to Registrations for one or more of the following situations: a) A purpose listed in the definition of an agricultural compound; b) Rate at which the product is applied; c) When the product must or must not be applied; d) How the product is applied; e) The withholding period for the product	Innovative Trade Name Products	No protection	Either the longer of the two periods of: a) End date for the protected period for the 10 years; or b) Five years from the granting or refusing the variation.
	Non-innovative Trade Name Products	No protection	Five years
Reassessment of Registrations	Trade Name Products	No protection	Five years' protection
Note: An 'Innovative Trade Name Product' refers to a product containing an innovative active ingredient – meaning the active ingredient is not in any previous registered product. Data protection commences on granting or refusing of an application.			

The Agricultural Compounds and Veterinary Medicines Amendment Act extends the period of protection for confidential information given in support of an application to register an innovative trade name product and also expands the scope of data protection coverage to include confidential information provided in support of applications to register non-innovative trade name products and uses.

With the passing of the new law, it is anticipated that a number of more targeted, environmentally-friendly and fit-for-purpose products will be researched, tested and brought to New Zealand. For our farmers and growers, this means that the toolbox available for protecting crops and treating animals will increase and improve.

It is hoped that our country will see a greater investment in research and development, which will increase productivity, sustainability and international competitiveness. It will also benefit trade and animal welfare.

Now there is an incentive for product manufacturers to invest in researching solutions specifically for New Zealand pests and diseases. This means growers and grower groups can concentrate on what they do best, or invest in other causes such as preventing biosecurity incursions.

Access to new chemistry is also essential to replace older, less sustainable products. Newer active ingredients and formulation types tend to be 'softer' chemistry than those traditionally used and, as such, have lower hazard classifications which pose less risk to human health, non-target organisms and the environment.

One of the key endeavours outlined by the Government is facilitating new antimicrobials to enter the market with novel modes of action that may be effective against microbes. With the new data protection regime, manufacturers will be encouraged to register new products in New Zealand, thus providing the necessary incentives to see antimicrobials enter the animal health market.

It also allows New Zealand farmers and growers access to new products favoured by trading partners. Access to the newest advances in technology allows them to comply with international best practice for the environment and food safety – and be internationally competitive. They are also more likely to have maximum residue levels set in our export markets. A greater variety of new products will mean more solutions for growers and more treatments for animals. It does not mean that product use will increase overall. Instead, there will be more to choose from – ones that in most cases will be more environmentally-friendly,

Mark Ross, Mark Christie (Agcarm Chair) and Paul Koffman (Agcarm, Vice-Chair) ready to present to Parliament on data protection

more effective and more targeted.

At this stage, it is too early to tell how much of an effect the extended data protection laws have had on the registrations of new and innovative animal medicines. However, it is anticipated that over time an increase in animal medicine registrations will occur in New Zealand, with a big driver being an additional five years to gain a return on the investment required to bring the medicines to the market.

Data Protection vs Patents

Amongst the New Zealand public, there is often confusion about the link between patents and data protection. Some assume that a new active ingredient brought into New Zealand is automatically covered by a 20-year patent. This is incorrect.

Patent and data protection are two distinct intellectual property rights. Patent protection is the reward you receive for disclosing your invention (investment in innovation) by preventing another party from using that invention in any form, for a defined period of time, while data protection is the reward you receive for the cost and risk associated with generating data on the required health, efficacy, and environmental safety studies.

During the lobbying for extended data protection, it was important to clarify this misunderstanding as it is easy to reach an incorrect view that a 20-year patent negated the need for data protection. A patent does not protect the data required for market approval, only the invention.

Innovator companies must patent new active ingredients very early in their development. This ensures their invention and significant early investment is protected. However, it can take a further 10 years to fully develop and gain approval to sell a product based on the new active. This time delay significantly erodes the benefits of the 20-year patent term. Hence, the effective patent period is typically only 10 years.

Markets for products develop over many years and at varying times around the world. It can take many years before innovator companies see a market opportunity to bring a new active to New Zealand, which represents less than one per cent of the global market in agrichemicals and animal health products.

Decisions about introducing an active ingredient to New Zealand are often made after a new active has come off patent, or at the end of the 20-year patent period. New Zealand's prior minimal data protection was, therefore, a key influencer on the decision to introduce the active ingredient into our country.

Doubling the data protection to 10 years for new actives encourages the registration of active ingredients new to New Zealand. This benefits New Zealand agriculture in three ways:

1. Bringing new technology to our farmers.
2. Increasing the pool of active ingredients that can be used to minimise the development of resistance to antibiotics and crop protection products.
3. Increasing the pool of products for subsequent approval/registration by generic companies (after the patent and 10-year data protection period has expired).

Mark Ross

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