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Since we launched the vaccine five years ago, I have had numerous requests from Americans wishing to buy Barbervax. We would like to sell it in your country but the cost of getting it registered with your authorities makes it unattractive financially, given the relatively small potential market ( e.g.USA has about 5m sheep, Australia, UK and NZ have 70, 25 and 20m, respectively)

Despite the fact that we have demonstrated that Barbervax works in controlled field trials in many countries with sheep (Australia, S. Africa, UK, Brazil, Switzerland, Mexico, Uruguay), the USDA insist on further protection and safety trials done in the US plus inspection of our manufacturing premises in Australia (which has a Good Manufacture Practice licence and which is already inspected frequently). These are all expensive and Wormvax, our company that makes and sells the vaccine, is a start-up without deep pockets which has to stand alone within the Moredun group.

Hence we would be delighted if The American Goat Federation were able to get an import permit for our vaccine!

A word of warning. Although Barbervax is registered for sheep in Australia and S. Africa, it isn't for goats. We did 3 controlled field trials in Boers in Australia in attempt to do this, but one trial failed, one was very successful and one was mediocre. It would have been too expensive to do further trials to overcome the failed trial, so we abandoned our attempt because the market was not considered big enough (Google Wormboss the excellent Aussie worm control website for more details).

Since then further successful controlled field trials have been done with Boers in S. Africa and Switzerland and in two dairy goat breeds in Brazil. It worked during lactation and unlike anthelmintics has no withdrawal period so could be used for goat milk or cheese If you need data (from sheep as well) to help obtain a permit, please ask.

Meanwhile, Barbervax is being used by Australian goat owners "off label" and so far we haven't received any complaints.

B.AHE.0232	Barbervax field efficacy and safety in adult sheep	15/06/2013	24/12/2014	I
B.AHE.0068	Barbervax commercial vaccine for Haemonchus contortus, the Barber's pole worm	01/08/2011	26/09/2014	

Details of the protocols of the sheep trials we done to get Barbervax registered for sheep in Australia.

There were two types of trial.

One type was conducted at Moredun here in Scotland with lambs reared indoors in worm free conditions and given an artificial challenge - we called those Pen Trials (The climate in Scotland is too cool for natural *Haemonchus* – hence no attempt to do Field Trials here).

The second type were trials done on commercial sheep farms in Australia – we called those Field Trials. They relied on natural challenge with *Haemonchus*. At first the field trials were done with lambs, the most susceptible type of sheep, but later these were repeated in yearlings and ewes to prove that the vaccine could work right across the flock. The protocols and results are published on the Meat and Livestock Australia website (Google Meat and Livestock Australia and then search for Barbervax) – two of the reports are shown above.

(Our Barbervax development work was funded by and large by Meat and Livestock Australia, where *Haemonchus* is common and important in some parts of the country. In case you don't know they are funded by levies collected from beef and mutton.)

Much depends on what your authorities, would demand in terms of new efficacy and safety data to be obtained on US soil. If they were to take into account the data from numerous (more than 30) published field trials from various counties, and were satisfied with a single Pen or Field trial, then that might be affordable. But if they would only accept a complete repeat of all our Australian trials it would be a non-starter. A few years ago we sought advice from a professional specialising in veterinary regulatory affairs in N. America and she estimated that it would cost hundreds of thousands of \$. Given the relatively small number of sheep and goats in N. America, this would be a risky business proposition

United States authorities also appear to demand regular inspection of our manufacturing plant in Western Australia. Since this already has a Good Manufacturing Practice certificate and is inspected regularly, that would seem to be another unnecessary expense in my view.

I have been in touch recently with Paula Menzies at Guelph vet school. She and colleagues and the Canadian sheep producers group are also very keen to have Barbervax registered in Canada too and have put me in touch with their registration authorities who have been very helpful. The Canadian vet registration system appears very similar to the Australian one, and I have the impression that, unlike the USA, they will accept protection data from trials done outside their country

Happy to provide you with any support which will persuade your authorities to reduce the expense of getting Barbervax registered in the US.