



Louping III Vaccine Update

June 2023

- The vaccination and challenge trials, kindly funded by grouse moor owners, for the new generation Louping III Virus (LIV) vaccine are now complete and the results analysed.
- The results confirmed that the vaccine raised a very strong immune response (antibodies against LIV) in the vaccinated sheep, protected them when challenged with LIV (no clinical signs recorded) and the pathology results confirmed that the virus did not enter the brain.
- So the very good news is that we have a prototype vaccine showing efficacy that can go forward to further development and commercialisation.
- After lots of approaches to potential vaccine manufacturers, we are delighted to say that we have an animal health company we are working with who are interested in taking the vaccine forward.
- The sales figures (based on previous sales of the MSD LIV vaccine) are low, but the cost of bringing any vaccine to market is high, due to the regulatory requirements for veterinary medicines, so this may require a funding model to allow progress.
- It will also rely on us being able to establish Limited Market Authorisation (LMA), which replaces the former EU Minor Use Minor Species regulations and should be a quicker, simpler and cheaper option to obtain regulatory approval to sell the LIV vaccine product.
- We have recently attended a meeting with the Veterinary Medicines Directorate (VMD) who control the legislative process to bring veterinary medicines to market in the UK and it has been agreed that Moredun, along with our potential partners, will complete an application for the LIV vaccine to be classified as a LMA product.
- However Post-Brexit, the process for registration remains unclear (as UK legislation has not yet defined the regulatory process) which is likely to lead to delays in the further development and commercialisation of the LIV vaccine.
- Please rest assured that we fully understand the urgent need for this vaccine and, despite the commercialisation challenges, are fully committed to seeing this vaccine available to all who require it.

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