

Target Product Profile: A Nipah virus vaccine for pigs

Attribute	Preferred	Critical or Minimal	Additional comments
Indications for use	<ul style="list-style-type: none"> For the immunisation of pigs of all ages in herds considered at risk of exposure to Nipah virus (NiV). To reduce the risk of infection, virus shedding and further virus dissemination. To be used in conjunction with other control measures including on-going diagnostic monitoring. 		An accompanying DIVA (Differentiation of Infected from Vaccinated Animals) test is required.
Target population	<ul style="list-style-type: none"> Swine of all ages will be targeted by this vaccine. 		<p>In order to prevent spread of NiV during an outbreak situation, it will be important to be able to cover all animals on a farm with an initial blanket vaccination and not leave a susceptible sub-population.</p> <p>One day old pigs are part of the target.</p>
Safety / Reactogenicity	<ul style="list-style-type: none"> Equivalent to current vaccines. Ideally no adverse effects but a mild rise in temperature and a short period of post-administration depression would be acceptable, as would mild injection site inflammation. Must be safe for use in pregnant and lactating sows and breeding boars. 	<ul style="list-style-type: none"> Reactogenicity could be higher as this vaccine is to be for emergency use. Anaphylactic type reactions, severe injection site lesions, loss of appetite or depression would be unacceptable. Any significant increase in abortions or reduction in reproductive performance after use in breeding animals would be unacceptable. 	
Measures of efficacy	<ul style="list-style-type: none"> Vaccinated pigs should resist challenge, with rapid elimination of challenge virus. There will be no persistent infection and no shedding. 	<ul style="list-style-type: none"> 100% sterilising immunity is probably an unreasonable target. A high level of efficacy will be required to generate confidence that a vaccinated herd will not act as a source for subsequent spread of NiV. 	<p>Protection of pigs from clinical disease is not the main parameter.</p> <p>Preventing virus spread, either to humans or other pigs, is the main objective.</p>

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Dose regimen - pigs over 3 weeks of age	<ul style="list-style-type: none"> • Single dose. • Probably given as part of a blanket vaccination of all pigs on the farm. 	<ul style="list-style-type: none"> • No more than two doses, 2 to 3 weeks apart, as primary course. 	<p>Ideally the vaccine should reliably induce immunity after a single dose.</p> <p>In practice, two blanket vaccinations of all pigs 2 to 3 weeks will minimise the risk of missed or non-responding individual pigs.</p>
Dose regimen - pigs under 3 weeks of age	<ul style="list-style-type: none"> • Two doses. • 2 to 3 weeks apart. • For on-going use on breeding farms (where piglets are born after a blanket herd vaccination), the first dose will be given in the first few days of life and the second at 3 weeks of age. 	<ul style="list-style-type: none"> • A third dose at 6 weeks of age to catch a few pigs not responding at 3 weeks of age. 	<p>Young piglets should receive 2 doses as there is a risk of non-response.</p> <p>Sow farms will need to vaccinate new piglets on an on-going basis and these will soon be from vaccinated sows. This will increase the risk of vaccine failure because of maternal antibody interference.</p>
Duration of protection	<ul style="list-style-type: none"> • 23 weeks. • This will cover the typical lifespan of a fattening pig if vaccinated at 3 weeks of age. 	<ul style="list-style-type: none"> • 3 months. 	<p>Compulsory blanket re-vaccination could be repeated every few months while the outbreak is ongoing.</p> <p>The objective will be to stop vaccination once an outbreak is controlled.</p>
Route of administration	<ul style="list-style-type: none"> • Intramuscular injection. 		<p>Intra-muscular injection is standard practice and likely to be the only satisfactory route when full compliance is important.</p>
Coverage	<ul style="list-style-type: none"> • Known strains of Nipah virus. 		
Product stability and storage	<ul style="list-style-type: none"> • Preferably, no cold-chain required. 	<ul style="list-style-type: none"> • Refrigeration until time of use. 	<p>Refrigeration with ambient temperature toleration for a few hours would be adequate.</p>
Co-administration with other vaccines	<ul style="list-style-type: none"> • Ideally, the vaccine can be administered at the same time as other standard vaccines for pigs, but at a different injection site. 	<ul style="list-style-type: none"> • Must be administered on a different day to other vaccines. 	<p>Piglets get a lot of vaccines.</p> <p>Having a lengthy period without administration of other products would be difficult.</p>

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Antigen	<ul style="list-style-type: none"> The choice of antigen is flexible but must have DIVA potential. The bulk antigen should be stable for 24 months at 4°C. 	<ul style="list-style-type: none"> The bulk antigen must be stable for 12 months at -80°C. 	<p>DIVA potential and an accompanying test are essential.</p> <p>Test must be able to confirm that a vaccinated herd has not been exposed to wild virus.</p>
Presentation	<ul style="list-style-type: none"> The vaccine should be in a ready-to-use liquid formulation with a dose volume of 1 mL. Supplied in multi-dose vials of 10, 50 and 250 doses. 	<ul style="list-style-type: none"> Lyophilised powder for reconstitution with diluent to create a dose volume of 2 mL. Supplied in multi-dose vials of 10, 50 and 250 doses, with accompanying vials of diluent. 	
Registration and Prequalification	<ul style="list-style-type: none"> The product and procedure must be pre-approved for implementation should defined circumstances (i.e an outbreak) arise. 		
Operator safety	<ul style="list-style-type: none"> No exceptional precautions. Preferably no mineral oil-related warnings about self-injection. 	<ul style="list-style-type: none"> Significant human safety risk from self-injection is unacceptable. 	
Withdrawal period	<ul style="list-style-type: none"> None. 	<ul style="list-style-type: none"> Short (<7 days) or local standard if there is one (some countries have a default withdrawal time for all vaccines). 	<p>Withdrawal times are not a problem for vaccines given to piglets, but this vaccine will also be given to sows and pigs in late fattening.</p>