UKHSA and Stablepharma highlight breakthrough with fridge-free tetanus and diphtheria vaccine

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'Fridge-free' vaccines have huge potential for vaccine delivery in emergency response situations and the developing world.

Scientists from the UK Health Security Agency (UKHSA) have provided specialist laboratory testing for a fridge-free tetanus and diphtheria vaccine that could help address the global challenges of distribution, storage, wastage, and CO2 emissions associated with temperature-sensitive medicines. UKHSA has been working with Stablepharma Ltd, a UK pharmaceutical company, to test their thermostable, fridge-free tetanus and diphtheria vaccine called SPVX02.

Phase 1 human trials have now been completed and evaluation of the trial results, conducted at UKHSA's Vaccine Development and Evaluation Centre (VDEC), suggests that the vaccine remains effective without the need for refrigeration, even after long-term storage at 30°C for 24 months. SPVX02 will now progress to the next stage of clinical trials to confirm these findings. This will involve a clinical trial in a larger number of healthy participants and will compare the effectiveness of SPVX02 to another vaccine already licensed for use in Europe. The trial is expected to be conducted at clinical study sites in the UK over the coming months, and UKHSA will continue to support the trial by testing immune responses to the vaccines administered to the study participants.

This a significant step towards overcoming one of the major barriers to meeting immunisation targets across the world. Most vaccines must be stored at a constant cold temperature from the point of manufacture until they are administered to a patient. This is known as the 'cold chain'. When that chain is broken, vaccines can lose effectiveness and may have to be discarded. The World Health Organization (WHO) estimates that up to half of all vaccines do not reach their intended recipients and cites the difficulty in maintaining this cold chain as a major reason for this wastage.

Maintaining the cold chain is particularly challenging in remote areas, during natural disasters, or in countries with unreliable electricity supplies. A vaccine that does not require a cold chain to be effective could therefore be an enormous benefit. It would have the potential to dramatically reduce wastage, simplify distribution, and make immunisation programmes more resilient, especially in the developing world or emergency response situations.

Supported by Innovate UK and the National Institute for Health and Care Research (NIHR) Southampton Clinical Research Facility, the SPVX02 programme is an example of the UK biotech industry, government, and academia working together to improve vaccine access, reduce waste, and strengthen global health resilience.

Dr Bassam Hallis OBE, Deputy Director and the lead for the Vaccine Development and Evaluation Centre at UKHSA, said:

> The progress in fridge-free vaccine technology is an excellent example of the huge contribution that the UK continues to make to transform public health through innovative technological and scientific advances. Fridge free vaccines could provide

> significant benefits for vaccine delivery and deployment across the world, particularly in areas where limitations in infrastructure make maintaining a cold chain more challenging.

Dr Karen O'Hanlon, Chief Operating Officer at Stablepharma and SPVX02 programme lead, said:

> Vaccines that do not require refrigeration at any point, from manufacture to deployment, offer a clear path to a more equitable, resilient, and sustainable healthcare system. They represent not just a scientific innovation, but a public health and climate solution—especially as we prepare for future pandemics and strive toward universal vaccine coverage.
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> SPVX02 represents a practical step toward fridge-free vaccines and medicines that reach more people, with fewer supply-chain constraints and lower environmental impact. We are really grateful for the continued support from UKHSA, Innovate UK, and NIHR, which is turning a bold concept into clinical progress.

Professor Saul Faust, Director of the NIHR Southampton Clinical Research Facility said:

> The NIHR Clinical Research Facility and UKHSA collaboration with Stablepharma has accelerated the translation of this technology from laboratory science to potential patient impact and reinforces the leading role that the UK plays globally in vaccine research, development, deployment and evaluation.

https://www.gov.uk/government/news/ukhsa-and-stablepharma-highlight-breakthrough-with-fridge-free-tetanus-and-diphtheria-vaccine