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## Disruptive Innovation – Game Changing Sustainable Insulation for Pharmaceutical Cold Chain Packaging.

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This paper addresses the compelling environmental and commercial arguments against the widespread use of polymer based passive insulated packaging materials for the global distribution of temperature sensitive pharmaceutical and healthcare products. It describes the successful design, development and commercialisation of an innovative and radical alternative, manufactured from a natural, sustainable, compostable and renewable fibre material.

As far back as 2005 The World Health Organisation (WHO) reported that up to half (50%) of all vaccines transported globally were ruined due to poor distribution procedures, with a resulting significant impact on human life. Vaccine damage is caused mostly by failings in cold chain logistics and current man-made insulated packaging materials.

Polymer-based insulated packaging materials, such as polystyrene, are not sufficiently effective at maintaining temperature control and are neither sustainable nor environmentally friendly.

Today, in 2015 the situation remains unchanged. It is now widely recognised by the Pharmaceutical industry - reinforced by new EU Good Distribution Practice (GDP) legislation in 2013 - that there is a growing and urgent need for an effective, genuinely sustainable and environmentally responsible passive insulated packaging solution for the global distribution of temperature sensitive healthcare products under varying climatic temperature conditions.

Cold-chain temperature control is necessary to prevent damage to life-saving vaccines caused by heat exposure. However, keeping vaccines too cold is just as harmful as keeping them too warm, since freezing damages many vaccines. Freezing of vaccines can cause loss of potency that can never be restored. Protecting vaccines from freeze damage remains one of the most poorly addressed problems in vaccine management. Using freeze-damaged vaccine makes it harder to achieve global disease-prevention goals. Cold-chain practices tend to prioritise the protection of vaccines from heat damage, often at the risk of inadvertently exposing them to freezing temperatures instead.

The maintenance of accurate and uniform temperatures is therefore, of significant importance in improvements to global human healthcare. Since vaccines are protein preparations, temperatures above or below the optimal range will cause unfolding and denaturing of the protein. Exposure to heating or freezing conditions will weaken and subsequently break the hydrogen bonds holding the tertiary structure together, causing the vaccine to lose its specific shape and become ineffective.

This paper demonstrates the design innovation process leading to the development of a high-performance, sustainable fibre material, with true cradle-to-cradle credentials, that has transformed the market for passive insulated packaging used in the global distribution of temperature sensitive pharmaceutical products for human use. The extensive scientific research into the characteristic insulation properties of this natural 'smart fibre' has resulted in an insulated packaging material that substantially exceeds the temperature performance criteria required by European and USA Good Distribution Practice (GDP) regulations for the distribution of medicines.

This 'Smart Fibre' is 100% pure sheep's wool.