

How Temperature-controlled Packaging Innovation is Helping the Animal Health Sector Ensure Vital Vaccine Compliance



Temperature-controlled packaging advancements are often automatically associated with the human healthcare and pharmaceutical sector, however they are playing an ever more pivotal role within the animal health field.

There is a growing trend for the type of sophisticated thermal packaging design traits, traditionally utilised within the human pharmaceutical industry, inspiring improved temperature-controlled packaging (TCP) solutions which are becoming more widely available to the animal health sector.

These more advanced TCP products are being increasingly incorporated within animal healthcare to ensure vaccines and medications are transported safely, while complying with rigid, regulatory requirements.

There are costly implications if vital vaccines are not stored and transported at the correct temperature, or if they are exposed to temperatures outside the recommended ranges.

If vaccines become too cold or hot at any point, it can have wide-reaching repercussions, with any temperature excursions potentially resulting in the vaccine losing its effectiveness. As they naturally biodegrade over time, storage outside of any recommended temperature range, including during transportation, may accelerate this deterioration and compromise the vaccines' capabilities when providing perceived protection.

Those handling such vaccines should ensure they are aware of, and meet *all* the necessary cold chain compliance requirements, to help protect vaccines and medications destined for use on animals.

New innovations within the TCP industry are aiding the day-to-day operations and necessary cold chain compliance requirements of professionals within the animal sector. This is beneficial for veterinary surgeons, like Richard Sanderson, who are at the frontline of animal welfare and healthcare on a daily basis.

Robust and highly-engineered packaging, though traditionally well-established within the pharmaceutical sector, is increasingly being utilised within animal healthcare for a range of essential practices, including vital vaccine compliance.

It's an industry step in the right direction as the working methods of vets continue to evolve; the professional sector is seeing a rise in the trend for home visits and more mobile veterinary care.

These emerging practices within the animal healthcare profession increasingly require the longer transportation of time and temperature-sensitive drugs.

As a consequence, those operating within the industry increasingly rely on TCP vendors, serving the sector, to provide ever more innovative products they can trust to ensure the safe and compliant transportation of medicines and vaccines.

As Neil Sherman, Technical Services Manager at Intelsius outlines the latest developments in the TCP sector, vet Richard Sanderson, who works in mobile veterinary care, said he welcomes these industry initiatives and explains the positive impact it is making to his profession...

In regard to vaccines, vaccination compliance or compliance of the storage of vaccinations, is absolutely paramount to the safe and legal use of these medications.

Vaccinations or core vaccinations are obviously very important in terms of protecting human and animal health and in a marketplace whereby there is more and more scepticism about vaccinations, I think it is absolutely paramount that we effectively store and effectively prescribe these medications.

The appropriate storage of medication and vaccinations is vital within the Veterinary Medicines Directorate (VMD) guidelines and the Royal Veterinary College Guidelines for the responsible prescription of medicines. In order to ensure we avoid avoidable vaccine reactions it is critical that we maintain vaccinations at the right temperature.

This is particularly important in the mobile veterinary services like mine, whereby we can be travelling for up to an hour with that medication. Without maintaining that vaccination at the right temperature, we can't be confident the vaccine is safe to administer and we can't be confident the vaccination will be effective and that it will remain biologically stable.

This is also very important in the large animal industry, particularly in farm animal or equine practice. Appropriate maintenance of vaccinations or the cold store of pharmaceuticals is paramount to stay within the right licensing guidelines, within the VMD recommendations and within the Royal College's Code of Professional Conduct.

In the case of farm animals or food producing animals, it is incredibly important to maintain vaccinations and pharmaceuticals at the correct temperature, because any withdrawal periods for the safe use of milk or meat are obviously based upon the safe and appropriate storage and transport of the drugs.

Without maintaining that, you would effectively establish a mandatory off licence withdrawal period. Therefore those animals may not just be unprotected and they may well be compromising the food chain, and subsequently human health.

So keeping vaccinations at the right temperature and storing them in the right way is paramount to their safe and legal use.

What does vaccine cold chain mean?

My definition of the vaccine cold chain would be that the vaccination was produced to an acceptable standard, is maintained and stored at the same standards, and then safely and legally prescribed.

In the case of vaccinations, that means that they need to be stored between the licensed parameters whilst waiting to be used and whilst being transported.

What are the consequences of a vaccine not being transported at the right temperature?

Without properly storing vaccines you can't be certain whether it is safe to administer and you can't be convinced that it will be effective. In the case of vaccinations, that would be providing protection to the individual (or herd). It would also cause a potential issue with vaccine reactions, which in the most extreme form can be fatal.

Severe vaccine reaction is more likely if the medication is not properly stored, which can obviously cause fatal consequences and in the food producing industry the failure to maintain that cold chain could have ramifications not just on animal health but also on human health.

Who will know if you are being compliant?

Any prescriber of medication must be suitably qualified, e.g. MRCVS, SQP. All veterinary practices in the UK must be Registered Veterinary Premises with the Royal College of Veterinary Surgeons. There is an optional Practice Standards Scheme, which sets out a series of guidelines including the responsible prescription of medicines. Those not in the scheme undergo compulsory Veterinary Medicines Directorate assessments.

The VMD standards inspector will assess the premises, they will assess the medications, and in the mobile or ambulatory services, will check the car/van, asking for demonstrations on how medications will be safely stored and transported.

I have a mobile, temperature-controlled storage device, which enables me to transport vaccinations for up to five days at a certain temperature that is suitable.

Vets are required not just to have these procedures in place but also to keep records. As part of an inspection, the inspector will ask to see my thermometer/temperature data logger readings, and my minimum, maximum and average readings, over a period of time, selected at their discretion.

Vets need to keep definite detailed data to demonstrate these temperatures with details of everything.

We have refrigerated items, so we have thermometers in the fridge where the vaccines are stored on site, as well as having temperature data loggers in our mobile transport

device, which will be monitored for required records.

A development within the medicine and vaccine compliance field helping vets ensure temperature-monitoring reliability is increasingly being aided by ever more sophisticated temperature data loggers, which are easier than ever to use.

These devices monitor temperature data inside the passive system (as opposed to a unit that requires a power source) being utilised by vets to store and transport vaccines and medications. Some data loggers can generate PDF reports straight away when plugged into a laptop, which helps with record-keeping.

Some temperature data loggers in the current marketplace have Bluetooth built in and come with mobile apps, meaning the data can be viewed without having to open up the box transporting the vaccines or medications.

Ultimately, the sector is well regulated to ensure that those medicines are being safely prescribed.

What are the consequences of not being compliant?

Very simply, you could be risking human and animal health. And this means the prescriber is susceptible to professional and legal consequences.

An incorrectly stored or prescribed product may lose its efficacy. In the case of vaccination, this means a failure to protect the individual from the disease. This also means a lower proportion of the population is protected, and this can promote the spread of disease.

You could have vaccine reaction from one end of the spectrum whereby the injection might be more "stingy" – for example, that could be something we see in small animals – right through to fatal consequences.

In the food producing industry we may well be compromising the food chain by using the vaccines outside of their licence, which would impact withdrawal periods. In the farming and equine industries, failure to be effectively medicated may breach the rules set out in the Animal Welfare Act, for example. A good example could be rabies vaccination in dogs. If the vaccine didn't work as it wasn't correctly stored, and the dog subsequently imported into the UK, it is not impossible for us to end up with an outbreak of a major and fatal human and animal disease.

The consequences for any veterinary surgeon could be, if we don't appropriately store and responsibly store those medications, that we are in breach of the Royal College's Code of Professional Conduct, so we could face a professional misconduct investigation.

It is potentially serious because, for me, the most important thing is that we have a responsibility for the safe storage and therefore the responsible prescription of these vaccinations, which is absolutely paramount to promoting and maintaining animal health.

I already have a fridge at my practice; what can I use when I'm off site?

Most practices will have a main pharmaceutical-only refrigerator, and then we may have approved chillers inside the consultation room, and these will be temperature-controlled and temperature-maintained.

In terms of a mobile business, we are organised and we try to take out no more than we require, because obviously maintaining within a static fridge is the best and the most appropriate place. So we try not to take out any more than we require in any one day.

So we feel you should stock your car on a day-by-day basis, not a week-by-week basis. What we have is a temperature-controlled box which maintains the inside temperature between 2 and 8 degrees for up to five days, and inside that we would have a thermometer and an indicator to ensure that temperature is being maintained as we would expect. We would stock that each morning and destock it each night.

How can I prove that I'm being compliant?

It is paramount to ensure everyone understands the legislation and understands the importance of the legislation. So an understanding of the potential ramifications is obviously key, and continuing professional development and regular education are vital. So we spend time with our staff on a regular basis reminding them of the importance of this.

We couldn't offer a mobile veterinary service and offer safe and responsible prescriptions and vaccinations or other pharmaceuticals, without such a mobile cooling device.

I don't think we could offer the wide level of care or stay within the RCVS Code of Professional Conduct otherwise, and for me a mobile device, like the one we utilise, is crucial to maintaining those standards.

How critical is continuing innovation and collaboration with the TCP industry to ensure you can carry out your work effectively?

Without ongoing innovation, without access to those products, my business couldn't operate and we wouldn't be able to offer the services we do – it would be impossible.

So far, the TCP industry has typically been based on human health, but increasingly vets are gladdened to see veterinary-focused providers and products entering the market to better support their work.

However, within the industry there is a further need for more education about the importance of cold storage, and these facilities being used correctly.

Having an interest in the legalities from my law education, I feel unfortunately we are now in a society where ignorance is not necessarily bliss, and not knowing is no longer acceptable in today's society.

It is absolutely crucial that sector education is given

towards veterinary surgeons and veterinary students, to physically get involved right from the veterinary university student days through to the profession, to remind people that this is important.

I am a prime example of this ongoing need; as a vet I didn't realise that these products existed until I felt I needed them in order to offer the right level of service.

I think that the TCP industry needs to work with the animal health profession more closely, to explain the benefits of these products and the reason they should do it, because as veterinary surgeons we are advocates for animal welfare. I believe these kinds of TCP products allow us to be better advocates for animal welfare.

From a TCP manufacturing standpoint, all those transporting and administering temperature-sensitive materials need to have an understanding of the impacts of temperature excursions and the measures needed to properly protect pharmaceuticals. A picnic box with a couple of ice blocks really doesn't cut it, but is currently one of the most used solutions.

Innovation-wise, in your career to date have you seen advancements within the innovation of the TCP products, and do you feel there is a need to raise greater awareness of what is on offer in the marketplace?

To help aid regulatory compliance, a greater understanding and awareness of the latest innovations within the TCP industry and what they have to offer the animal health sector would be beneficial.

When looking for a suitable mobile device, I was surprised to find out these mobile devices had been in existence for several years.

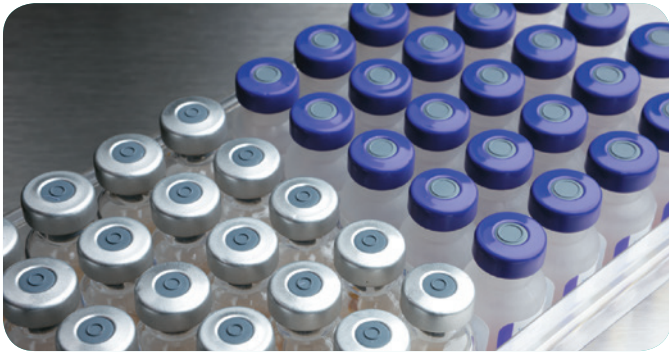
I think these more advanced TCP products are innovative because they are able to maintain temperature for five days confidently, which I think is revolutionary. That was the key factor when deciding what to buy; the fact that in an emergency situation we could get five days out of one – however, I think we could move them on further.

These devices could become more innovative and I would massively encourage the opportunity to increase awareness that these products exist to the wider animal health industry.

Another major change is the use of phase change materials over water ice. These are materials which melt at temperatures other than zero, and so are incredibly effective at holding vaccines at these alternative temperatures. A lot of vaccines and pharmaceuticals are incredibly sensitive to damage from freezing, so by removing all elements at 0°C you vastly decrease the chance of temperature excursions from going too cold.

When selecting your TCP mobile device, how important was it to opt for a passive product as opposed to a portable fridge, which requires power sources?

The passive TCP mobile product I use is completely power-



free, and this was key for me. One of the big drivers for us is not inconveniencing clients – it's a very demanding client base given the nature of what we do, and the key for me is that we should be able to maintain temperature in the car – but we should also be able to take that device into the house and not require support from that house.

So we can go to any site – any farm or field, any stables, any property anywhere – and be completely independent of electricity.

We freeze the product overnight and then we do our routine quality checks to ensure that it is the right temperature, and then we are good to go.

It was important for us to be independent of any car or electric support, as this widens the scope and range of its application.

There are relatively few mobile vets and it is a relatively innovative area within the profession, and we are looking to grow and expand. We want to increase the opportunities for clients to access the mobile world.

When it comes to vaccines and the large animal industries, what is interesting is the evolution of the profession towards a more companion animal bias. The number of large animal practices is reducing, the number of horse practices is reducing, and the number of small animal practices is growing.

That means that farm and horse vets are travelling greater and greater distances and that makes mobile cold chain devices, like we have, become even more important and more crucial.

The mobile companion animal visits will grow, and in rebound, so will the mass corporatisation of the profession. So as the profession becomes more corporate, more people will take on mobile services, and mobile services are, in my

opinion, one of the most effective ways of offering high-level veterinary care.

In equine and livestock, as these practices reduce in number and the distances increase, an effective mobile cold storage becomes more paramount and they will not be able to safely run without such devices.

It is important to remember it is not just vets having these products. Lots of products can be used by farmers, for example, on herds (which are getting larger in size). As such, the products may be in the field for several hours, and often this is done in the warm summer weather. This is an active role where we should be educating farmers on having safe storage of these products and effectively administering them.

We use our mobile temperature-controlled device for vaccinations and pharmaceuticals. Anything that needs refrigerating or kept at a cool temperature, we carry in our mobile device, but we stock on a day-by-day basis to maximise efficiency and reduce risk; if we had a fail in the box, everything would go with it.

In some circumstances, a vet could be carrying pharmaceuticals and vaccines worth thousands of pounds, so having a device that is trustworthy is crucial.



Neil Sherman is Technical Services Manager at Intelsius, responsible for overseeing new product development, assessing new marketplace technologies, assisting with technical sales enquiries and managing the ISTA-certified testing laboratory. He is responsible for driving continuous

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Neil holds a Master's degree in physics from the University of York and has been instrumental in the design and development of some of Intelsius' most innovative packaging.



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