

Sofrigam

THE COLD CHAIN NEWSLETTER



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Sofrigam



3rd Seminar on the Cold Chain for Healthcare Products, November 2012: Mr Jean-Pierre Paccioni, Chairman of Section B of the National Council of the Order of Pharmacists,

drew attention to the ineffective nature of the insulated packaging solutions distributed to patients for the transportation of medicinal products from the pharmacy to their homes.

We have encountered many such cases during our visits to healthcare establishments and pharmacies. These professionals are suffering from a lack of familiarisation and information regarding the practical aspects of managing and securing the cold chain. As privileged representatives in direct contact with patients, their role of providing advice and raising awareness is, however, particularly important.

In this regard, the quality and performance of the insulated packaging solutions used for supplying medicinal products are highly variable and do not comply with precise sets of specifications, a problem that has been reported over many years by the manufacturers of packaging solutions. Sofrigam has invested in the creation of the Certicold Pharma label, which guarantees the quality and performance of insulated packaging solutions and all the cold storage equipment used for the transportation of healthcare products.

This label was awarded to our Nomad Slim insulated sheath in June 2014. This solution has revolutionised the market: made entirely of fabric, it can be reused more than a hundred times and its thermal properties can be adapted for use by patients. We designed this pouch to comply with a request by the Council of the Order, in order to have commercial access to a suitable packaging solution, with a minimum cooling capacity of half-an-hour within the strict temperature range of +2 to +8°C.

We will be delighted to show you our Nomad Slim sheath, with its Certicold Pharma label, at the 4th Seminar on the Cold Chain for Healthcare Products on November 26 and 27 this year.

In the meantime, enjoy your reading.

GILLES LABRANQUE
Chairman

CERTICOLD PHARMA, THE LABEL FOR REFRIGERATION EQUIPMENT IN THE HEALTHCARE SECTOR

Faced with the absence of sets of precise specifications for the various insulated packaging solutions used in the commercial sector, the National Council of the Order of Pharmacists asked Cemafruid, an independent certification organisation specialising in the cold chain, to conduct a survey of the 'suitability for use' of these products.

The findings were beyond doubt. 10 insulated packaging solutions were tested: on average, their endurance failed to exceed 5 minutes (the full set of results will be presented at the 4th Seminar of the Cold Chain). In parallel, a committee of independent members, composed of players associated with the cold chain, working with the Order of Pharmacists and under the guidance of Cemafruid, created the Certicold Pharma label. The committee consisted of users (pharmaceutical laboratories, hospitals, distributors), manufacturers of cold storage equipment (insulated containers, refrigerated trucks, climatic chambers...), cold chain experts and administrative institutions. As a result, the Certicold Pharma label guarantees the quality and performance of cold chain equipments used in the healthcare sector: climatic chambers, temperature indicators, insulation and refrigeration equipment and insulated packaging solutions.



The label exceeds existing statutory requirements by defining, in a set of precise specifications, a number of additional characteristics that are indispensable for guaranteeing the quality of the cold chain elements: enhanced insulation, control and inspection of the insulating materials, equipment leak tests and efficacy tests, etc. The set of specifications combines thermal and mechanical properties, criteria of conformity with the relevant regulations and standards (GDP 2013 / AFNOR Standard NF S 99-700) and environmental performance indicators based on 3 criteria: the effects of greenhouse gases, destruction of the ozone layer and depletion of resources.

A guarantee of quality, safety and fair pricing which enables users to compare products with similar characteristics at an objective price base. A pledge of transparency which has become necessary in a market which nowadays offers numerous tested and qualified solutions for the transportation of pharmaceutical products but no guarantee regarding their reliability and their conformity with current regulations.

A list of equipment certified to the Certicold standard is available on the website at www.certicold.fr

A QUALITY LABEL THAT COMPLIES WITH THE REQUIREMENTS OF GDP

By Eric Devin, Chairman and Managing Director of Cemafruid and Marie Boned, Quality Control Pharmacist at Cemafruid

The pharmaceutical regulation of good distribution practice requires that the choice of packaging solution must be based on the volume required for the quantity of medicinal products, the anticipated peaks of outside temperature, the estimated maximum time in transit and the qualification status.

Certicold Pharma Emballage is a quality label that guarantees that these requirements have been verified and tested. Certicold is a voluntary initiative which enables the pharmacist to have confidence in the labelled products based on evaluations made by the third party organisation in the form of quality audits and thermal tests.

INSULATED POUCHES

Between 8 and 10 million – that is the number of insulated pouches sold every year in France. They are intended for the short-duration transportation of small quantities of heat-sensitive healthcare products. In the main, these are vaccines and insulin, transported from the pharmacy to patients' homes or during very short trips.

The challenges are considerable, since a period of two minutes at ambient temperature is sufficient for heat-sensitive treatment to exceed a temperature of +8°C, often without any outward indication on the product. At best, the product becomes ineffective and, at worst, it may even become toxic. In order to maintain the therapeutic properties of the product while it is in transit, it is essential to use the appropriate insulated or cooling pouch.



The most common types of pouch used for this purpose are made from white or aluminised polyester. They offer the benefit of protecting the product for a limited period of time and they are cheaper. The main disadvantage is that their effective cooling capacity is often less than 30 minutes, which leaves little room for manoeuvre on the part of the patient, who must keep in mind that this is because the product is protected by an insulated pouch which he must place in a cool box as quickly as possible. Finally, while it is true that this type of pouch is reusable, its reuse is very limited if the effectiveness and reliability of the product are to be maintained.

For longer storage periods, the best form of protection is offered by insulated shoulder bags or more sophisticated insulated pouches, which maintain a constant storage temperature of +2 to +8°C and which can be reused for several years.

NOMAD SLIM, THE INSULATED POUCH WITH THE CERTICOLD PHARMA LABEL

An understated and elegant design, slim enough to fit discreetly almost anywhere, all-fabric construction for maximum durability and performance characteristics certified by the award of the Certicold Pharma label, the Nomad Slim pouch is a small insulated pouch with a deceptively large carrying capacity.

Specially designed for transporting vaccines, insulin or other heat-sensitive treatments that must be stored at a constant temperature of between +2 and +8 °C, the Nomad Slim pouch will maintain products at a temperature of +30 °C for up to one-and-a-half hours and for more than two-and-a-half hours in an environment at +20° C*. Sufficient to easily transport medicinal products from the pharmacy to a patient's home in complete safety.

Designed with great care, every effort has been made to ensure that they are easy to use. Two pockets have been provided for inserting eutectic gels, the cold source that prevents fluctuations in temperature in order to safeguard the efficacy of the treatment. The gel packs do not come into direct contact with the product, so as to prevent it from freezing. The pouches include 3 compartments to accommodate pen injectors.

Its Certicold Pharma label attests to the fact that it has been certified compliant with the standards and requirements defined in the set of Certicold Pharma specifications, in order to satisfy the expected functionalities and that it has been the subject of continuous quality control by Cemafroid.

A top-quality and effective insulated pouch, the very first to be awarded Certicold Pharma certification.

* Performance characteristics guaranteed subject to proper use in accordance with the product instruction leaflet.



NEWS

Sofrigam will be exhibiting at the following events:



IQPC
'Cool Chain Europe 2015'
26/29 January,
Frankfurt, Germany



'Pharm Connect Congress'
25/26 February,
Budapest, Hungary



Arena
'Clinical Trial Supply Europe'
25/26 February,
Cannes, France



Hopipharm
20/22 May 2015,
Reims,
France

CONVERSATION WITH GÉRALD CAVALIER, CHAIRMAN OF CEMAFROID

Interview by Martine Geslin



Tell us more about Cemafruid.

Gérald Cavalier: As an independent private certification centre, Cemafruid has 60 years of experience in conducting trials and the certification and qualification of companies, products or services. Shareholders in the Company include its experts, the State and professional associations. Actively involved in statutory certifications, in particular for the World Health Organisation (WHO), Cemafruid is also concerned with voluntary certifications, such as Certicold Pharma. Our objective is to provide a guarantee of conformity for the products that our specialists analyse, compare, test and measure. Our experts (technicians, engineers, doctors) and certification teams visit companies in order to perform audits and evaluate the performance characteristics of the various products to be assessed, as well as providing training for users.

What are the various stages in the certification process?

A 'Labelling Committee' is set up, comprising users of the packaging solution and government agencies. For example, in the case of the Certicold Pharma label, the Committee consists of pharmaceutical laboratories, distributors, hospitals, equipment manufacturers – such as Sofrigam – experts such as Cemafruid and administrative bodies such as La Direction Générale de l'Offre de Soins (DGOS) [French Directorate General for Care Provision] and the Council of the Order of Pharmacists.

The Committee draws up a set of specifications containing all the requirements for obtaining the label. After a general description, tests and trials conducted internally by the manufacturer in order to qualify his product, he then formulates a qualification request dossier. For its part, Cemafruid performs conformity checks in its laboratories, based on the rules applicable to the label. The experts then conduct an audit within the company in order to provide a guarantee of best practice in the production process. Samples of the product, taken from the production line, are inspected in the Cemafruid laboratories in order to guarantee that the key performance parameters of the product have in fact been maintained and that they satisfy the levels of quality required by the specifications. If every one of these stages is successfully completed, the label is awarded.

More specifically, how did Sofrigam approach the certification process?

Naturally, Sofrigam was involved in the certification process for its Nomad Slim pouch, in order to confirm the quality of its products and its desire for innovation. Sofrigam is the first manufacturer in its commercial field to be awarded the Certicold label. Certification of the pouch represents a real advance in the transportation of heat-sensitive healthcare products dispensed to patients. It satisfies the expectations of healthcare professionals and the requirements of the last link in the cold chain, faced with shortcomings in terms of the quality of packaging solutions.



YOUR INSULATED PACKAGING SOLUTION IS JUST A FEW CLICKS AWAY WITH THE COLDSHOP



The Coldshop is the online sales website created by Sofrigam to provide healthcare professionals and individual customers with professional-standard insulated packaging solutions for transporting medicinal products via the cold chain. More than 100 different types of insulated packaging solutions are available to buy online: containers, cooling boxes, cooler bags, insulated pouches, together with a range of accessories, to satisfy any requirement.

Don't delay, find out more at www.coldshop.com!

SOFRIGAM, NO. 1 IN EUROPE IN INSULATED SHIPPING PACKAGING

Expert in cold chain logistics, Sofrigam develops insulated and temperature-controlled packaging solutions designed to secure, optimise and ease heat-sensitive pharmaceutical products transportation.

Key figures

- +50 employees
- +85 % export turnover
- F3 rated by the Bank of France
- 2 sites in France: Rueil-Malmaison (headquarters) and Monchy-le-Preux (plant)
- 1 site in North America
- Certifications: ISO 9001:2008, ISO 14001:2004 and ISTA.