





Whitepaper Pharmacy

Maintain quality: transport your medication under the right conditions

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## Regulatory framework: the GDP guidelines

Let us first consider what the law prescribes. In order to guarantee the quality of medication, the Good Distribution Practices (GDP) guidelines have been drawn up in the Netherlands. Such guidelines exist in other countries as well. These apply to wholesalers and manufacturers of human medicines.

The GDP guidelines are intended to maintain the quality of medication at all stages of the distribution chain. Both at the time of transport and at the time of storage. The GDP guidelines are regularly tightened, for example because newly developed, complex medication is even more sensitive to temperature changes during distribution.



The importance of the temperature at which medicines are stored and transported is reflected in two prominent issues discussed in the GDP guidelines:

- Temperature conditions: For temperaturesensitive products, appropriate means must be used to ensure correct transport conditions between manufacturer, wholesaler and customer. Means of transport may include, for example, packaging or certain means of transport.
- Temperature monitoring: In order to ensure that the medication is transported at the correct temperature, monitoring equipment should be installed to identify any temperature anomalies and fluctuations.

# Professional standards outside wholesalers and manufacturers

The Health Care Inspectorate inspects compliance with GDP and issues certificates to an organisation when a location meets these requirements. However, it is important that everyone in the chain, not just the pharmaceutical companies, guarantees the quality of the medicines.

Hospital pharmacists and community pharmacists, for example, have drawn up their



own professional standards. These lay down requirements for the storage and transport of medicines. In practice, however, it appears that the refrigerated shipment of temperaturesensitive medication from (hospital) pharmacies is not always carried out correctly.

### The right transport conditions for medication

During the storage of medication, the temperature can be regulated reasonably easily. However, when the medication has to be transported, this presents new challenges. There are a number of important points to consider when transporting medication. These points of attention are important for both small-and large-scale transport.

Firstly, the temperature of the medicines must be monitored. The medicines must be kept at the correct temperature throughout transport. Different temperature ranges may be required for different types of medicines. For example, the range of 2-8 degrees Celsius is suitable for many types of medicines. Such a temperature can be achieved perfectly well with regular gel packs. But there are also medicines that have to be transported within a specific temperature range below freezing or above 8 degrees. For certain medicines, these must be transported at an ambient temperature of 15-25 degrees Celsius. To achieve this, gel packs can be filled with Phase Change Material: a special filler with which a wide and specific range of temperatures can be reached. The longer such goods are on the road, the higher the quality of the PCM must be.

Secondly, it is essential to ensure that medicines and their packaging remain dry. When refrigerants such as gel packs are used during transport, surface condensation can form along the way. This condensation can be captured by using absorption mats. In this way, the medicines remain dry and the quality is guaranteed.

Thirdly, the GDP guidelines stipulate that certain medicines must not come into contact with cooling elements during transport. There are several simple ways of achieving this. Think, for example, of placing a partition between the cooling element and the medicines. You can use all kinds of materials for this. A suitable option, for example, is an absorption mat.

#### Different options for medicine transport

There are various options for the refrigerated transport of your medication. For example, you can choose to use a refrigerated or freezer van. There are several companies in the Netherlands that offer refrigerated transport in this way. The downside of this, however, is the dependence and low flexibility of this transporter. Moreover, for small deliveries it is a shame to use an entire refrigerated van: if the van remains largely empty, this is unfavourable from a cost point of





view as well as in terms of energy consumption. The cost of transport by refrigerated or freezer van is already relatively high.

Another popular option is the use of special packaging. Customisation is possible. For example, you can pack the medicines in an insulating EPS box and add absorption mats and cooling elements as gel packs. An environmentally friendly alternative to this is the EcoCoolbox in combination with the No sweat gel packs.

Gel packs are available in all shapes and sizes, so that a customised solution can also be realised for your situation. This refrigerant is particularly suitable for transports where there is no return procedure. The gel packs are usually used for deliveries that are on the road for up to 24 hours. The standard gel packs are suitable for deliveries that have to be transported within the temperature range of 0-8 degrees Celsius.

However, some medicines must be transported below freezing or above 8 degrees Celsius. Gel packs can also be used as a refrigerant in such cases. In that case, the gel packs must be filled with Phase Change Material (PCM) instead of regular cooling gel. The Phase Change Material can increase or decrease the freezing point of the gel pack due to the adjustable composition of substances. For example, by adding salt, the freezing point can be lowered, allowing you to transport products at a temperature of up to -21 degrees Celsius.





By using absorption mats in combination with the EPS box and the gel packs, any condensation released during transport is immediately absorbed. If you prefer to use the EcoCoolBox, the No sweat gel packs are the solution. They contain a non-woven outer layer that absorbs any condensation that may arise during transport. In this way the medicines remain dry and there is no risk of loss of quality.

## Reliable and flexible shipping

The advantage of this shipping method is that it offers you a lot of flexibility. For example, a pharmacist can keep a small stock of dispatching products himself, so that he can

> send medicines directly when needed and is not dependent on external parties.

The use of special packaging is also a popular option on a large scale. This is because the packaging can be used in virtually any means of transport. For example, our own lorries can be used, and the medicines can also be transported cooled or conditioned by air.



## Tailor-made solution for you

Are you curious about the possibilities for your specific issue? At De Ridder Packaging we have over 25 years of experience in supplying the best refrigeration materials. Our product range varies from standard to customised refrigerated packaging, gel packs, ice packs, absorption mats and EPS boxes to total solutions for refrigerated and conditioned transport. Everything to ensure that your medicines and other goods arrive at their destination in optimal condition. Our experts will be happy to provide you with specialised advice.

Thanks to our own production facilities on site, customised solutions can be delivered that are specifically designed for your application. De

Ridder Packaging's products are of excellent quality and meet all the requirements of the law.

Do you have any questions, would you like to order or would you like advice? Feel free to contact us using the details below. Our experts will be happy to help you.







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