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KÖRBER SOLUTIONS

CARTON PACKAGING SYSTEMS FOR PARENTERALS

Set against the background of prefilled syringe and injection devices such as auto injectors as increasingly attractive presentations for both new and established parenteral pharmaceuticals, Christoph Hammer, Chief Executive Officer, Dividella, explores how innovative carton packaging solutions can enhance these presentations whilst meeting the stringent requirements of product protection.

Biotech products are rapidly becoming more important because of their extraordinary pharmaceutical potential. The active ingredients of biotech products are often too unstable to be incorporated into solid pharmaceutical products (tablets or powders). Well over 90% of these products are therefore packaged as liquids in syringes, injection devices, vials or ampoules.

Since the products are distinctly more expensive than other pharmaceuticals, they must be packed as securely as possible. Moreover, often the products have to be transported in a precisely defined temperature environment. Cold chain logistics are needed to ensure that a product is transported at the correct temperature from manufacture through transport, and storage to administration.

Many pharmaceutical companies produce and market a wide range of products worldwide. The different demand in the respective market and product segments therefore requires a highly flexible packaging system which can handle a wide range of different items and, at the same time, provide optimal product protection. It is also essential to guarantee efficient, low-cost packaging of small, medium and large lot sizes. Other requirements of a modern packaging system include item and code checks (vision systems), inspection systems, track and trace, printing and checking of variable data, the shortest possible machine set-up times and compliance with GMP standards.

> "In the case of a syringe pack, for example, the syringes are inserted in front of and behind the barrel of a syringe in such a way that the product itself virtually "floats" and is connected to the actual box only by the two flutes. In this way multiple products can be packaged close to each other without touching."

PREFILLED SYRINGES & INJECTION DEVICES

Prefilled syringes and injection devices have gained wide acceptance, driven by various factors including lifecycle benefits that can be identified as follows:

- The prefilled syringe or injection device is easy for healthcare professionals to handle
- The risks of spillage, contamination and ampoule cuts are reduced or eliminated. Furthermore, the potential risks of misidentification or dosage error are greatly reduced
- The potential risk of needlestick injury, associated with all methods of injection, is greatly reduced by the addition of a safety needle device to the syringe

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- The availability of such devices enables compliance with current and envisaged legislation
- Self-administration by patients on long-term therapies is practical
- For the pharmacist, requirements for storage, preparation and disposal are simplified
- For the pharmaceutical manufacturer, the prefilled syringe and injection device offer advantages in both marketing and distribution
- For the prefilled syringe and injection device there is no overfilling required, as it is filled with less drug substance per dose than a vial or ampoule, hence leading to significant cost savings.

Prefilled syringes and injection devices are being used increasingly frequently, so that application of liquid pharmaceutical products at the doctor's surgery, by nursing personnel or by patients at home, can be more simply and reliably handled. In the simplest case, it is necessary only to remove the needle protection prior to injecting the drug. There is no longer any need to break off the heads of ampoules, with the possible ensuing injuries, or for troublesome handling of vials or syringes.

THE REQUIREMENTS OF THE PACKAGE

All packages must safeguard the product throughout its route from manufacture to final point of use. The package must also convey sufficient information to ensure that the product is used correctly. Each package provides the vital link between manufacturer and consumer; it is an essential component of the product itself.

The prefilled syringe and injection device are examples of a high-value product that must be safeguarded throughout a long shelf-life and yet be readily and accurately used whenever required. The proper selection of the package and the attention to its design will promote the benefits of the product in addition to fulfilling these fundamental functions. The syringe or device is not viable without a secondary package.

The package must enable rapid access to each of the products it contains, and must remain intact until the last of the syringes or devices has been removed, if that last product is to be safeguarded. The printing of the package will clearly present essential product information. Further features may confirm that the syringe or device is untouched until required for use.

A re-closable package can be retained for subsequent use without difficulty. If the package contains a course of treatment for a single patient, features to assist dosage compliance are appropriate. If the contents are to be used over an extended period, opening features that release only one product at a time can assist the user. Examples are shown in Figure 1.

> "A reduction in pack volume of 50% cut the expensive cold-chain shipping and storage costs in half."

LOGISTICS OF DISTRIBUTION

Costs are affected by the volume of the package itself. Where the product must be held in a temperature-controlled environment, it is particularly important to adopt a package of minimum volume relative to its contents. Minimising package volume also benefits storage immediately prior to use; for example in a hospital pharmacy.

The immense cost pressure within the medical sector encourages the increasing trend towards self-medication. The branch of liquid pharmaceuticals is also drawn into this development with the use of prefilled syringes and injection devices on the increase. They are not only easy and safe to handle by the patients themselves, but are also favoured by both doctors and hospitals. The potential dangers involved with breaking the ampoule are therefore avoided. Another important factor for this development is found in the low logistical costs which, thanks to optimal packaging solutions, are easily accomplished.

THE PARTITION CONCEPT

This space saving is achieved thanks to Dividella's special design concept. Since the whole box is made of flat cardboard, customised partitions, specially adapted to the products, can easily be glued inside the box (see Figure 2). The product is placed crosswise in relation to these flutes. In the case of a syringe pack, for example, the syringes are inserted in front of and behind the barrel of a syringe in such a way that the product itself virtually "floats" and is connected to the actual box only by the two flutes. In this way multiple products can be packaged close to each other without touching. Since the products do not touch the base or the lid of the box, they are highly impact-resistant and the firmly anchored products cannot break even if they are dropped onto the floor. This flute concept is highly versatile, so the layout within a box can easily be adapted to individual customers' needs. In so-called combi packs, not only the syringes but also the accompanying vials and accessories, such as needles, filters and the like can be inserted at fixed points.

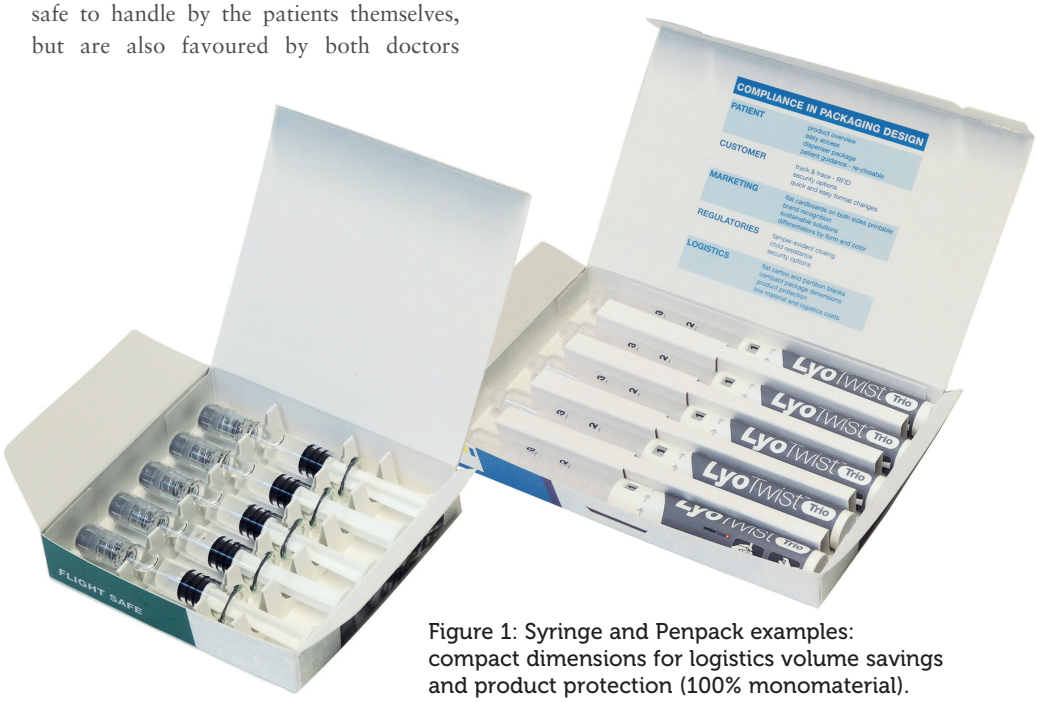

Figure 1: Syringe and Penpack examples: compact dimensions for logistics volume savings and product protection (100% monomaterial).

VOLUME SAVINGS OF UP TO 50 %

Dividella folding boxes are pure mono-material packaging, i.e. the folding box is made from 100% cardboard material. This distinguishes it from other conventional Top-Load packs. For customers in the pharmaceutical industry, this means that by using only one packaging material the space required and the transport costs can be significantly reduced. Dividella reports volume savings of 25% to 50% compared with traditional blister packs. These figures are important in that many of these highly sensitive drugs are cold-chain products. In other words, they must be cooled continuously from production until they are used by the patient. The less space these products take up the better. This includes space in the refrigerator in which general practitioners keeps their sensitive vaccines, for example.

WORLD STAR PACKAGING AWARD

The Dividella NeoTOP Syringe pack designed for Sanofi Pasteur (Figure 3) received the World Star Packaging and Sustainability Award. A reduction in pack volume of 50% cut the expensive cold-chain shipping and storage costs in half. Major benefits were obtained by replacing pre-made plastic trays & lid material with a 100% paperboard material, consisting of a carton and partition. The new package uses a specially designed paper partition that precisely fixes each syringe in a nest. There is no glass-to-glass contact, thus preventing cracks and breakage. The plunger movement is limited by the tight tolerances between the syringe and inner walls of the pack.

Figure 3: Sanofi Pasteur Dividella Syringe Pack, WorldStar award winner.

Figure 2: Highly versatile partition concept, so the layout within a carton can easily be adapted to individual customers' needs.

TAMPER-EVIDENCE & ANTI-COUNTERFEITING

The pharmaceutical industry has been concerned with guaranteeing originality for many years. The NeoTOP packstyle allows the integration of a number of protection features – conforming to directive 2011/62/EU. We solved the problem quite simply by applying a spot of hot-melt in the right place. If the box has been opened, this is immediately apparent to the user – and it involves virtually no extra machine costs and has no effect at all on performance. This solution can be applied for the box, placing a glue spot on one or all the three flaps of the carton before the fully automated, in-line closing.

With smart package design, we not only apply tamper evidence for the outer carton but also for the individual products in the pack as well. As an alternative for the tamper-evident (TE) glue spot we can also apply a TE label in-line, after the closing process. The unique Dividella NeoTOP pack style is hard to manufacture without our machinery and thus can itself also be considered as a level of brand protection.

ANTI-COUNTERFEITING AS LIFE INSURANCE

Biotechnology products in particular require considerable effort to produce and are therefore expensive to manufacture. However, the risk of these products being counterfeited or manipulated is unfortunately omnipresent and has already become a major issue on some continents. If a counterfeit product is used for cancer therapy, or even for antibiotic therapy, the consequences for the patient could be fatal.

Concepts relating to guaranteeing originality and counterfeit protecting have been developed, which can also be implemented in the short term on existing packaging solutions. An invisible code for the pack, and product and information on usage, ensure the necessary security – and also permit effective track and trace.

SMALL BATCHES

Dividella's small batch machines are a one-up machine, which means that no more than one magazine needs to be filled and cleared per packaging component. The machines have small and simple format parts, and digital read-outs for a safe format changeover. The carton-vacuum transfer allows the machine to be fully accessible, so products can be inserted manually or with a flexible robotic feeding system. Dividella also offers a variety of other features from white-line printing to personalised production (see Figure 4). For very small lot sizes, clinical trials or product launches, Dividella's sister company, Rondo (Allschwil, Switzerland) offers a carton-erecting service, using Dividella machines. This way, a customer can start using NeoTOP cartons without having to invest in a machine.

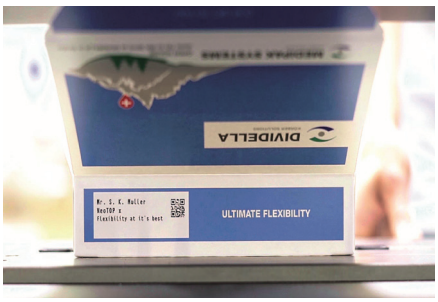

Figure 4: Personalised production for small lot sizes, clinical trials or product launches.

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KEEP YOUR PRODUCT SAFE AND GO FOR THE RIGHT PACKAGING

..and profit from volume savings of up to 50 %

Dividella packaging solutions - 100% recyclable cardboard material. By using only one packaging material the space required and the transport costs can be significantly reduced.
Dividella TOPLoading cartoners report volume savings of 25% to 50% compared with traditional blister packs. Customised partitions, specially adapted to the products, are easily glued inside the carton and multiple products can be packaged close to each other without touching. Since the products do not touch the base or the lid of the box, they are highly impact-resistant and the firmly anchored products cannot break even if they are dropped onto the floor.

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