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PHARMACEUTICAL PACKAGING

How Advances in Pharmaceutical Packaging Are Better Meeting Patients' Needs

By: Detlev Haack, PhD, and Martin Koeberle, PhD

INTRODUCTION

The pharmaceutical industry is increasingly recognizing the needs of individuals who experience difficulties taking conventional tablets, and is responding with products that are easier to swallow and more convenient to take. Alternative oral dosage forms, such as orally disintegrating granules (ODGs), instant drinks, lozenges, and chewable and effervescent tablets, are becoming increasingly popular with consumers. But there is little point in formulating more user-friendly dosage forms if the packaging they come in is difficult to open or does not easily integrate into consumers' daily lives.

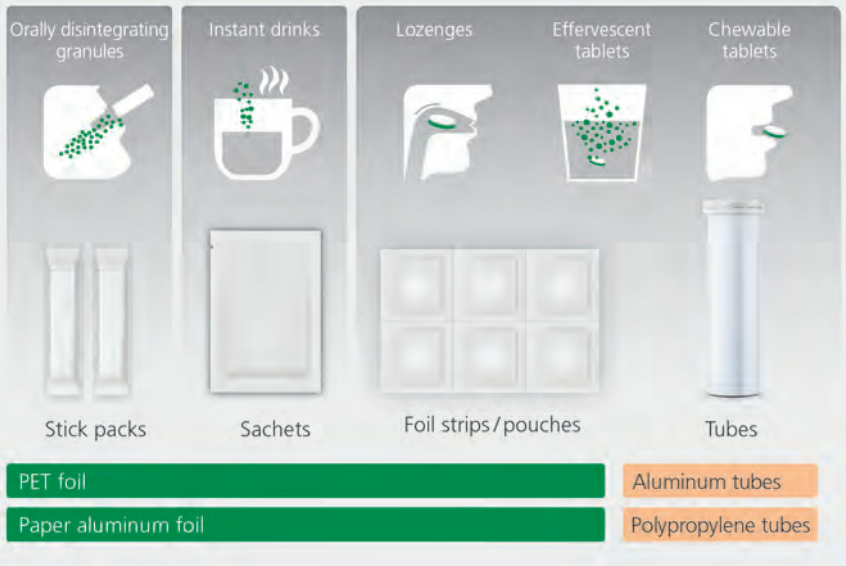
Recent advances in packaging design, materials, and technologies mean that today, there is a wide variety of user-friendly primary and secondary packaging options to choose from. Most importantly, the packaging must fulfill its primary purpose – to protect the medicine it contains. However, beyond this is a wealth of other considerations. The design elements that make packaging more convenient to open and accessible, for elderly people for example, need to be carefully balanced with child-resistant mechanisms, anti-tamper devices, and other safety features. Additionally, packaging plays an important role in shaping the product-customer relationship, and can be a way of building brand identity and boosting product value. So, what are the key packaging considerations for pharmaceutical companies when bringing a user-friendly dosage form to market?

PRODUCT PROTECTION

One of the most important functions of packaging is to shield products from the damaging effects of the external environment. Many formulations become unstable when exposed to air, moisture, or light, and therefore protection from these factors is necessary to ensure medicines remain effective and safe.

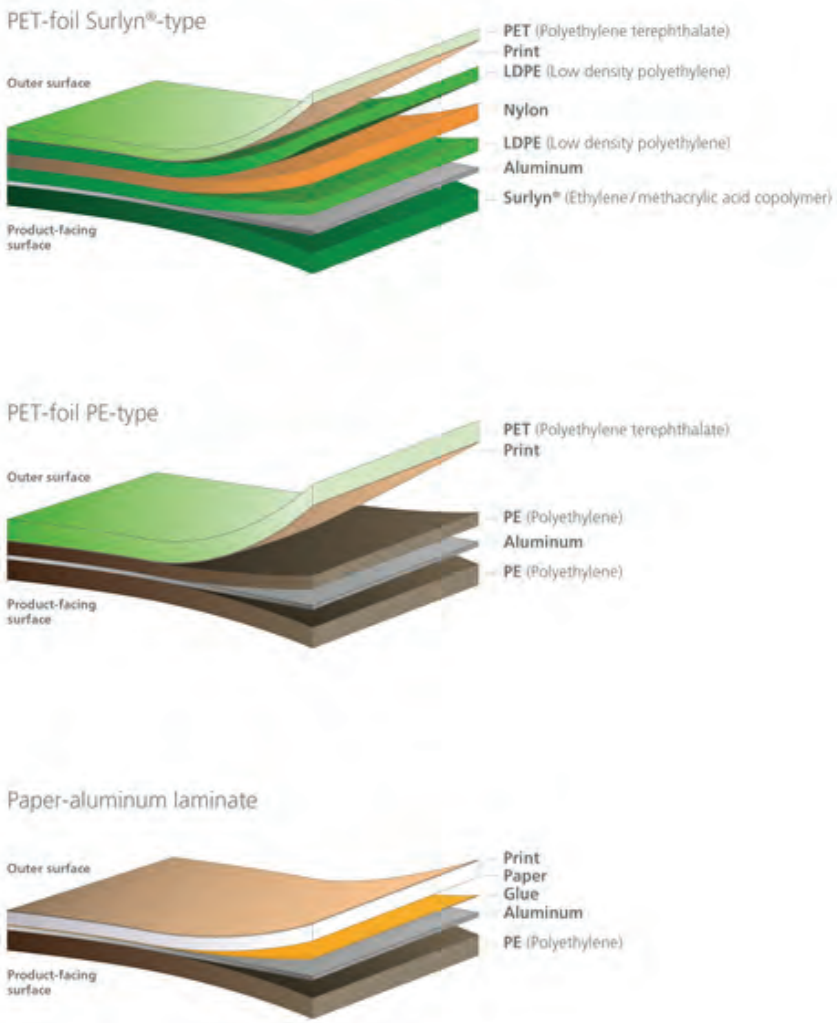
For user-friendly dosage forms, such as instant drinks, ODGs, lozenges, and effervescent and chewable tablets, four primary packaging options are commonly used (Figure 1).

FIGURE 1



User-Friendly Dosage Forms & Appropriate Packaging Options

FIGURE 2



Structure of Typical Laminated PET Aluminum Foils & Laminated Aluminum Paper Foil

For instant drink formulations, sachets are the ideal primary packaging option as they come in a range of sizes and can be made from laminated polyethylene terephthalate (PET) aluminum foil or laminated aluminum paper foil, which offer good protection against moisture and light (Figure 2). The aluminum layer present in both laminated aluminum paper foil and laminated PET aluminum foil offers a similar level of protection from sunlight and moisture.

Stick packs are ideally suited for ODGs, and just like sachets, can also be made from laminated PET aluminum foil or laminated aluminum paper foil. However, their elongated shape makes them better suited for pouring the contents into the mouth and swallowing directly. Both sachets and stick packs can be manufactured with or without tear notches for easy opening. For lozenges and effervescent and chewable tablets, foil strips/pouches or tubes are the ideal packaging solution. Foil strips/pouches can be made from laminated aluminum paper foil, whereby two, four, or six individually sealed tablets are packaged together. Alternatively, tubes can be manufactured from polypropylene (PP) or aluminum. Aluminum tubes offer the best possible protection against light and moisture. Nevertheless, PP offers good and sufficient protection against these two factors for most products and is also a more cost-effective option.

For effervescent tablets that react vigorously with water, protection from moisture is particularly important. Tubes offer a number of design features to protect their contents from humidity. As well as being manufactured from materials that prevent moisture from permeating through and reaching the contents, tube stoppers usually include drying agents, such as silica gel or molecular sieves, to absorb the humidity that can penetrate through the tube or be introduced into tubes after repeated opening and removal of tablets.

DESIGNING PACKAGING FOR OLDER PATIENTS

A significant proportion of people taking medication are elderly; however, for this patient group, product packaging can be a significant barrier to accessing medicine and complying with treatment regimens.[1,2] This is particularly true for the packaging of traditional tablets and capsules, with many older patients experiencing difficulties pushing tablets through blister packs. Another commonly reported problem is difficulty opening the tamper-evident closures and screw caps on medicine bottles.[3]

Design features can be incorporated into the packaging to make opening easier. Sachets and stick packs, for example, can be manufactured with tear notches to simplify opening. With tubes, conventional stoppers can be difficult to open, especially for people with weak hands or wrists, such as elderly persons or arthritis and osteoporosis patients. However, the latest generation of easy-to-open tube stop-

FIGURE 3

Automated Attachment of Leporellos to Tablet Tubes

pers can be removed with a short rip of the safety ring, and are easily lifted off using an ergonomic finger mold grip.

Another important usability factor to consider when choosing packaging concerns the readability of the patient information leaflet (PIL). It is a regulatory requirement that information must be clearly readable so that patients and consumers can use their medicines safely and appropriately.[4]

While a PIL can easily be added to products that require secondary packaging (such as stick packs, sachets, and strip-foils), this outer packaging can be omitted for tubes. Because the space on a tube is often too small to incorporate all the required information, a folded paper sheet (known as a leporello) can be attached directly to the tube (Figure 3).

INCREASED DEMAND FOR CONVENIENCE & CUSTOMIZATION

Modern patients and consumers increasingly expect convenience in their lives and products to be tailored to their individual preferences and needs. Pharmaceutical companies have responded to this demand and have developed medicines that can be taken on the go, such as ODGs and chewable tablets, or those that can be dissolved in water before being taken to accommodate the needs of patients having difficulties swallowing tablets or capsules.

But it's not just the medicines themselves that have evolved to meet changing consumer and patient preferences. Packaging has also adapted to become, for example, more portable and re-closeable in order to be used on the move, as the modern consumer is more mobile than ever.

The use of cardboard lids and cut-out slots to create re-closeable flaps can make secondary packaging more convenient for those who are always on the go. Flip-top cartons (Figure 4), for example, are small and re-closeable, and are ideal for packaging sachets or stick packs as they can be taken on the move and prevent the individual sachets from spilling out of the box. Moreover, packaging can be designed to be more streamlined and have fewer sharp corners in order to fit more easily into pockets or bags.

And for those who need to take only a single dose on the go, sachets and stick packs containing individual doses of medicine eliminate the need to carry around whole blister packs or medicine bottles, which are bulky and may be exposed to unsuitable conditions (such as being left in the car on a sunny day).

SAFETY CONSIDERATIONS

Ease of opening and convenience must be balanced with appropriate design to ensure packaging is resistant to opening by children. The latest user-friendly packaging options can have child-resistant features built in.

Stoppers designed to be removed by first pushing a lever at the side of the cap, before being moved upward, are more resistant to opening by children. These mechanisms are designed in a way that also ensures maximum accessibility for older people.

Sachets and stick packs can also be made child-resistant through the use of laminated PET aluminum foil. The PET-based foil is more difficult to tear than laminated aluminum paper foil, and can be opened only by cutting the packaging with scissors. It is also possible to add a specific type of tear-notch or a laser-perforation that weakens a defined area of the PET-layer (without harming the barrier properties).

The potential for product tampering is another important factor that must be con-

Small & Re-Closable Flip-Top Carton

"But it's not just the medicines themselves that have evolved to meet changing consumer and patient preferences. Packaging has also adapted to become, for example, more portable and re-closeable in order to be used on the move, as the modern consumer is more mobile than ever."

sidered when designing packaging for medicines. Many modern options can include tamper-evident safety features that allow users to identify when the packaging has been opened.

Tubes, for instance, can be designed with tamper-evident seals to identify whether the stopper has been removed. These measures not only serve to protect the safety of consumers, they can also boost consumer trust in a particular brand or product. Safety features can also be included on secondary packaging; flip-top cartons, for example, can be designed with perforations that clearly show when the box has been opened.

The latest regulations around medicine serialization, designed to safeguard patients from counterfeiting and falsification, are also adding to the packaging requirements for the pharmaceutical industry. Legislation under the US Drug Supply Chain Security Act, as well as the European Union's Falsified Medicines Directive, require an alpha-numeric code to be printed in both human-readable and two-dimensional barcode form on the packaging of prescription medicines.[5,6]

This individual identifier, containing information, such as product code, batch number, and expiry date, must be unique for each package and will be used to track and verify the authenticity of medicines at every stage – from the manufacturing plant to the patient collecting the medicine at the pharmacy.

This requirement presents an additional consideration for pharmaceutical companies, as the technology used to produce packaging and materials must be able to support the printing of small barcodes on products, and the production line must have space for this printing step to be introduced. For many manufacturers, this will require a significant investment in equipment, software, and associated workforce expertise that will enable them to comply with these new regulations.

BUILDING A STRONG CUSTOMER CONNECTION

As well as providing a practical solution to containing and protecting medicines, packaging has become a useful way of boosting brand identity, adding value to a product, and building a strong consumer connection.

Similar to fast-moving consumer goods (FMCG), for over-the-counter (OTC) medicines, it is important to ensure that a product's packaging is easily visible and recognizable, and that it differentiates the product from the competition. Shelf-ready cardboard packaging with design features such as "feet," keep the product upright while on display. They help ensure that products such as long tablets tubes packaged in folding boxes with a small base stand out on the shelf and do not fall over, while also meeting retailers' handling and shelf-presentation requirements.

Packaging is also used for information transmission. Well-designed packaging should imply trustworthiness and thus encourage potential customers to purchase the product. For high-end nutraceuticals and health supplements, the use of laminated PET aluminum foil – which has a more glossy finish than laminated aluminum paper foil – can help to establish a more premium brand.

Likewise, cartons printed on metallized or holographic board or with an embossed finish can be used to support the image of a more high-value product. Thicker card-based packaging materials such as carton board are also providing new ways of creating distinctive packag-

ing that can be molded into eye-catching shapes, whilst being more sustainable than plastic packaging.

As well as its importance for marketing purposes, distinctive packaging can also help boost patient compliance, particularly for elderly people and those who experience vision difficulties, by making the medicine more easily distinguishable from other products in the medicine cabinet.

SUMMARY

The pharmaceutical industry increasingly recognizes the needs of people who experience difficulties swallowing conventional tablets and capsules, and is responding with products that are more convenient to take. An industry-wide focus on the design of packaging that can protect these user-friendly dosage forms, as well as improve patient compliance and fit into modern consumers' lifestyles, has resulted in a wide range of primary and secondary packaging solutions. These options are helping pharmaceutical companies incorporate the necessary safety and product protection features required to ensure products are safe and effective, while better meeting the individual needs of customers. Similar to FMCG, pharma has been recognizing the importance of packaging in the marketing mix, which is particularly relevant in the OTC sector, where the consumer makes the buying decision. To improve brand recognition and differentiate products from the competition, packaging must be intelligently designed and clearly convey the product promise.◆

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BIOGRAPHIES

Dr. Detlev Haack is the Director Research & Development at HERMES PHARMA. He earned his PhD at the University of Hamburg on the subject of chemical and physical stability of Piroxicam in solid dispersion with PEG and PVP. In 1997, he received approbation as a pharmacist. From 2003-2007, Dr. Haack was Manager Sales & Business Development at Hermes Arzneimittel GmbH. He held the position of Associate Director R&D there from 2007-2012 before becoming Director R&D in 2013. His career includes a previous position as Head of Production at Altana Pharma Oranienburg GmbH.

Dr. Martin Koeberle the Head of Analytical Development & Stability Testing at HERMES PHARMA, where he is responsible for the analytical aspects of development projects, including the evaluation and implementation of new analytical techniques and approaches. Dr Koeberle earned his PhD in Pharmaceutical Sciences at the University of Strathclyde in Glasgow on the subject of ocular drug delivery and pharmacokinetics. His career includes previous positions in analytical development at AstraZeneca in the UK, Aenova in Switzerland, and an affiliate of Ratiopharm in Germany.