Navigating the Shift in Pharmaceutical Packaging:

Beyond Traditional Structures towards Healthier and more Sustainable Future

In the past the choice of packaging strategy in pharmaceutical industry was often purely based on functional criteria that defined which packaging material delivers the most stable performance for a safe, secure, and efficient drug delivery.

Predictable interaction between active ingredients and the packaging material can only be guaranteed through extensive testing of a specific combination of a drug formulation and dedicated packaging material. It is a time consuming and rather expensive process. Once the winning match has been confirmed, it becomes a part of an official pharma dossier that is submitted for a legal approval and registration by regulatory bodies. In this context it needs to be understood that most changes to primary packaging specification would directly require new stability testing and new submission of a dossier with all the associated costs and effort. Which is why such changes are unlikely to be implemented unless public safety is at stake, great financial risk or gain has been identified or a new legal requirement has been introduced.

For years, the pharmaceutical industry has relied on combinations of PVC and aluminum for medication packaging. However, as sustainability climbs up the global agenda, this traditional approach is coming under scrutiny. With products like mono-polymer and PVC-free aluminium coldform blisters leading the change, the industry is adopting innovative and more environmentally sound packaging solutions. Read how a transition is both timely and challenging and how to maneuver through this journey.

The Changing Landscape of Pharmaceutical Packaging

Driven by the quest for more sustainable solutions, the material choices for blister packaging will shift towards less complex substrates. Halogenated polymers like PVC, PVDC, and PTFE for mid to high barrier applications will most probably be less acceptable as the need for alternative solutions, that are more compatible with circular systems requirements will grow.

The Rise of Coldform Blisters

Coldform blisters without PVC sealing layers are increasingly garnering attention for their ability to substitute other less preferential options for high barrier applications. While not a new concept, it's quickly becoming a low-hanging fruit in the mission for sustainable packaging transition due to several other benefits that those structures have to offer.

In addition to being PVC-free, the new generation of coldform blisters contains less plastic in weight and therefore the relative share of aluminium is increased without adding more metal. Higher aluminium content contributes to a better sorting and higher material recovery rate in waste processing in all life cycle stages of the material, including the end-of-life of the final blister pack.

Replacing PVC with polyolefins also results in coldform blister material that is flatter and less prone to wrinkling, which then leads to a better machinability with a potential for a more efficient blister forming performance.

Exploring Alternative Polymers

Not all pharmaceutical products require the level of protection the coldform blisters deliver. In cases where an absolute barrier isn't a top priority, and the packaging mainly functions as a protective dust cover, companies' main priority tends to be moving away from PVC-based bottom webs. They're opting instead for alternative polymers such as PET, PP, and PE because these materials are better suited for recycling, aligning closely with sustainable design principles. It's becoming an increasingly common choice for corporations focused on environmental responsibility.

The Quest for Mono-material Blister Packaging

Medicine blister is a two-component packaging structure, so the challenge doesn't stop at replacing the bottom web. Pharmaceutical companies must also embark on the search for new lidding materials that can be paired with non-PVC bottom webs to create a mono-material blister that complies with design-for-recycling guidelines and can be therefore considered recyclable.

While it seems like a straightforward and most logical solution, is it the most effective one for a pharma packaging?

Recyclability is a System Challenge

The Complexity of Recyclable Pharma Packaging

Just because a material is technically recyclable doesn't mean the finish packaging will be. Even if a package adheres to design-for-recycling guidelines, it's not automatically guaranteed to be recycled. The recyclability of packaging depends on several factors such as local collection systems and the sorting and recycling infrastructure that is in place for specific materials. Moreover, the type of product being packaged further complicates matters. While the material itself may be recyclable, pharmaceutical packaging often can't be included in general recycling streams due to the risk of contamination from medication residues.

Study of EPR systems of 68 countries worldwide shows that merely 17 countries explicitly mention pharmaceutical packaging in recyclability and sorting guidelines. Only 5 of those countries allow certain medicine packaging in their recycling streams, one of it being medicine cardboard boxes in South Africa, which is not representative for the case, as this is not the immediate packaging of medicinal products associated with the contamination risk.

Most countries, work with a positive list for the recyclables collection. If a packaging type is not mentioned, it is not included in the collection, as only items that are on the list are allowed. Those are typically beverage containers, glass, and metal packaging. Therefore, it is rather unlikely that plastic pharmaceutical packaging will be considered recyclable in any of the remaining 51 countries where the blister packs are not mentioned.

But that's not all. Even when the blister material complies with the design for recycling guidelines and contamination risk is mitigated, the small size of most

pharmaceutical packaging makes it difficult to sort and recycle within the existing waste management infrastructure.

The only flexible pharma format that can currently be considered recyclable in practice is PVC free aluminium coldform blister. Although they will not be collected for recycling, unlike plastic, when aluminium coldform foil blisters end up in general waste the resources are not entirely lost. Polymers and potential medicine residues are incinerated but a large percentage of aluminium is recovered from bottom ashes of the furnaces, allowing that part of the material to be returned to the loop.

The Dilemma of Polymeric Film Lidding

Replacing aluminum lidding with polymeric film is a trend that comes with its own set of complications. Aluminium provides a robust barrier against migration from inks used for printing the necessary medicine information on the lidding, something that might not be entirely replicable with polymer films. In addition, the sealing of polymeric lidding film comes with challenges that don't apply to traditional aluminum blister lidding foils. Last but not least, aluminum lidding offers a well-established, child proof and senior friendly opening mechanism for the blister: pushing the tablet through the lidding allowing for convenient and safe access to the medicine. This straightforward, push-through experience is difficult to replicate with polymeric options. Plastic-based materials often lack the same functional ease, making it less convenient for the patient to access their medication. Therefore, before making the transition to polymeric film liddings, it's crucial to weigh the benefits and drawbacks carefully. The material you choose could have a lasting impact on user satisfaction and convenience, while the potential environmental benefit of enhanced recyclability might not be available in practice.

Advanced Recovery Technologies

As the industry struggles with recycling of multi-layer, multi-material structures, new technologies are emerging to tip the balance. Advanced, solvent-based technologies are being developed to allow for the full material recovery of both aluminum and polymeric films. These technologies are not only being tested but are also being scaled up to fit into existing waste management and recovery ecosystems.

Case Studies: German and EU Initiatives

- **Saperatec in Germany:** This technology specializes in post-patient/consumer resource recovery by separating multi-layer, multi-material packaging into mono substrates without damaging the structure of the material. It produces clean flakes that are ready for mechanical recycling process. A first industrial scale plant is currently under construction in East Germany.
- **AR in Germany:** Another German program targets advanced recovery methods for packaging materials generating sorted recyclates that are suitable for processing in a wide range of applications. Pilot plant is operating in the industrial Park in Frankfurt.
- **Solrec:** Part of the Horizon2020, this EU-wide project is pioneering scalable solutions for sorting and recycling of multilayer, flexible packaging materials.

The Path Forward in Pharmaceutical Packaging

While the most apparent solutions may seem logical, they may not always offer the best long-term benefits. The primary function of pharmaceutical packaging—ensuring product protection – must be balanced against its environmental impact. Packaging that does not fulfil its necessary function is not sustainable.

Although sustainable packaging is no longer a consumer goods domain, it is yet to be seen if applying the same criteria to consumer goods packaging and pharma packaging will leads us towards the future proof, circular packaging system that the industry and society are looking for. There's no room for compromise when public health is concerned, and a one-size-fits-all solution is illusory, especially with forthcoming legislation likely to raise the bar even higher.

Business as usual scenario is no longer viable. Being agile and proactive in adopting new technologies and legal requirements has never been more crucial. It's equally important to choose a partner who understands these complex system dynamics. With introduction of innovative more sustainable products and the development of advanced recovery technologies, the industry is taking steps in the right direction, but the journey toward sustainable pharmaceutical packaging is far from over.

The right packaging partner can help navigate this complex landscape, ensuring compliance, sustainability, and – most importantly –patient safety.

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