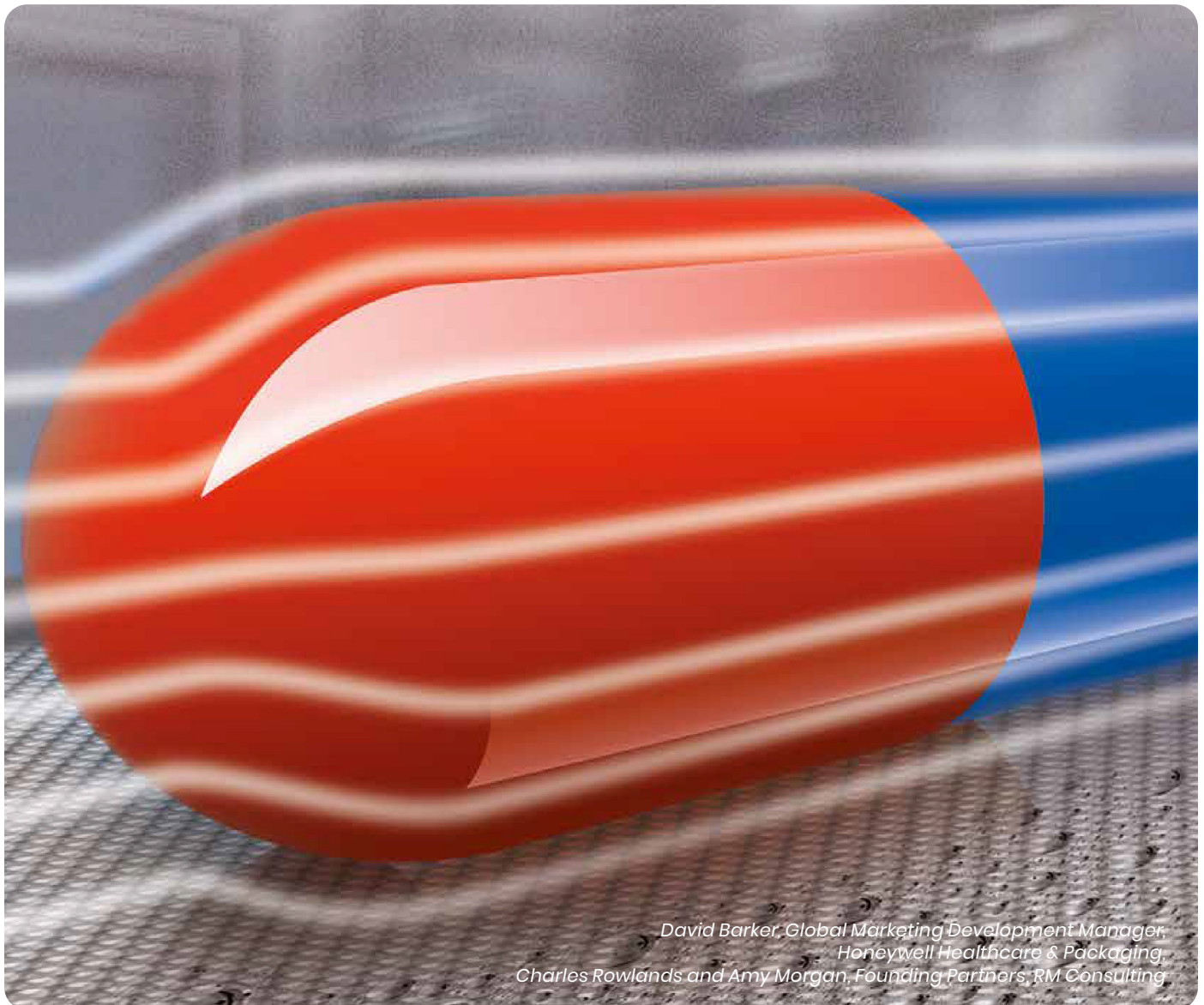




STRATEGIC IMPLICATIONS OF PACKAGING CHOICE IN THE GENERIC SECTOR



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ABSTRACT

This paper reports on the issues highlighted at the Honeywell Generics Forum and examines the strategic implications of packaging choice in the generics industry. It looks at how companies are leveraging ultra high barrier thermoform solutions like Aclar® to create new value propositions. Meeting regulatory and quality needs are a basic standard and a given requirement for any primary packaging solution.

However, in order to meet the challenges of today's generics marketplace, innovative generic companies are now looking beyond these basic technical needs and are optimizing packaging platform choice to realise market advantage and profitability gains. It is now recognised that pack differentiation offers an ideal opportunity to create a sustainable competitive market advantage.



INTRODUCTION – ISSUES HIGHLIGHTED AT THE HONEYWELL GENERICS FORUM

The Honeywell Generics Forum, held in 2009 in Brussels, brought together over 20 senior management attendees from 15 companies in 11 countries for a topical debate on the current issues facing the industry as well as to examine new packaging strategies.

The generics sector has been experiencing an unprecedented period of growth and generic firms are set to further capitalise on the opportunities offered by patent expiry on an estimated \$150 bn worth of revenues by 2015.

Generics contribute to the long-term affordability of healthcare systems. Drivers such as aging populations, increasing medical consumption, cost containment and restrictions in government healthcare budgets have all brought about increasing focus on the cost savings offered by the generic drug industry.

On closer examination; however, this is an industry in transition as the implications of existing trends work their way through the sector:

- Increasing pressure to lower drug costs as healthcare cost containment gains greater impetus driven by the Economic Crisis.

- Globalisation of the industry increasing pressure for companies to develop both regional and global strategies.
- Fewer launches by innovators in recent years will translate into fewer opportunities for generic companies down the line.
- Increasing number of originator evergreening strategies to stop generics coming to market.

The result will be intense competition and to survive generic companies need to seriously improve product profitability while avoiding commoditisation through innovative competitive strategies e.g. packaging.

Generic companies need to find cost savings and efficiencies to maintain profit margins. One approach is to standardise primary packaging as much as possible on efficient high barrier thermoforming solutions such as Aclar®.



ALU / ALU PIPELINE

Recent market research conducted by Solstice with generic manufacturers highlighted some major concerns:

- Large numbers of pipeline products packed in Alu / Alu even when not necessary for barrier reasons.
- Increasing Capex required to accommodate latest Alu / Alu pipeline.
- The need to increase OEE and plant utilisation
Internal strategic marketing teams demanding differentiated packaging to exploit profit pools.
- Wholesalers and pharmacies both demanding smaller pack sizes.

Not all products packed in Alu / Alu actually need to be in Alu / Alu – many can be moved to high barrier thermoform materials. But why does the generics sector continue to use so much Alu / Alu? The answer often results from 2 simple reasons firstly generic companies are copying originator choices, and secondly they are not fully considering all packaging options in the development phase. Generic companies can be too restrictive in material choices with only 2-3 materials on stability.

At the time of patent expiry the originator's packaging decision may be 16 years old. It was probably taken in a hurry with little regard to pack size and prior to the launch and common use of ultra high barrier thermoform materials. Therefore the major question for generic developers is: "Do we really want to copy an old product or should we develop something better?".

GENERICS CAN BE DIFFERENT

Generic drugs are pharmaceutical preparations that contain the same active ingredients in the same concentration as the originator product. On one hand they must be therapeutically equivalent to the originator drug; but on the other, the generic product's shape, size, colour and packaging material can be different and better! The old maxim: "originators innovate while generics differentiate", is often forgotten in the race to get a new product to market. Pack differentiation is an ideal opportunity to create a sustainable competitive market advantage. Increased marketing considerations during the generic development phase are already tipping the balance in favour of high barrier thermoforming – a process which enables a broader selection of design possibilities for a differentiated pack solution.

PACKAGING DECISIONS

Pharmaceutical packaging is no longer purely functional. It can deliver value both internally (improved operational efficiency, reduced complexity, reduced total costs) and to the end-user (wholesalers, patient, caregiver); but to leverage this value, packaging decisions should result from informed, cross-functional, collaborative processes. Primary packaging decisions that may have been correct for R&D during development may not be correct, or may even hamper, manufacturing operations and marketing post launch and for years to come. The strategic impact of packaging choice on crucial factors such as pack size, total costs and machine utilisation is often not fully considered.

Increasingly generic companies are choosing to revisit packaging choices. Many have already initiated a switch-OUT strategy¹ and are turning existing "inefficient packs" into "efficient packs." Others are initiating switch-IN strategies² and building packaging material flexibility into their development process by adding a high barrier thermoform material such as Aclar® to their stability protocols.



¹ Migrating a product already launched in Alu/Alu into an ultra high barrier thermoform pack.

² Migrating a product out of Alu/Alu and into an ultra high barrier thermoform material prior to launch.

THERMOFORMING ADVANTAGES

One of the greatest challenges for generic companies is managing very large drug portfolios often consisting of 200+ drugs in multiple pack variants for different countries.

This vast array of products and packs creates massive complexity in packaging and operations and drives up costs. The situation has been further complicated by industry consolidation with some companies struggling to maximise site and machine utilisation across multiple sites, multiple geographies and multiple, non-uniform capabilities.

Initial packaging material choices have far-reaching and long-lasting impact. The choice affects total packaging costs beyond the cost of material per square meter due to factors such as: cost of secondary materials, material usage, scrap rate, maintenance and production rates, etc. In addition, choice of packaging platform has major supply chain implications. Industry feedback strongly indicates that pack size can be the main differentiator after price for major wholesalers and pharmacies.

Figure 1 demonstrates that by choosing an ultra high barrier thermoform material such as Aclar® instead of Aluminium Cold Form Foil can result in a 55% reduction in pack size.

Thermoform packaging can dramatically increase tablet density providing cost savings across the board. The increase in tablets packaged per machine stroke increases the effective capacity and speed of each packaging line compared to Aluminium Cold Form Foil. Faster production rates and the ability to use machines interchangeably can be translated into fewer packaging lines required, lower maintenance labour costs, and lower capital equipment expenditures. Thermoforming offers increased production capacity and flexibility which impacts on the bottom-line and a major reason why many generic firms are now developing robust Switch-IN and Switch-OUT strategies – see Figure 2.

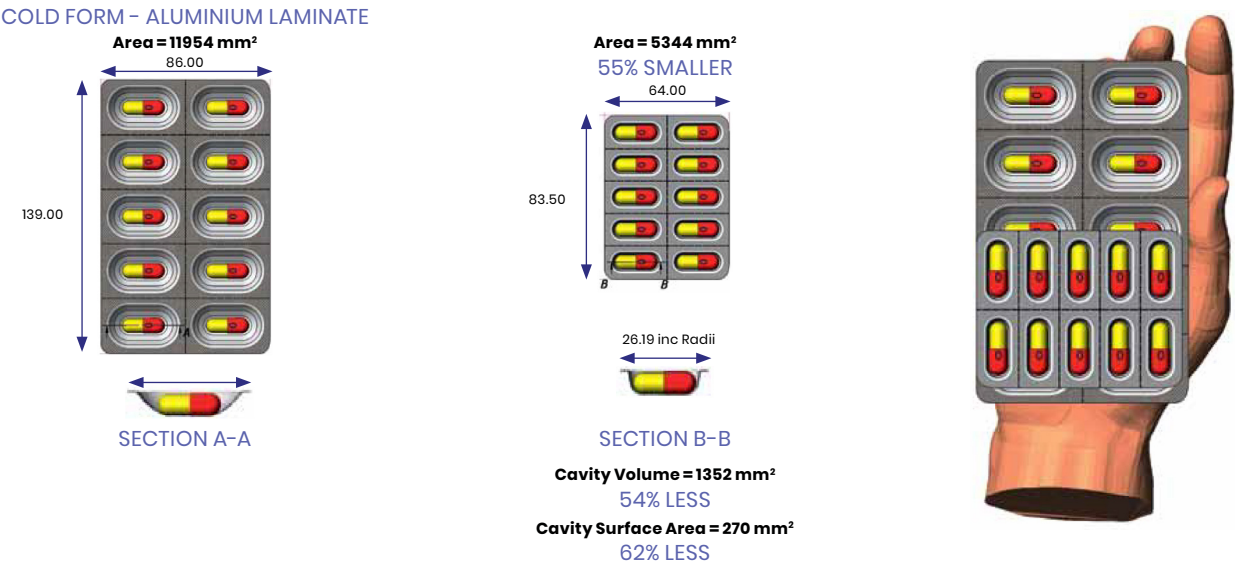


Figure 1: Alu / Alu-Thermoform Pack Size Comparison. Reproduced with permission from Prodieco Pharmaceutical Components.

	PVC (low barrier)	ACLAR® (ultra high barrier)	Alu / Alu (highest barrier)
CHANGE-OVERS	Quick & easy	Quick & easy comparable to PVC	Slower
RUN RATE	High	High	Medium to high
CONTROLLING PROSPERTIES (QUALITY)	Easy	Easy	More difficult: • Pinholes • Delamination • Product Feeding
COST OF TOOLING	Standard	Standard	High (increased maintenance)

Figure 2: OEE Considerations. Thermoforming vs. Cold Forming

SWITCH-IN

Adding a high barrier thermoform material to a stability protocol can have a relatively low impact on development time, resources and costs while increasing the potential for launch in the most advantageous material. This in turn can potentially offer substantial benefits in downstream costs and efficiencies as well as increased sales.

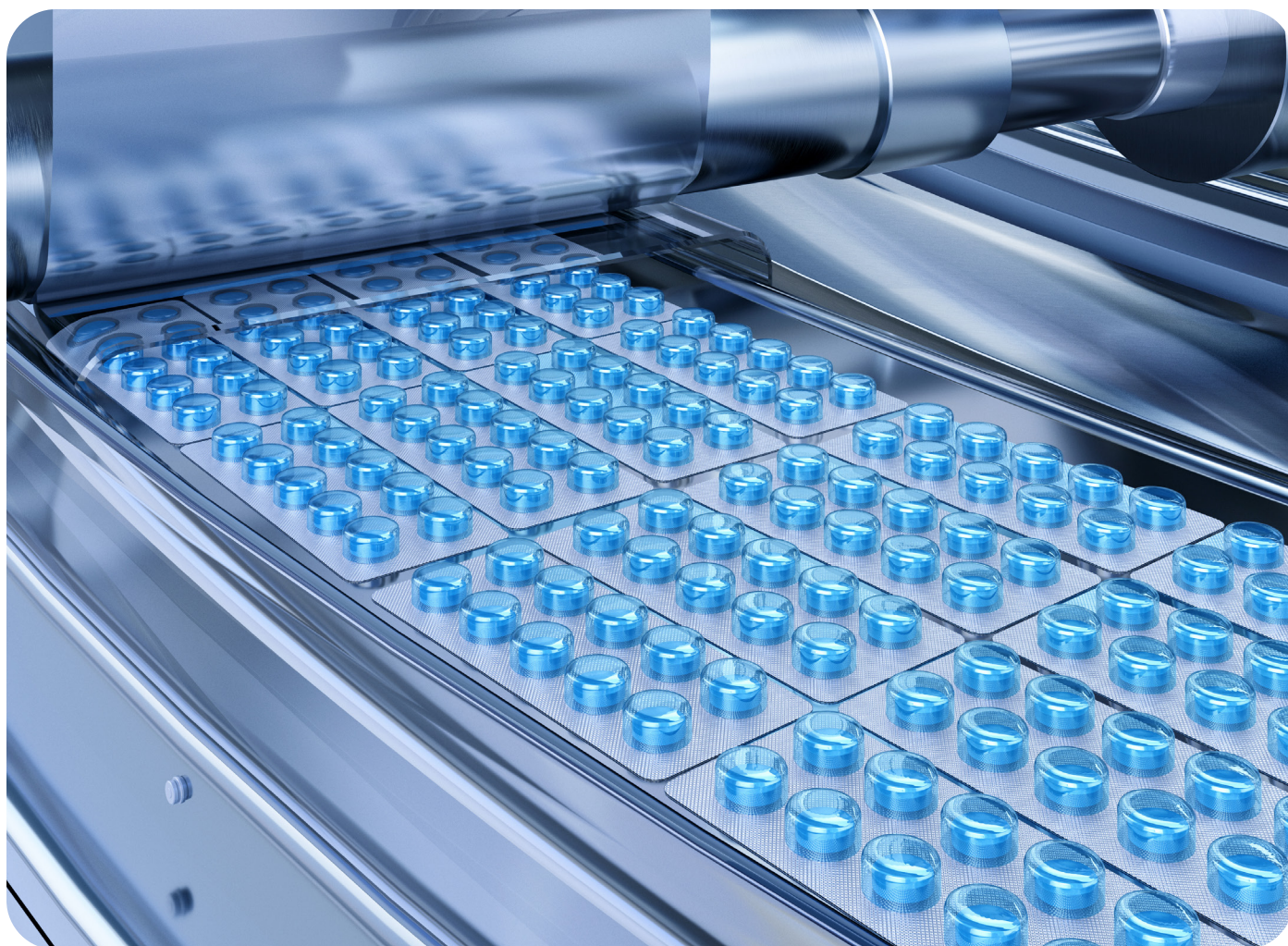
Generic companies are greatly increasing their product advantage by simply adding Aclar® to stability studies.

SWITCH-OUT

Switch-OUT is a process to change an existing launched product from Alu / Alu to an ultra-high thermoform pack e.g. Aclar®. The resultant reduction in pack size and increased efficiencies offer many advantages to Generic firms.

There are cost and resource implications in making this variation but increasingly generic companies are finding that resources spent maximising the profitability of existing packs can offer greater returns than launching new products alone.

Smart companies are now choosing to piggyback material switch-OUT on top of existing scheduled variations.



CONCLUSION

Ever strengthening competition in the generics sector is placing more importance on creating and exploiting a competitive advantage through packaging choice.

A marketing advantage can be achieved by offering wholesaler and pharmacy advantages through an improved pack format. Equally a competitive advantage can be obtained by cost reduction and/or efficiency gains thus improving product margins and overall portfolio profitability. Choice of packaging platform has strategic implications for generic firms because it can have profound implications on overall company profitability. Standardising where possible on high barrier thermoforming materials such as Aclar® can enable generic companies to reduce complexity costs, improve operational flexibility and overall profitability.

While Cold Form Foil has a vital part to play in blistering in the future, when total barrier is not required generic firms have much to gain by moving to a high barrier thermoform solution.

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Are founding partners of RM Consulting, an international market and competitive intelligence consultancy focused on providing management support services to the global pharmaceutical, biotechnology, chemical and healthcare sectors. Jointly they have more than three decades' experience and have worked on numerous strategy development and market research projects in both developed and emerging markets.



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6773800 | Strategic Implications of Packaging Choice
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