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Using Differentiated Drug-Delivery Technologies To Deliver Competitive Advantages

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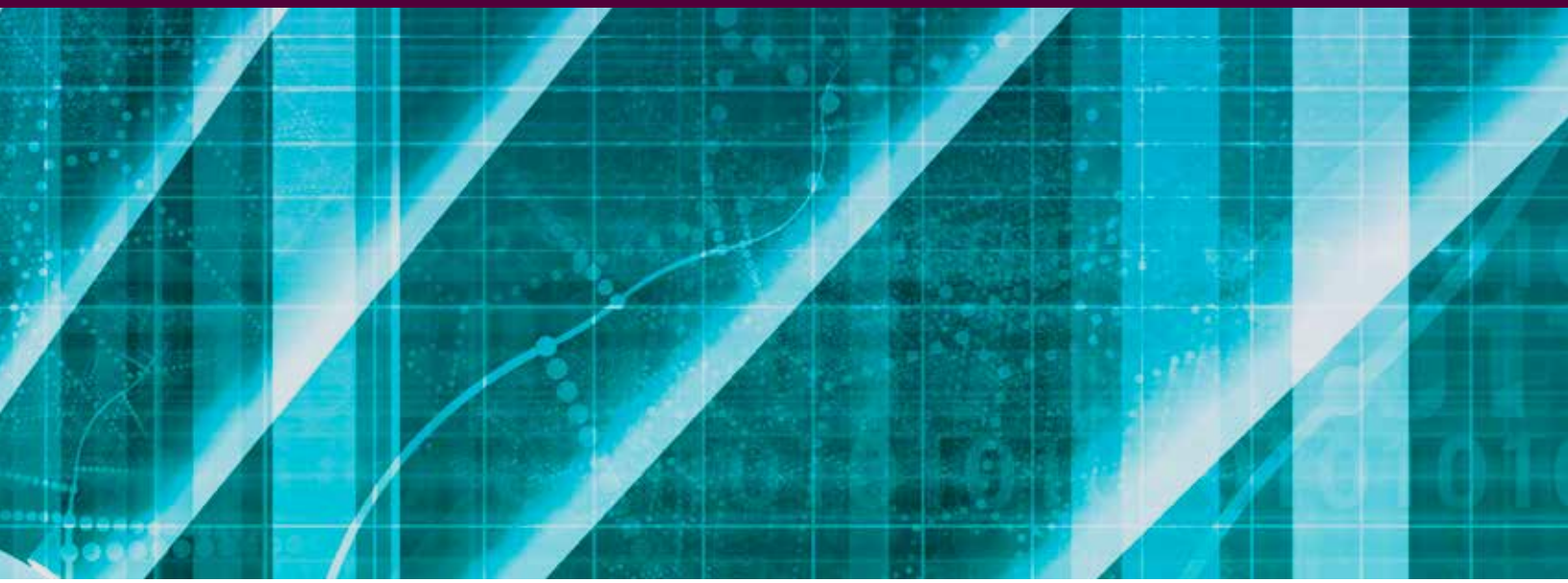
Novel drug delivery technologies enable manufacturers of all types to gain a competitive advantage by better meeting the needs of patients, physicians and nurses, and the broader health care system. By reformulating ingredients into more convenient dosage forms, branded manufacturers can defend existing franchises, generics companies can improve on incumbent products and consumer health businesses can stand out and command premium prices in the competitive over-the-counter (OTC) market. Most importantly, these projects improve the lives of patients and other key stakeholders.

Yet, while there is a clear need for patient-centric formulations, particularly in pediatric and geriatric populations, a thicket of technical, regulatory and commercial obstacles makes it hard to deliver the products people want. To better understand the issues and how the industry is tackling them, Unither Pharmaceuticals and Informa Pharma Intelligence convened a roundtable of experts from across the drug manufacturing landscape.



MODERATED BY:

Aidan Fry
Executive Editor, Informa Pharma Intelligence

PANELISTS:

Robert Knerr
Executive Vice President, Stada

Nathalie Masson
Director of Innovation and Development, Unither Pharmaceuticals

Florian Turk
Global Head of Commercial, Sandoz

Markus Weigandt
Head of Pharmaceutical Technologies, Merck KGaA

The Value Of Patient-Centric Formulations

Advances in formulation technologies have created new ways for patients to take medicines. Today, pre-measured doses can be delivered in portable liquid stick packs that enable people to fit taking medicines into existing routines. Similarly, powder stick packs and orodispersible tablets are making it easier for people to swallow medicines, while particle coatings are masking unpleasant tastes.

The availability of formulations that improve the lives of patients has created opportunities for drug developers to stand out in competitive generics markets characterized by the availability of multiple products with the same active ingredient.

"We see value-added medicines as a very nice opportunity to differentiate our portfolio, which is not always that easy, especially in the Rx segment," Robert Knerr, executive vice president for global portfolio and product development at generics and OTC manufacturer Stada, said at the roundtable.

Manufacturers of OTC medicines are attracted to differentiated drug-delivery technologies for similar reasons. The globalization of drug production and intense competition have driven the price of OTC medicines down, squeezing profit margins and reducing opportunities to stand out by undercutting rival products on price. Manufacturers of branded OTC products have responded by developing more convenient, patient-centric formulations that command premium prices.

Establishing multiple sources of input increases the likelihood a company will gain deep behavioral insights on each indication and will build the holistic view of health care delivery and outcomes that is needed to see the true value of an innovation.

Another set of benefits applies to producers of branded prescription medicines. As a medicine nears its patent expiration, a manufacturer can use formulation technologies to create additional layers of intellectual property protection, differentiate its product from generic rivals and improve the patient experience.

The full extent of the value of a differentiated drug-delivery technology is determined by how the product is used and by whom. Panelists on the roundtable identified some therapeutic areas in which patient-centric formulation technologies are particularly valuable.

"We have some consulting populations with some 'on-the-go' formats which are particularly friendly and needed for certain types of indications, like analgesics or antihistamines or antacids," Nathalie Masson, director of innovation and development at contract development manufacturing organization (CDMO) Unither Pharmaceuticals, said.

The indications identified by Masson share some characteristics. In each case, the patient may need to take a medicine outside of a pre-planned regimen in response to the development of symptoms. Powder and liquid stick packs work well in these therapeutic contexts as they make it easier for patients to ensure they always have a medicine with them and enable quick, discrete administration.

As that suggests, convenience is a key attribute of value-added formulations but it is far from the only one. Ease of swallowing is also critical, particularly in pediatric and geriatric populations, and taste masking is valued in many contexts.

However, it is not always obvious what patients and health care professionals will value, as Markus Weigandt, head of pharmaceutical technologies at Merck KGaA, explained. Merck expected pediatric doctors in South Africa to want taste-masked formulations for their patients. However, Merck found that the doctors saw taste masking as a secondary priority. "In the end you need to answer … one basic question: do you address an important need with your value add?," Weigandt said.

HOW COMPANIES IDENTIFY OPPORTUNITIES

The example of the perceived and actual value of taste-masked formulations to doctors in South Africa illustrates the need for companies to understand what other stakeholders want. Gaining such understanding is central to how companies find opportunities to use drug-delivery technologies to add value to active ingredients.

Florian Turk, global head of commercial at Sandoz, explained at the roundtable how his company handles this task. "It's happening through listening, understanding and engaging at the point of care. [It's about] understanding what health care delivery efficiency and outcomes mean, and why this improvement is so important and what are all the different touch points you can look at," Turk said.

The importance of point-of-care input from physicians, nurses, pharmacists and patients came up again and again at the roundtable. Knerr, for example, described how Stada tasks its salesforce with gathering feedback on products from health care professionals and relaying it to headquarters to inform the work of development teams.

Companies complement feedback from these point-of-care sources with other initiatives, such as the formation of expert and patient advisory groups. Establishing multiple sources of input increases the likelihood a company will gain deep behavioral insights on each indication and will build the holistic view of health care delivery and outcomes that is needed to see the true value of an innovation.

While the roundtable panelists primarily focused the discussion on getting input from stakeholders, they also touched on other sources of ideas for innovations. Upcoming patent expiration is one other source of inspiration.

"We are looking especially for the patent life … to get the medicines at the end of their patent cover and start to develop some new clinical forms," Masson said. As discussed in the section on the value of patient-centric formulations, the upcoming expiration of patents spurs both branded and generics drugmakers to use differentiated drug-delivery technologies.

Many companies supplement these sources of ideas with suggestions from third parties. CDMOs often have access to more drug-delivery technologies than branded, generics and OTC companies and have a clear picture of the needs of their customers, giving them the resources to identify and act on opportunities to add value.

Companies that sell medicines have recognized the potential for CDMOs to come up with good ideas and products, leading them to take an agnostic approach to the source of value-added concepts. "We do not care at all where the idea comes from. We just look at the idea. If it's interesting we go for it. If the product as a whole comes from an external supplier or only the idea or only the formulation piece, that definitely does not play a role. We do not differentiate between internal and external development, it's just development," Knerr said.

WHAT COMPANIES WANT FROM CDMOS

The important role CDMOs play in both the generation of ideas and delivery of products makes the selection of a service provider a key decision. Pharmaceutical companies that establish

an effective way of choosing CDMOs that meet their need for innovation stand to gain a competitive advantage.

In some cases, the choice of CDMO will be motivated by technological considerations. Even leading companies have gaps in their expertise and infrastructure. Rather than invest internally to fill those gaps, companies often conclude it is more efficient and economical to turn to a third party for the required capabilities.

"Roughly a quarter of our development activities may be external, a quite substantial piece, especially the ones where there are special technologies needed, which we don't have in-house. Then we will go external. That's a driver for us," Weigandt said. Turk expanded on that theme, stating that even a company as big as Sandoz "cannot be brilliant at everything" and needs partners.

When multiple CDMOs possess similar formulation capabilities, companies need to look at other factors to help decide which partner to pick. Turk said companies have a "long catalog of criteria when it comes to reliability and many other components."

By selecting CDMOs that fit the criteria, companies seek to ensure they choose partners that reliably deliver against the goals of the collaboration. In making that assessment, companies pay no attention to one obvious difference between CDMOs: their size.

"There are always some factors which you like more and some which you like less in your partner site, but in the end, there is definitely no exclusion criteria, saying, 'This company is too big, we don't want to collaborate' or 'It's too small.' It's really about the idea, and following our approach external becomes internal and we want to make sure that it happens at the proper site," Knerr said.

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FACTORS SHAPING COMMERCIAL SUCCESS

Companies that take a concept from the idea stage through to the delivery of an approved product face a new set of challenges. While novel formulations add value on paper, companies still need to make this case to the stakeholders with the power to shape whether a product will be a commercial success.

The task of communicating value is perhaps most challenging in the prescription drug market, which features counterintuitive incentives and a structure that empowers decision-making to people a long way from the point of care. Turk noted at the roundtable that sometimes providers make money from administering injections, disincentivizing them from adopting more convenient formulations. More broadly, companies face the challenge of communicating value to distant decision-makers. "At the moment, the price and reimbursement discussions are still rather centralized and the valuation of the reward for those innovations can be driven by the individual purchasers or purchasing groups or others," Turk said.

The OTC market is simpler in some regards. Consumers get to choose whether an OTC product represents good value to them. People who are willing to pay for convenience will buy premium products in on-the-go formats. More cost-conscious consumers will buy basic tablets. There is no

reimbursement system between manufacturers and the people who use their products.

However, OTC manufacturers face another set of challenges. In Knerr's view, it is impossible for OTC companies to sell incremental improvements without an existing recognized brand. Advertising can raise the recognition of unknown brands in the near term, but Knerr thinks it is hard for promotional campaigns to have lasting effects on consumer awareness.

Even OTC companies with recognized brands face challenges. Masson cited a recent survey run by Unither that found patients have minimal knowledge of stick packs. That fact is an impediment to OTC companies that want to introduce value-added formulations. "If patients don't know that it exists, they cannot ask for it at the pharmacist level, and if the pharmacist does not advise for this type of product it is very difficult," Masson said.

The challenges companies face in the prescription and OTC markets reemphasize the value of taking the time up front to understand the needs of all stakeholders and how differentiated drug-delivery technologies can address them. In doing so, companies increase their chance of coming to market with a product and messaging that resonates with key decision-makers.

THE FUTURE OF VALUE-ADDED FORMULATIONS

Stakeholders are becoming more receptive to value-added messaging. Health care systems' tendency to make purchasing decisions based on mortality and other hard endpoints led them to undervalue incremental improvements to existing products, but there are now signs of a newfound openness to patient-centric formulations.

In the Nordic region, purchasers are asking health care professionals and patients what they value, increasing the likelihood that products with convenience and quality-of-life benefits will be adopted. That approach reflects evidence that health care professionals and patients value incremental gains that make their lives better, plus knowledge that noncompliance with treatment regimens is stopping people from getting the full therapeutic benefits of medicines.

The Nordic example, which is echoed in other parts of the world, and the weight of evidence favoring incremental improvements suggests use of differentiated drug-delivery technologies will continue to grow in the coming years. Using these technologies, manufacturers across the branded, generics and OTC markets will create products that make a meaningful difference to people who take, prescribe and administer drugs. In doing so, manufacturers will improve health care efficiency and outcomes.

ABOUT UNITHER

Unither Pharmaceuticals is a global development and manufacturing partner for proprietary and generic dosage forms and a global leader in single unit dosage forms, specializing in blow-fill-seal (BFS), liquid and powder stick-packs. Our technologies enable line extensions and product differentiation that support modern on-the-go lifestyles, with the potential to improve dosing safety and medication adherence. Our mission is to provide innovative, competitive, and sustainable solutions to our customers.

For more information contact:
hugues.benevent@unither-pharma.com

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