

Tackling the disconnect in OTC innovation

Hans Regenauer has learnt a lot about OTC innovation management during his 30 years in senior positions at Bayer Consumer Care, Boehringer Ingelheim Consumer Health Care, Merz Pharma and Sanofi Consumer Healthcare. The biggest challenge is the disconnect between product development and marketing, he believes, while the biggest opportunities lie in beauty aesthetics and switching.

THE BIGGEST BARRIER to innovation in self-medication companies, according to Hans Regenauer, is the “strong disconnect” between product development and marketing teams. “Management spends an awful lot of time trying to moderate the misunderstandings between development people and marketing people,” comments Regenauer, adding that this disconnect has been a challenge everywhere he has worked.

These two groups of people have different mindsets when it comes to developing new products, says Regenauer. “Marketing focuses on consumer insights,” he remarks, “while development focuses on medical benefits.”

Regenauer’s observations are based on his experience during more than 30 years in the self-medication industry. Up until recently, he was managing director of Germany’s Merz Pharma. He had previously spent five years as worldwide head of Boehringer Ingelheim’s Consumer Health Care division, and has also worked for Bayer Consumer Care and Sanofi Consumer Healthcare.

Attempts to solve the problem

Tackling the disconnect is a tough challenge. In the past, Regenauer tried to solve this problem by recruiting development people with a good understanding of consumers and marketing. However, this proved “almost impossible”, he recalls, pointing

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out that “global searches produced only a handful of candidates”.

Regenauer maintains it is easier the other way around. Finding marketeers with a “reasonable” understanding of the technical aspects of product development is less of a challenge, he says.

Set against this background, Regenauer believes the solution is to create a joint explorative team of experts within the self-medication or consumer healthcare business.

This team would gather consumer insights for the overall business including all of the existing brands, explains Regenauer, and would pass on its conclusions to classical marketing and product development teams. These classical teams would then develop new products using frameworks established by the joint team of experts, he adds.

In addition to marketing and product development people, the joint explorative team of experts should include a “trend scout”, says Regenauer. This trend scout should “travel around the world, particularly in the Asia-Pacific region, looking out for ideas, ideas, and more ideas”, he explains.

Don't forget to involve regulatory experts

The joint team of experts should also include at least one regulatory affairs person, continues Regenauer, observing that all too often companies view regulatory affairs as an operational rather than a strategic discipline.

“Regulatory experts are often ignored in creative stages of product development processes,” says Regenauer. “They tend to be consulted at the end of the idea generation process, but they should be involved at the first stage.”

Regenauer also urges companies to get input from young people. “If you want to generate new business, you need to understand young people,” he insists.

“Experienced middle-aged brand managers may feel young, but they are not young anymore,” he comments. “Marketing teams must understand the needs and desires of young people.”

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Regenauer says the self-medication industry should tap into the global trends affecting young people. “In the past, a Chinese person was a Chinese person and a German was a German, and the two were different,” he says. “Today, young people around the world have a lot more in common.”

Asked to identify the big opportunities for the self-medication industry, Regenauer says the beauty aesthetics market offers “tremendous growth potential”.

Regenauer points out that the market is still at an early stage in its development. Global sales of dermal fillers and botulinum toxin products, such as Allergan’s Botox, are “quite small”, he says, at around US\$2 billion a year at manufacturer’s selling prices. Sales of energy-based devices are also around US\$2 billion, he added, and sales of cosmeceuticals, or active cosmetics, are approximately US\$1 billion.

Although the media is full of information about beauty aesthetics, observes Regenauer, market penetration is still relatively low. “Most people don’t know how good, simple and safe these products are to use,” he comments.

Regenauer maintains that the market is set to expand rapidly over the next few years. “The population is ageing, the desire to look young or younger is increasing, and disposable income is rising,” he says, adding that there could be a four-fold increase in sales of these products over time.

A good way of entering the market

Acquiring a company would be a good way of entering the beauty aesthetics market, says Regenauer, noting that there are a lot of local companies in the marketplace. “Many of these local players are successful and offer good quality products, but lack the capability to internationalise the business,” he remarks.

Regenauer gained extensive knowledge of the global aesthetics market during his time as managing director of Merz Pharma, which has a stated strategy of becoming “a leader in the field of medical and aesthetic dermatology”. Merz struck a number of aesthetics deals during Regenauer’s three years at the German pharmaceutical company.



The beauty aesthetics market offers tremendous growth potential for the self-medication industry, says Hans Regenauer

The most recent deal, announced in June 2014, saw Merz acquire US-based Ulthera, a leading energy device company in the field of non-invasive lift. Merz said the deal, which was worth up to US\$600 million, was the largest in its history.

Towards the end of 2013, Merz acquired Anteis for an undisclosed sum. The Swiss company marketed a range of wrinkle-filling gels, resorbable implants and rehydration gels in a number of countries worldwide.

The deal came a few months after Merz acquired another Swiss company, Neocutis, for an undisclosed sum.

Founded in February 2003 as a spin-off from the medical faculty of Lausanne University Clinic in Switzerland, Neocutis was a privately-held company that developed and distributed a portfolio of aesthetic dermatology products including formulations for anti-ageing, pigmentation problems, sun protection and dryness. Many were used as pre- and post-treatments for aesthetic procedures, primarily in the US.

Regenauer believes the self-medication industry's "credibility" could be a competitive advantage in the beauty aesthetics market. "The credibility of the self-medication industry in delivering efficacious products is very high," he adds, noting that quality is an issue with some products in the beauty aesthetics market.

Unlikely candidates for self-medication?

At first glance, dermal fillers, botulinum toxin and other beauty aesthetic products seem unlikely candidates for the self-medication industry. The legal status varies from country to country, but they are generally either medical devices or prescription-only medicines, and have to be applied by doctors or other healthcare professionals.

However, decision-making about the specific product to be used remains, in most cases, with the consumer. Furthermore, the product and treatment is paid for by the consumer.

"The widely-accepted limitation to self-medication is that the consumer chooses and buys products on his or her own in a

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retail outlet or a pharmacy,” says Regenauer. “But this is a self-limitation that I don’t think the self-medication industry has to respect.”

Regenauer urges the self-medication industry to push into new fields, such as beauty aesthetics, which he describes as OTX rather than OTC.

He points out that the beauty aesthetics marketplace encompasses hundreds of medical devices, laser-based products, dermo-cosmetics and other options. “If a product is efficacious and safe, and the consumer has decision power, then it could be considered by the self-medication industry,” he insists, citing lasers for beauty applications as an example.

Switching offers opportunities

Another big opportunity for the self-medication industry, according to Regenauer, lies in switching medicines from prescription to non-prescription status.

Speaking at a global OTC industry conference in June 2014, Andy Tisman, senior principal for Consumer Health at market researcher IMS Health, pointed out that switching medicines from prescription to non-prescription status had produced some “game changing” innovation. “Switch has been an important provider of new products and a key driver of growth in OTC over the years,” he told delegates attending the combined 50th Annual Meeting of the Association of the European Self-Medication Industry (AESGP) and 18th General Assembly of the World Self-Medication Industry (WSMI).

In the US, said Tisman, six of the top 10 brands, accounting for 9% of OTC sales, were recent switches. In Western Europe, he added, eight of the top 20 brands, representing 6% of OTC sales, were switches.

According to Tisman, switching would be “a key future growth driver for the industry”, but creating new consumer categories through innovative switches would remain a challenge, particularly in Europe.

Recent high-profile switches have mainly targeted traditional

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non-prescription product categories, such as allergy remedies, heartburn products and pain relievers. A number of companies are working on game changing switches that would create new product categories in the non-prescription arena, but they face many challenges.

A new consumer category was created in the US in 2013 when Merck & Co launched Oxytrol for Women. The product was the first-ever OTC treatment in the US for women suffering from overactive bladder. Furthermore, the US was the first country in the world to make the active ingredient, oxybutynin, available without a prescription.

First hand experience with Flomax Relief

Regenauer saw first hand the challenges faced by switch innovators during his time at Boehringer Ingelheim, which achieved a “first-in-class” UK switch of Flomax Relief (tamsulosin) for treating an enlarged prostate.

The UK became the first country in the world to make Flomax a non-prescription medicine for treating benign prostatic hyperplasia, or an enlarged prostate, in December 2009. The UK’s Medicines and Healthcare products Regulatory Agency (MHRA) approved the switch of 0.4mg tamsulosin hydrochloride capsules from prescription-only to pharmacy (POM-to-P) status for treating lower urinary-tract symptoms in men aged between 45 and 75.

However, commercial success proved elusive for Flomax Relief in the UK, and the medicine has not yet been switched in other countries.

Regenauer points out that industry is concerned about the future of switching worldwide, but is particularly worried about the attitude towards switching seen at regulatory bodies of the European Union’s member states.

Only three medicines have gained non-prescription status through the European Union’s centralised procedure. GlaxoSmithKline Consumer Healthcare’s Alli (orlistat) weight-loss medicine was the first in January 2009, followed by Nycomed’s 20mg pantoprazole tablets in June of the same

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year, and AstraZeneca's Nexium Control (esomeprazole) in 2013.

Industry is keen to take advantage of the benefits of the centralised procedure, which include approval in all member states. The procedure will play an increasingly important role in switching medicines, as the proportion of prescription medicines with a centralised licence is rising.

Regenauer describes switching as a “learning process for both industry and regulators”. There will eventually be a more positive environment for switching, he believes, because it offers benefits to consumers, public health and healthcare systems.

However, Regenauer is less optimistic about prospects for medical devices. Some companies have introduced OTC medical devices as a way of circumventing medicines legislation, he says, but regulators are now wise to this and are looking to tighten up the rules.

Regenauer highlights the tendency for companies to focus on active pharmaceutical ingredients (APIs) rather than consumer benefits. “The industry is still trying to optimise its existing APIs,” he says, adding “APIs are pushed into combination products and extended into different indications”.

The regulatory framework supports this approach, he adds, as regulators are hesitant to approve non-prescription products with different APIs. Nevertheless, he urges companies to “think outside the API box”.

Understand your capabilities

Regenauer stresses the importance of having “a complete and holistic” approach to OTC innovation management. The key to success – for the smallest player up to the largest multinational – is to have a “good understanding of your capabilities and philosophy and what you can do”, he says.

He notes that companies often have a “shotgun approach, involving a bit of investment here and a bit of investment there”. Some companies focus on reshaping usage of existing non-



Switching is a learning process for both industry and regulators, says Hans Regenauer

prescription APIs, some favour switching, and others bolster innovation through acquisitions, he says, but it is rare for companies to address all aspects of innovation.

“At the end of the day,” says Regenauer, “this shotgun approach is too thin to drive a brand towards the innovative edge.”

Regenauer understands only too well that OTC innovation management is challenging. “Self-medication/consumer healthcare is a hybrid of fast-moving consumer goods (FMCG) and pharmaceuticals,” he says, “but lacks the economies of scale of either.”

Some brands are only available in a single market and few have a strong enough global presence to support a major research and development programme, says Regenauer. Self-medication products are mostly for occasional use, he adds, and consumer research suggests the upper limit for retail prices of self-medication products is generally around €10.00 (US\$13.00) or £10.00 in Europe.

“At the end of the day, the magnitude of the business is not sufficient to provide critical mass in research and development for single brands,” he says, which means companies “cannot afford to waste their investment in research and development”.

Stresses the importance of focus

Regenauer stresses the importance of focus. But he maintains that “many companies are failing from a strategic perspective to identify what has to be done to drive innovation”.

Asked which self-medication companies are good at innovation, Regenauer says Reckitt Benckiser (RB) is ahead of the rest of the industry. “RB is really good at transferring technologies from its consumer-goods business into its self-medication business,” he explains adding that RB is “fast and brings new ideas into self-medication”.

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Hans Regenauer has set up HVR-Advice to offer strategy consulting to entrepreneurs with an emphasis on consumer healthcare and medical beauty.

Visit the website at www.hvr-advice.de.

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