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OTC bulletin

THE BUSINESS NEWSLETTER FOR THE CONSUMER HEALTHCARE INDUSTRY

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Issue Number 468

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Retzlaff steps down in Stada shake-up

Stada's Hartmut Retzlaff has resigned from his position as chairman of the management board at the German company "due to personal circumstances".

The move came shortly before Stada announced the make-up of its new supervisory board following a period of instability after minority shareholder Active Ownership's attempts to gain control of the committee (**OTC *bulletin***, 27 May 2016, page 6).

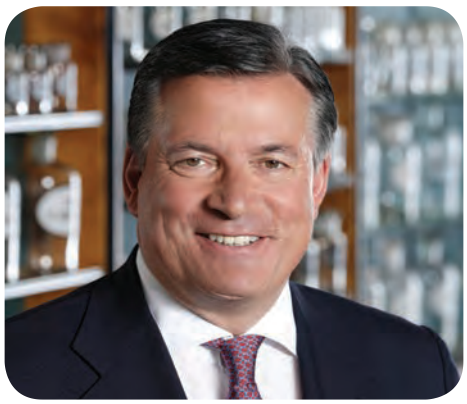
In June, Stada announced that Retzlaff had taken leave from his role as chief executive officer at the firm "due to a serious, long-term illness" (**OTC *bulletin***, 17 June 2016, page 27).

Executive board member Matthias Wiedenfels has taken over the chief executive officer role "until further notice", along with responsibility for corporate strategy and production.

Joining Stada in 1986 as sales and marketing director for its Stadapharm division, Retzlaff became head of Stadapharm in 1991. He stepped up to lead the German group two years later, and in September last year, Stada extended Retzlaff's employment contract by five years until August 2021 (**OTC *bulletin***, 25 September 2015, page 23).

Shortly after Retzlaff stepped down, Stada thwarted attempts by Active Ownership to replace the majority of the company's supervisory board with its own candidates.

Prior to a vote at the company's annual general meeting, Stada had warned that Active Ownership's desire to replace six supervisory board directors would be a "disruptive action", as well as "ill-considered and irresponsible" (**OTC *bulletin***, 12 August 2016, page 23).



Hartmut Retzlaff

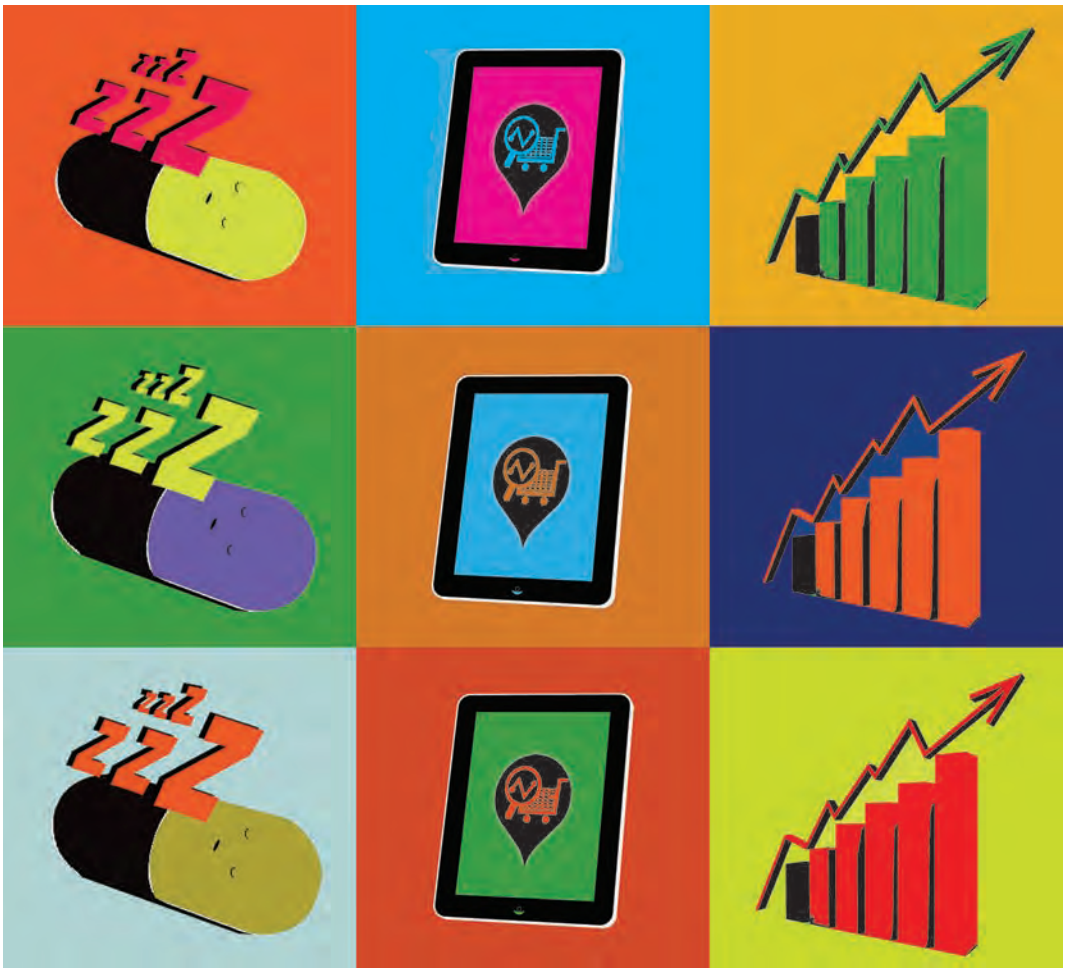
Following the vote, five new members joined the supervisory board, four of which had been nominated by Stada. Only Eric Cornut, Novartis' former chief ethics, compliance and policy officer, was elected from the list of candidates drawn up by Active Ownership.

Joining Cornut on the board are Stada candidates: Rolf Hoffmann, former senior vice-president of US commercial operations at Amgen; Dr Birgit Kudlek, previously chief operating officer at Aenova; Tina Müller, chief marketing officer at car manufacturer Opel; and Dr Gunnar Riemann, previously head of Environmental Science at Bayer Crop Science.

Stada's Carl Oetker has been elected chairman of the supervisory board, replacing Martin Abend, who was removed at the meeting.

Meanwhile, Stada announced that Dieno George had been promoted to take charge of the firm's Branded Products unit as part of a "fundamental change to the firm's reporting structure" (see page 4). OTC

Are your challenges giving you sleepless nights?



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Licensing Agreements

Mundipharma grows in MEA

Mundipharma has broadened its OTC product portfolio in the Middle East and Africa by striking a licensing deal with Jordan-based Munir Sukhtian group.

Under the terms of the agreement, UK-based Mundipharma has gained the commercial rights for 10 years to market Munir Sukhtian's HiGeen consumer healthcare brand in more than 50 countries across the Middle East and Africa.

The HiGeen line includes foot creams and powders, as well as hand sanitisers and creams.

"The HiGeen range complements very well our consumer health portfolio, which includes our Betadine range," commented Raman Singh, president of Mundipharma in Asia-Pacific, Latin America, Middle East and Africa. "The partnership will also help Mundipharma build on our strong leadership in the sector and help expand our presence."

"Mundipharma's expertise in emerging markets," continued Singh, "will increase access to these treatments for millions of people."

Deemah Sukhtian, Munir Sukhtian's manging director, claimed the "complementary nature" of HiGeen with Mundipharma's products would "provide a stronger proposition to consumers in the area of wound care and prevention of infectious diseases".

"We are confident that our alliance, leveraging Mundipharma's expertise and global network," Sukhtian added, "will enhance access to our innovative products and further improve the quality of life of consumers." OTC

Business Strategy

J&J is researching treatments for skin

Johnson & Johnson (J&J) Consumer has partnered with development company Xycrobe Therapeutics to research new treatments for skin conditions.

The partnership, the US-based firm said, would focus on "further understanding applications of Xycrobe's platform technology developed for the treatment of inflammatory skin diseases".

"The planned collaboration is intended to provide both companies with information on how Xycrobe's technology may be best applied to future therapeutic and commercial applications," J&J explained.

According to California-based Xycrobe, its platform technology "consists of a library of commensal [bacterial] strains from the skin microbiome engineered to grow and secrete biotherapeutics as needed to help treat an array of skin issues".

The company says it has developed "several strains of commensal skin bacteria that show potential for the significant reduction of inflammation, promising potential relief from a number of ailments including acne, dermatitis, eczema and psoriasis".

Commenting on the partnership, Thomas Hitchcock, Xycrobe's chief executive officer, said the company was "thrilled" to collaborate with J&J Consumer.

"It is our hope that this collaboration can help expedite getting our therapies into the hands of physicians and their patients who truly need better solutions," Hitchcock added.

J&J will work with Xycrobe Therapeutics

"The current paradigm for treating skin conditions, such as acne, completely disregards the importance of the commensal skin flora," Hitchcock argued.

"Overuse of antibiotics has led to a higher prevalence of resistant strains of bacteria," he insisted, "and along with that comes less efficacy of conventional treatments."

"We feel that the key to better treatment solutions for skin disease lies in understanding our body's interaction with the skin microbiome," Hitchcock explained, "and how we can leverage this information."

The partnership was facilitated by J&J Innovation, the firm's venture capital arm which aspires to find "the best science and technology, no matter where it is, to solve the greatest unmet needs of our time".

Most recently, the Innovation unit participated in a round of funding for the US-based firm First Aid Shot Therapy (FAST) to help the fledgling company expand its portfolio of single-dose liquid OTC medicines (**OTC *bulletin***, 27 November 2015, page 4). OTC

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Business Strategy/First-Half Results

George to lead Stada Brands

Dieno George has been promoted to take charge of Stada's Branded Products as part of a "fundamental change" to the firm's reporting structure.

In his new role, George – who is chief executive officer of Stada's UK subsidiary Thornton & Ross – would be responsible for "internationalising" Stada's brands and taking them into new markets, the firm explained.

Claiming that there existed a "lot of untapped growth potential" in the Branded Products portfolio, with some of its biggest brands only available in one or two markets, Stada said George would ensure a more "centralised" approach to its internationalisation strategy.

The Branded Products business unit will sit alongside a Generics business unit, led by Stada's regional director for Europe, Luc Slegers. As a result of this change, Stada said it would now manage the firm by operating segment rather than by both operating segment and market region.

"This measure is primarily designed to take account of our growth strategy, including central management of the core segments, increasing internationalisation of the product portfolio, as well as stricter cost control," the firm explained.

The change to Stada's reporting structure follows the departure of Hartmut Retzlaff, who has resigned from his position as chairman of the management board at the German company "due to personal circumstances".

Retzlaff had recently taken leave from his role as chief executive officer at the firm "due to a serious, long-term illness" (**OTC *bulletin***, 17 June 2016, page 27).

A Stada spokesperson said that while George would remain in his present role at the UK subsidiary, Barry Draude would run the business' "day-to-day" operations.

Stada announced the organisational changes as it reported turnover from Branded Products up by 5% to €407 million in the opening six months of 2016, as sales improved in five of its six biggest markets.

In Stada's home market, sales of Branded Products – under the Stadavita and Stada GmbH brand names – moved ahead by 48% to €98 million (see Figure 1).

Country	Group sales (€ millions)	Change (%)	Branded Products' sales (€ millions)	Change (%)	Branded Products' share in Stada (%)
Germany	247	+18	98	+48	40
Russia	110	-13	60	-29	55
Italy	101	+5	21	+23	21
UK	94	+7	84	+12	89
Spain	62	+1	9	+22	15
Belgium	46	-34	5	+8	11
Other	375	–	130	–	35
Total Stada	**1,035**	**+1**	**407**	**+5**	**39**

Figure 1: Sales by Stada and its Branded Products division in the opening six months of 2016, together with the proportion of group sales accounted for by Branded Products (Source – Stada)

"High seasonal orders", in combination with successful efforts to "optimise" the firm's OTC offering in Germany, had been behind the double-digit improvement, Stada said.

Branded Products' turnover accounted for 40% of group sales in Germany, which advanced by 18% to €247 million.

Meanwhile, Branded Products' sales had been held back, Stada noted, by a weaker performance in Russia.

A "decrease in purchasing power" among consumers in Russia, due to the economic situation, had caused sales of Branded Products to decline by 29% to €60 million, the firm said. Lower sales had also been compounded by negative currency effects related to the Russian rouble.

Branded Products accounted for 55% of group sales in Russia, which slipped back by 13% to €110 million.

In the UK, where Stada acquired Thornton & Ross in 2013 (**OTC *bulletin***, 23 August 2013, page 1), Branded Products' sales improved by 12% to €84 million.

Acquisitions and good performances from key brands had driven the rise in sales, Stada said, adding that growth had been held back by a "weak cold season" at the start of the year.

During the period, Stada expanded its Branded Products portfolio in the UK by striking a licensing deal with Reckitt Benckiser (RB) for the K-Y range of personal lubricants (**OTC *bulletin***, 30 June 2016, page 3).

Stada has been granted the rights to market K-Y in the country for an eight-year period.

Branded Products accounted for 89% of UK turnover in the first half, which increased by 7% to €94 million.

In Italy, turnover from Branded Products had improved by 23% to €21 million, Stada reported, thanks to acquisitions.

Branded Products accounted for 21% of total turnover in Italy, which moved forward by 5% to €101 million.

Branded Products generated 39% of Stada's total sales in the first half of 2016. These moved forward by 1% to €1.04 billion (see Figure 2). Stada's dominant Generics business accounted for the bulk of the remainder. OTC

Business	First-half sales (€ millions)	Change (%)	Operating profit (€ millions)	Change (%)
Generics	604	-2	104	+22
Branded Products	407	+5	71	-1
Commercial	23	+10	0.3	>100
Group/Other	0.1	–	-39	–
Total Stada	**1,035**	**+1**	**136**	**+22**

Figure 2: Stada's sales and operating profit in the opening six months of 2016 (Source – Stada)

Mergers & Acquisitions

Lonza grabs InterHealth

Switzerland's Lonza has expanded its portfolio by acquiring dietary supplements ingredients manufacturer InterHealth Nutraceuticals for €300 million.

Describing InterHealth as a "leader in the research, development, manufacture and marketing of value-added nutritional ingredients for dietary supplements", Lonza said the deal represented a step forward on its "strategic path".

"Lonza will leverage the successful product portfolio of InterHealth on a global level, and in turn will be able to benefit from InterHealth's proven management and branding capabilities to promote Lonza's existing product portfolio," commented the Swiss firm. OTC

Business Strategy/Second-Quarter Results

Perrigo reviewing its options

Perrigo is "beginning to explore strategic alternatives" for its Branded Consumer Healthcare operations in Argentina, Russia and South Africa, according to the firm's chief executive officer John Hendrickson.

Speaking as the store-brand specialist announced the results of its second quarter ended 2 July 2016, Hendrickson said Perrigo was reviewing its options in all three countries as part of a plan to "enhance value across the portfolio".

The company was taking "tangible actions to address market structures in certain countries", Hendrickson noted.

These actions would "reduce operating costs and improve profitability", he said, and allow the firm to "reinvest resources into the high-performing parts of our business".

In Argentina, Russia and South Africa, Perrigo was reviewing how it could "change the way we're doing things", Hendrickson revealed. "As we look at those [businesses] that are not performing as well as we want, we're saying 'how do we get those performing well, or is there another way to manage that asset or to do those things?'," he explained.

Perrigo revealed its decision to explore its options in Argentina, Russia and South Africa as it continued to wrestle with problems at its Branded Consumer Healthcare business.

Sales at Branded Consumer Healthcare – comprising the Omega Pharma business and the basket of brands the company snapped up from GlaxoSmithKline (GSK) last year (**OTC *bulletin***, 12 June 2015, page 1) – slipped back by 2% to US$394 million (€354 million) in the second quarter.

Business	Second-quarter sales (US$ millions)	Change (%)	Operating income (US$ millions)	Change (%)
Consumer Healthcare	686	-8	134	-16
Branded Consumer Healthcare	394	-2	59	-24
Prescription Pharmaceuticals	293	+5	127	-8
Specialty Science/Other	108	–	73	–
Total Perrigo	**1,481**	**-3**	**393**	**-10**

Figure 1: Perrigo's sales and operating income in the three months ended 2 July 2016 (Source – Perrigo)

"Lower sales in the lifestyle and natural health/vitamins categories" had been behind the drop in sales, Perrigo said.

Adjusted operating income was US$59 million, giving the business an adjusted operating margin of 14.9%.

To improve Branded Consumer Healthcare's performance the company was "prioritising brand strategies in core markets", Hendrickson explained, and making "structural changes" to ensure the business was more efficient.

"There's substantial work to be done," Hendrickson admitted, "but I am confident we can create greater shareholder value by improving and further leveraging this important Branded Consumer Healthcare platform."

"The path of steadily-improving margins is multifaceted and it will take time, but the team has an actionable, multi-layered plan to improve profitability," he insisted.

Perrigo revealed earlier this year that it was experiencing problems at Branded Consumer Healthcare when the business posted fourth-quarter results that recently-departed chairman and chief executive officer, Joseph Papa, described as a "personal disappointment" (**OTC *bulletin***, 4 March 2016, page 1).

These problems continued into 2016, with the company reporting in May that first-quarter sales at the unit had fallen "considerably short of top-line expectations" (**OTC *bulletin***, 27 May 2016, page 4).

Lower Branded Consumer Healthcare sales in the second quarter, combined with a drop in turnover at the firm's store-brand Consumer Healthcare unit, left Perrigo's total sales in the three months down by 3% to US$1.48 billion (see Figure 1).

Consumer Healthcare's sales had dropped by 8% to US$686 million, Perrigo noted, due to a "relatively weak allergy season" and lower orders in the contract manufacturing business.

Perrigo's Consumer Healthcare and Branded Consumer Healthcare divisions accounted for 73% of group turnover in the second quarter. The remainder was generated by the firm's Prescription Pharmaceuticals and Specialty Sciences divisions, plus 'other' sales.

Separately, Perrigo has expanded its US operation by acquiring for an undisclosed sum distribution company Geiss, Destin & Dunn.

A privately-owned distributor of OTC and consumer goods to the non-chain retail and institutional markets in the US, Geiss, Destin & Dunn also owns the GoodSense range of OTC and personal-care lines.

Commenting on the deal, Hendrickson said acquiring Geiss, Destin & Dunn would "further strengthen and diversify" the firm's US distribution and retail network and provide it with "direct access to the non-mass retail market".

"While we currently distribute products to this channel through Geiss, Destin & Dunn, I am pleased we will now bring the management of this business completely in-house," Hendrickson added. OTC

Mergers & Acquisitions

Life Wear snaps up TriCalm

Sports medicine firm Life Wear Technologies has made its first foray into the consumer healthcare market by acquiring the TriCalm anti-itch brand from Cosmederm Bioscience for an undisclosed sum.

"The TriCalm brand is an excellent fit for our company," commented US-based Life Wear's chief executive officer Brad Waugh.

"It is a natural extension of our product offering," Waugh insisted, "and allows us to leverage and strengthen our existing relationships with national and regional retailers."

Comprising three products – TriCalm Hydrogel, TriCalm Clinical Repair Cream and TriCalm Extra Strength Spray – the TriCalm range is sold across the US through retailers such as Walgreens, Walmart and Rite Aid.

Commenting on its plans for TriCalm, Life Wear said it intended to invest heavily in "brand media and marketing programmes" to drive sales.

"We will continue to partner with Cosmederm," Life Wear added, "as our ultimate goal is to deliver new and innovative products to our end consumers."

Cosmederm's chief executive officer, Joseph Pike, said it was the right time to offload TriCalm to allow the firm to "focus on our strengths in the field of drug development".

Established in 1974, Life Wear markets a range of private-label and branded sports medicine products including elastic bandages, athletic tape, sports supports and heat packs.

The firm recently launched in the US its Flex-Aid range of knee and ankle supports. OTC

Business Strategy

Cold-EEZE up for sale

ProPhase Labs has revealed its board is weighing up a "wide range of strategic initiatives and alternatives", including the potential sale of its core Cold-EEZE brand, in an effort to "further enhance shareholder value".

Speaking as the US-based firm reported second-quarter sales up by 27% to US$2.8 million (€2.5 million), chief executive officer Ted Karkus said ProPhase would listen to offers for its Cold-EEZE homoeopathic cold and flu range.

"Everything is on the table," Karkus revealed, "with the goal of increasing shareholder value."

Claiming that Cold-EEZE was a "growing brand", Karkus said the timing was right to explore a potential sale. "There are lots of buyers out there," he insisted. "It's a seller's market."

However, ProPhase would only be open to selling Cold-EEZE to a buyer "willing to pay

ProPhase's Cold-EEZE cold and flu brand

a significant price", Karkus noted.

"I am highly confident that the Cold-EEZE brand alone is worth significantly more than the entire market capital of the company, which is around US$26 million," he insisted.

In addition to weighing up the possible sale of Cold-EEZE, Karkus said ProPhase would "explore a variety of acquisition opportunities" to grow the business.

"We are searching for acquisitions of other products," he explained, "including brands both inside and outside our industry."

"Smaller" acquisitions could be financed right away, Karkus noted, while larger deals would be dependent on first finding a buyer for Cold-EEZE.

Karkus indicated that ProPhase was not intending to sell its TK Supplements brand, which the firm launched earlier this year to diversify its portfolio into the dietary supplements category (**OTC *bulletin***, 22 April 2016, page 5). Under the TK umbrella, ProPhase markets the Legendz XL male sexual enhancement supplement. OTC

Business Strategy

Sanofi prepares for growth in Australia

Sanofi Consumer Healthcare is expanding its production facilities in Australia in response to increasing demand for its vitamins, minerals and supplements (VMS) in the Asia-Pacific region.

Noting that it had already invested A$30 million (€20 million) this year in its Brisbane manufacturing facility, Sanofi said it was committed to spending a further A$5 million to grow the site, which produces the Cenovis, Nature's Own and Ostelin VMS lines.

Brett Charlton, general manager of Sanofi Consumer Healthcare Australia, revealed the firm was seeing "strong" and growing demand for its Australian-produced VMS brands in China.

A "large proportion" of Sanofi Consumer Healthcare's sales growth in Australia was being driven by Chinese consumers, Charlton explained, who wanted "clean and green, quality Australian products".

"Certain niche products and segments are influencing this growth," he noted, "in particular vitamin D and fish-oil supplements, plus women's health and children's health lines."

"Women's health is a big opportunity," Charlton insisted, noting that the firm's Nature's Own products in this category were especially popular with Chinese consumers.

While Sanofi was currently experiencing strong demand from China, Charlton claimed

Sanofi's Nature's Own supplement range

that there was demand for "quality Australian products from all across Asia-Pacific".

Sanofi's growth in Australia was recently highlighted by Vincent Warnery, global head of the French firm's Consumer Healthcare unit.

Speaking to **OTC *bulletin***, Warnery said Australia had become a "success story" for Sanofi, following an impressive turnaround in the country (**OTC *bulletin***, 19 February 2016, page 7).

"We had some issues in Australia a few years ago," Warnery admitted, "and we weren't equipped to run the business properly."

"So we took the time to react," Warnery said. "We appointed the right leader, added capabilities in OTC regulatory and industrial affairs, and in 2015 Australia was, together with the US, our top-performing business."

"We overachieved our objectives and grew market share not only in VMS with brands like Nature's Own, but also in OTC, with Telfast, the local equivalent to Allegra." OTC

Mergers & Acquisitions

WBA ups stake in Amerisource

Walgreens Boots Alliance (WBA) has exercised warrants ahead of schedule to buy almost 22.7 million shares in US pharmaceutical wholesale firm AmerisourceBergen.

Noting that the warrants were originally scheduled to be exercisable in March 2017, the US wholesale and retail giant said it had come to an agreement with AmerisourceBergen to activate the option earlier than planned.

The US$1.19 billion (€1.05 billion) cash transaction gives WBA a 23.9% stake in AmerisourceBergen with nearly 56.9 million shares.

WBA and AmerisourceBergen forged an alliance three years ago as part of a 10-year long distribution agreement between the two companies (**OTC *bulletin***, 29 March 2013, page 1).

"Today's announcement builds on the strong and collaborative working relationship our firms have built together, and further strengthens the long-term strategic relationship we launched in 2013," commented WBA's chief executive officer Stefano Pessina.

"Since the beginning of the strategic relationship," Pessina noted, "we have worked together with AmerisourceBergen to improve the customer experience by delivering the right products at the right time to ensure that we are able to provide exceptional patient access and care in our US pharmacy operations."

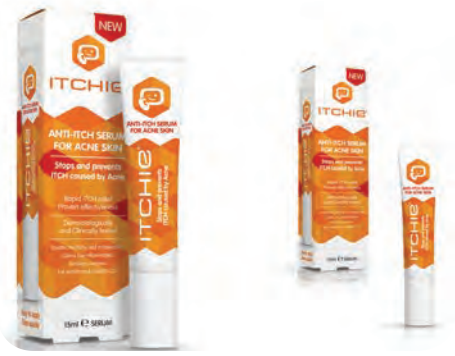
Net earnings attributable to the investment in AmerisourceBergen will be classified within the operating profit of WBA's Pharmaceutical Wholesale business.

The deal marks the second time this year that WBA has grown its stake in AmerisourceBergen, following a similar transaction in March. OTC

Spotlight on…
Lahurque International

- **ESTABLISHED:** 2012
- **BASED:** Valkenswaard, the Netherlands
- **SALES:** Around €5 million (2017 forecast)
- **LEADERSHIP:**

Peter van den Hurk, managing director



- **PRODUCTS:** ITCHIE acne treatment
- **MARKETS:** Ecuador, Norway, Peru, Switzerland,Turkey, the Middle East
- **WEBSITE:** *lahurqueinternational.com*

LAHURQUE® INTERNATIONAL

ABOUT

"Lahurque International's main goal is to develop innovative OTC medical devices for skin problems that provide solutions for consumers worldwide," according to managing director Peter van den Hurk. "We are passionate about discovering gaps and opportunities within the dermatological OTC segment and identifying consumer product needs."

The Netherlands-based company's portfolio currently comprises one OTC medical device, the ITCHIE acne treatment, which it recently launched into a number of markets across Europe, the Middle East, and South America. Lahurque markets its portfolio through a network of international distributors.

Noting that the firm was currently investing in innovation to expand its product offering, van den Hurk said Lahurque's greatest strength was its ability to "create first-class OTC medical devices that stand out in the market, have unique benefits and are highly effective".

KEY BRAND

"ITCHIE is a serum for the treatment of acne and especially, but not limited to, itchy and irritated acne skin," van den Hurk explained.

There was a gap in the market for ITCHIE, he claimed, as no other OTC product could treat itchy acne as "effectively and instantly".

"ITCHIE creates an invisible layer on the acne skin which provides a direct cooling sensation, rapidly soothes the itching and irritated acne skin and effectively calms the acne inflammation," van den Hurk noted. "At the same time, the invisible layer acts as a barrier to protect the acne skin against irritating environmental influences."

ITCHIE was different from other acne products on the market containing benzoyl peroxide and salicylic acid, he claimed, because it was based on natural ingredients.

"Part of the success we have already had with ITCHIE is that it works rapidly and consumers will see and feel direct results."

BUSINESS STRATEGY

"Our ambition for the coming years is to expand our products' availability into new markets," van den Hurk stated.

"We would like to establish a presence in the major European countries, as well as in the US and the key Latin American and Asian markets," he pointed out.

"To achieve this, we are interested in entering into new partnerships with distributors who are enthusiastic about representing and selling our products in specific countries or markets," van den Hurk noted.

In addition to expanding into new markets, Lahurque was also "dedicated" to widening its portfolio, van den Hurk explained, noting that the company was hoping to introduce a "steady flow" of innovative products.

"We already have several new and promising products in the pipeline, which we plan to launch over the next few years," van den Hurk promised. OTC

For the opportunity to feature in the Spotlight section, email Tom.Gallen@otc-bulletin.com

Second-Quarter Results

Sales down at Moberg

Moberg Pharma reported a double-digit drop in second-quarter sales to SEK71.3 million (€7.45 million), as turnover declined in all three of its global business regions.

The Sweden-based firm's sales fell back by 23% overall, with Europe recording the biggest plunge in turnover.

Peter Wolpert, Moberg's chief executive officer, explained that a 43% slide in sales in Europe had been due to "increased competition".

"Going forward, we expect European sales to be at a lower level," he admitted.

Turning to the firm's North and South America region, Wolpert reported turnover down by 21% to SEK53.9 million, as a result of "discontinued product variants" and lower sales of its Kerasal Ointment line.

"All other products" had delivered growth, Wolpert pointed out, including the firm's key Kerasal Nail antifungal product.

Widening distribution meant that Kerasal Nail – known as Emtrix or Nalox in a number of markets – now accounted for over a quarter of sales in the US retail fungal-nail segment, Wolpert explained.

Expanded US portfolio

Following the close of the period, Moberg strengthened its US OTC portfolio by acquiring three brands from Prestige Brands for US$40 million (€36 million).

The three brands – Fiber Choice, New-Skin and PediaCare – had generated sales of around US$24.4 million in the year ended 31 March 2016, Moberg noted, and were "well-established" in the US OTC market (**OTC *bulletin***, 22 July 2016, page 2).

Commenting on the rationale behind the deal, Wolpert said the acquisition was "in line with our strategy to add critical mass to our US operations, as well as a leading topical brand to our core dermatology franchise".

Turning to Moberg's Rest of World business, Wolpert reported turnover down by 13% to SEK10.5 million.

"Volume discounts", in combination with a number of product divestments, had been to blame for the drop in sales, Wolpert explained.

Despite the overall fall in sales in the region, Wolpert noted that Kerasal Nail was "reaching a market leading position" in "most countries" across Asia where Moberg had a presence. In addition, test launches of the product had been initiated in China and Japan, he said. OTC

First-Half Results

Latin America lifts turnover at Merck

A strong performance in Latin America helped drive up sales at Merck KGaA's Consumer Health business by 3.2% operationally in the opening six months of 2016.

However, negative currency effects of 14.0% had wiped out the operational gain, the German firm pointed out.

This left Consumer Health's first-half sales down by 10.8% at €427 million.

The Neurobion and Dolo-Neurobion vitamin B brands had boosted sales in Latin America in the six months, Merck noted, along with a solid showing from 'local brands'.

During the period, Merck expanded its Consumer Health portfolio in Latin America with the Anemidox/Confer and Hepabionta brands, which were transferred from its Biopharma business (**OTC *bulletin***, 5 February 2016, page 15).

Anemidox/Confer was for "the treatment and prevention of iron deficiency-related anaemia at every stage of life", Merck explained, while Hepabionta was designed to support and protect the liver.

Commenting on the transfers, Uta Kemmerich-Keil, chief executive officer of Merck Consumer Health, said the brands had "great potential for consumerisation", adding that the company planned to "further develop" them and "thereby generate future growth".

Outside Latin America Consumer Health had recorded "low single-digit growth" in Europe in the six months, Merck said.

"Strong demand" for the Femibion women's health supplement had driven up sales in many Eastern European markets, the firm noted.

Meanwhile, in Consumer Health's Asia-Pacific region, the business had enjoyed growth in India, Indonesia, Thailand and Singapore, Merck noted.

Indonesia remained the Consumer Health unit's "growth engine" in the region, the company pointed out, thanks to a strong showing from the Sangobion anaemia supplement.

During the six months, Merck expanded its portfolio in the Asia-Pacific region with three dietary supplements transferred from the Biopharma business.

The Evion vitamin E product, Livogen iron and folic acid supplement and the Polybion vitamin D brand were all marketed in India, Merck explained, and generated combined annual sales of around €45 million.

Consumer Health accounted for 5.7% of Merck's total sales in the opening six months of 2016, which moved forward by 19.3% to €7.47 billion. OTC

Business Strategy

Vitamin Shoppe grows footprint

Vitamin Shoppe has expanded its footprint in Central America with the opening of three stores in Costa Rica.

Located in the country's capital, San José, the three franchise outlets were opened as part of a partnership between Vitamin Shoppe and local player Vita Vida.

The partnership between the US-based natural products retailer and the local firm will see Vita Vida open a further eight Vitamin Shoppe stores in Costa Rica over the next five years.

Each store in Costa Rica would offer consumers a "curated selection of Vitamin Shoppe's proprietary brands", the retailer said, as well as "other leading third-party brand products".

"The Vitamin Shoppe brand continues to resonate with customers outside the US, and we are pleased to be launching in another new country this year," commented David Denker, the firm's director of international development.

"Working with partners, such as Vita Vida," continued Denker, "Vitamin Shoppe is able to educate consumers about the supplements industry as well as how to live a health and wellness lifestyle."

Expanding in Panama

Separately, Vitamin Shoppe said it planned to open two new outlets in Panama to take its total number of stores in the country to four.

The company took its first steps into Central America earlier this year with the opening of three stores in Guatemala (**OTC *bulletin***, 5 February 2016, page 8).

Located in Guatemala City, the three outlets were opened in collaboration with Swiss company Grupo Unipharm.

The partnership will see Grupo Unipharm open a further 12 Vitamin Shoppe stores in Guatemala over the next 10 years. OTC

Annual Results

P&G suffers tough year

Procter & Gamble's (P&G's) Personal Health Care business endured a "difficult" year ended 30 June 2016 with several "headwinds" holding back growth, according to the US firm's chairman David Taylor.

Personal Health Care had suffered through a "very weak cough/cold season in the US", Taylor pointed out, while also facing a tough comparison with the prior year when a number of line extensions to the Metamucil and Vicks brands had been launched.

Despite this, organic sales had moved forward in the 12 months, he noted.

The Personal Health Care unit includes sales from P&G's wholly-owned US OTC business and the PGT Healthcare OTC joint venture it established with Teva in 2011 (**OTC *bulletin***, 16 November 2011, page 1).

Personal Health Care is part of P&G's wider Health Care business – along with the Oral Care unit – which reported sales down by 5% to US$7.35 billion (€6.59 billion) in the 12 months.

Negative currency effects and adjustments for acquisitions and divestments had been enough to offset 3% growth driven by increased pricing and a better product mix, P&G said.

By contrast, Health Care's pre-tax profits rose by 7% to US$1.81 billion in the 12 months.

Health Care accounted for 11% of P&G's annual sales, which declined by 8% to US$65.3 billion, due mainly to negative currency effects.

By contrast, total group pre-tax profits advanced by 21% to US$13.4 billion, thanks to reduced costs.

Health Care not a priority

In February, P&G said that its Health Care business was not a "particular priority" for the US consumer giant (**OTC *bulletin***, 5 February 2016, page 6).

Jon Moeller, P&G's chief financial officer, made no mention at the time of the firm's Health Care business as he revealed that the firm had put a "particular priority" on strengthening its "four largest categories: Baby Care, Fabric Care, Grooming and Hair Care".

Despite this, Taylor revealed that the company had restructured its Personal Health Care sales team in the US to ensure that the average experience level was more than five years of healthcare sales exposure.

He also insisted that the team was solely dedicated to selling the company's OTC brands in the country. OTC

First-Half Results

BI reports OTC rise before Sanofi deal

Boehringer Ingelheim reported a rise in first-half sales at its Consumer Health Care unit as the privately-owned German firm prepares to hand over the business to Sanofi.

Turnover at Consumer Health Care had improved by 5% on a currency-adjusted basis to €750 million in the opening six months of the year, Boehringer said. In euro terms, sales were down by 4%.

Exit the OTC market

In June, Boehringer reached a definitive agreement to swap its Consumer Health Care business for Sanofi's Merial animal healthcare unit (**OTC *bulletin***, 30 June 2016, page 1). The deal will see Boehringer exit the OTC space in all markets around the world, except China.

Announcing the definitive agreement, Boehringer cited ongoing consolidation in the global OTC industry as the company's primary motivation for offloading Consumer Health Care.

Speaking in May, Andreas Barner, chairman of firm's management board, said Boehringer had decided to enter talks with Sanofi as the company would have had to "invest considerable amounts in acquisitions" in order to "survive the consolidation process" in the OTC arena and "retain the critical mass required" (**OTC *bulletin***, 6 May 2016, page 5).

"This is a market in which, in the long run, Boehringer would no longer be competitive," Barner admitted.

Consumer Health Care accounted for just over a tenth of Boehringer's total first-half sales, which moved forward by 2% to €7.3 billion. The firm's Prescription Medicines business accounted for the bulk of the sales, with turnover rising by 4% to €5.5 billion, with the Animal Health and Biopharmaceuticals units responsible for the remainder. OTC

Annual Results

Blackmores enjoys rise

Australian natural health firm Blackmores reported sales up by 52% to A$717 million (€491 million) in the year ended 30 June 2016, driven by a double-digit rise in turnover in its core domestic market.

Sales in Australia advanced by 56% to A$495 million in the 12 months, accounting for just over two-thirds of Blackmores' total turnover.

Christine Holgate, Blackmores' chief executive officer, said "growing consumer demand for high quality, natural wellness products" had been behind the double-digit rise in domestic sales.

"In addition," continued Holgate, "the Australian business continued to benefit from increased sales to Chinese tourists and entrepreneurs shopping in Australia, as well as Chinese Australian consumers purchasing for relatives and friends and shipping to China."

During the 12 months, Blackmores expanded its domestic operation by acquiring for A$23 million traditional Chinese medicine manufacturer Global Therapeutics (**OTC *bulletin***, 27 May 2016, page 4).

The firm claimed at the time that the deal would give Blackmores a "foothold in the rapidly-growing Chinese herbal medicines market".

Turning to the company's sales in Asia, Holgate noted that turnover in the region had improved by 54% to A$129 million.

Singapore, Hong Kong and Taiwan had delivered "record growth" in the 12 months, Holgate said, thanks to "line extensions, increased distribution and further investment in our brand".

China – Blackmores' biggest Asian market – had also enjoyed a good year, she pointed out, driven by a rise in e-commerce sales.

Blackmores recently expanded its presence in Asia by establishing a joint venture with Kalbe Farma to "facilitate" its entry into the Indonesian market (**OTC *bulletin***, 6 November 2015, page 3).

At the time, Blackmores said that establishing a presence in Indonesia was an important part of its "Asia growth strategy".

Meanwhile, commenting on the BioCeuticals business – the Australian nutritional supplements firm Blackmores acquired in 2012 (**OTC *bulletin***, 29 June 2012, page 1) – Holgate said its sales had advanced by 25% to A$69 million in the 12 months, driven by launches of "innovative new products".

BioCeuticals markets supplements to medical practitioners, natural health professionals and pharmacists, primarily in Australia and New Zealand. OTC

First-Half Results

OTCPharm boosted by demand for VMS

"Increasing demand" for vitamins, minerals and supplements (VMS) in Russia lifted turnover at OTCPharm by 68.4% to RUB11.3 billion (€155 million) in the opening six months of 2016, the company reported.

Sales of wholly-owned brands had risen by 65.9% to RUB9.29 billion in the period, OTCPharm noted, driven by an 86% rise in turnover from VMS products.

The stand-out performer in the period had been the Magnelis supplement, the company pointed out, posting sales of RUB643 million, up from RUB216 million in the prior-year period. This growth propelled Magnelis from tenth to sixth position in the ranking of OTCPharm's top-10 brands (see Figure 1).

Introducing the Magnelis B6 Forte line extension, in combination with increased demand for VMS products, had been behind the jump in the brand's sales, the firm explained.

Sales of Complivit vitamins had improved by 43.9% to RUB1.09 billion, the company noted, helping to maintain its position as OTCPharm's second-best selling brand. Launching a range of line extensions, such as Complivit Shine and Complivit Chondro, had driven the double-digit rise, OTCPharm pointed out.

Meanwhile, OTCPharm said better sales of cold and flu products had also boosted turnover.

Flu pandemics in January and March had lifted demand for Arbidol in the period, the company explained, with sales of the brand up by 58.2% to RUB950 million. This rise in incidences of flu had also benefitted Amixin, with sales growing by 63.9% to RUB949 million.

In addition to the overall rise in sales of wholly-owned brands, OTCPharm also reported better turnover from products that the company markets in Russia on behalf of other manufacturers. Sales from these products advanced by 80.7% to RUB2.05 billion in the six months.

OTCPharm was established via a spin-off of Pharmstandard's branded OTC business in 2013 (**OTC *bulletin***, 17 January 2014, page 6). OTC

Business	First-half sales RUB millions)	Change 2015/2016 (%)	Proportion of sales (%)
Pentalgin	*1,502*	*+41.9*	*13.2*
Complivit	*1,087*	*+43.9*	*9.6*
Arbidol	*950*	*+58.2*	*8.4*
Amixin	*949*	*+63.9*	*8.4*
Aphobasolum	*656*	*+55.6*	*5.8*
Magnelis	*643*	*>100*	*5.7*
Acipol	*508*	*+64.9*	*4.5*
Rinostop	*441*	*+47.9*	*3.9*
Codelac	*359*	*+7.1*	*3.2*
Flukostat	*357*	*+9.5*	*3.1*
Other	*1,841*	*–*	*16.2*
Wholly-owned brands	9,294	+65.9	81.9
Third-party products	2,054	+80.7	18.1
Total OTCPharm	**11,348**	**+68.4**	**100.0**

Figure 1: OTCPharm's sales in the first half of 2016 broken down by business (Source – OTCPharm)

IN BRIEF

NUGO NUTRITION – the US-based sports-nutrition company – had expanded its portfolio by acquiring for an undisclosed sum the **Promax protein brand** from Promax Nutrition. "Promax has been a mainstay in the sports-nutrition category for more than 20 years," commented NuGo's chief executive David Levine. "NuGo recognises the great potential of the Promax brand and will leverage its expertise in the nutrition bar category, and its extensive sales network, to create a solid growth platform for the brand under NuGo's umbrella." OTC

Mergers & Acquisitions/Annual Results

Adcock to sell Ayrton

South Africa's Adcock Ingram is set partially to realise plans to withdraw from Ghana to focus more on its domestic market, after agreeing to sell a majority stake in its Ghanaian Ayrton Drug Manufacturing business to local manufacturer and distributor Dannex for an undisclosed sum.

Adcock has agreed to divest a 53.47% share of Ayrton, representing just over two-thirds of Adcock's existing 78.57% Ayrton stake.

Adcock first approached Ayrton with an offer to acquire at least 51% of the Ghanaian company's shares late in 2009, with an agreement for 65.59% of Ayrton tied up in April the following year.

No expected completion date for the transaction was disclosed, with the deal "subject to a number of conditions precedent". "The mode of payment for the shares will be cash," Adcock revealed.

Established in 1965, Ayrton manufactures a range of prescription and OTC drugs, including the Baby Paralex children's pain-relief line, Clobet dermatology range, Medi-Keel A throat lozenges and the Samalin cough and cold brand.

In March this year, Adcock chief executive Andy Hall announced that the firm was actively looking to exit both Ghana and India, the latter being partially achieved shortly after through the agreed sale of the sales and marketing arm of Adcock's Cosme Farma operation to a local private-equity company (**OTC *bulletin***, 22 April 2016, page 8).

Adcock retained Cosme's regulatory services business covering "quality control and assurance, medical affairs, information technology support and research and development services".

Both Ghana and India were thus listed as discontinued operations in Adcock's financial report for the year ended 30 June 2016, during which time group sales improved by 7.5% to ZAR5.55 billion (€335 million), thanks to advances by its Southern African OTC and Consumer businesses.

During the 12 months, OTC sales had improved by 14.7% to ZAR1.67 billion, Adcock pointed out, driven by "greater volume demand" for its Adco-Dol analgesic, Corenza C cold and flu line, and its Allergex allergy line.

OTC turnover accounted for 31% of Adcock's Southern Africa sales – which advanced by 7.3% to ZAR5.39 billion – with the firm's Consumer, Hospital and Prescription businesses generating the remainder. OTC

First-Half Results

Krka posts sales drop

Turnover from Krka's non-prescription products – including self-medication lines and cosmetics – slipped back by 1.1% to €50.3 million in the opening six months of 2016.

The Slovenian firm said gains in its domestic market and South-East Europe region had been offset by lower sales in East Europe.

Krka blamed the overall decline in sales in East Europe on the company's performance in Ukraine, where the non-prescription medicines market had shrunk dramatically in the six months.

On a more positive note, Krka reported non-prescription turnover up by 22% to €4.2 million in its domestic market, thanks to better sales of analgesics.

The naproxen-based product Nalgesin had been the firm's leading non-prescription product in Slovenia in the six months, Krka said, with the paracetamol brand Daleron also performing well.

Turning to South-East Europe, Krka said non-prescription sales had risen by 19%, thanks to growth in Romania and Croatia.

Better sales of Nalgesin and Septolete throat lozenges had helped to lift turnover in Romania by 31%, the firm noted, while sales had improved 23% in Croatia, driven by the performance of Ginkgo biloba-brand Bilobil.

Non-prescription products represented 9.2% of Krka's Human Health sales in the first half of 2016, which slipped back by 1.6% to €550 million. This accounted for 91% of Krka's total group sales, which edged up by 0.7% to €604 million.

IN BRIEF

BIOGAIA reported **sales down by 1% to SEK270 million** (€28.3 million) in the opening six months of 2016, as turnover declined at its dominant Paediatrics business. Paediatrics' turnover had dropped by 4% to SEK215 million, the Swedish firm said, due to lower sales of digestive-health tablets in Brazil and across Europe. This had been compounded, BioGaia said, by falling sales of cultures for infant formula. On a more positive note, BioGaia reported sales at it Adult Health business up by 11% to SEK46.8 million in the six months. Better sales of digestive-health tablets in Europe had been behind the rise, the company revealed. Sales of oral-health tablets had also improved in all regions except Asia, BioGaia noted. OTC

Business Strategy

Amazon brings its Dash service to EU

Consumers in Europe can now buy OTC products such as Durex and Nicorette at the push of a button, after e-commerce giant Amazon launched its Dash instant-order service in a number of markets across the region.

Launched in the US in 2015, the Dash service has been expanded to allow consumers in Austria, Germany and the UK instantly to order products – ranging from consumer healthcare lines to household goods – by pressing a Wi-Fi connected physical device, known as a Dash Button.

Each Dash Button costs €4.99 and will order a set item to the user's home when pushed. Consumer healthcare companies including Reckitt Benckiser (RB) and Johnson & Johnson (J&J) have made a number of their products available through the service.

Consumers in the UK can obtain Dash Buttons for numerous J&J products including Aveeno, Listerine, Nicorette, and Regaine. Dash Buttons are also available for RB's Durex and Glanbia's Optimum Nutrition and BSN sports-nutrition lines.

Austrian and German consumers can also purchase a Dash Button for Durex, as well as for Diadermine's skin-care products.

"Dash Buttons offer the convenience of one-click shopping from anywhere in the home," commented Daniel Rausch, director of Amazon Dash. "They can be placed near those frequently-used items you don't want to run out of, and when you see supplies running low, the Dash Button makes it easier than ever to order more. Just press the button and your item is on its way."

Dash Buttons for Durex and Nicorette


Reckitt Benckiser's Taryn Mitchell

Taryn Mitchell, RB's global vice-president of digital sales, claimed the Dash service made it "even easier to stay stocked up on the essential items you use every day".

"We've seen great engagement from our consumers in the US," Mitchell noted. "In fact, a significant number of orders we see through Amazon today are placed via a Dash Button."

"It is a remarkably convenient way for consumers to reorder everyday items," she added, "and it even adds a bit of fun to the process."

RB offers US consumers a wide range of brands through the Dash service, including Airborne vitamins, Mucinex cold and flu products and Schiff glucosamine supplements. Companies such as Church & Dwight, Procter & Gamble (P&G) and Rexall Sundown also operate on the platform in the US.

Commenting on the US operation, Amazon said the Dash service was enjoying "continued growth", with the number of brands available "increasing at a rapid pace".

"Dash Button orders have increased three-fold and orders take place at a rate of over twice a minute," Amazon revealed. OTC

IN BRIEF

CHURCH & DWIGHT reported turnover at its **US Personal Care Products business up by 9.9% to US$272 million** (€244 million) in the second quarter of 2016, thanks to higher sales of Vitafusion vitamins. The brand had enjoyed a "solid quarter", Church & Dwight pointed out, with sales advancing at a "high-single digit" rate. US Personal Care Products accounted for 41% of Church & Dwight's Consumer division's domestic sales, which moved forward by 4.9% to US$670 million. The firm's US Household Products business made up the remaining 59% of the Consumer division's domestic turnover. International Consumer sales improved by 4.2% to US$136 million, while Specialty Products turnover fell by 8.6% to US$71.2 million. Total group sales advanced by 3.6% to US$877 million. OTC

Research

Danes lack knowledge

Danish consumers have "very little knowledge" about dietary supplements and in particular plant-based supplements, according to new research by the University of Denmark's National Food Institute.

Despite being among the highest consumers of dietary supplements in Europe, most of the users interviewed for the research did not know what dietary supplements actually were, the study's authors say, and had no precise knowledge on nutritional recommendations.

The study – which focuses on the reasons why people take plant-based supplements – shows that 64% of the adult Danish population aged 18-75 years uses supplements, with 48% using multivitamin and mineral supplements.

Supplements with various herbs and herbal extracts are used by about 5 % of the population.

Those taking plant-based supplements are the least educated about the products they are using, the study finds, with the majority stating that any information they receive comes from magazines, newspapers or advertisments.

Despite this, many users want more documented information on the effects of plant-based supplements, the study says.

Used for specific health problems

Looking at the reasons why plant-based supplements are used, the study finds that most people take the products for a specific health problem or as a preventive measure.

Users strongly believe the products work for them, with long-term use often based on the perceived effect and the belief that plant-based supplements are harmless and less dangerous than medicinal products, the study points out.

Furthermore, long-term users claim that they take the products out of habit, the study finds, and that the products act as insurance against potential future health problems.

"The users do not know how healthy they would feel without taking plant-based supplements," the study's authors noted "and they have therefore chosen to believe that the supplements have a beneficial effect on their health."

Currently, there are no official recommendations from the Danish health authorities on using plant-based supplements.

Only certain at-risk population groups are recommended to use of dietary supplements by the Danish Veterinary and Food Administration, but no plant-based supplements are recommended to those groups. OTC

Pricing & Reimbursement

Homoeopathy gets trade body support

German patients must be allowed to choose homoeopathic medicines as part of their treatment through the country's statutory health insurance system, two leading pharmaceutical associations have insisted.

The associations have criticised comments made to the *Frankfurter Allgemeine Zeitung* (*FAZ*) newspaper by Professor Josef Hecken, chairman of Germany's decision-making federal joint committee on reimbursement, the G-BA. Hecken argued in an interview with the *FAZ* that statutory insurance funds should not pay for homoeopathic treatments because there was no evidence to show that such medicines were effective.

Since 2012, statutory insurance funds have been able to choose whether to fund certain non-prescription medicines, such as homoeopathic remedies, as an optional service to attract customers. Most OTC medicines were barred from reimbursement by statutory funds in 2004.

Dr Elmar Kroth, scientific director of Germany's medicines manufacturers' association, the BAH, said delisting homoeopathy from reimbursement would "endanger in an irresponsible manner the range of medicines and therapeutic options that are available". As homoeopathic remedies had pharmacy-only status in Germany, patients had access to expert advice on such products, he added.

Furthermore, Kroth argued, such suggestions went against the wishes of empowered patients, as proven by a 2014 survey conducted for the BAH by Demoskopie Allensbach that found that more than half of the German public had already used homoeopathy (**OTC *bulletin***, 7 November 2014, page 13).

Henning Fahrenkamp, chief executive of the association of the German pharmaceutical industry, the BPI, stressed the role that homoeopathy could play as a supportive therapy for serious conditions that was typically without major side effects. "Homoeopathy is no ineffective hocus pocus, it is a recognised and proven form of therapy," he insisted. OTC

Regulatory Affairs

SA widens supplement definition

South Africa's Medicines Control Council (MCC) and Department of Health is considering broadening its definition of complementary medicines to allow a number of natural health products to remain on the market.

In 2013, in an attempt to clean up the complementary medicines market, the MCC proposed a new definition of complementary medicines, which industry argued would lead to 60% of all natural products on the market being banned.

The law defined natural or complementary medicines as products making medicinal claims that were linked to established healthcare traditions such as herbal or Ayurvedis medicines.

Manufacturers of such products had to submit evidence for the products' claims by the end of 2014. If the products did not fit with the criteria they would have to be withdrawn from the market by 2019.

However, the South African authorities are now considering adding a new category – 'health supplement' – to the legislation, which would enable many more natural products to be sold.

MCC registrar Joey Gouws said manufacturers wanting to sell products under the new category would still have to submit safety and quality data.

Previous dossiers for products such as slimming aids and sexual-health products submitted under earlier legislation had all failed to meet the standard required, Gouws said, but in many cases this was because the dossier was incomplete, rather than the evidence did not meet the right standard. OTC

IN BRIEF

CMDh – the European Medicines Agency's Co-ordination Group for Mutual Recognition and Decentralised Procedures – said **15 decentralised procedures related to non-prescription drugs had been started in June 2016** out of a total of 120 procedures. Three of the procedures related to herbal-based products. Meanwhile, 28 mutual recognition procedures had been started in June, but none were related to non-prescription medicines. OTC

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Research

US ignores safety text

A fifth of US adults do not consider "key safety factors" – such as pre-existing health conditions, current medicines and age – when choosing an OTC analgesic, according to a survey by pain charity the US Pain Foundation.

While 97% of the 1,300 participants said they were "confident" when selecting an OTC painkiller, the survey – supported by Johnson & Johnson's (J&J's) McNeil Consumer Healthcare unit – found that consumers placed more emphasis on how quickly and effectively a product would relieve their pain than whether it was the most appropriate option for them, with 58% failing to take into account their current ailments.

Many respondents were also unconcerned by potential interactions with other drugs they were taking, with nearly half – 45% – of those surveyed saying their choice of pain-relief product was not influenced by their current prescription medicines, and around two-thirds stating that they did not consider their consumption of other OTC products when choosing pain relief.

Meanwhile, almost three-quarters – 73% – of participants aged 60 years and over said they disregarded their age when making a purchase.

The US Pain Foundation's founder Paul Gileno stressed that consumers should "always balance finding effective relief with important safety considerations". OTC

Market Research

Global market to rise by 6%

The global OTC market is expected to grow by over 6% in the next four years, according to a new report by Research and Markets.

Forecasting a compound average growth rate (CAGR) of 6.19% in the 2016 to 2020 period, the firm said that the growing importance of self-medication to help control healthcare budgets would be a key driver of the rise in sales, especially given the increased demand on healthcare services from an ageing population.

However, one challenge for the market would be counterfeit medicines, Research and Markets claimed. The sale of counterfeit OTC medicines was increasing, especially in emerging markets, it maintained, and was a problem that usually went unreported to the authorities.

"It is estimated that counterfeit drugs account for 10% of the global market, as compared to just 1% in the developed world," the firm said. OTC

Regulatory Affairs

FDA issues revised supplement rules

The US Food and Drug Administration (FDA) has released revised draft guidance to help dietary supplement companies improve the way they provide pre-market safety notifications for new dietary ingredients (NDI).

Noting that while there were an estimated 55,600 dietary supplements on the US market and that 5,560 new supplements came onto the market each year, the FDA said that it had received "fewer than 1,000 NDI notifications" since the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994.

An initial draft guidance was released in 2011, but following feedback from the dietary supplements industry, the agency had decided to issue a revised version, the FDA pointed out, to "clarify several important points" which had been misunderstood or not fully explained.

The draft guidance had several purposes, the FDA said. First, it was intended to "help dietary supplement manufacturers and distributors decide whether to submit an NDI notification".

"In addition, the draft guidance is intended to provide recommendations on how to properly conduct a safety assessment for an NDI notification and what to include in the notification," the agency continued.

In question and answer form, the draft guidance presented the FDA's views on what qualified as an NDI; when an NDI notification was required; and the procedures for submitting an NDI notification, the FDA said, along with the types of data and information that manufacturers and distributors should consider when evaluating the safety of a dietary supplement containing an NDI, and what should be included in an NDI notification.

Furthermore, the draft guidance contained questions and answers about parts of the dietary supplement definition – section 201(ff) of the Food, Drug & Cosmetic Act – that could affect whether a substance might be marketed as an ingredient in a dietary supplement, the FDA said.

Steven Tave, acting director of the FDA's Office of Dietary Supplement Programs, said the revised draft guidance was an "important step forward" in the agency's work to protect the public from potentially dangerous new dietary ingredients.

"Notification of new dietary ingredients is the only pre-market opportunity the agency has to identify unsafe supplements before they are available to consumers," Tave pointed out. "The revised draft guidance is intended to improve the quality of industry's new dietary ingredient reporting so the FDA can more effectively monitor the safety of dietary supplements."

Comments on the revised draft guidance should be submitted to the FDA by 11 October 2016. OTC

Regulatory Affairs

AESGP joins eHealth group

The Association of the European Self-Medication Industry, the AESGP, is set to play a role in developing European Union (EU) eHealth policy after becoming a member of the European Commission's (EC's) eHealth Stakeholder Group.

The eHealth Stakeholder Group had been established to contribute to the "development and implementation of eHealth policy at the EU level", the AESGP pointed out.

As a selected member of the group for a period of three years, the AESGP would give its input into the "design, implementation and evaluation of eHealth policy activities" and comment "in particular on the implementation of the Digital Single Market Strategy and the eHealth Action Plan 2012-2020".

Furthermore, as part of the group, the association would give input on the advice given to the EC on eHealth-related activities.

The eHealth Stakeholder group also covered the area of mobile health, or mHealth, the association said. The group had closely followed EU policy actions in the mHealth area, the AESGP pointed out, since the launch of the EU mHealth Green Paper in 2014.

Noting that the Green Paper raised issues around data protection and reliability as well as the validity of collected data, the AESGP said that these issues still needed to be addressed to build consumer trust in mHealth technologies.

Policy initiatives in the mHealth area were underway, including building a framework for health and wellbeing apps, such as an industry-led code of conduct and mHealth assessment guidelines, the AESGP said. OTC

Market Research

Vits & tonics lead Korea

Vitamins and tonics were the best-selling local consumer healthcare products in Korea in the opening six months of the 2016, according to research by local news agency Yonhap.

Using data gathered from first-half reports of local OTC players, Yonhap said that Ildong Pharmaceutical's vitamin brand Aronamin was the biggest seller in the period with sales of KRW33.5 billion (€27.2 million).

Aronamin was followed by Daewoong Pharmaceutical's liver supplement Ursa with sales of KRW30.9 billion. Dongwha Pharm's digestive health supplement Gas Whalmyungsu-Q and Kwangdong Pharmaceutical's Cheongshimwon both recorded turnover of KRW18.1 billion.

In the first half, nine OTC drugs reported sales of more than KRW10 billion, up from six in the prior-year period.

Yonhap said the growth had been due to the wider awareness of self-care.

Among local OTC medicines brands, Jeil Pharmaceutical's topical pain-relief plaster Kefentech reported the strongest growth, with sales rising by 65% to KRW9.3 billion. OTC

Regulatory Affairs

ASMI welcomes labelling changes

Changes to the way non-prescription medicines are labelled in Australia have been welcomed by the Australian Self-Medication Industry (ASMI).

Following the conclusion of the Therapeutic Goods Administration's (TGA's) review of medicines labelling and packaging, the ASMI said it was pleased that the regulator had approved "sensible" reforms to non-prescription labelling.

"For non-prescription medicines, the major changes are an increase in the prominence of active ingredients on the front of the pack," the ASMI explained, adding that the changes would also see a standardised format for critical information on the back of the pack.

Commenting on the labelling changes, the TGA said its goal was to "make important information easier to find" on product packaging.

Medicine labels would now be "clearer and more consistent", the regulator insisted, and provide users with "enough information to make safe and informed decisions".

Noting that the new labelling requirements would "not change the overall appearance of well-known non-prescription medicine brands", the ASMI said that this consistency was "important for consumers".

"Industry also welcomes the pragmatic transition period of four years," the ASMI added, "which allows adequate time for manufacturers to phase out current packaging before transitioning to the new format."

While the majority of non-prescription medicines would be able to accommodate the new labelling requirements, the ASMI warned that some products might "have difficulty meeting the requirements and need TGA exemptions".

The labelling review began in 2012, but the initial changes were deemed impractical. The ASMI said the original proposals would have "significantly impaired consumers' ability to recognise and select non-prescription medicines as they did not take into account differences between OTC and prescription products. OTC

Regulatory Affairs

Brazil has new code

The Brazilian Food and Drug Administration – ANVISA – has updated its OTC regulation to help expand the number of OTC medicines available in the country.

Published in Brazil's *Official Gazette*, the new regulation has been designed to allow ANVISA simultaneously to reassess the status of currently available OTC drugs while approving new products.

The new regulation is expected to increase competition in the OTC category and prompt a shift towards consumer marketing rather than physician detailing.

Under the new regulation, medicines must meet seven criteria to be approved for OTC sale:

- The drug must have been commercially available for a minimum of 10 years – five years in Brazil – as a prescription drug. Alternatively, the drug must have been registered for five years as an OTC drug in countries where regulations are similar to ANVISA's own.
- The drug must exhibit a high level of safety: the causes of adverse reactions must be well known and easily reversed, the drug must have a low level of toxicity, a safe therapeutic window, and a low level of interactions with other drugs and food.
- The clinical condition treated by the drug cannot evolve rapidly, and its symptoms must be easily identifiable by the consumer.
- The drug must pose a low risk when used off-label or in overdose scenarios.
- The drug cannot be indicated for continuous use; rather, it can only be used for a short period of time or a fixed period of time, which must be identified in the drug's label (except for drugs labelled for prevention).
- The consumer must be capable of using the drug without any physical assistance from a healthcare professional.
- The drug cannot cause chemical dependency in consumers.

Furthermore, an application for OTC status must be supported by a risk-reduction plan, detailing how post-marketing safety monitoring would be carried out.

Once switches to OTC have been approved by ANVISA and published in the *Official Gazette*, companies will have 180 days to amend packaging and labels.

The new regulation replaces the rules introduced in 2003, which established the drugs that could be sold OTC according to their therapeutic indications. OTC

Regulatory Affairs

FDA rules against antibacterial wash

Consumer antiseptic wash products containing triclosan and triclocarban can no longer be marketed in the US after the Food and Drug Administration (FDA) ruled that there was no evidence that they were safe for long-term daily use.

Issuing a final rule banning the products, the FDA said that as well as a questionable safety profile, OTC products such as antibacterial hand and body washes that contained either triclosan or triclocarban – as well as another 17 other less widely-used ingredients – had not been proven by manufacurers to be more effective than plain soap and water in preventing illness and the spread of certain infections. The other 17 ingredients have also been banned.

The ban did not impact consumer hand sanitisers or wipes, the agency noted.

Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research (CDER), said that while consumers might think that antibacterial washes were more effective at preventing the spread of germs, the agency had seen "no scientific evidence that they are any better than plain soap and water".

"In fact, some data suggests that antibacterial ingredients may do more harm than good," she added.

Proposing the rule at the end of 2013, the FDA pointed out that some data suggested that long-term exposure to certain active ingredients used in antibacterial products – for example, triclosan in liquid soaps and triclocarban in bar soaps – could pose health risks, such as bacterial resistance or hormonal effects (**OTC *bulletin***, 17 January 2014, page 10).

The widespread consumer use of antibacterial products, the accumulated scientific information, and concerns raised by healthcare and consumer groups, the FDA said, had prompted a re-evaluation of what data was needed to classify the active ingredients in consumer antibacterial products as "generally recognised as safe and effective" or GRASE. OTC

Research

PAGB defends paracetamol

The Proprietary Association of Great Britain (PAGB) has defended the use of paracetamol during pregnancy, after a recent study claimed that using the pain-reliever while pregnant may be associated with an increased risk of behavioural problems in children.

Donna Castle, PAGB's director of communications, pointed out that the UK National Health Service (NHS) advised that paracetamol could be used throughout pregnancy to reduce a high temperature and relieve pain.

"This is supported by a large body of evidence from over 50 years of paracetamol use," Castle noted.

Research recently published online by *JAMA Paediatrics* assessed questionnaires completed by 7,796 mothers at 18 and 32 weeks pregnant, along with partners and children aged five and seven years old. The questionnaires formed part of the Avon Longitudinal Study of Parents and Children carried out between 1991 and 1992.

The authors claimed the result showed an increased risk of multiple behavioural problems in children whose mothers had taken paracetamol during pregnancy. However, the authors of the study admitted that their findings were from an observational, rather than a randomised controlled study, with the results based on questionnaires completed at various intervals over a long period of time.

The study also did not account for the amount of paracetamol taken and duration of use, Castle pointed out, and it was therefore "impossible to understand whether paracetamol was taken within the guideline levels".

"Furthermore, the authors have also highlighted the potential risk of not treating fever or pain during pregnancy," Castle noted, "over any potential harm that prenatal paracetamol use may cause to offspring." OTC

IN BRIEF

FDA – the US Food and Drug Administration – has launched its **Drug Safety Labeling Changes (SLC) database**. The agency said the database would also enable healthcare technology firms to more efficiently gather, organise and distribute information to drug safety labels. OTC

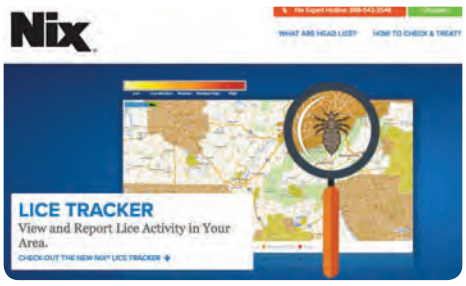
Digital Marketing

Nix helps US to track lice

Prestige Brands is helping US parents and school nurses to prepare for head-lice outbreaks in their community with an online Lice Tracker tool on behalf of its Nix brand.

Claimed by the firm to be the first data-driven tool of its kind, the Nix Lice Tracker works by combining retail sales information with "crowd-sourced outbreak reports" from parents and school nurses – as well as Google Trends data – to develop a map of communitieswhere lice outbreaks are currently occurring.

The Nix Lice Tracker could be found on the brand website, *nixlice.com/lice-tracker*, the firm pointed out, adding that the tool had been designed easily to be used on mobile devices.



The Nix Lice Tracker is available online

Prestige pointed out that the website also informed users of the location of the nearest Nix stockist. Money-off coupons were available online for the brand, the company added, which included the recently-launched Nix Ultra product (**OTC *bulletin***, 6 May 2016, page 16) and a Lice Elimination Kit containing a Crème Rinse, Combing Gel, Lice Control Spray and comb. OTC

Ricola claims it is providing US consumers with a "proactive approach to wellness" by adding immunity lozenges to its range of herbal drops.

Formulated to "meet the needs of today's hectic lifestyle", Ricola Herbal Immunity lozenges combined a blend of 10 Swiss herbs with a purified form of panax ginseng – as well as vitamins B6, B12 and C – to support the immune system and fight fatigue, the Swiss firm pointed out.

The lozenges were available in Honey Herb and Citrus Herb flavours from CVS, Walgreens and Rite Aid stores across the country, Ricola noted. OTC

Product Launches

Lanes strengthens Earex range in UK

Lanes Health has strengthened its Earex ear-care brand in the UK with the launch of a Pain Relief Ear Spray and Olive Oil Ear Drops, following its acquisition of the brand from Reckitt Benckiser (RB) last year.

Earex Pain Relief Ear Spray is positioned as providing "first aid for common ear problems" – such as pain, infection, irritation, and accumulated earwax – and is claimed by Lanes Health to contain "a carefully-selected blend of natural plant extracts known for their antiseptic, antibacterial, and anti-inflammatory properties".

The "unique, advanced triple-action formula" includes olive oil, sesame oil, spearmint oil, sea whip extract and a "phytosterol complex".

Meanwhile, Lanes Health said Earex Olive Oil Ear Drops contained "medicinal-grade olive oil" to gently soften and remove ear wax, pointing out that general practitioners (GPs) recommended the ingredient as an effective treatment for ear wax build-up.

Both the Earex Pain Relief Ear Spray and Olive Oil Ear Drops were suitable for children aged over five years, Lanes Health noted, adding that they could also be used on those under five when recommended by a medical professional.

The two new products joined the existing Earex Advance ear drops – formulated with ingredients such as glycerin and urea peroxide – to provide consumers with a "variety of affordable, high-quality, tailored ear-care solutions", the company said.

Two new products join the Earex range

Earex Pain Relief Ear Spray and Earex Olive Oil Ear Drops were currently being supported by consumer public-relations activity, Lanes Health pointed out, while a press campaign was planned for early next year.

The brand website, *earex.co.uk*, had also been updated to include the two new products, the firm added, while point-of-sale materials were available to pharmacists and retailers.

Marketing support was expected to continue until April 2017, the company said.

In January last year, Lanes Health gained Earex – along with the Derbac M head-lice treatment – from RB, which acquired the brands when it bought SSL International in 2010 (**OTC *bulletin***, 3 July 2010, page 1).

The recommended retail price for Earex Pain Relief Ear Spray is £9.99 (€11.88) for a 15ml bottle, while it is £3.99 for a 10ml pack of Earex Olive Oil Ear Drops. OTC

Product Launches

Regaine adds foam in Germany

Once-a-day application is the key product benefit of the latest option for German women of Johnson & Johnson's (J&J's) Regaine hair-loss treatment brand.

Regaine Frauen Schaum is a 5% minoxidil foam that is applied to the scalp. J&J said women could easily and quickly integrate applying the foam into their daily beauty regimes.

Regaine 5% is available to German women

Available in pharmacies from this month, the 5% foam has a recommended retail price of €59.90 for a pack of two 60mg bottles, each of which is sufficient for two months of treatment.

The firm – which is supporting the launch with public-relations activity – said "visible results" could be expected after 12 weeks of use.

J&J – which also markets a twice-a-day 2% Regaine solution for women in Germany – introduced its 5% minoxidil foam in the US almost two years ago under the Rogaine brand name (**OTC *bulletin***, 28 November 2014, page 15). In France, the 5% foam is sold under the Alostil brand name (**OTC *bulletin***, 8 November 2013, page 21). OTC

Advertising Complaints

ASA raps FW Medical

FW Medical's claims that Silicolgel can treat a range of gastrointestinal symptoms were unsubstantiated and misleading and must not appear again in their current form, the UK's Advertising Standards Authority (ASA) has ruled.

A national press advertisement for Silicolgel showed an image of a torso with a stomach and digestive tract superimposed over it, while text stated that the colloidal silicic acid gel – a class IIa medical device – provided "fast, effective treatment" for irritable bowel syndrome (IBS) symptoms, as well as heartburn and reflux, diarrhoea, stomach ache, flatulence and nausea.

Explaining its decision, the ASA said that consumers would understand the claim to mean that Silicolgel was proven to treat each of the individual problems listed.

Furthermore, noting that all the symptoms mentioned – with the exception of heartburn and reflux – were common symptoms of IBS, the watchdog said there were "additional common and associated symptoms" of the condition, such as constipation, bladder problems and lethargy, which were not referred to in the advertisement. Consumers would expect the efficacy claim regarding "IBS symptoms" to include all indicators, the ASA added.

While FW Medical had provided evidence in response to the ASA's investigation, this had not been "sufficiently robust" to support the claims in the advertisement, the watchdog said.

As a result, the claims were found to be unsubstantiated and misleading, and must not appear again in their current form. Additionally, FW Medical must not claim in the future that Silicolgel can treat specific symptoms or conditions unless the firm holds sufficient documentary evidence to support such statements.

Meanwhile, the ASA banned sports-nutrition company Science in Sport's online advertisement for its energy gels, as it featured an unapproved nutrition claim.

As the statement that the products worked "twice as fast as any other energy gel" was not listed in the annex to the European Union's regulation on nutrition and health claims made on foods, the watchdog said the advertisement must not appear again in its current form. OTC

IN BRIEF

EMSER has grown in Germany its eponymous range of **pastilles for sore throats and cough** with a sage-flavoured option. OTC

Marketing Campaign

'No drama' for Hedrin

"To itch, or not to itch?" asks a young wannabe thespian in Thornton & Ross' latest UK television commercial for its Hedrin head-lice treatment brand.

Created by Bray Leino as part of Hedrin's "no drama"-themed multimedia campaign, the 30-second advertisement shows the boy's recital ending abruptly when his mother turns on the bathroom light, before he drops to the ground and begins furiously scratching his head.

As the woman shakes her head in despair, a voiceover states: "Head lice causing drama in your house? Bring the curtain down on it with Hedrin Once", adding that the spray gel kills lice and eggs in 15 minutes.

The voiceover also points out that Hedrin "protects, detects, treats and clears", as the entire product range – which also comprises a Treat & Go Mousse, Head Lice Detection Comb, and the Stubborn Egg Removal Kit launched in June (**OTC *bulletin***, 30 June 2016, page 16) – is shown.

"Taking the fuss and bother out of head lice", the voiceover continues, before announcing: "no drama". The tagline also appears on screen.

Hedrin's latest campaign has a "no drama" theme

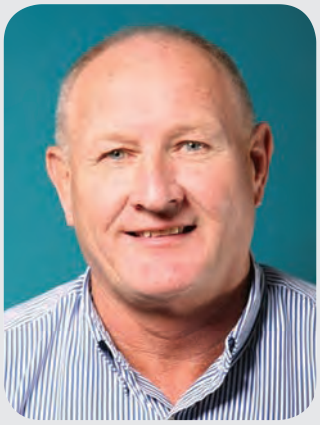
Public-relations activity in trade and consumer press also formed part of the "no drama" campaign, Bray Leino noted, as well as print advertising in trade titles.

There was also digital promotion on websites such as *boots.com, netdoctor.co.uk, patient.co.uk*, and the 'Back to School' digital magazine for parents with children in primary school, the company pointed out.

Thornton & Ross is also targeting 'influencer blogs' popular with the brand's target audience of mothers.

Hedrin's new-look packaging – introduced earlier this year – is being highlighted to retailers and pharmacies (**OTC *bulletin***, 25 March 2016, page 16).

The refreshed livery – which includes colour coding and simpler, clearer on-pack instructions – was designed to help parents better navigate the self-selection product range and improve product compliance, Thornton & Ross said. OTC



Q&A with

Boehringer's Tim Templeman

Head of Consumer Health Care, Australia and New Zealand

Q What has been the biggest achievement of your OTC marketing career?

A I am very proud of Boehringer Ingelheim's 'Got Mucus' campaign for Bisolvon and the 'Rope' campaign for Buscopan, which we developed locally and was then successfully adopted in many other countries. Being part of a global team which initiated the turnaround of our Japanese Consumer Health Care unit a number of years ago is also one of my most rewarding achievements.

Q What has been the biggest challenge of your OTC marketing career?

A There have been many – but the biggest challenges have centred on managing the changing environment we work in, whether it be from a market or regulatory perspective, or from the growing globalisation of our business.

The so-called 'digital revolution' and the changing dynamic of the media landscape is a big challenge we are currently facing. Free-to-air television is simply not delivering the reach it used to, although the costs keep rising. The relevance of digital media needs to be carefully considered; the challenge is that while the digital space certainly provides new opportunities to build greater intimacy with consumers, it still lacks a bit of credibility around the measurement tools and post-activity data.

Q How have consumers changed over the course of your career, and how have you responded?

A The average consumer is definitely more aware of prices these days. They are also more open to store brands and generics. Over the past few years we have set out to increase awareness of our brands through consumer advertising. While recommendation is extremely important, if consumers are familiar with our brands then price does not become their only reference when they are faced with a self-selection decision.

We continue to focus resources in pharmacy staff education in an effort to build knowledge about our brands and the benefits they offer when a recommendation is needed.

Q What has been the most important lesson of your career?

A A key mantra of mine has been not to get too caught up in the theory of marketing. I try not to overcomplicate things. I trust my gut instincts and others around me – especially our sales team, which is a terrific barometer for giving a 'real world' perspective. Pharmacy staff can be a powerful ally for your brand; they are the front-line link to consumers, so I am a strong believer in providing both brand and category information to this group and listening to their feedback.

Q How do you see OTC marketing developing in the future?

A I believe that media will become increasingly difficult to manage. At some point, advertisers are going say 'enough is enough' with regard to free-to-air channels. Mobile devices will become more important, as they provide a great vehicle not only to communicate, but also to build real intimacy with consumers.

Medical devices based around technology, rather than medicines, will feature more and more in the OTC space in the future, and I wouldn't be surprised to see a freeing-up of the channel restriction currently in place for many OTC products, so multichannel marketing will become more prominent. I also live in hope that medicines switched to pharmacist-only status can be advertised in Australia. The current regulations do not make sense to me as they are now, and I have no doubt they dampen the desire of manufacturers to switch. OTC

OTC Marketing Awards

Awards reflect digital growth

Digital and social media offer OTC companies more ways than ever before to promote their brands to consumers. Mobile apps, interactive websites and social media are just some of the myriad channels and platforms now available to marketers, but they will all be captured by **OTC *bulletin*** in its OTC Marketing Awards 2017.

Since 2014, when the Digital and Social Media Award was first introduced to reflect its increasing importance, there has been a rapid increase in the Award's popularity. This has resulted from both more use of digital and social media by OTC firms and the rapid expansion of the channels and platforms available.

Such is the number and variety of choices now facing OTC marketers that **OTC *bulletin*** has created three new Awards fully to cover the markedly different types of campaign.

Television advertising now forms a part of the Award for Best OTC Audio-Visual Advertising. Sponsored by IRI, the co-presenter with **OTC *bulletin*** of the OTC Marketing Awards 2017, this Award encompasses television and video advertising campaigns, including television commercials, videos created for social media, and YouTube channels and videos.

Social media now have their own Award. The Award for Best OTC Social Media Campaign will reward the most creative and effective social media campaigns aimed at consumers, patients or healthcare professionals. These could be on platforms like Facebook, Twitter and LinkedIn, or use other social networks such as Instagram and Snapchat.

Meanwhile, the third new Award – for Best OTC Digital or Mobile Marketing Campaign – is open to all types of marketing activity involving such platforms as mobile device apps, games, websites and email.

The OTCs reflect the changing digital landscape

Spanning 19 categories in total, **OTC *bulletin's*** prestigious OTC Marketing Awards 2017 also embrace other marketing communications activities like public relations, sponsorship and advertising in more traditional types of media.

The Awards will be presented at a Gala Dinner & Awards Presentation on Thursday, 9 March 2017 at London's Park Lane Hotel, Piccadilly.

A detailed breakdown of criteria for each Award can be found in the Entry Information Pack at *otc-bulletin.com/awards*. The deadline for entries is Friday, 9 December 2016.

Sponsorship packages are now available to suit all budgets.

There is no better way to present your name, your business and your contribution to the British OTC industry than to sponsor an OTC Marketing Award. Before, during and after the Gala Dinner & Awards Presentation, your brand will enjoy the highest of profiles in the industry through coverage in **OTC *bulletin*** and involvement on the night.

Find out more about the OTC Marketing Awards 2017 by contacting Natalie Cornwell at **OTC *bulletin***. Call +441564 777 550 or email Awards@OTC-bulletin.com. Alternatively, visit the OTC Marketing Awards website at *otc-bulletin.com/awards*. OTC

Beiersdorf has expanded its ABC local pain therapy products in Germany with a smaller version of its capsaicin-containing heat plaster.

The latest ABC Wärme-Pflaster contained 4.8mg of the active ingredient – extracted from cayenne pepper – Beiersdorf noted, compared with the 11mg capsaicin plaster currently in the range. It also featured "thinner backing material for optimal wearing comfort", the firm claimed.

Other products in the line include a capsaicin-based heat cream and a patch for sensitive skin with nonivamide and "soft fleece" fabric. OTC

OCTOBER

4 October

Global Generics & Biosimilars Awards 2016

Barcelona, Spain

These Awards will recognise the achievements of the global generics and biosimilars industries.

Contact: **Generics *bulletin***.
Tel: +44 1564 777 550.
Email: awards@generics-bulletin.com.
Website: generics-bulletin.com/generics-biosimilars-awards.aspx.

5-7 October

Health Ingredients Japan

Tokyo, Japan

A three-day health ingredient and services exhibition and conference.

Contact: UBM Media.
Tel: +81 3 5296 1017.
Email: yosuke.horikawa@ubm.com.
Website: hijapan.info.

13-14 October

WSMI/APSMI Conference

Nagoya City, Japan

A two-day conference run by the World Self-Medication Industry (WSMI) and the Asia-Pacific Self-Medication Industry (APSMI).

Contact: Japan Federation of Self-Medication Industries (JSMI).
Tel: +81 3 5657 0789.
Email: info_apsmi2016@jfsmi.jp.
Website: jfsmi.jp/apsmi/index.html.

26-29 October

CRN's Annual Symposium

California, US

This four-day meeting is organised by the US Council for Responsible Nutrition (CRN).

Contact: CRN.
Tel: +1 202 204 7700.
Email: webmaster@crnusa.org.
Website: crnusa.org/2016events.

27 October

ASMI Annual Conference

Sydney, Australia

Subtitled 'Advancing consumer health through responsible self-care', this one-day conference, organised by the Australian Self-Medication Industry (ASMI), will be accompanied by the ASMI's Diamond Awards.

Contact: ASMI.
Tel: +61 1 300 878 815.
Email: asmiconference@nectarcc.com.au.
Website: asmi.com.au/events/.

27 October

Profitable Growth in Consumer Healthcare

Frankfurt, Germany

'Growing your business in times of constrained markets' is the theme of this one-day workshop.

Contact: Simon Kucher & Partners.
Tel: +49 89 544793.
Email: baerbel.eberhard@simon-kucher.com.
Website: simon-kucher.com/consumer healthforum.

31 October-1 November

Health and Nutrition in Russia and CIS

Moscow, Russia

A two-day exhibition and forum based on last year's 'Vitafoods in Russia and CIS'.

Contact: Adam Smith Conferences.
Tel: +44 20 8004 5707.
Email: enquiries@adamsmithconferences.com.
Website: nutritionrussia.com.

1-3 November

Ceuta Healthcare International Alliance Conference

Athens, Greece

'A new generation' is the theme of this three-day health and beauty global conference, which will bring together manufacturers, global outsource solutions providers and key opinion leaders in the health and beauty industries to explore global growth opportunities.

Contact: Ceuta Healthcare.
Tel: +44 1202 449 709. Email: lorian.pitman@ceutahealthcare.com.
Website: ceutahealthcare.com.

NOVEMBER

7-8 November

The Future of Pharmacy

Frankfurt, Germany

'Growth in supposedly mature markets' and 'Pharmacies with added value' will be among the sessions at this two-day conference.

Contact: Inspirato.
Tel: +49 151 624 179 41.
Email: info@inspirato.de.
Website: inspirato-zukunft-apotheke.de.

15 November

Consumer Healthcare Investment

London, UK

A one-day showcase of innovations in OTC, consumer health technology, digital, well-being and lifestyle.

Contact: Kisaco Research.
Tel: +44 203 696 2920.
Email: events@kisacoresearch.com.
Website: consumerhealthinvest.com.

15 November

Advertising of Medicinal Products

Bonn, Germany

Advertising and competition law and misleading and comparative advertising will be among the topics addressed at this one-day event run by Germany's medicines manufacturers' association, the BAH.

Contact: BAH.
Tel: +49 228 957 4556.
Email: abresch@bah-bonn.de.
Website: bah-bonn.de/widi-services/fachseminare.

19 October

AESGP Conference

Bucharest, Romania

'The role of self-care in healthcare' is the theme of this one-day event run by the Association of the European Self-Medication Industry, the AESGP, and the Romanian Assocation of the Self-Care Industry (RASCI).

There will be sessions on: 'The value of self-care'; 'The importance of adequate communication rules in self-care': and 'European Union regulation of health and nutrition claims'.

Contact: AESGP.
Tel: +32 2 735 51 30. Email: o.bua@aesgp.eu. Website: aesgp.eu.

21-22 November

EuroPLX 62

Nice, France

This two-day meeting will provide a forum for business development decision makers for discussing and negotiating collaborative agreements in licensing, marketing, and distribution of patented medicines, generics, biosimilars, OTC products, medical devices and food supplements.

Contact: RauCon.
Tel: +49 6221 426 2960.
Email: meetyou@europlx.com.
Website: europlx.com.

MARCH

9 March 2017

OTC Marketing Awards 2017

London, UK

These Awards recognise the best of the British OTC industry. Organised by **OTC *bulletin***, new categories include Best OTC Social Media Campaign, Best OTC Digital or Mobile Marketing Campaign and Best OTC Audio-Visual Advertising. Entries close 9 December. Follow the OTC Awards on Facebook, LinkedIn, Twitter and YouTube.

Contact: OTC *bulletin*.
Tel: +44 1564 777 550.
Email: awards@otc-bulletin.com.
Website: otc-bulletin.com/awards.

Technological change, and the greater economic power of growing urban populations in emerging markets will shape the OTC market in coming decades, but Pfizer's Suneet Varma insists his firm is grasping these disruptive trends. Matt Stewart reports.

Leading Pfizer to a new future

Asking whether an OTC company wants to be a train company or a transportation company might seem an odd question, but to Suneet Varma, president and general manager of Pfizer Consumer Healthcare, it is one the OTC industry needs to answer if it wants to survive and thrive in a rapidly changing healthcare environment.

Explaining the analogy, Varma points out that if you are a train company, you offer just one solution: the train. However, if you are a transportation company, you offer every possible travel solution to consumers. This, he says, is something OTC companies need to do.

The industry cannot just be about "pills in bottles" any more, he insists. "Our mission at Pfizer Consumer Healthcare is to discover how we can bring to market a broader array of solutions to positively impact consumers' daily lives," Varma maintains.

Speaking to **OTC *bulletin***, Varma is enthusiastic about not only macro-trends driving the OTC industry – technological change, and the greater economic power of growing urban populations in emerging markets – but also the sometimes-questioned future of the Consumer Healthcare business he leads within the wider Pfizer group.

Bolstered by a series of positive statements from the US-based group's chief executive officer Ian Read – who, in May, described the business as a "very valuable asset" (**OTC *bulletin***, 27 May 2016, page 7) – Varma believes that the company's senior management have noticed the opportunities in consumer healthcare and how they may be "beneficial not only to Pfizer, but beneficial to consumers, and beneficial to healthcare systems".

However, performance also matters, Varma is quick to point out. "If we look at 2015, the major players in the OTC market and in every region in which we operate – Asia-Pacific; Europe, Middle East and Africa; Latin America; and North America – we are first, second or third in terms of growth," he claims.

Within Pfizer, he adds, there is a sense that Consumer Healthcare is "well run and contributing to the group overall, not just internally, but also in the wider marketplace".

Having joined Pfizer when the company acquired Wyeth in 2009, Varma took over global leadership of the Consumer Healthcare business in May 2015. Since then, he has been plotting how the firm will take advantage of the key macro-trends he believes will define not only the future of Pfizer Consumer Healthcare, but the industry as a whole, the latter in his capacity as chair of the World Self-Medication Industry (WSMI).

High on the agenda is the pace of technological development at the consumer level, an issue Varma claims is fundamentally changing how consumers shop.

"The internet put information at people's fingertips. Now with smartphones and wearables, people have the tools to track their own health," Varma points out. "But these technologies have also led to a shift towards e-commerce and omni-channel retailing. Consumers now demand access to products and services wherever they may be."

Ensuring Pfizer is able to give consumers information and access to products on demand is crucial, Varma explains, offering up the example of how people – especially millennials – are moving away from television to online streaming.

"I had a conversation with a colleague the other day," he notes. "He had been working on a new television commercial when he realised that the previous evening he had watched a film and some shows on Netflix. He had not been exposed to any advertising at all during those programmes."

"We, as a company and an industry, have to connect with consumers where they are searching for solutions and information about our products," Varma maintains.

"There is a massive convergence happening between healthcare, technology and consumer behaviour," Varma insists. "The potential to have disruption in a positive way for the consumer exists. As an industry, we are obligated to engage with this convergence."

Asked what Pfizer Consumer Healthcare was doing to engage with faster-moving technology, he points to the company's decision to

find and help develop innovative start-ups specialising in health and wellness.

In February, Varma notes, Pfizer launched its 'Health and Wellness Innovation Program' in partnership with the US education company Galvanize (**OTC *bulletin***, 19 February 2016, page 8). This has already successfully worked with and supported 12 start-ups.

More recently, the company announced it would help a second cohort of firms access Galvanize's network of technical talent and investors to develop innovations targeting ageing, energy, improved sleep, nutrition or stress management (**OTC *bulletin***, 30 June 2016, page 7).

"In the past six months, we have brought in a dozen 'entrepreneurs-in-residence' to the Galvanize incubator space in San Francisco," Varma says. "The solutions they are developing really are at the frontiers of technology, covering all different areas from apps, to devices, to the cloud. What they all have in common is that the solutions are all aimed at driving consumer self-selection and empowerment."

The Galvanize incubator project is "specifically geared to tapping into the entrepreneurial atmosphere" of San Francisco, he adds, while plugging Pfizer into the "ecosystem of innovation" that exists there.

A focus just on Silicon Valley would not be enough, Varma continues, adding that the firm is also looking for innovation in other technology hotspots such as China, Ireland and Israel.

"Pfizer is engaged with the tech world," Varma insists, "and it is crucial that as an industry we engage with it."

Staying in tune with technology to ensure a constant connection with the consumer also plays into another of Varma's key macro-trends: the changing make-up of the world's population.

People are living longer, Varma points out, and becoming more urban. This is thanks to the mass-urbanisation of previously rural populations in emerging markets.

Mass-urbanisation is already playing as big a role as technology in disrupting distribution channels, Varma declares. While the traditional model of distributing through pharmacy will remain a key component, he maintains, Pfizer and other OTC firms need to be flexible enough to take advantage of new opportunities.

Citing UN figures that forecast that 90% of urban population growth to 2050 will take place in Africa and Asia, Varma says that this trend is already "changing the way we operate".

The company is constantly addressing "the channels we market and sell in", he says, citing the access Pfizer has gained to China's growing and increasingly affluent urban consumer base through Tmall Global, Alibaba's cross-border online marketplace.

"Companies such as Tmall Global give us a great platform quickly to introduce new products from outside of the Chinese market and test consumer response," Varma continues.

"E-commerce is important to our overall strategy and we've driven substantial growth through it over the past several years. We are putting increased resources against it on a global basis," he adds.

Changes like this may, of course, lead to a shift in the products Pfizer Consumer Healthcare offers in those markets.

"These new urban areas present new healthcare challenges to consumers," Varma explains. "Let's take allergy. Allergy would traditionally be thought of together with cough and cold. But what you are seeing now is the rise of other respiratory challenges that the consumer is seeking solutions for."

"Mass urbanisation is leading to pollution levels rising in certain markets, leading to higher levels of inhaled irritants," he continues. "The solutions these consumers are seeking are now different to the ones provided within the traditional cough, cold and allergy category."

Drawing on his own experience in the marketplace, Varma points out that, on a visit to one of China's leading online retailers, the screens dotted around the workspace showed that surgical and neoprene masks were among the best-selling products.

> **"Pfizer is engaged with the tech world, and it is crucial that as an industry we engage with it."**

"Is this different to what we used to see with traditional cough, cold and allergy because of mass urbanisation? The answer is yes. The solution is different, and in this case it was a device, not a pill in a bottle."

"As an industry, we have to be on top of that shift, and at Pfizer Consumer Healthcare we are," he insists. "We are considering these changes."

The economic impact of the population trends has also opened up an opportunity for the OTC industry, Varma maintains, pointing out that governments around the world – and payors in general – are focused on the cost of providing healthcare.

"The role of consumer healthcare within a country's healthcare system is changing," he insists. "Consumer healthcare has a more important economic role to play than ever before."

"We know that if consumers have more information they can make better choices," Varma states. "We know that consumers have a desire to take control of their own health and wellness, and we know that, if they do, it's economically beneficial to the system."

"Our products cost pennies per pill," he explains, "but on the prescription side, they can be substantially more expensive."

"The more products that are readily available at an affordable price, the more people are shifted into the self-care part of the healthcare spectrum," Varma maintains. "This frees up more resources within a country's healthcare system, and those extra resources can be reallocated to the most innovative, breakthrough solutions in the marketplace."

While this shift has been at the forefront of the minds of governments for some years, Varma says he believes that consumers now also understand that healthcare resources are finite. They are ready to take control of their own health and wellbeing when it is appropriate.

While reluctant to speculate on what individual governments should do to drive this shift further, Varma is insistent that the more successful countries have managed to position the shift as an expansion of choice, rather than as having something taken away.

Taking the switch in the US of Pfizer's leading pain-relief brand Advil in 1984 as an example, Varma points out that it worked because both consumers and healthcare professionals felt the move was right.

Consumers believed they could self-manage minor pain and physicians believed the same, Varma adds.

Widening access does not mean preventing someone from going to their physician for a headache, Varma notes. What it does is give more choice to the consumer.

It also allows a physician to start someone on an appropriate path to safe self-care, he adds. "We know many of our Consumer Healthcare products are recommended by physicians when it is appropriate for a patient to self-care."

"The path to purchase and journey to self-care is different for each person. It's about giving people the choice. When you do it that way, it is successful," Varma maintains.

Bringing together his picture of the future of the Pfizer Consumer Healthcare business and that of the industry as a whole, Varma says that it is crucial that all concerned "open up their minds" to the opportunities ahead.

"Companies tend to play in areas where they can add value. While that remains Pfizer's criterion, we have to remain expansive in our thinking and ensure we are in the right places to fulfil our mission," Varma states.

"Our management understands this and the dynamics in play," he adds. "We are able to expand our consideration of opportunities beyond what may have been the case 20 years ago. And that is an exciting place for Pfizer Consumer Healthcare to be." OTC

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Industry Associations

CHPA gets Brikman

The US Consumer Healthcare Products Association (CHPA) has named **Anita Brikman** to the dual role of vice-president of communications and public affairs and executive director of the CHPA Educational Foundation.

Over the past two decades Brikman worked as a news anchor and health reporter in the major television markets of Philadelphia and Washington DC, the association pointed out.

Following her time in broadcast journalism, Brikman had moved into the association world, the CHPA said, working as senior vice-president of communications and outreach at the National Hospice and Palliative Care Organization.

Commenting on her new role, Brikman said that throughout her career she had been passionate about educating consumers on "all their healthcare options to aid them in making informed

Anita Brikman

choices for themselves and their families".

"I am thrilled to have the opportunity to lead the communications team at CHPA," she added, "and spearhead the critically important consumer education programmes of the foundation."

Scott Melville, CHPA's chief executive officer, said Brikman's experience made her the ideal leader for the association's communications function and its educational foundation.

"It is an exciting time for self-care," Melville added, "and Brikman brings a lifetime of communicating about healthcare issues that will make the CHPA an even more effective voice for consumer healthcare." OTC

IN BRIEF

BAH – Germany's medicines manufacturers' association – has appointed **Christof Weingärtner** as press spokesman. He is part of the BAH's public relations department that relocated to Berlin at the end of last year. OTC

Manufacturers

Recordati changes management team

Recordati has appointed **Andrea Recordati** – formerly its chief operating officer – as vice chairman and chief executive officer, and **Alberto Recordati** as chairman of its board of directors.

The changes to the Italian firm's leadership were announced following the death last month of chief executive **Giovanni Recordati**, who had held the position for over 25 years. He had also chaired the privately-owned company's board of directors since 1999.

Prior to his new appointment, Andrea Recordati was promoted in 2013 to the newly-created role of chief operating officer, Recordati pointed out, after spending just over two years as general manager of its international pharmaceuticals division (**OTC *bulletin***, 11 October 2013, page 22). Alberto Recordati had been responsible for coordinating the firm's "drug discovery" and "drug development" activities since 2008, it noted, and had handled its licensing-in activities since 2011.

Meanwhile, in a statement announcing Giovanni Recordati's passing, the company pointed out that the group had grown "vigorously" under his management, "becoming a well-known international pharmaceutical player with subsidiaries in Europe, North America, South America and North Africa, as well as developing a presence in the rare-disease segment".

Recordati recently snapped up Italian pharmaceutical company Italchimici for €130 million (**OTC *bulletin***, 17 June 2016, page 5). In

Andrea Recordati

Giovanni Recordati

2014, the firm announced the creation of a new Spanish subsidiary – Casen Recordati – following the completion of its acquisition of Madrid-based Laboratorios Casen Fleet (**OTC *bulletin***, 24 October 2014, page 8).

Commenting on his new position, Andrea Recordati said his priority would be to "proceed along the lines of the development strategy outlined by Giovanni Recordati with the objective of continuing the growth of the group". OTC

Manufacturers

Valeant reshuffles leadership

Troubled Canadian company Valeant has appointed **Paul Herendeen** as chief financial officer and executive vice-president of finance. Herendeen replaces **Robert Rosiello**, who will remain at the firm as executive vice-president of corporate development and strategy.

The move is part of a broader series of leadership and organisational changes aimed at creating "the new Valeant".

The company – which has been led by former Perrigo chief executive officer Joseph Papa since May (**OTC *bulletin***, 6 May 2016, page 1) – has promoted six people: **Dennis Asharin**, **Joe Gordon**, **Barbara Purcell**, **Tage Ramakrishna** and **Kelly Webber,** to the firm's realigned executive committee.

Further changes include the appointment of investor and analyst **Scott Hirsh** as senior vice-president for business strategy and communications, while **Pavel Mirovsky**, president and general manager of the firm's Europe operation, will retire "later this year".

Expanded roles

Valeant has also expanded the roles of joint group chairmen **Ari Kellen** and **Anne Whitaker**, and elevated to the role of company group chairman, **Tom Appio**, who will now have responsibility for "all of Valeant's markets outside the US and Canada". OTC

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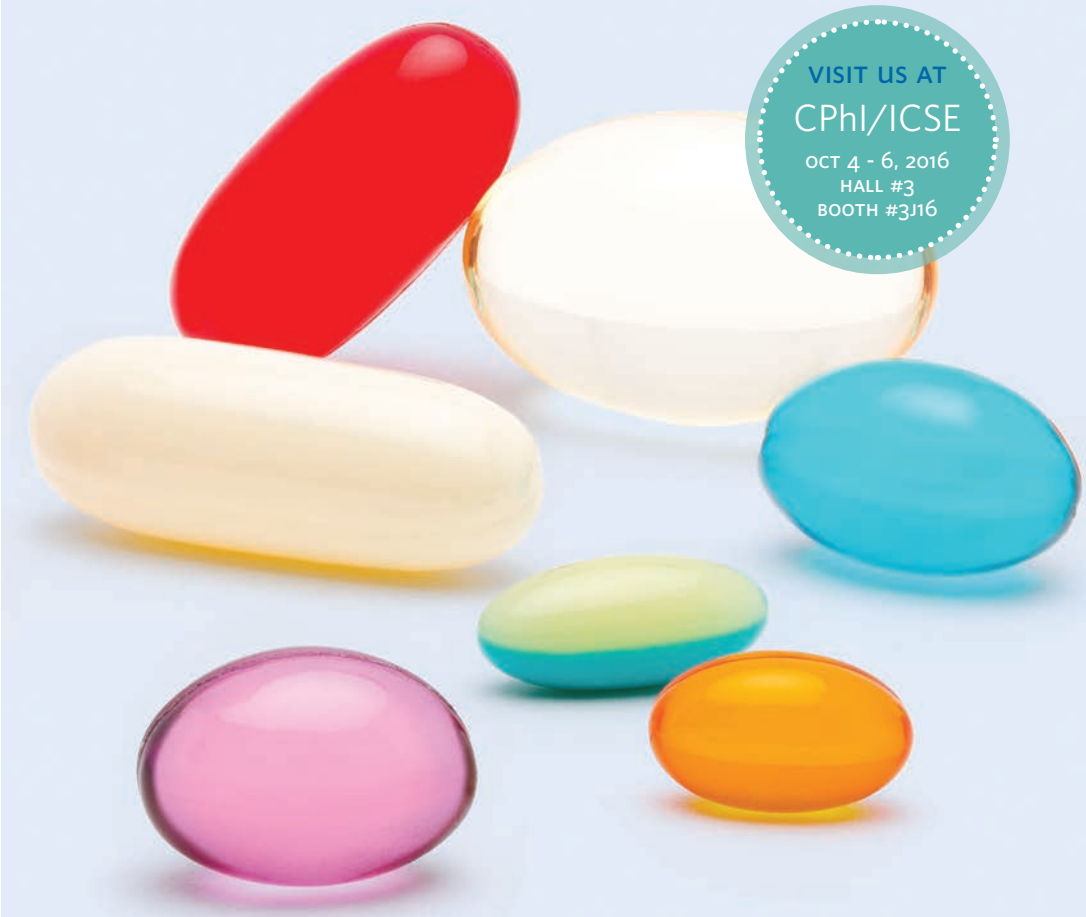

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