17 April 2015

OTC bulletin

THE BUSINESS NEWSLETTER FOR THE CONSUMER HEALTHCARE INDUSTRY

Perrigo considers its future as Mylan offers US$29bn

Mylan has offered US$205 per share (€192 per share) for Perrigo in a cash-and-shares bid that values Perrigo at almost US$29 billion, based on Perrigo having 140.8 million shares outstanding as of 30 January 2015. The combined firm would have 2014 proforma sales of US$15.3 billion.

Perrigo said its board would meet to discuss Mylan's "unsolicited, indicative proposal".

Both firms have now made filings to the relevant authorities regarding the potential deal.

According to Mylan, its offer represents a premium of more than 25% to Perrigo's closing share price on 3 April, the last trading day before Mylan's executive chairman, Robert Coury, wrote to Perrigo's president, chief executive officer and chairman, Joseph Papa, outlining the non-binding takeover bid.

"This proposal is the culmination of a number of prior discussions between Mylan and Perrigo about the compelling strategic and financial logic of this combination," Coury commented.

Robert Coury, Mylan's executive chairman, said acquiring Perrigo would create an "unmatched global platform"

Critical mass in OTC

Combining the two firms, he said, would "produce a company with critical mass in speciality brands, generics, OTC and nutritional products; a powerful commercial platform with reach across all customer channels; an exceptional, high-quality operating platform; and opportunities to generate enhanced growth".

In his letter to Papa sent on 6 April, Coury argues that "in an environment where scale and reach are becoming increasingly important, the combination of our companies would result in an unmatched global platform, substantial revenue and operating synergies, and enhanced long-term growth potential".

Promising "a very significant cash payment to Perrigo shareholders", Coury said the combined entity would possess a "powerful commercial platform with strong reach across multiple channels".

This would be "an increasingly important strategic advantage in light of the evolving distributor and payor dynamics across geographies", he insisted.

Papa would serve as co-chairman, Coury suggested, with Mylan's chief executive officer Heather Bresch and president Rajiv Malik retaining their current positions.

He expressed hopes that Perrigo's chief financial officer Judy Brown and general counsel Todd Kingma would take up "important roles" within the combined entity, alongside "members of Marc Coucke's Omega Pharma management team".

Mylan's proposed offer comes shortly after Perrigo expanded its presence in Europe's branded OTC market by closing its €3.8 billion acquisition of Omega (see page 3). Papa said the deal had created an "industry-leading global healthcare company" with the structure and cash flow to accelerate its international growth "even further".

Explore OTC opportunities

In mid-2014, Mylan said that it intended to explore opportunities to build an OTC operation in Europe to complement its US$5.3 billion purchase from Abbott of a roster of more than 100 mature brands and branded generics in developed markets (**OTC *bulletin***, 15 August 2014, page 3).

At the time, Bresch told investors that Mylan thought OTC was an "interesting channel" that

■ *Continued on page 5*


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Mergers & Acquisitions

P&G clears out Vicks VapoSteam

Procter & Gamble has sold its Vicks VapoSteam liquid-inhalant business in the US for an undisclosed sum to the consumer products firm Helen of Troy.

The consumer goods giant has also granted Helen of Troy a licence for its Vicks VapoPads scented pad products in the US.

The vast majority of Vicks VapoSteam and VapoPads products are used in Vicks humidifiers, vaporisers and other healthcare devices already marketed by Helen of Troy.

Helen of Troy said that the Vicks VapoSteam business generated annual sales of approximately US$10 million (€9.4 million).

The two products were part of a wider Vicks range of allergy, cold and flu products – including the DayQuil and NyQuil lines – which Procter & Gamble continues to market in the US.

Cut number of brands

Procter & Gamble announced in August last year that it planned to cut radically its portfolio of brands and focus on just 70 to 80 core brands organised into a dozen business units (**OTC *bulletin***, 15 August 2014, page 9).

The company said that the 70 to 80 core brands were "consumer-preferred and customer-supported". However, it did not provide a list of which brands would stay with the firm.

OTC

Mergers & Acquisitions

Perrigo ready for growth as it closes Omega deal

Perrigo is well placed to "accelerate" its international expansion, following the completion of its deal for Omega Pharma, according to the firm's chief executive officer Joseph Papa.

Speaking as the US store-brand specialist closed its €3.8 billion acquisition of the Belgian OTC firm, Papa said the deal had created an "industry-leading global healthcare company" with the structure and cash flow to accelerate its international growth "even further".

Omega's "strong and established" commercial, regulatory and distribution platforms provided Perrigo with "multiple opportunities" to launch its existing portfolio in the "high-barrier-to-entry European OTC market", Papa claimed.

Noting that the deal – which was announced late last year (**OTC *bulletin***, 28 November 2014, page 1) – had given Perrigo "critical mass" in all "key" European countries, Papa said the firm would now enjoy greater opportunities for "continued strategic bolt-on acquisitions".

The combination of Perrigo and Omega created a "top-five global OTC company", Papa pointed out, noting that with Omega on board, Perrigo's total annual sales would increase to around US$5.7 billion (€5.2 billion).

Sales would also be more evenly split between the US and the rest of the world, Papa noted, with 43% of Perrigo's turnover coming from markets outside the US.

Omega gives Perrigo a diverse range of OTC brands covering a number of categories – including analgesics, cough and cold remedies, skin-care treatments, and vitamins, minerals and supplements (VMS) – that generated sales of €1.27 billion in 2014.

The bulk of Omega's sales are generated in Belgium, France and other Western European markets. The firm also has a growing interest in a number of emerging markets, including those of Latin America.

Commenting on the deal, Papa said acquiring Omega would immediately increase Perrigo's scale and footprint in Europe, giving the business access to an "established commercial network connected to 211,000 pharmacists, 105,000 retail stores and 3,900 parapharmacies".

"In one transaction, we acquire a comprehensive commercial European infrastructure, a leading portfolio of OTC brands and country-by-country regulatory experience," Papa noted.

Furthermore, the deal would enhance the company's "already sizeable" OTC offering and "accelerate the distribution" of both Omega and Perrigo's products.

OTC

17 April 2015 **Number 441**

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ISSN 1742-0784.

Company registered in England No 2765878.

Printed by Warwick Printing Company Limited, Leamington Spa CV31 1QD, UK.

Business Strategy/Second-Quarter Results

Walgreens Boots Alliance open to deals

If any "big opportunities" for mergers and acquisitions emerge, Walgreens Boots Alliance (WBA) "will be ready" to capitalise on them, according to acting chief executive officer Stefano Pessina.

Speaking as the US-based wholesale and retail giant reported the results for its second quarter ended 28 February 2015, Pessina said that if WBA identified an acquisition target it would go after it.

Noting that the firm was still in the early stages of integrating the Alliance Boots and Walgreens businesses, following the completion of a merger deal (**OTC *bulletin***, 16 January 2015, page 5), Pessina insisted that this would not stand in the way of any potential mergers or acquisitions.

"It will take a while to build a solid WBA platform," Pessina admitted, "but just because we haven't finished the job, it doesn't mean we can't pursue new opportunities in the meantime."

Open to joint ventures

In addition to acquisitions, WBA would also consider any opportunity to establish a joint venture, Pessina revealed.

"We are open to [working with] any kind of organisation which can improve the value of our company," he explained.

Prior to the formation of WBA, when he was in his previous role as executive chairman of Alliance Boots, Pessina said big deals in Europe were no longer possible, adding that if the company wanted to be truly global, it needed to have scale in the Americas and Asia (**OTC *bulletin***, 31 May 2012, page 4).

"Global wholesalers and multinational retailers can thrive," Pessina said at the time, "but we need scale."

Commenting on the progress that had been made since the completion of the merger, Pessina said WBA had "achieved much in a short time" and had already identified areas of the business that needed attention.

WBA planned to "refresh and reinvest" in its retail stores in the US "to improve the customer experience and expand retail margins", Pessina explained.

Based in Illinois, US, Walgreens Boots Alliance operates in more than 25 countries worldwide

The firm would also restructure its cost base, he noted, with a focus primarily in the US, to "create a more efficient cost model and become a more agile company".

Meanwhile, Pessina said WBA was in the "process of reviewing candidates" to find the firm's first permanent chief executive officer.

Searching for new chief executive

WBA is searching for a chief executive after the former head of Walgreens, Gregory Wasson, decided to retire and not take up the role (**OTC *bulletin***, 16 January 2015, page 19).

Pessina admitted that it had been "challenging to find suitable candidates with the required attributes".

However, WBA "remained confident" that in "due course" it would find "the right person for the job", he insisted.

Turning to WBA's second-quarter results, Pessina reported a "solid start for our new firm" with turnover of US$26.6 billion (€25.1 billion), excluding intersegment sales of US$387 million.

George Fairweather, WBA's global chief financial officer, noted that the second-quarter figures included the results of Alliance Boots for two months – January and February – on a fully consolidated basis and one month, December, as equity income from Walgreens' pre-merger 45% interest.

Noting that WBA began recording sales as a consolidated entity part-way through the quarter, Fairweather said comparing the figures to the results in the prior-year period was "a challenge and of little use".

Turnover at the company's Retail Pharmacy USA division – which comprises Walgreens and Duane Reade drugstores and online sales in the US – advanced by 7.4% to US$21.0 billion in the three months.

Prescription sales, which accounted for 64.4% of the total, had increased by 10.1%, WBA noted, while prescription sales in comparable stores improved by 9.7%.

The division generated an operating income of US$1.29 billion in the three months.

As of 28 February 2015, the division was operating 8,232 drugstores across all 50 US states, the District of Columbia, Puerto Rico and the US Virgin Islands.

Pessina noted that the company had identified "opportunities for cost savings" in the Retail Pharmacy USA division that would generate US$500 million by the end of WBA's fiscal 2017.

Alex Gourlay, president of Walgreens, revealed that the company had decided to close 200 drugstores in the US after conducting a "thorough review" of all its outlets.

These would be replaced by "around 200" new stores in locations where there were more opportunities for growth, Gourlay explained.

Meanwhile, Pessina reported sales of US$2.0 billion at WBA's Retail Pharmacy International division – consisting of health and beauty chains in eight countries, the largest of which is Boots UK – after two months of operation.

Retail Pharmacy International posted an operating income of US$8 million for the period.

As of 28 February 2015, the division was operating 4,559 health and beauty stores across Chile, Ireland, Lithuania, Mexico, the Netherlands, Norway, Thailand and the UK.

Commenting on WBA's plans for Boots UK – the country's biggest pharmacy chain – Pessina said the company would continue to develop the retailer's online offering.

WBA wanted to integrate Boots UK's online presence with its physical stores to "enhance consumer choice", he noted.

The firm was already working to keep Boots UK's product offering "fresh" through innovation, Pessina explained, so the chain could continue to grow in the "extremely competitive UK retail market".

Outside of the UK, Pessina said WBA had identified "strong opportunities for growth" in Latin America through its two pharmacy chains in the region.

Alliance Boots snapped up Chile's Farmacias Ahumada and Mexico's Farmacias Benavides pharmacy chains from Mexican wholesaler and retailer Grupo Casa Saba for MXN8.3 billion (€488 million) last September (**OTC *bulletin***, 12 September 2014, page 8).

Mexico's third-largest chain

At the time of the deal, Alliance Boots noted that as the third-largest retail pharmacy chain in Mexico, Farmacias Benavides operated around 1,000 stores across 21 of the country's 31 states.

Farmacias Ahumada was one of the three biggest pharmacy chains in Chile, the company said, with approximately 400 stores.

Noting that Latin America was one of Alliance Boots' "priority areas for investment", Pessina said at the time that the acquisition would give the company a "major presence" in what was an "attractive market". The deal also represented a further step towards Alliance Boots' goal of achieving a "truly global footprint", he added.

Stefano Pessina, Walgreens Boots Alliance's acting chief executive officer, said the firm would be ready to capitalise on any acquisition opportunities

Meanwhile, Pessina said that WBA's Pharmaceutical Wholesale division – which mainly operates under the Alliance Healthcare brand – had generated sales of US$3.9 billion after two months of operation.

The division generated an operating income of US$81 million in the period.

WBA noted that its Pharmaceutical Wholesale division supplied medicines, other healthcare products and related services to more than 140,000 pharmacies, doctors, health centres and hospitals from 299 distribution centres in 12 countries.

Synergies on track

Turning to group-wide synergies, Pessina said combined synergies from the merger had totalled US$310 million in the six months ended 28 February 2015, and were "on track" to reach at least US$650 million in the year ending 31 August 2015.

Pessina pointed out that the company was targeting synergies of "at least" US$1 billion by 31 August 2016.

WBA's total operating income for the period amounted to US$1.37 billion, after eliminations.

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Business Strategy/Annual Report

Reckitt looking to China to provide global ideas

Reckitt Benckiser (RB) will use China as a test bed for new ideas that have the potential to be rolled out around the world, according to chief executive officer Rakesh Kapoor.

In the UK-based, consumer-goods firm's recently-released annual report, Kapoor points out that RB is witnessing a "revolution in digital commerce" in China, noting that a fifth of the company's revenue in the country is generated online.

As a result of this shift, RB would now take what it had learnt in China, Kapoor explains, and seek to apply these lessons to its businesses elsewhere in the world.

"This is a reversal of the traditional model," he claims, "which saw most business ideas travel in the opposite direction."

Meanwhile, RB has already started to "massively" step-up its investments in digital media, Kapoor says, as the company has seen how digital marketing provided opportunities to "build more engaging relationships with our consumers at lower cost".

"The digital revolution we are all witnessing is disrupting many industries and creating opportunities in others," Kapoor claims. "In some markets, we are now delivering over 50% of our media impressions in digital media," he adds, "rather than in traditional print or broadcast channels."

"This shift is driven by both strategic and commercial considerations," he points out.

These ideas, Kapoor says, all play into the firm's recently-announced 'Project Supercharge' (**OTC *bulletin***, 6 March 2015, page 4), which has been designed to reduce complexity and cut costs.

Under the plan, RB's innovation and product-launch functions will be centralised to reduce the workload of the company's country units and enable them to focus better on getting products into stores.

The aim, Kapoor explained at the project launch in March, was to create a firm that would be "as global as possible, as local as needed".

Furthermore, the project was set to lead to savings of up to £150 million (€203 million) annually by streamlining supply and production processes, including job cuts.

The company has also reduced the number of its geographic businesses to two from three by merging its RUMEA unit – which currently consists of the Middle East, North Africa and Turkey, Russia and the Commonwealth of Independent States (CIS), and Sub-Saharan Africa – with the LAPAC region, which covers Australia/New Zealand, Latin America, North Asia, and South and South-East Asia.

The merged unit is called Developing Markets, or DvM.

As part of this process, Australia/New Zealand and Russia/CIS have been moved into the Europe and North America (ENA) operation.

Commenting in the annual report on 'Project Supercharge', Kapoor says that as the world changes, RB has "no intention of standing still".

"We continue to sharpen our portfolio focus," he adds, "and ensure we are organised in a way that allows us to be even faster and more consumer-centric."

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IN BRIEF

■ **HI-TECH PHARMACEUTICALS** – the US-based dietary supplements and OTC products firm – is set to acquire Mexico's **Advanced Pharmaceuticals and Nutritionals (APN)** for an undisclosed sum. The deal would enhance Hi-Tech's international presence, the company noted, and would give the firm critical mass in "all key Latin American countries". APN distributed a range of cough/cold, gastrointestinal, nutritionals, pain-relief, sports-nutrition and weight-management brands, Hi-Tech pointed out, across Mexico, Central America and South America.

OTC

Mergers & Acquisitions

Perrigo considers US$29bn Mylan takeover

■ *Continued from front page*

in "some respects is even more interesting outside the US".

"The Abbott transaction certainly gives us a beginning foothold in OTC," Bresch stated. "We have got real opportunities to look at some of these brands that we have acquired, as well as perhaps to add some products that would be very strategic and would allow us to build upon the Mylan equity through all channels."

The bulk of the proposed combined company's OTC turnover would come from Perrigo, whose store-brand Consumer Healthcare business reported sales up by 6% to US$2.22 billion in the year ended 28 June 2014, the majority of which was generated in the US (**OTC *bulletin***, 12 September 2014, page 4).

Consumer Healthcare accounted for 55% of the Perrigo's annual turnover of US$4.06 billion, with the remainder coming from its Prescription Pharmaceuticals, Nutritionals and Active Pharmaceutical Ingredients divisions, as well as other smaller operations.

OTC

Business Strategy/Annual Report

Moberg sees potential for OTC growth

"Significant growth opportunities" exist for Moberg Pharma in what remains a "highly fragmented" global market for OTC products, according to the firm's chief executive officer Peter Wolpert.

Speaking as the Sweden-based company released its 2014 annual report, Wolpert said Moberg planned to move its OTC business forward by building strong brand equity and pursuing bolt-on acquisitions.

"We will continue to seek out in-licensing and acquisition opportunities as important sources of new products that will expand our portfolio," Wolpert explained.

Moberg would focus on three "strategic areas" – foot care, dermatology and pain management – Wolpert said, noting that the company planned to expand its portfolio into new categories "over time".

Turning to the firm's 2014 results, Wolpert said the double-digit rise in sales to SEK200 million (€21.4 million) had been driven by an improved performance in two of its three global business regions.

The company's sales advanced by 27%, led by growth in the North and South America and Rest of World regions.

Wolpert said an increase in sales of 57% to SEK148 million in North and South America had been driven by the performance of its Kerasal Nail anti-fungal product.

Widening distribution had given Kerasal Nail – known as Emtrix or Nalox in a number of markets – a 22% market share of the US retail fungal-nail segment, Wolpert explained.

Acquired three brands

Moberg's US turnover had also been boosted by sales of the three OTC brands the company acquired from Bayer in December 2013 (**OTC *bulletin***, 13 December 2013, page 1), Wolpert noted.

The acquired portfolio consisted of the Domeboro topical anti-itch irritation brand, the Fergon iron supplement and the Vanquish oral analgesic.

Meanwhile, sales in the North and South America region had also been lifted by the launch of Emtrix in Canada during 2014, Wolpert said.

The introduction had been a "tremendous success", Wolpert insisted, noting that the brand now held a 50% market share of the Canadian retail fungal-nail segment.

Turning to Moberg's Rest of World sales, Wolpert reported turnover up by 12% to SEK22.0 million for the 12 months, thanks to the launch of Kerasal Nail in China, Hong Kong and Malaysia.

Moberg expected Asia to become the firm's "fastest-growing" market in 2015, Wolpert explained, with product launches currently being prepared for a number of countries in the region.

By contrast to Moberg's Rest of World and North and South America regions, sales at the firm's European business slipped back by 30.8% to SEK30.1 million.

The company did not give a reason for the decline in turnover.

Despite the drop in sales, Wolpert said the approval in May 2014 of an expanded indication for Nalox provided prospects for future growth in the region.

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Business Strategy/Annual Results

Alliance looks for more OTC products

Alliance Pharma will continue to add to its growing OTC product portfolio and will consider acquiring not only brands, but also small companies to boost its range, according to chief executive officer John Dawson.

Speaking to **OTC *bulletin*** as the firm posted a 4% drop in 2014 sales to £43.5 million (€59.9 million), Dawson said that the UK-based company wanted a "good fraction" of its sales to come from consumer healthcare products to help shield the firm from the price pressures on its prescription business.

"It's good to have a range of different clubs in the bag," Dawson insisted, "and we recognise the attraction of consumer products."

Having acquired the MacuShield supplement said to be for treating age-related dry macular degeneration, consumer healthcare products now accounted for a fifth – around £8.7 million – of the company's turnover, Dawson noted, up from just a tenth previously.

Alliance paid £5.5 million for MacuShield, a figure that could rise to £6.0 million if certain sales targets are met, which Dawson was convinced would be the case.

"MacuShield meets a very real medical need and the largest cause of blindness in the elderly," Dawson pointed out. "We liked the dynamics of the product, the scientific backing it has got and the opportunity for growth it presents."

Alliance was also well set up to sell the product, Dawson claimed, as the company knew how to promote to specialists, which was how initial sales of MacuShield were made.

"It is those eye-care specialists who initially recommend that patients use the product and thereafter it becomes a consumer product," he pointed out. "This hybrid nature really suits the blend of skills we have in the company."

MacuShield also had great potential geographically, Dawson said, noting that three-quarters of its sales were currently generated in the UK and the rest via distributors in Europe.

"There is a big opportunity to expand the sales outside the UK," Dawson insisted. "Alliance is a much bigger organisation than the one that sold the product to us – we have more reach and experience – so we see strong international potential."

Geographic expansion was also a key strategic ambition for Alliance as a whole, Dawson noted, adding that it remained on track to have a company presence in all the major European markets within the next five years.

Dawson said that the company had "good leads" on potential acquisitions across the "big five" European Union (EU) markets and he was "confident that within that timeframe we will have found the right products on which to base a small infrastructure across these five".

"We already have a presence in France, Germany and the UK, so we are confident of finding platforms in Italy and Spain," he insisted.

Outside of Europe, Alliance's fledgling business in China was performing well, Dawson said, and the firm was keen to expand it further.

In China, Alliance – which operates through a joint-venture company called Unigreg – was establishing a mother and baby range, built on the Forceval supplement for pregnant women.

The firm had also taken a stake in a Shanghai and Hong-Kong-based infant-formula firm called Synthasia International last year, Dawson pointed out, which complemented Forceval.

A recent Chinese government review of the imported infant formula market had seen a number of competitors taken off the shelves, Dawson noted, which meant its Suprememil brand was now operating in a much friendlier environment.

Looking for buys in China

Alliance now had two people on the ground in China looking at leads for other mother and child products, Dawson said, adding that while a deal would not be "struck tomorrow" the acquisition environment was "very encouraging".

Turning to the 2014 results, Dawson said that Alliance's non-prescription products had performed well. The firm's consumer healthcare portfolio includes the Ashton & Parsons teething powders and MolluDab skin-infection treatment, as well as the Lypsyl skin-care brand.

Alliance paid Novartis US$3.0 million (€2.0 million) for the Lypsyl range in the UK and Ireland at the end of 2013 (**OTC *bulletin***, 17 January 2014, page 3).

Lypsyl had generated sales of around £1.0 million in the 12 months, Dawson pointed out, as the company stabilised distribution.

The product was starting to reappear in stores, he noted, but there was still more work to do as the brand was not as ubiquitous as it once was.

"We have been doing a lot of work on repositioning it, finding the best place for it in the market," Dawson explained, "while also improving the physical characteristics of the product."

However, Dawson said that Alliance would not start really pushing the brand until 2016.

Meanwhile, marketing activity behind the firm's Ashton & Parsons teething powders would be ramped up during 2015, he revealed.

Production problems which had hampered the teething powders had been overcome, he noted, and this had enabled the company to return the product to wider distribution. This had helped triple sales to £1.4 million.

John Dawson, Alliance Pharma's chief executive officer, said the firm was on the look out for brands and small companies that would bolster its OTC business

A large consumer marketing campaign would be launched later in the year, Dawson said, which would be built around the brand's efficacy and its long history which dated back to the 1890s.

While the smaller consumer healthcare side of the business had performed well in 2014, the company's prescription products had had a more difficult year, Dawson acknowledged, leading to the drop in group sales.

Generic competition had damaged sales of its Nu-Seals brand, he noted, while one of its toxicology brands had suffered from the loss of a tender.

Pre-tax profits had also declined, Dawson said, falling back by 10% to £10.8 million.

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IN BRIEF

■ **KARO BIO** – a Swedish development firm – has acquired drug-research company **Tanomed** and its in-development product to tackle the common cold. Karo said Tanomed's "unique product" would help "relieve and prevent" the progression of a cold by "reinforcing the body's own defences" and help fight common cold viruses. The patented technology used in the product was based on research conducted with the University of Umeå, Karo pointed out, which showed that when the enzyme glucose oxidase was used in combination with glucose, it effectively counteracted "rhinovirus infections and other viral and bacterial pathogens". Karo acquired Tanomed in an all-share deal. It said Tanomed's product should be on the market within 18 months.

OTC

Distribution Agreements

Vitabiotics to expand in Asia

UK supplements firm Vitabiotics has signed a deal to distribute its products in Asia through expansion specialist DKSH.

Under the terms of the agreement, DKSH's Healthcare unit will provide marketing, sales, distribution, logistics and regulatory services for Vitabiotics in Hong Kong and Malaysia.

DKSH claimed it would broaden Vitabiotics' "established market position" in Hong Kong by increasing the distribution of the UK firm's products to more pharmacy outlets.

Noting that Vitabiotics was currently seeking approval to sell its products in Malaysia, DKSH said it would begin distribution in the market as soon as approval was granted.

Commenting on the deal, Robert Taylor, Vitabiotics' vice president, said working with DKSH would allow the firm to "accelerate" its growth and "enter new strategic markets".

"The diverse Asian market shows excellent long-term growth potential for Vitabiotics' products," Taylor added.

Andrew Frye, head of DKSH's Healthcare unit, said the company would use its "broad capillary distribution" networks and capitalise on the knowledge of its local experts in Hong Kong and Malaysia to "spur further growth" for Vitabiotics in Asia.

OTC

Manufacturing Agreements

Sohm gets the nod for nutraceuticals

Sohm – a manufacturer of generic pharmaceutical, nutraceutical and cosmeceutical products – said its Indian unit had taken on the manufacture of a range of nutraceuticals for an unnamed local company.

Shailesh Shah, Sohm's president and chief executive officer, said the firm's Indian operations would produce 10 nutraceuticals for its new partner and that the deal would add significantly to its revenues.

The Indian nutraceuticals market was set to be worth almost US$3 billion (€2.8 billion) in value terms by 2016, Sohm claimed, with the wider nutraceuticals, supplements and vitamins market expected to achieve a compound annual growth rate (CAGR) of 9% for the 2013-2018 period as demand increased.

OTC

Annual Report

Krka posts OTC decline as currency effects hit

Krka reported turnover from non-prescription products – including self-medication lines and cosmetics – down by 16% to €122 million in 2014, caused by currency changes in key markets.

Local currency devaluation in Russia and Ukraine – the firm's two largest markets for non-prescription products – had hit sales, the Slovenian company explained in its annual report.

This had been compounded by lower incidences of cold and flu across Europe, Krka said.

Sales in Russia dropped back from just under €60 million in 2013 to just over €40 million in 2014 (see Figure 1).

Meanwhile, turnover in Ukraine slipped from just under €20 million in 2013 to just above €10 million in 2014.

On a more positive note, Krka reported higher sales of non-prescription products in four of its 10 biggest markets, with the best growth recorded in Romania and Uzbekistan.

Turnover in Romania had been boosted by the launch of the Septanazal nasal decongestant product, Krka said, while sales in Uzbekistan had benefitted from the release of a line extension to the firm's Herbion cough and cold brand.

Herbion remained Krka's biggest-selling non-prescription brand, the company noted, adding that the herbal cough syrup line was available in 30 markets.

During 2014, the Herbion Ivy Syrup product had been launched in Kazakhstan, Poland, Serbia and a number of other Eastern European markets, Krka said, while the Herbion Iceland Moss Syrup variant for sore throats and hoarseness had been taken into Bosnia and Herzegovina, Ukraine and Uzbekistan.

Ginkgo biloba-brand Bilobil was Krka's second-biggest non-prescription seller in the 12 months, the firm pointed out, having retained its market-leading position across Central, Eastern and South-Eastern Europe.

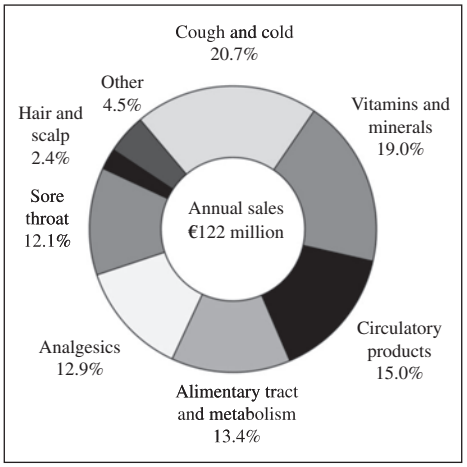


Figure 2: Krka's non-prescription sales of €122 million in 2014 by therapeutic claim (Source – Krka)

Bilobil had been extended in Russia and Mongolia during the year with the Bilobil Intense variant, Krka noted.

Turning to sales of non-prescription products by therapeutic category, Krka pointed out that cough and cold products led the way, generating turnover of €25.3 million in the 12 months. Cough and cold products accounted for 20.7% of Krka's total non-prescription sales in 2014 (see Figure 2).

Vitamins and minerals accounted for 19.0% of sales, with products for improving circulation generating 15.0% of turnover.

Non-prescription products represented 11% of Krka's Human Health sales in 2014, which declined by 1.2% to €1.11 billion.

OTC

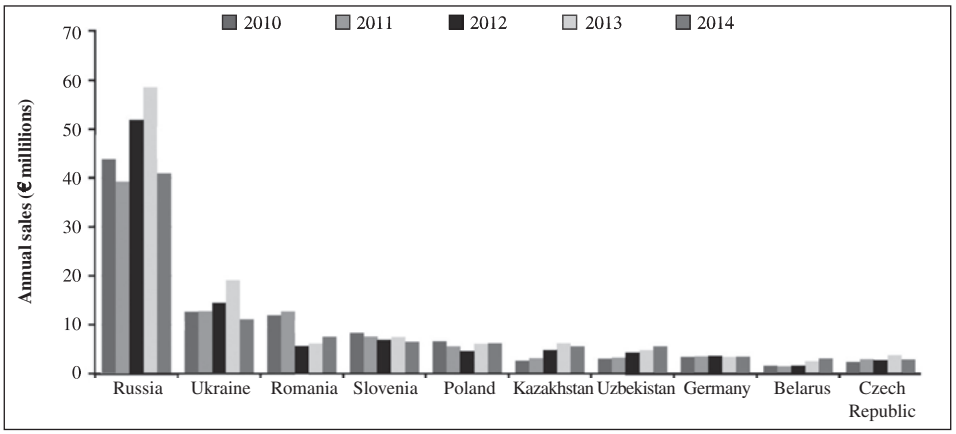


Figure 1: Krka's non-prescription sales in its 10 biggest markets from 2010 to 2014 (Source – Krka)

Mergers & Acquisitions

Green Light gets two pharmacies

UK-based Green Light Pharmacy has expanded its presence in London, UK, after snapping up two pharmacies in the capital for an undisclosed sum.

Noting that the deal took its total number of outlets to seven, Green Light said it planned to rebrand both pharmacies – which were currently operating as independents – under its own name and increase the services on offer to consumers.

Sanjay Ganvir, a director at Green Light, told **OTC *bulletin*** that the firm planned to refit both pharmacies with "consulting booths" next to the counter to give consumers more privacy when discussing ailments and purchasing medicines.

Green Light was a "clinically-focused" pharmacy chain, Ganvir explained, so neither store would offer cosmetics or perfumes.

Established in 1999, Green Light now generated annual turnover in excess of £4.0 million (€5.5 million), Ganvir pointed out, and had ambitious plans for growth.

Carry on expanding

"Absolutely we want to carry on expanding," Ganvir insisted, noting that the company had set a target of operating 20 branches by 2020.

John Foreman, founder of Green Light, said the firm's ambition was to "change the predominant pharmacy model from its narrow focus on prescriptions and retailing to a model that puts wellness, education and prevention at its focus".

By doing this, Green Light had gone from "strength to strength", Foreman pointed out, and had secured backing from a number of established financiers.

Expanding on this approach, Ganvir claimed that pharmacy had an important role to play in patient education and in encouraging self-care.

"Self-care is about having a two-way conversation with patients about medicines and their health, and educating them so that they can make an informed decision," Ganvir explained.

When it came to promoting self-care, pharmacy was an "amazing asset" that was currently being "underutilised", he argued.

Noting that the UK was facing a general practitioner (GP) crisis – with not enough medical students choosing general practice – Ganvir said the National Health Service (NHS) needed to "think differently" and encourage patients with minor ailments to visit pharmacies.

OTC

Business Strategy

NBTY to expand use of Holland & Barrett name

NBTY is set to grow its Holland & Barrett chain to over 900 stores, after announcing plans to rebrand all of its De Tuinen and Essenza outlets.

Noting that all 167 stores from its Dutch De Tuinen chain and its Belgian Essenza line would be rebranded as Holland & Barrett outlets, NBTY said the process would begin this month and take around 18 months to complete.

Acquired De Tuinen in 2003

The US-based natural products wholesaler and retailer has operated in the Netherlands for 12 years, after it snapped up De Tuinen in 2003. The retailer moved into Belgium in 2013, with the acquisition of health and wellness chain Essenza (**OTC *bulletin***, 17 June 2013, page 3).

Commenting on the move, Colinda Hoegee, chief operating officer of De Tuinen and Essenza, said both chains would benefit from the "international recognition and strong heritage" of the Holland & Barrett name.

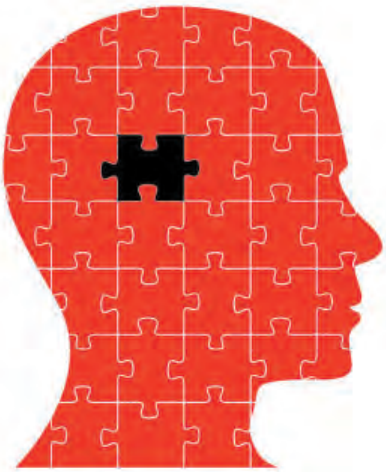
In addition, NBTY would be able to take its "innovative" Holland & Barrett branded products into Belgium and the Netherlands, she added.

NBTY currently operates over 750 Holland & Barrett stores in the UK and franchise outlets in a number of countries including China, Malta and the United Arab Emirates (UAE).

Holland & Barrett was the "leading vitamins, minerals and supplements (VMS) speciality retailer" in the UK, NBTY claimed, and offered consumers a "broad range" of products amounting to over 4,800 stock-keeping units (SKUs).

NBTY acquired Holland & Barrett from the German firm Gehe in 1997 (**OTC *bulletin***, 29 August 1997, page 3), when the chain had around 400 stores.

OTC



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Regulatory Affairs

FDA approves bladder device

ApexM – a medical device to treat urinary incontinence in women – is now available OTC in the US, after the Food and Drug Administration (FDA) approved the product for sale without a prescription.

InControl Medical, the US-based manufacturer of the device, said the FDA had cleared ApexM for OTC sale to treat "stress, urge and mixed urinary incontinence in women".

The device provided "muscle stimulation through a customisable probe", InControl explained, "to strengthen the pelvic floor and calm spasms of the bladder muscle".

ApexM was one of only three devices available to female consumers in the US to treat urinary incontinence, InControl claimed, adding that only ApexM was available without a prescription.

Commenting on the approval, Herschel Peddicord, president of InControl, said by simultaneously treating stress, urge and mixed urinary incontinence, ApexM "rendered unnecessary" expensive urodynamic testing to diagnose the type of incontinence.

"This product is highly efficacious, simple to use and by far the least expensive treatment available for female urinary incontinence," Peddicord claimed.

Citing figures from the National Association for Continence, InControl said "up to 40 million" women in the US had experienced bladder-leakage issues "at some point in their lives".

Earlier this year, Bayer discontinued its overactive bladder treatment Oxytrol for Women in the US following poor sales (**OTC *bulletin***, 6 March 2015, page 1).

Oxytrol was launched to great fanfare in the autumn of 2013 (**OTC *bulletin***, 11 October 2013, page 15) having become the world's first oxybutynin-based OTC product when it was switched earlier that year (**OTC *bulletin***, 8 February 2013, page 1).

OTC

IN BRIEF

■ **GNC** – the US-based natural supplements retailer – has agreed with the US state of New York to use **DNA barcoding to authenticate plants** used in its herbal supplements. The move comes after accusations the products did not contain the ingredients claimed (**OTC *bulletin***, 13 February 2015, page 18).

OTC

Regulatory Affairs

PRAC proposes updating high-dose ibuprofen advice

The product information provided with ibuprofen medicines looks set to be updated to warn of the small increased risk of cardiovascular problems associated with taking high doses of the anti-inflammatory.

Following a review instigated just under a year ago (**OTC *bulletin***, 27 June 2014, page 8), the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) said that while the benefits of ibuprofen continued to outweigh the risks, it felt that the advice on the use of high-dose ibuprofen – 2,400mg per day or higher – should be updated to minimise the cardiovascular risk.

High doses of ibuprofen should also be avoided in patients with serious underlying heart or circulatory conditions, such as heart failure, heart disease and circulatory problems, the PRAC pointed out, or in those who had previously had a heart attack or stroke.

At its June 2014 meeting, the PRAC decided to begin a review to evaluate the cardiovascular risks linked with regularly taking 2,400mg ibuprofen per day for long periods.

Noting at the time that ibuprofen was usually taken at lower doses and for short periods of time, the PRAC insisted that there was "no suggestion of a similar cardiovascular risk with ibuprofen as used by the overwhelming majority of patients".

"Ibuprofen is one of the most widely-used medicines for pain and inflammation," the PRAC pointed out, "and has a well-known safety profile, particularly at usual doses."

However, the PRAC said that data – in particular the results of an analysis of clinical trial data – had suggested that the cardiovascular risk with the non-steroidal anti-inflammatories (NSAIDs) diclofenac and high-dose ibuprofen might be "similar to the known risk" with another form of NSAID, COX-2 inhibitors.

In 2013, the PRAC considered the data in relation to diclofenac and recommended that patients with serious underlying heart conditions should not use the anti-inflammatory due to a small increased risk of heart attack and stroke (**OTC *bulletin***, 26 July 2013, page 13).

Meanwhile, the PRAC said it had also reviewed evidence of the interaction of ibuprofen with low-dose aspirin, taken to reduce the risk of heart attacks and strokes.

Laboratory studies had shown that ibuprofen could reduce the anti-clotting effects of aspirin, the PRAC reported, but it "remained uncertain whether the long-term use of ibuprofen reduced the benefits of low-dose aspirin in preventing heart attacks and strokes".

However, the committee recommended that information on the interaction should be included in the product information.

OTC

Regulatory Affairs

New Zealand monitors guaifenesin

Medsafe – New Zealand's medicines regulator – has added guaifenesin to its medicines monitoring scheme following reports linking the OTC expectorant to tinnitus.

The agency said that a patient who had been taking 600mg guaifenesin for an upper respiratory-tract infection had reported experiencing "profound tinnitus followed by deafness in the right ear with facial and outer-ear numbness".

In a second report, another patient who had been using guaifenesin for a different problem had experienced hearing loss in their right ear, Medsafe noted, after the dose had been increased to 600mg twice daily.

There had been no "relevant literature reports of tinnitus, deafness or numbness with use of guaifenesin", the agency pointed out.

Medsafe said that guaifenesin had been placed on the medicines monitoring scheme to obtain further information on this "possible adverse reaction".

Used primarily to relieve the symptoms of a productive chesty cough, guaifenesin is available OTC in New Zealand as a single ingredient or combination product.

Single-ingredient guaifenesin brands include: Johnson & Johnson's Codral Relief Mucus Cough 20mg/ml; Reckitt Benckiser's Mucinex 600mg and Maximum Strength Mucinex 1200mg; Pfizer's Robitussin Chesty Cough 20mg/ml; and Procter & Gamble's Vicks Cough Syrup Honey Flavour Chesty Cough 13.33mg/ml and Vicks Formula 44 for Chesty Coughs 1.333%w/v.

OTC

Market Research

Mail-order buys drive German market

Purchases made through mail-order services, both online and by telephone, were largely responsible for Germany's pharmacy OTC healthcare market expanding by 2.5% to almost €11.8 billion at retail prices last year.

Mail-order sales climbed by 11.0% to €1.25 billion, accounting for 11% of the total market, according to data just released by market researcher IMS Health (see Figure 1).

Retail channel	Annual sales (€ millions)	Change (%)	Proportion of total (%)
Community pharmacy	10,539	+1.6	89
Mail order	1,249	+11.0	11
OTC healthcare market	**11,788**	**+2.5**	**100**

Figure 1: Germany's OTC healthcare market in 2014 by retail channel at retail selling prices (Source – IMS Health)

Non-prescription medicines and healthcare products were largely responsible for the mail-order growth with an 11.6% increase to approximately €960 million.

Mail-order retailers achieved double-digit value growth in product categories including analgesics, gastrointestinal remedies, skin-care, eye-care and vitamins, minerals and supplements (VMS).

Turnover of cosmetic and body-care products through mail-order pharmacies rose by 12.1% to €183 million, boosted by strong demand for hair-care products, especially products for hair loss and lice infestations.

Sales of nutritional products advanced by 10.9% to around €35 million. But sales of medical equipment such as tests and thermometers almost stalled at about €75 million.

OTC rise in community pharmacy

In community pharmacies, turnover of all OTC healthcare products increased by a relatively modest 1.6% to €10.5 billion, as growth in gastrointestinal remedies and analgesics helped to offset lower cough and cold sales.

The market's value improvements came despite a 1.0% overall volume decline to 1.15 billion packs in the OTC healthcare market.

A 7.5% volume rise for mail-order outlets to 122 million packs was not sufficient to offset fully a 1.9% volume slide to 1.03 billion packs through community pharmacies (see Figure 2).

"A major reason for the volume decline in community pharmacies is that the previous year's strong wave of colds and flu was not repeated in 2014," IMS Health commented.

Within the mail-order segment, non-prescription medicines and healthcare products were once again the key driver with an 8.4% increase to around 96 million packs, or almost four out of every five packs sold through this type of retailer.

Mail-order sales of cosmetic and body-care products, nutritional products and medical equipment each showed low single-digit advances.

Retail channel	Annual sales (million packs)	Change (%)	Proportion of total (%)
Community pharmacy	1,029	-1.9	89
Mail order	122	+7.5	11
OTC healthcare market	**1,151**	**-1.0**	**100**

Figure 2: Breakdown by retail channel of Germany's OTC healthcare market in 2014, measured by millions of packs (Source – IMS Health)

OTC

IN BRIEF

■ **FDA** – the US Food and Drug Administration – has warned consumers not to use a dietary supplement for muscle growth due to a risk of serious liver injury. **Tri-Methyl Xtreme**, distributed by Las Vegas-based Extreme Products Group, was said to contain anabolic steroids, the agency pointed out, and was available online and in some retail stores and gyms. The FDA said it had begun an investigation to identify the manufacturer of the product after it received adverse event reports from consumers in California, New Jersey and Utah. Charles Lee, a senior medical advisor at the FDA's Center for Drug Evaluation and Research's Office of Compliance, warned that anabolic steroids could cause a "range of serious adverse events on many organ systems" and that the damage might be irreversible. The FDA has advised consumers who suspect that they are experiencing problems associated with the product to consult a healthcare professional.

OTC

Regulatory Affairs

India signs agreement with Mauritius

Co-operation in the fields of traditional medicine and homoeopathy is the objective of a new agreement between India and Mauritius, according to the Indian government.

A 'Memorandum of Understanding' signed by the two countries, the Indian government explained, would provide a framework to explore the health benefits of both Indian and Mauritian traditional medicines.

Traditional medicines culture

India and Mauritius shared a "common culture" when it came to traditional medicine, India said, noting that the agreement would be "mutually beneficial" to both parties.

The Indian government pointed out that it would finance research into the health benefits of traditional medicines currently used in both countries.

India has previously signed similar Memorandums of Understanding related to traditional medicines and homoeopathic products with a number of countries including China, Hungary and Malaysia.

In an attempt to boost exports of traditional medicines, India announced plans late last year to establish a quality control regulator to manage such products (**OTC *bulletin***, 28 November 2014, page 14).

Harsh Vardhan, government minister for Health and Family Welfare, said at the time that the creation of a dedicated traditional medicines regulator would provide better oversight and give the sector "pride of place" in India's mainstream healthcare system.

Manufacturers of traditional medicines would also be given "financial support", Vardhan promised, to "enhance the quality" of their products and help them to "meet global standards".

OTC

Product Recalls

Vitamin Shoppe recalls products

Vitamin Shoppe has removed all dietary supplements containing the herb *acacia rigidula* from its stores and website due to concerns that they may contain an amphetamine.

The retailer said it was acting "out of an abundance of caution" in response to a study which found the amphetamine isomer β-methylphenylethylamine (BMPEA) in a number of dietary supplements labelled as containing the ingredient *acacia rigidula*.

"We are concerned by the findings outlined in the study – published in *Drug Testing and Analysis* – which state that some *acacia rigidula* containing products may also contain BMPEA," Vitamin Shoppe explained.

"If these findings are confirmed by the US Food and Drug Administration (FDA), these products should not be sold as dietary supplements," the firm insisted.

Vitamin Shoppe pointed out that it required all manufacturers of products sold in its retail stores or through its branded website to "comply with all applicable laws".

The study analysed 21 brands of *acacia rigidula* supplements and found that 52.4% of the tested products contained BMPEA.

Consumers of these supplements "may be exposed to pharmacological dosages of an amphetamine isomer that lacks evidence of safety in humans", the study's authors say.

"The FDA should immediately warn consumers about BMPEA," the authors insist, "and take aggressive enforcement action to eliminate BMPEA in dietary supplements."

The study's authors claim that the FDA previously identified BMPEA in *acacia rigidula* supplements in 2013 but that the agency "has yet to warn consumers".

OTC

IN BRIEF

■ **TGA** – Australia's Therapeutics Goods Administration – is calling for comments on plans to amend the scheduling of weight-loss drug **orlistat 120mg or less** from schedule 3 – pharmacist-only medicine – to a schedule 2 pharmacy medicine. Comments are also being sought on proposals to delete the current schedule 3 entry for codeine and reschedule the medicine as a schedule 4 or prescription-only product. The agency is also looking at whether to amend codeine's schedule 2 status.

OTC

Market Research

German doctors identify value in recommending

Two-thirds of German general practitioners (GPs) believe recommending non-prescription medicines to their patients saves the healthcare system money, according to a survey conducted by Sempora Consulting and market researcher GfK.

Just over half of the 150 GPs questioned felt that proposing that patients use an OTC medicine was a "useful addition to therapy".

And just 3% of doctors were against recommending non-prescription medicines because they did not feel there was a sufficient correlation between cost and effectiveness.

"The result is that of an average of 75 patients treated each day, 15 patients leave the surgery with an oral recommendation to self-medicate, of whom 12 act on that advice," Sempora and GfK commented.

Two-thirds of the 203 pharmacists interviewed said it was difficult to convince customers to accept an alternative to a particular OTC medicine that a doctor had recommended.

Furthermore, two-fifths of pharmacists said doctors' recommendations for specific brands improved the image and standing of those products' producers.

When questioned about the relevance of doctor-initiated self-medication, more than four-fifths of the 45 OTC firms that participated in the study felt it was important or very important.

Moreover, 62% of the firms expected the relevance of doctor-initiated self-medication to rise over the next few years.

"For 75% of companies it is clear," Sempora and GfK stated. "They will raise their efforts to increase doctors' recommendations."

When asked about the strategic benefits of endorsement by general practitioners, 86% of the firms believed recommendations would help to combat OTC medicines being "trivialised".

According to GfK's Medic*Scope panel, German patients bought almost 96 million packs of non-prescription medicines last year on the advice of a doctor. This accounted for 16% of all OTC purchases, making doctors almost as influential as pharmacists in initiating self-medication.

Outlining three key effects of doctor-initiated self-medication, the researchers said firstly consumers paid up to 54% more than on average when buying a specific product that had been recommended.

Secondly, the number of packs they purchased was up to 55% higher when done so on the advice of a doctor.

And thirdly, consumers remembered recommendations for far longer than they recalled advertising messages, with only a fifth of patients acting on a doctor's advice within two days, but three-fifths not making a purchase until at least three months after their doctor had suggested a particular product.

OTC

Research

ASMI backs new omega-3 research

Claims in a new study that omega-3 dietary supplements are beneficial to people with certain cardiovascular conditions have been backed by the Australian Self-Medication Industry (ASMI) .

The association said it was "pleased" that the study's authors supported omega-3 supplementation "in patients with heart failure and for those with high levels of blood triglycerides".

Published in the journal *Heart*, *Lung and Circulation*, the study examined the importance of dietary fish oils for cardiovascular health.

The study's authors found that an "adequate dietary intake" of fish was consistently found to be of benefit for protection from heart disease and stroke and that a higher intake of fish was associated with lower rates of heart failure.

The study recommended that to lower their risk of coronary heart disease, all Australians should consume 500mg of omega-3 fatty acids a day through a combination of: two or three servings of oily fish per week; fish-oil capsules or liquids; and products enriched with marine n-3 polyunsaturated fatty acids.

"With the majority of Australians continuing to not eat enough fish, omega-3 supplements still play an important role in helping people to consume marine-sourced omega-3," the ASMI claimed.

OTC

Regulatory Affairs

Australia's regulations are "anti-competitive"

Current restrictions on the ownership and location of pharmacies in Australia are anti-competitive and should be removed, according to a government review of the country's competition laws.

The Competition Policy review says that the existing regulations on the location of pharmacies are "anti-competitive", and the requirement that only pharmacists can own pharmacies, are "not needed to ensure the quality of advice and care provided to patients".

"Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services and the ability of providers to meet consumers' preferences," the review argues.

Replace location rules

The pharmacy ownership and location rules should be replaced with regulations that do not unduly restrict competition, it states, and that "ensure access to medicines and advice regarding their use".

"In particular," the review argues, "tendering for the provision of pharmacy services in underserved locations and/or funding through a community service obligation should be considered by the authorities."

Noting that access to medicines is less likely to be an issue in urban areas, the review says the rules targeted at pharmacies in such locations should continue to be eased. At the same time, mechanisms should be established to address issues concerning access to medicines in rural locations, it insists.

Pointing out that negotiations for the Community Pharmacy Agreement – between the government and the Pharmacy Guild of Australia – are underway, the review says this provides an opportunity to implement "targeted relaxation of the location rules, as part of a transition towards their eventual removal".

Negotiated every five years, the Community Pharmacy Agreement regulates many aspects of the pharmacy sector in Australia.

"If changes during the initial years of the new agreement prove too precipitate, there should be provision for a mid-term review to incorporate easing of the location rules later on," the review argues.

The review points out that the recent National Commission of Audit also recommended "opening up the pharmacy sector to competition, including through the deregulation of ownership and location rules".

OTC

Industry Associations

PAGB defends UK OTC marketing

The Proprietary Association of Great Britain (PAGB) has defended the marketing of branded OTC painkillers in the UK, following claims on a BBC television programme that consumers were being tricked into buying products that claimed to target certain types of pain.

Responding to the accusations made in the show *The Truth About…Your Medicine Cabinet* broadcast on 9 April, Matthew Speers, the PAGB's chief executive, insisted that the marketing of all OTC medicines was "strictly regulated to ensure a responsible approach to self-medication" and was "not misleading".

"Claims made in advertising and on packaging about what the product can be used to treat, how fast the product works and how long it works for must reflect the product's Summary of Product Characteristics (SmPC)," Speers said, "which is part of the marketing authorisation that is granted by the Medicines and Healthcare products Regulatory Agency (MHRA)."

Research had also found that people looked for products to treat specific symptoms, such as headaches, migraines or period pain, he noted, and therefore different labelling and packaging helped people navigate the range more easily.

Speers also defended OTC cough medicines, which the programme claimed were only as good as many simple homemade remedies such as honey and lemon.

"Cough medicines will not cure a cough," Speers admitted, "but they can help relieve the symptoms and provide people with a ready-to-use product that is easy to access."

"Some OTC cough medicines also contain a combination of ingredients to treat the most common symptoms of a cold," he added.

OTC

Switches

JSMI welcomes switch agenda

Proposals by the Japanese government to make more medicines available OTC in the country have been welcomed by the Japan Self-Medication Industry (JSMI).

Motohito Nishizawa, senior advisor at the JSMI, told **OTC *bulletin*** that the association "appreciated" plans put forward by Japan's Ministry of Health, Labour and Welfare (MHLW) to help increase the number of medicines switched from prescription-to-OTC status.

Under the MHLW's proposals, consumers and health insurers in Japan will be able to suggest prescription medicines that they would like to see available OTC.

These suggestions will then be assessed by the MHLW and those medicines that are considered suitable for OTC status will be switched.

Currently, only pharmaceutical companies can put forward applications to switch medicines from prescription to OTC status in Japan.

Noting that it intended to start accepting submissions later this year, the MHLW said it was looking to switch medicines that treated easily identifiable symptoms and that could be easily administered by consumers.

According to press reports in Japan, the country's National Federation of Health Insurance Societies intends to take advantage of the MHLW's plans and will request that six medicines – including eye drops and digestive medications – be switched to OTC status.

Nishizawa noted that in the past, industry had not seen eye-to-eye with the Japanese government, due to a lack of "substantial progress" in approving more prescription-to-OTC switches.

Despite these problems, Nishizawa insisted that Japan's OTC industry supported the MHLW's plans as it "sincerely" believed that the promotion of prescription-to-OTC switches would improve access to medicines.

Nishizawa explained that the MHLW's proposals to reinvigorate OTC switches in Japan reflected the government's current healthcare policy of promoting self-medication.

OTC

IN BRIEF

■ **EMA** – the European Medicines Agency – has released a draft second revision of the guideline on the use of the **Common Technical Document format** in the preparation of a registration application for traditional herbal medicines.

OTC

Marketing Campaigns

Rescue Remedy debuts on UK TV

Natural products company Nelsons is encouraging UK consumers to "stop and take a moment" in the first television advertising campaign for its Rescue Remedy flower-essence range.

Voiced by British actress Emilia Fox, the 30-second commercial begins with the statement: "And…stop" before the screen is filled with yellow – the colour of the Rescue Remedy brand – accompanied by silence.

"Take a moment every day with Rescue Remedy," the voiceover then instructs, before the dropper and Soothing Pastilles variants appear on screen.

Pointing out that "97% of people who try Rescue Remedy would buy it again," the voiceover adds: "Isn't it time you tried it?"

The creative "disrupts the advertising break with a moment of calm", Nelsons claims, while also positioning the Rescue range – which includes a Rescue Night dropper, Gummy Stars and chewing gum, as well as balm and cream options – as "products to use every day".

Targeting women who recognised "the demands of juggling their busy lives", the television commercial builds on the current 'I can do this' themed campaign first rolled out last year (**OTC *bulletin***, 28 March 2014, page 14), which includes print advertisements, sampling and posters at London Underground stations.

The firm is also running a Facebook competition until 1 May. Entrants who complete the "Stop, take a moment and win" games within 80 seconds, have the chance either to win one of four £100 (€138) Champneys spa vouchers, one of two Amazon Kindle Fire electronic readers or one of 20 tins of Rescue Pastilles.

Meanwhile, Nelsons has returned its animated 'apologetic tooth' character to UK television screens for the third consecutive year to support its Teetha homoeopathic teething-pain gel and granules.

The 30-second spot – first aired in summer 2013 – shows a tooth apologising to parents of teething children for making their babies cry (**OTC *bulletin***, 25 April 2014, page 18), and offering the Nelsons Teetha Gel as a product to help soothe teething pain.

Airing throughout April and May, the commercial was supported by print advertising featuring the granule variant in titles such as *Mother&Baby*, the firm noted, as well as a digital campaign.

Product Launches/Line Extensions

Omega adds liquid option to Nytol sleep-aid range

Omega Pharma says its Nytol Herbal Simply Sleep & Calm Elixir will appeal to UK customers wishing to treat their sleeping problems with a liquid format rather than a tablet.

Indicated for the temporary relief of symptoms of mild anxiety and to aid sleep, the general-sale list (GSL) Elixir – containing 1.5ml of tincture from dried valerian root per 5ml – was aimed at women aged over 35 years, Omega noted, as difficulty sleeping was "particularly prevalent amongst this group as a result of their busy lifestyles".

Two spoonfuls of Nytol Herbal Simply Sleep & Calm Elixir should be taken three times a day with water or fruit juice, the company advises, to treat mild anxiety in adults aged over 18 years.

To aid sleep, two spoonfuls should be taken 30 minutes before bedtime, with an earlier dose during the evening if necessary. The maximum dose is four single doses per day.

The line extension was being supported by a £1.5 million (€2.1 million) television campaign promoting the entire Nytol range of sleep aids, Omega noted.

Featuring 'Joan', the animated character from previous Nytol commercials created by production company Aardman Animations, the television commercial uses the overall tagline "Good mornings follow a good Nytol".

Nytol Herbal Simply Sleep & Calm Elixir is included in a £1.5 million television campaign promoting the entire Nytol range

This is followed by a shot of the Elixir next to a book on a bedside table, with the message that the product is "new to Nytol".

The Nytol range also includes GSL Herbal tablets and pharmacy-only (P) Nytol Original and One-A-Night tablets, with 25mg and 50mg of diphenhydramine, respectively, as well as the Anti-Snoring Throat Spray launched just over two years ago (**OTC *bulletin***, 22 February 2013, page 18).

A 100ml bottle of Nytol Herbal Simply Sleep & Calm Elixir has a recommended retail price of £4.99 excluding VAT.

Queisser Pharma's Doppelherz System pharmacy-exclusive supplement brand in Germany now includes hyaluronic acid capsules to help promote healthy skin.

In addition to 70mg of hyaluronic acid to "care for cells from within", each one-a-day Doppelherz System Hyaluron capsule provides 30mg of co-enzyme Q10, 40mg of vitamin C, 5mg of zinc and 100µg of biotin.

A month's supply of 30 capsules has a recommended retail price of €14.95.

Queisser is supporting the launch with consumer- and trade-press advertising, as well as with point-of-sale displays.

Animated cold and flu "virus-monsters" are shown training in the gym in OTCPharm's latest television advertisement for its Arbidol Maximum antiviral capsules in Russia.

The 10-second national commercial played on the popular belief that cold and flu viruses became "stronger" every year, the Russian firm noted.

A pack of Arbidol Maximum is shown landing on the viruses and squashing them, before the creative signs off with the message: "Colds subside quickly with Arbidol Maximum."

Launched earlier this year, Arbidol Maximum contains 200mg of the active ingredient umifenovir per capsule – double the amount in the original Arbidol variant – and is indicated to act on the main cause of colds, flu and other acute respiratory infections by "inhibiting the multiplication of viruses".

Product Launches/Line Extensions

Kowa grows OTC portfolio in Japan with two additions

Japanese firm Kowa has grown its domestic OTC portfolio with additions to its Unakowa insect bite-relief range and Q&P line.

Indicated to relieve itching caused by bites from insects such as mosquitoes and ticks, Unakowa Cool Punch contained double the amount of lidocaine per ml – 10mg – than that provided by the original Unakowa Cool topical antipruritic, Kowa noted.

The latest addition to the lidocaine- and diphenhydramine-based Unakowa range – which includes the α, Ace G and Ace L variants – is formulated with 20mg diphenhydramine and 20mg camphor per 1ml, in addition to lidocaine. It also contains 40mg menthol, which is 10mg more than in Unakowa Cool.

Kowa added that Unakowa Cool Punch's soft brush-tip applicator ensured a more accurate and hygienic distribution of the product.

Recommended retail prices for 30ml and 50ml packs of Unakowa Cool Punch, without tax, are ¥580 (€4.52) and ¥900, respectively.

Meanwhile, the firm has extended its Q&P line of supplements with an iPlus variant.

Suitable for adults and children aged over 15 years, the Q&P-iPlus tablets – said to help relieve conditions such as eye strain and stiff necks – contained an updated formulation to that of the original Q&P-i product, Kowa noted.

Unakowa Punch treats itching caused by insect bites, while Q&P-iPlus is positioned to help relieve eye strain and stiff necks

In addition to vitamins B1, B12 and E, garlic extract, magnesium-potassium aspartate and gamma-oryzanol (rice bran oil) – which are all present in Q&P-i – the company has added hepuronikato, a vasodilator, to iPlus.

This new ingredient caused the peripheral blood vessels to expand, Kowa claimed, which resulted in increased blood flow to the eye.

Q&P-iPlus complements Kowa's nine-strong Q&P supplement range. This includes products for joint pain, fatigue, and energy, as well as the original Q&P-i product, which also contains vitamins B2 and B6.

A pack of 27 Q&P-iPlus tablets has a recommended retail price of ¥1,200, while 80- and 180-tablet packs have recommended retail prices of ¥2,600 and ¥5,500, respectively.

OTC

Product Launches/Line Extensions

Brazilians offered "extra analgesic power"

"Quick action and extra analgesic power" is Hypermarcas' promise to Brazilian consumers about its Doril Enxaqueca migraine pain-relief tablets.

Claiming that an estimated 70% of women and 50% of men suffered at least once a month from headaches, the Brazilian firm pointed out that each Doril Enxaqueca tablet combined 250mg acetylsalicylic acid with 250mg paracetamol and 65mg caffeine to relieve mild-to-moderate pain and migraines. The recommended dose is two tablets.

Doril Enxaqueca is being supported by a television campaign starring Brazilian actor Reynaldo Gianecchini

The Enxaqueca variant complements the original Doril product, which contains 500mg acetylsalicylic acid and 30mg caffeine and is indicated as an analgesic and antipyretic.

Available in pharmacies nationwide, Doril Enxaqueca is being supported by a television campaign starring Brazilian actor Reynaldo Gianecchini. He was a "credible personality" who reinforced "the strength of the Doril brand", Hypermarcas explained.

The television spot would be backed further by advertisements in magazines, the firm noted, as well as radio spots and online activity.

OTC

Product Launches/Line Extensions

Vitamin D drops added to Colief

Vitamin D3 supplement drops are the latest addition to Crosscare's Colief infant-care line in the UK and Ireland.

Pointing out that the UK Department of Health (DoH) had identified "a number of specific groups who could be at risk of vitamin D deficiency" – including infants and young children aged under five years and all pregnant and breastfeeding women – the firm said the Colief Vitamin D3 Drops, containing 2µg (80IU) of vitamin D3 per drop, provided a "competitive and relevant" solution for consumers.

Four drops a day met the current guidelines for vitamin D supplementation in young children, Crosscare noted, while five drops provided mothers and pregnant women with the required amount. The product could be mixed easily with food or liquids for children and mothers and given directly by mouth to young babies, the company added.

Colief Vitamin D3 Drops are said to provide 2µg (80IU) of vitamin D3 per drop

Available in pharmacies nationwide, Colief Vitamin D3 Drops would be supported throughout the year by a "comprehensive" public-relations and advertising campaign beginning next month, the firm noted.

Using the current tagline, "Mums know to call on Colief", the campaign would cover the entire Colief product range, Crosscare pointed out, which includes the the lactase-based Infant Drops for colic and Baby Scalp Oil, as well as the Vitamin D3 Drops.

In stores, the brand would be backed by point-of-sale materials, the company added.

A 20ml bottle of Colief Vitamin D3 Drops contains the equivalent of five months' supply for infants and children and a four-month supply for pregnant women and breastfeeding mothers, and has a recommended retail price of £9.99 (€13.68).

Noting that the drops were currently only available in the UK and Ireland, Crosscare said it "may launch in other countries in 2015".

OTC

"Rennie räumt den magen auf" – which translates as "Rennie clears up stomachs" – is the tagline for Bayer Healthcare's first German television campaign to support its Rennie Direkt orodispersible antacid.

In the 15-second creative, an animated stomach – Bayer's 'happy tummy' character – quickly eats a meal in an airport lounge, causing it to suffer from heartburn as it rushes to board the plane.

As the character is shown taking a portable stick-pack of Rennie Direkt – which each contain 680mg of calcium carbonate and 80mg of magnesium carbonate – the advertisement highlights that the product's 'micro-granule' formula quickly dissolves on the tongue and then gets to work immediately on contact to "free you from heartburn".

Rennie Direkt is depicted as having a cooling effect as it travels down the oesophagus, allowing the 'happy tummy' to board the plane completely relieved of excess acid.

Scheduled to run throughout 2015, the creative would target adults who occasionally suffered from heartburn and indigestion and were "looking for an uncomplicated treatment", Bayer pointed out. It would be supported by point-of-sale materials.

Launched earlier this year, Rennie Direkt was claimed by Bayer to be Germany's first antacid in granular form (OTC *bulletin*, 13 February 2015, page 21).

Sanofi has stopped marketing its Avibon vitamin A skin ointment in France.

After batches of the ointment were recalled in March 2013 due to "product stability" problems, Sanofi's "various attempts at improvement" had not resulted in "a product that met current quality standards", a spokesperson for the French firm told OTC *bulletin*.

Sold exclusively in France in 30g and 60g tubes, Avibon contains 1 million IU of retinol (vitamin A) per 100g of ointment, and is indicated for "adjunctive treatment of irritant dermatitis".

IN BRIEF

■ **BOOTS** is encouraging UK consumers to make sure they are "ready for hayfever season" by offering an own-brand **Hayfever Care Kit** until 26 May. Priced at £11.99 (€16.56), the kit – containing Boots Pharmaceuticals One-A-Day Allergy Relief loratadine tablets and sodium cromoglicate-containing Allergy Relief Eye Drops, as well as the drug-free Allergy Barrier Nasal Spray launched last year (**OTC *bulletin***, 25 April 2014, page 16) – is said to "protect, treat and relieve your symptoms".

Product Launches/Line Extensions

Anthisan patches set for launch in major retailers

Sanofi Consumer Healthcare says it is "liaising with major UK retailers" to launch its Anthisan Citronella Patches in time for summer.

The latest addition to the Anthisan bite- and sting-relief range – which also includes the mepyramine maleate-based Anthisan Bite & Sting Cream – had been "well received" when it was rolled out into independent pharmacies in June last year, the firm told **OTC *bulletin***.

Positioned as "a natural preventative product suitable for the whole family", the transparent, self-adhesive strips contained "micro-encapsulated" natural essential oils to deter insects, Sanofi pointed out, and gradually released the fragrance of citronella up to a 50cm radius for up to 12 hours.

Suitable for adults and children aged over six months, Anthisan Citronella Patches would appeal particularly to mothers who preferred to use natural remedies on their children rather than biocide- or diethyltoluamide (DEET)-based products, Sanofi claimed. The patches' resealable pouch packaging made them convenient for travelling, the firm added.

A "dedicated" digital and public-relations campaign would support the entire Anthisan range, the company explained, targeting both trade and consumer audiences throughout the "key bite and sting season".

Sanofi's Anthisan Citronella Patches have been available in independent pharmacies since June last year

The digital campaign would focus on websites such as BootsWebMD and the music-streaming service Spotify, Sanofi pointed out, as well as on "relevant websites relating to bites and stings".

Pharmacies would also be provided with point-of-sale materials and literature for consumers, the firm noted.

A pack of 24 Anthisan Citronella Patches has a recommended retail price of £3.99 (€5.49).

Product Launches/Line Extensions

Max Strength addition boosts XLS-Medical

A maximum-strength variant has been added to Omega Pharma's XLS-Medical weight-loss range in the UK.

Formulated with the "patented organic plant-based complex" clavitanol, XLS-Medical Max Strength – a class IIb medical device – is said by the firm to be "up to 33% more effective for weight loss" compared with the original XLS-Medical Fat Binder variant, which contains the "natural fibre complex" litramine.

XLS-Medical Max Strength is claimed to be up to a third more effective for weight loss than the original XLS-Medical Fat Binder

The Max Strength addition – which is already available in other markets such as France and Greece – reduces the breakdown of dietary carbohydrates, sugar and fat to lower calorie intake, Omega claims. It is also said to lower blood glucose and insulin levels to help curb food cravings.

Launched in 2012, the original XLS-Medical Fat Binder product is positioned as helping consumers potentially lose "three times as much weight as dieting alone" (**OTC *bulletin***, 12 October 2012, page 10).

The XLS-Medical range also comprises a Carb Blocker variant launched in 2013 (**OTC *bulletin***, 13 September 2013, page 15) and a Direct sachet variant of the Fat Binder, which was introduced last year as the first-ever "on-the-go" orodispersible weight-loss powder product (**OTC *bulletin***, 12 September 2014, page 18).

Product Launches/Line Extensions

GSK offers Thai consumers "new-generation" analgesic

"A new-generation pain reliever" is how GlaxoSmithKline (GSK) is positioning its Panadol Actifast analgesic caplets in Thailand.

Indicated to relieve mild to moderate pain – including headache, migraine, muscle pain and tooth pain – as well as to reduce fever, the product's formulation of 500mg paracetamol and sodium bicarbonate per caplet meant that it could be absorbed into the bloodstream at twice the speed of conventional paracetamol, GSK claimed.

Targeted at "upper-middle class" adults aged over 20 years, Panadol Actifast, which is available in various other markets including Australia – where it is known as Panadol Rapid – Malaysia and the UK, had been launched to "respond to today's consumers' busy lifestyles", the firm pointed out.

Launching the Actifast variant – which was suitable only for those aged over 12 years – meant that the Panadol range in Thailand now offered "pain-relief products for consumers across all age groups", GSK added.

The Panadol line also includes infant drops for children up to two years, as well as two Panadol Children suspensions – for children aged six months to six years and between six and 12 years, respectively – and 500mg paracetamol tablets, which can be used by those aged six years and above.

Panadol Actifast had been launched to respond to Thai consumers' busy lifestyles, GSK claimed

A television campaign began this month to support the latest line extension. This was scheduled to run until October, GSK noted, and would be supported by out-of-home advertising on train station billboards until June and by online videos until August.

Advertising banners would feature on websites until the end of the year, the firm added. The Panadol website has also been updated.

A box of eight caplets has a recommended retail price of TBH39.00 (€1.11).

Claiming the "growth rate of high-end medicines" in the Thai oral pain-relief market – said to be worth TBH3.0 billion – was "higher than that of general products", GSK pointed out that consumers were willing to pay extra for options that delivered "fast and effective relief".

A "purifying" nasal spray has been added to Laboratoire Gomenol's tea-tree oil-based aromatherapy range in France.

Claiming that the essential oil was used as an antiviral and antibacterial to fight against respiratory-tract infections, the French firm pointed out that Spray Nasal Gomenolé was indicated to help promote "more comfortable breathing" by moistening and clearing the nasal mucosa in those suffering from colds and rhinitis.

Suitable for use by adults only, the spray adds to Laboratoire Gomenol's existing range of joint and foot creams, muscle-relief gels, and products for 'heavy' legs.

One to two sprays should be administered up to three times a day, the firm pointed out, adding that the product was not recommended for use for more than five consecutive days.

One-a-day tablets are Schaper & Brümmer's latest addition to its Remifemin herbal medicine in Germany.

Each Remifemin mono tablet contains 5mg of dried cimicifuga root extract. The pharmacy-only medicine is indicated for relieving complaints associated with the menopause, such as hot flushes and excessive sweating.

Packs of 30, 60 and 90 tablets have recommended retail prices of €12.48, €19.88 and €27.81 respectively.

The Remifemin range also includes two-a-day 2.5mg tablets, Remifemin Plus tablets that combine cimicifuga extract with St John's wort, and Remifemin FeuchtCreme, a witch hazel cream for vaginal dryness that Schaper & Brümmer launched in October last year.

Product Launches

23andMe finds UK retail partner

23andMe has expanded the reach of its eponymous genetic-testing kit in the UK by launching the product in Superdrug, its first retail partner.

The kit – first made available in the UK late last year through the company's website, *23andme.co.uk* (**OTC *bulletin***, 12 December 2014, page 14) – could now be found in the pain-relief aisle of over 600 Superdrug stores, the firm noted, priced at £124.99 (€171.18).

23andMe said that the product would be supported in stores through point-of-sale materials.

Positioned as providing "affordable access to personal genetic information", the kit enables consumers to take samples of saliva, which are then sent back to the company for analysis. Once the analysis is complete, the user can access more than 100 reports, covering "health, trait and ancestry information".

The Personal Genome Service (PGS) could reveal "risk factors" for diseases or conditions such as Alzheimer's, Parkinson's and blood clotting, 23andMe claimed, and could test for genes associated with certain inherited conditions, including cystic fibrosis and sickle-cell anaemia.

Furthermore, the test could allow consumers to learn more about certain traits, the company noted, including why a person might be a frequent smoker, how they metabolised caffeine and how their body responded to diet and exercise.

It also provided a full genetic ancestry report, 23andMe explained, so a user could potentially discover and communicate with new relatives as part of its DNA Relatives service.

Commenting on the Superdrug deal, Andy Page, president of 23andMe, said the collaboration with the retailer marked a "significant milestone" for the company and would "improve accessibility for UK consumers".

Last month, 23andMe said it had taken an "important first step" towards returning the kit to the US market, after the Food and Drug Administration (FDA) approved the product to test for Bloom syndrome (**OTC *bulletin***, 6 March 2015, page 13).

In 2013, the FDA banned the sale of the product – five years after its launch – for violating the Federal Food, Drug and Cosmetic Act, as most of the intended uses for PGS listed on the company's website made the product a class III medical device that required approval from the agency.

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Geneva, Switzerland
A three-day exhibition and conference focusing on nutraceuticals, and functional foods and drinks.
Contact: *Informa UK.*
Tel: +44 20 3377 3616.
Email: maria.sidiropoulou@informa.com.
Website: www.vitafoods.eu.com.

8 May

■ **Marketing Authorisation**
Berlin, Germany
Countries to be covered at this one-day course include Azerbaijan, Georgia, Kazakhstan, Turkey and Uzbekistan.
Contact: *Forum Institut für Management.*
Tel: +49 6221 500 680.
Fax: +49 6221 500 555.
Email: h.wolf-klein@forum-institut.de.
Website: www.forum-institut.com.

11-12 May

■ **Pharmacovigilance, Drug Safety and Risk Management**
London, UK
Speakers from Novartis, Pfizer and Takeda will attend this two-day conference.
Contact: *SMi Group.*
Tel: +44 20 7827 6000.
Fax: + 44 20 7827 6001.
Email: events@smi-online.co.uk.
Website: www.smi-online.co.uk.

14-15 May

■ **2015 Regulatory Scientific and Quality Conference**
Washington DC, US
The future of consumer healthcare, collaboration, innovation, and quality will be discussed at this two-day conference, organised by the US Consumer Healthcare Products Association (CHPA).
Contact: *CHPA.*
Tel: +1 202 429 9260.
Fax: +1 202 223 6835.
Email: meetings@chpa.org.
Website: www.chpa.org/rsq.

19-21 May

■ **EU Pharmaceutical Law Forum**
Brussels, Belgium
A three-day seminar focusing on competition law and patent litigation, regulatory frameworks and licensing agreements.
Contact: *Informa UK.*
Tel: +44 20 7017 7481.
Fax: +44 20 7017 7823.
Email: registrations@informa-ls.com.
Website: www.informa-ls.com/pharmalaw.

19-21 May

■ **Russian Pharmaceutical Forum**
Saint Petersburg, Russia
Speakers from GlaxoSmithKline, IMS Health, Janssen, Pfizer, Stada, Takeda and Teva will attend this three-day event.
Contact: *Adam Smith Conferences.*
Tel: +44 20 3377 3182.
Fax: +44 20 7017 7447.
Email: nataliapr@adamsmith conferences.com.
Website: www.russianpharma.com.

21 May

■ **Basics of Pharmaceutical Regulatory Affairs**
London, UK
This one-day course is run by The Organisation for Professionals in Regulatory Affairs (TOPRA).
Contact: *TOPRA.*
Tel: +44 20 7510 2560.
Fax: +44 20 7537 2003.
Email: info@topra.org.
Website: www.topra.org.

28-29 May

■ **Pharmaceutical Regulatory Affairs in the Middle East**
London, UK
Countries to be discussed at this two-day meeting include Bahrain, Egypt, Israel, Kuwait, Lebanon, Saudi Arabia and Yemen.
Contact: *Management Forum.*
Tel: +44 1483 730071.
Fax: +44 1483 730008.
Email: registrations@management-forum.co.uk.
Website: www.management-forum.co.uk.

JUNE

1-2 June

■ **EuroPLX 58**
Munich, Germany
This two-day conference 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.
Fax: +49 6222 9807 77.
Email: meetyou@europlx.com.
Website: www.europlx.com.

26-28 May

■ **51st AESGP Annual Meeting**
Barcelona, Spain
'Citizen empowerment: A megatrend of the 21st century' is the theme of this three-day event run by the Association of the European Self-Medication Industry, the AESGP.

There will be sessions on: 'New technology – new guidance – better self-care'; 'Self-care medical devices and food supplements: New drivers in the self-care market?'; and 'Switching: A mega trend?'.

Speakers will include: Werner Knöss, Andreas Pott and June Raine of the European Medicines Agency (EMA); Bernhard Url of the European Food Safety Authority (EFSA); Dagmar Roth-Behrendt, former member of European Parliament; Jaume Pey of the Spanish self-medication association (ANEFP); Roger Scarlett-Smith of GlaxoSmithKline Consumer Healthcare Europe; Brian McNamara of GlaxoSmithKline Consumer Healthcare; Sastry Chilukuri of McKinsey; Vincent Warnery of Sanofi; and Andy Tisman of IMS Health Consumer Health.
Contact: *AESGP. Tel: +32 2 735 51 30. Fax: +32 2 735 52 22.*
Email: info@aesgp.eu. Website: www.aesgp.eu/51.

9 June

■ **FDA: Marketing Authorisation in the US**
Frankfurt, Germany
US Food and Drug Administration (FDA) regulations will be compared with European Union (EU) law at this one-day meeting.
Contact: *Forum Institut für Management.*
Tel: +49 6221 500 680.
Fax: +49 6221 500 555.
Email: h.wolf-klein@forum-institut.de.
Website: www.forum-institut.com.

14-18 June

■ **51st DIA Annual Meeting**
Washington DC, US
This five-day annual meeting is organised by the Drug Information Association (DIA).
Contact: *DIA.*
Tel: +1 888 257 6457.
Fax: +1 215 442 6199.
Email: customerservice@diahome.org.
Website: www.diahome.org.

18-19 June

■ **EU Pharmaceutical Regulations**
London, UK
A two-day course providing an overview of the European regulatory environment, procedures and obligations.
Contact: *Management Forum.*
Tel: +44 1483 730071.
Fax: +44 1483 730008.
Email: registrations@management-forum.co.uk.
Website: www.management-forum.co.uk.

22-24 June

■ **Pharmacovigilance**
London, UK
This three-day event will look at the principles and practice of global pharmacovigilance for those working in drug safety.
Contact: *Management Forum.*
Tel: +44 1483 730071.
Fax: +44 1483 730008.
Email: registrations@management-forum.co.uk.
Website: www.management-forum.co.uk.

25 June

■ **OTC Medicines Growth Perspective**
London, UK
OTC drugs, food supplements, medical devices and prescription-to-OTC switches will be covered at this one-day workshop.
Contact: *SMi Group.*
Tel: +44 20 7827 6000.
Fax: + 44 20 7827 6001.
Email: events@smi-online.co.uk.
Website: www.smi-online.co.uk.

OCTOBER

14-15 October

■ **AESGP Conference**
Brussels, Belgium
This two-day conference, subtitled 'Substance-based medical devices: An important part of self-care', is being organised by the Association of the European Self-Medication Industry, the AESGP.
Contact: *AESGP.*
Tel: +32 2 735 51 30.
Fax: +32 2 735 52 22.
Email: info@aesgp.eu.
Website: www.aesgp.eu/events/Brussels2015/.

Bestway helps Co-op Pharmacy get Well

When the Co-operative Pharmacy was put up for sale just over a year ago, the future of the UK's third-largest pharmacy chain was uncertain. However, having been snapped up by wholesaler Bestway and rebranded as Well, things are now looking bright, Well's chief John Nuttall told Matt Stewart.

"OTC manufacturers need to know that we are determined to grow. So if they invest in us, Well will invest in them, and both parties will benefit as we acquire more pharmacies and gain more market share," is the message to OTC firms from John Nuttall, chief executive officer of the UK's newest pharmacy chain, Well.

Talking exclusively to **OTC *bulletin***, Nuttall said that Well's parent company Bestway had not placed a limit on how big the chain could get, but that growth would be achieved in a managed way that took advantage of the chain's connection with the communities it served.

"Part of what we are trying to do is deliver something a bit different," Nuttall claimed, "by taking the best of what we have got – and we believe we are giving the best service out there in the community currently – and adding it to our local connections and building around that."

"We are taking the business more towards health and wellbeing," he added, "and ensuring that we can deliver the agenda laid out by the National Health Service (NHS)."

Bestway – a privately-owned UK-based wholesaling conglomerate – snapped up the 780-store Co-operative Pharmacy chain for £620 million (€850 million) in July last year (**OTC *bulletin***, 25 July 2014, page 1). The deal was struck barely five months after the troubled Co-operative Group put the business up for sale (**OTC *bulletin***, 17 March 2014, page 3) and shortly before the group reported its worst-ever annual results.

The deal has brought a new player into a UK pharmacy market that is led by the 2,385-strong Boots chain and the 1,650-member LloydsPharmacy chain. Boots and LloydsPharmacy are backed by the US-based drugstore retailer Walgreens Boots Alliance and US pharmaceutical wholesaler McKesson respectively.

The Co-operative Pharmacy chain grew to become the UK's third-biggest before its parent company sold it to Bestway for £620 million last year

Bestway is the UK's 18th largest privately-owned company with sales of £2.4 billion and a pre-tax profit of £53.5 million. Adding the Co-operative Pharmacy to the group would help lift sales to around £3.4 billion, the firm noted.

The company claims to be the UK's second-largest independent wholesaler, serving 125,000 independent retailers and caterers from 64 warehouses nationwide.

Furthermore, the firm operates Pakistan's second-largest cement manufacturing business with sales of US$282 million (€209 million) and its second-largest private bank with assets under management of US$10.3 billion.

> ***"A significant chunk of the £40 million-a-year investment fund will be going to acquire pharmacies to grow our market share"***

Explaining why Bestway had entered the pharmacy arena, Nuttall said that the company had been keen to "diversify" its UK business and balance its business-to-business side with a retail offering.

"Bestway looked at the health sector and decided that it was a market that had longevity and potential thanks to the UK's demographic trends," he added. "Furthermore, the company was looking for a sizeable business that shared the same community-based ethos and values."

Bestway unveiled the Well brand in February, along with plans for a five-year, £200 million investment in the chain with the goal of lifting its turnover from £750 million to around £1.0 billion by 2019 (**OTC *bulletin***, 6 March 2015, page 6).

The £40 million-a-year investment plan demonstrated Bestway's determination to grow the Well chain, Nuttall said, noting that the money would be spread across a number of areas, including store acquisitions.

"A significant chunk of the investment fund will be going to acquire pharmacies to grow our market share," Nuttall said, "but we are also looking at expanding in care-home provision, as it is an area where we are under-represented. We need to invest in both people and premises to drive that part of the business."

"The balance will go on rebranding – the majority of that work will be carried out this year – and investing in our existing estate through refurbishments and relocations," he said.

Expanding on the improvements the company had planned, Nuttall explained that it was "working on a number of formats" and had begun piloting "a variety of different offers, all of which position Well as a health and well-being provider".

Former Co-operative Pharmacy chief Nuttall said that further details on the store formats would not be released until the pilot schemes had been completed. However, he did reveal that the services that Well pharmacies provided would play a key role in the offering.

"We need to find the right combination of private paid-for services," he pointed out, "as we believe people will really respond positively to that. But at the same time, we are aware that competitors have tried this before and have not been successful, so we have to look carefully at that type of offer."

Furthermore, Well would consider how best it could deliver services that the NHS was keen for pharmacies to provide to the public, Nuttall said.

"I do believe we are going to see some significant changes this year. Pharmacy will be playing a bigger role in the NHS and this is something we have been campaigning for behind the scenes," he stated.

"I'm not sure all community pharmacies are ready for it," Nuttall warned, "but we certainly want to be in a position to take advantage."

Piloting of store formats would continue throughout 2015, Nuttall said, adding that the company would have a "clear idea" by the end of the year how it wanted to change its retail format to "best align Well to what customers are asking for and what the brand stands for".

"I'm confident that at the end of the year we will be at a place where we know what our proposition looks like and we can get busy landing that in the business," he insisted.

Whatever the final format turned out to be, it would be flexible, Nuttall noted.

"We have to have flexibility," he pointed out, "as we recognise that local variances matter a lot and mistakes have been made in the past with 'one-size-fits-all' offers which were not necessarily what our customers wanted."

"We have to look at the communities we are in and ask: 'What do the people want?' and 'What works in a particular community?' But we also need to retain an element of central control so we can maximise the value of what we are doing," Nuttall pointed out.

One key element of any new format would be making the pharmacist more accessible to the consumer, Nuttall said.

"How to bring the pharmacist into the front of the store is an ongoing challenge across the sector," Nuttall claimed, "and to overcome it we have to find better ways of managing the prescription-end of the business."

"We are tackling this in an intelligent way," he explained. "Where we have electronic prescription services, we are looking at how we can manage the workload in a more efficient way. Where possible we want to manage patients' repeat-prescription cycles for them."

"This allows us to control the work and it allows the pharmacist more time to get front and centre, and talk to customers," Nuttall said.

"Another area where we have had a lot of success is where we have piloted non-pharmacist managers," Nuttall revealed. "This allows the pharmacist to express their clinical freedom without the burden of the management of the store and commercial activities."

"It is not something that will work for everybody but we are presenting it as an option in the business and we can see it working for us commercially," he pointed out.

Pharmacy assistants would also play a key role in the growth of Well, Nuttall insisted. "They are the engine room of our business and they are absolutely vital," he added. "How we engage and motivate them is very important as they are the face of the company."

John Nuttall, chief executive officer of Well, said that its owner Bestway had not put a limit on how big the chain could get and was keen to invest in the UK pharmacy sector

Supported by wholesale unit

Well's retail pharmacy chain will also be backed up by its own pharmaceutical wholesaling arm, Nuttall noted.

The wholesaling business would be based at Well's existing national distribution centre, Nuttall pointed out, so would not be overly capital-intensive.

"The Co-operative Pharmacy had already built up a pretty good relationship with its independent pharmacy colleagues through the distribution centre," he said, "and we plan to leverage that and offer them something we don't think they are getting currently, which is the best value business-to-business offer that is out there."

"The national distribution centre has the capacity to serve double the number of pharmacies it is at the moment," Nuttall pointed out. "We built it with growth in mind."

"The Co-operative Group was less focused on a business-to-business offer," Nuttall claimed. "It always saw itself as a consumer-only business."

"But now we are free to get into the wholesale market," he said. "We understand it and we are the largest independently-owned pharmacy chain, so our buying power is significant and we can share that with our independent pharmacy colleagues and give them something they are not getting from their short-line or major wholesaler."

"I think Well is going to be the business to watch in the pharmaceutical wholesaling arena," Nuttall insisted.

Turning to how best consumer healthcare companies could work with Well, Nuttall reiterated that the pharmacy chain's growth plans should demonstrate to suppliers that Well was worth investing in.

"Where you see some sectors of the market in flat and negative growth, then the opportunities we are opening up for suppliers are something they should to look forward to."

"As we change our proposition on the consumer healthcare side, it gives us the opportunity to test new ranges, explore new product areas and build on the work we have done in the past on how we allocate space in our stores," he said.

"We are looking to give more space to medicines, more space to health," Nuttall insisted, "and we are seeing some very positive numbers off the back of that."

"The key is how our suppliers engage with our in-store colleagues that sell products," Nuttall explained. "There is a clear opportunity to do more in that area."

"Remember, those counter assistants are the mechanism to get healthcare products to patients in an effective way," he maintained.

"Better training and engagement with the product is also key," Nuttall said. "Hands up, in the past we have not been as active as we should have been in that area," he admitted, "but it's an open door now for suppliers to talk to us and we will make it happen on the ground."

The future of consumer healthcare in the UK is going to rely on how well the industry and the NHS educate the consumer on how best to self-care, Nuttall pointed out.

Pass services to pharmacy

"We also have to ask about the affordability of healthcare in the UK and what we can pass down the chain to the lower-cost providers," he added.

"I think the answer is pretty clear," Nuttall insisted. "If you go to see your doctor about a minor ailment, it costs the NHS £45, but if you go to a pharmacist the whole process costs considerably less."

"Why are we allowing our accident and emergency departments and doctor's surgeries to be blocked up with people presenting with minor ailments?" Nuttall asked.

"It's up to the NHS to signpost to pharmacy, engage with us, and get a package that works as it is doing in Scotland," he argued. "Let's get the public coming into pharmacy to talk about minor ailments and get the products they need."

"It has worked in Europe," Nuttall pointed out. "We just need a different engagement strategy and for our NHS policy makers to drive this home."

Nuttall said he believed that there would be some "clear opportunities in 2015 for pharmacy to engage with consumers in a different way".

"Doors will be opened by the NHS and it's

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Registered in England No: 2765878. VAT No: GB 608 0432 69

Well will benefit from a five-year, £200 million investment plan that will be focused on growing the 780-store chain

incumbent upon us as a profession to deliver," he warned. "What we can't do is approach it as we may have done in the past in a haphazard and half-baked way. We have to land this and make it work."

"When you look at medicines-use reviews (MURs), the level of take-up at first across the profession – including ourselves – was really poor," Nuttall admitted. "But looking back now, they have been really effective and have been a success across the UK."

"What the NHS wants," Nuttall claimed, "is the confidence that we will deliver when something new is presented to us."

Asked whether the recent reverse-switch of the oral analgesic diclofenac by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) showed a lack of confidence in pharmacy, Nuttall was clear that he felt the decision was simply the act of a risk-averse regulator.

Pharmacy market over-regulated

However, Nuttall said he did believe that the UK pharmacy market was "over-regulated". "The volume of information we have to deal with on a daily basis has gone up exponentially over the past few years and there are well-documented reasons for that."

"But if you are the regulator, you are risk-averse," Nuttall conceded. "I think it's for us as a profession to get ourselves to a place where we can deliver and I think it's coming."

"I feel more confident now about pharmacy than at any point in my career," Nuttall said, "and that is a long time!"

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Retailers

AS Watson selects Gray to head international health

Steve Gray, currently Superdrug's healthcare director, will take up the newly-created position of international healthcare director at the retailer's parent company, AS Watson, in January 2016.

Pointing out that Gray's appointment in the new role reflected the "growing importance of health" to AS Watson's future strategy, the firm said he would work "closely" with its chief operating officer, **Malina Ngai**, to "accelerate the increase of healthcare sales" across the group.

After joining Superdrug in 2012, Gray had grown the retailer's health division by over a fifth, AS Watson – the retail subsidiary of Hong Kong-based Hutchison Whampoa – pointed out, through the development of its Wellbeing concept store, as well as building successfully its "online health offer" with its Online Doctor web service.

Gray would "continue to concentrate on delivering health-category growth in Superdrug for the remainder of 2015," the company added.

Steve Gray

Currently, AS Watson operates 20 health and beauty retailers, including Kruidvat, Superdrug and Watsons, with over 11,000 stores in 33 markets worldwide.

Most recently the company expanded its presence in the Netherlands by gaining the 50-strong Dirx Drugstore chain for an undisclosed sum (**OTC *bulletin***, 2 February 2015, page 3).

Prior to joining AS Watson, Gray held the role of chief operating officer at LloydsPharmacy's parent company Celesio.

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Wholesalers & Retailers

Lederer joins WBA board of directors

Walgreens Boots Alliance (WBA) has elected **John Lederer**, chief executive officer of food distributor US Foods, to its board of directors.

Prior to his current position, Lederer had served as chairman and chief executive officer of New York-based drugstore chain Duane Reade, which was acquired by Walgreens in 2010 (**OTC *bulletin***, 17 March 2010, page 9), WBA pointed out.

John Lederer

He had also spent 30 years – six as president – at Loblaw Companies, the firm noted, which was Canada's largest food distributor.

Commenting on the election, Jim Skinner, WBA's executive chairman, said Lederer's "successful record of leading and transforming major retail and wholesale companies" would help the newly-established global enterprise – created through Walgreens' takeover of Alliance Boots at the end of last year (**OTC *bulletin***, 16 January 2015, page 5) – "realise its vision to be the first choice for pharmacy, wellbeing and beauty".

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IN BRIEF

■ **SANTEN** has appointed **Shigeo Taniuchi** to lead the Japanese firm's European business. Since joining the company in 1996, Taniuchi had held a number of posts within Santen, the firm noted, and brought "15 years of top-level management experience and global leadership" to his new role.

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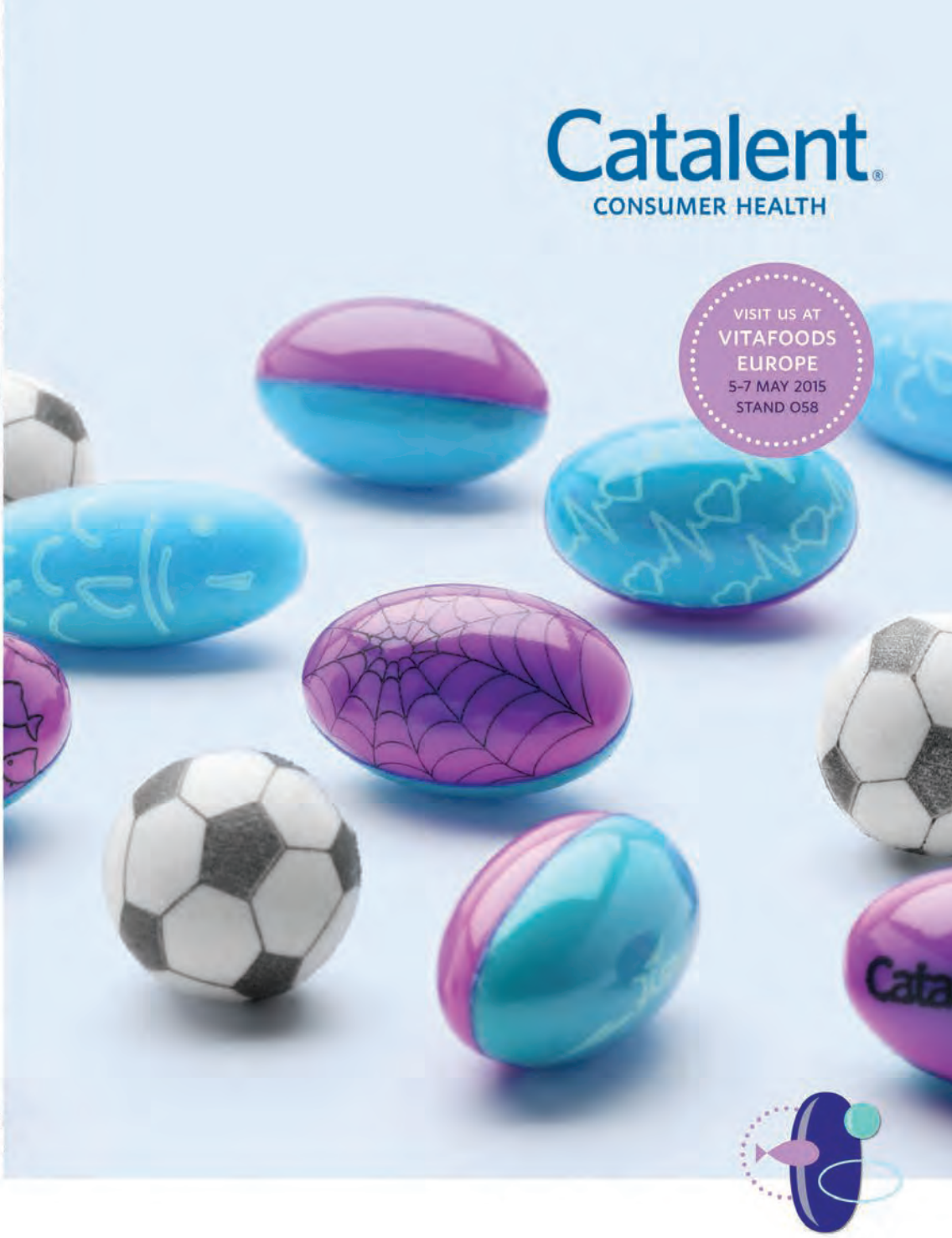

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