21 January 2011

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Reckitt Benckiser grows in US with Combe brands

Reckitt Benckiser has purchased a portfolio of brands, including the Lanacane skincare line, from privately-owned US firm Combe for an undisclosed sum. It is the UK-based company's third OTC acquisition in recent months.

Through the deal, Reckitt Benckiser has expanded its consumer healthcare business with the Cepacol sore-throat brand, Hemoal haemorrhoid treatment, Lanacane anti-itch range, LiceMD head-lice remedy and Scalpicin scalp-itch medication.

A spokesperson for Reckitt Benckiser said it was "very unlikely" that any of these brands would become global 'powerbrands'.

Noting that the products were mainly sold in the US, the spokesperson added that in the UK, Lanacane would join Reckitt Benckiser's existing skincare portfolio and complement its E45 core range.

The deal comes soon after Reckitt Benckiser announced it would boost its consumer healthcare business by acquiring India's Paras Pharmaceuticals, together with its D'Cold winter remedy and Moov topical analgesic, for INR32.6 billion (€545 million) (**OTC *bulletin***, 16 December 2010, page 1).

Prior to the announcement, Reckitt Benckiser purchased SSL International and its Durex and Scholl brands for £2.54 billion (€3.06 billion) in October of last year (**OTC *bulletin***, 30 July 2010, page 1).

Meanwhile, Combe has sold its Foot Care business, which includes the Odor-Eaters brand, to US-based Blistex for an undisclosed sum.

Christopher Combe, chairman and chief executive officer of Combe, said the divestments enabled Combe to "increase our company-wide focus on our largest global brands".

The firm's retained brands – including the Just For Men hair colour products, Sea-Bond denture products, Vagisil feminine care range, and the Brylcreem, Aqua Velva and Lectric Shave men's personal grooming lines – had strong growth opportunities worldwide, he maintained, adding they were backed by a pipeline of "innovative and potentially game-changing new products".

Atrium grows with Seroyal and Minami

Atrium Innovations said that it had made "one of the largest acquisitions" in its history after purchasing fellow Canadian-firm Seroyal International and its portfolio of dietary supplements for US$110 million (€84.7 million) in cash.

In addition, Atrium has bought Belgium's Minami Nutrition and its 16 omega-3 supplements for €5.5 million in cash and an earn-out payment of up to €2.0 million.

The price-tag for Seroyal represents 2.8-times its 2010 sales of around US$40 million, and 7.5-times the company's earnings before interest, tax, depreciation, and amortisation

■ *Continued on page 6*

FDA limits strength of acetaminophen

The maximum US prescription dose of acetaminophen – paracetamol in other markets – has been reduced by the Food and Drug Administration (FDA) to 325mg. The agency said the move would "provide an increased safety margin to help prevent liver damage, [which is] a serious public health problem".

But non-prescription products containing the active ingredient – such as McNeil's Tylenol – are not affected by the measures. The FDA said it was continuing to evaluate ways of reducing liver injury from OTC acetaminophen products and was working to address the recommendations of its advisory committee.

■ *Continued on page 7*

Mergers & Acquisitions

Troy Healthcare acquires Stopain

Troy Healthcare has acquired the Stopain OTC analgesic brand in the US from DRJ Group for an undisclosed sum. Troy Healthcare is a subsidiary of Troy Manufacturing, which has made Stopain products since 2002.

At the same time, Troy Healthcare said that it was set to launch Stopain Pain Relieving Gel in early 2011. The US-based firm claimed the new addition contained "38% more of the active ingredient menthol than any other product in the cooling gel category".

Stopain Pain Relieving Gel will join a range of Stopain products including Original Strength Stopain Spray, Extra Strength Stopain Spray and Extra Strength Stopain Roll On.

Troy Healthcare said that it would use its experience in manufacturing Stopain, together with its "expertise in research and development" to take the brand's product line "to the next level".

"The release of Stopain gel," continued Troy Healthcare, "substantiates the company's pledge to develop scientifically-advanced products for healthy living".

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Joint Ventures

German duo target Hemospray launch

German firms SanguiBioTech and Sander-Strothmann have formed a joint-venture company to obtain a CE safety mark for Sangui's Hemospray woundcare spray.

The joint-venture company – named sastOmed – had been granted the exclusive global license to Hemospray, the two companies noted, and once the CE mark had been granted, sastOmed would begin producing, marketing and distributing the product globally.

Project management, financing and execution of projected activities would be undertaken by the joint venture, which would be led by the managing directors of SanderStrothmann, Michael Sander and Rene Strothmann, the companies said.

Under the terms of the joint-venture agreement, sastOmed will pay milestone-based down payments to Sangui as compensation for the Hemospray licences and has granted Sangui royalties on all future sales of the product.

OTC

Mergers & Acquisitions

Ilex Consumer snaps up St Joseph low-dose aspirin

Ilex Consumer Products has acquired McNeil Consumer Healthcare's St Joseph low-dose aspirin brand in the US for an undisclosed sum.

Robert Bailey, Ilex' president and chief operating officer, said the deal was consistent with the company's strategy of acquiring businesses that had "strong consumer franchises" and were "important to retailers".

"St Joseph Aspirin is a scalable brand that competes in an attractive category," pointed out Bailey, "and provides a clear path for shareholder-value creation through increased brand support and line extensions."

As one of the top three brands in the low-dose aspirin category, St Joseph Aspirin was "well positioned for growth in the broader cardio-wellness segment", Bailey claimed.

"We fully intend to make a significant commitment to communicating the benefits of the brand through an aggressive marketing campaign," he continued, adding that the company was "very excited" about the growth prospects for the cardio-wellness segment.

Ilex' acquisition of St Joseph Aspirin comes a year after McNeil recalled certain lots of the brand's products – along with certain lots of a number of the company's other OTC brands – following problems at its Las Piedras manufacturing plant in Puerto Rico (**OTC *bulletin***, 10 February 2010, page 22). The recall had led to some of the St Joseph Aspirin range being unavailable at retailers, McNeil noted.

Ilex said the St Joseph low-dose aspirin brand was well positioned for growth in the cardio-wellness segment

Established in 2008 and backed by private-investment firm Ilex Capital Group, Ilex Consumer Products Group already owns the Calgon health and beauty brand and Healing Garden botanical and organic bath and body-care line.

Strategy built on OTC acquisitions

Strategic acquisitions in the OTC pharmaceutical market were core to the company creating value for its shareholders, Bailey noted.

To support the deal for the St Joseph brand, private-equity firm JPB Capital Partners II had made a "significant equity investment" in Ilex Consumer Group, the company said. Majority ownership of the business is now split between JPB and Ilex Capital Partners.

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Mergers & Acquisitions

Vemedia gets Podosan footcare line

Vemedia Pharma has bolstered its footcare portfolio by acquiring the Podosan brand in Spain and Portugal from Faes Farma for an undisclosed sum.

Podosan was expected to generate sales of €300,000 in 2010, a spokesperson for Vemedia told **OTC *bulletin***, from the powders, creams and liquid sprays in the range.

The acquisition has been driven by Vemedia's rising interest in footcare products, after the "very successful launch" of the Footner and Nailner products in Italy, and Footner in the Netherlands, the company said.

Yvan Vindevogel, Vemedia's chief executive officer, pointed out that Podosan was an "old brand with a large consumer heritage".

Footcare would be a "growing part of our product portfolio", Vindevogel added, noting that the company would "capitalise on this brand by the introduction of several very innovative line extensions" and would expand Podosan into other European markets.

Acquired Sleepzz brand

The Podosan deal comes three months after Vemedia expanded in the Dutch OTC sleep-aid market by acquiring the Sleepzz brand from Liberty Healthcare for an undisclosed sum (**OTC *bulletin***, 10 September 2010, page 10).

OTC

Business Strategy

Merck & Co considers Consumer options

Merck & Co is now evaluating all options for its Consumer Care division but has not set a deadline for deciding the future of the business, according to the US company's new chief executive officer Kenneth Frazier.

Asked at a conference in New York whether Merck & Co would consider spinning off Consumer Care, Frazier admitted the company had to consider whether investing in growing the business would "maximise shareholder value". It would look at all options, he added.

A spokesperson for Merck & Co told **OTC *bulletin*** that Frazier's recent comments had not signalled a "change in Merck's strategy" in relation to the Consumer Care division.

The company considered Consumer Care a "valuable business", the spokesperson continued, that was "consistent with Merck & Co's overall commitment to innovation".

"As part of our ongoing planning efforts, we are evaluating ways to build greater global scale and revenue growth, plus how [Consumer Care] can best return the maximum long-term value to Merck & Co's shareholders," the spokesperson continued.

Frazier – who became Merck's chief executive officer on 1 January (**OTC *bulletin***, 16 December 2010, page 23) – pointed out that the Consumer Care division gave Merck & Co the "ability to switch products in the right context". However, he admitted that the business was "not global enough" and did not have the "kind of scale outside the US" that the company thought it needed.

Merck & Co had to decide what role the division could play in the longer term, Frazier said, and whether it could be a "significant contributor" to the company.

Richard Clark – Frazier's predecessor and Merck & Co's chairman – has continually backed the Consumer Care division since Merck & Co obtained the business by acquiring Schering-Plough for US$41 billion (€31.7 billion) in 2009 (**OTC *bulletin***, 17 March 2009, page 1).

In November, Clark insisted the Consumer Care division was an important part of Merck & Co's future and was a business for which it had global ambitions (**OTC *bulletin***, 16 November 2010, page 15).

Three months earlier, Clark said expanding the Consumer Care business in Europe and emerging markets represented an exciting opportunity for Merck & Co (**OTC *bulletin***, 13 August 2010, page 1), while in May 2010, he said that the business had a "critical part" to play in the company's strategy going forward (**OTC *bulletin***, 14 May 2010, page 11).

Inviting third-party investment

However, in July 2009, Clarke did not rule out inviting an outside company to invest in the Consumer Care business (**OTC *bulletin***, 31 July 2009, page 1).

Led by the Claritin (loratadine) allergy remedy, Merck & Co's Consumer Care division reported sales in the US and Canada up by 3% to US$291 million in the third quarter of 2010.

The division's portfolio also includes the Coppertone suncare brand and the Dr Scholl's footcare line.

OTC

Business Strategy

Boehringer makes changes in Japan

Germany's Boehringer Ingelheim will bring all four of its Japanese subsidiaries – including its OTC business, SSP – underneath the Boehringer Ingelheim Japan umbrella company on 1 April 2011.

Established in October 2010, Boehringer Ingelheim Japan will handle all administrative operations for the Nippon Boehringer Ingelheim prescription business, SSP OTC operation, Boehringer Ingelheim Vetmedica animal health business and Boehringer Ingelheim Seiyaku manufacturing unit.

A spokesperson for Boehringer Ingelheim told **OTC *bulletin*** that by centralising the communications, human resources, information, legal and procurement functions, the firm's four Japanese units would be able better to concentrate on the areas in which they specialised.

The new umbrella company will be led by Masao Torii, Boehringer Ingelheim noted, who had also been named chairman and representative director of all four Japanese subsidiaries.

A year ago, Boehringer Ingelheim strengthened its position within the Japanese consumer healthcare market by acquiring the 40% stake in SSP that it did not already own (**OTC *bulletin***, 26 February 2010, page 3).

At the time, Boehringer Ingelheim said that by making SSP a wholly-owned subsidiary, the company's global Consumer Health Care business would be able to benefit from the Japanese firm's "unique pharmaceutical development and production technologies". Meanwhile, SSP would benefit from more efficient decision-making processes as well as shared corporate resources, it added.

In 2009, SSP's sales fell by 2% to ¥47.5 billion (€441 million) in an OTC market Boehringer Ingelheim claimed had been stagnant for the previous 10 years.

SSP's portfolio of brands includes the S-Cup tonic drinks, S-Tac cough and cold medicines and the Hythiol-C vitamin C products.

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Mergers & Acquisitions

Novartis set to integrate Alcon

Novartis is poised to take full control of Alcon after agreeing to pay US$12.9 billion (€9.7 billion) in cash and shares for the 23% stake it does not already own in the US-based eyecare company.

The deal comes three months after the Swiss firm lifted its stake in Alcon to 77% after paying Nestlé US$28.3 billion for another 52% of Alcon's shares in a deal the two companies had agreed more than two years earlier (**OTC *bulletin***, 15 April 2008, page 4).

Daniel Vasella, Novartis' chairman, said that taking full control was the "logical conclusion" to Novartis' strategic investment in Alcon.

"With this step, Novartis takes full ownership, becoming the global leader in eyecare, a rapidly expanding, innovative platform based on the growing needs of an ageing population," Vasella added.

Maintaining that the two firms had complementary pharmaceutical portfolios for diseases in the front and back areas of the eye, Novartis noted that Alcon was also global leader in ophthalmic surgical products and these would sit alongside its own broad contact-lens portfolio.

Kevin Buehler, president and chief executive officer of Alcon, will lead the new Alcon division within Novartis, which will also include the Ciba Vision business. The combined eyecare division had a proforma turnover last year of US$8.7 billion.

The new division will also include Alcon's US$1.0 billion consumer business, deriving primarily from contact-lens disinfectants under the Opti-Free brand as well as artificial tears and products for dry eyes under the Systane label. Alcon also offers ICaps vitamin and mineral supplements.

OTC

IN BRIEF

■ **CELESIO** is half way towards reaching its medium-term target of opening **100 DocMorris Apotek pharmacies** in Sweden. The pan-European wholesaler and retailer said that the 50th pharmacy to be added to its fledgling Swedish chain had opened on 29 December 2010. Celesio announced in November that it planned to open 50 pharmacies in Sweden by the end of 2010. This was up from a revised target of 30-40 stores announced in May (**OTC *bulletin***, 14 May 2010, page 3).

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Mergers & Acquisitions

Meda expands in the US with five brands from GSK

Meda has expanded its fledgling US OTC business by acquiring five brands from GlaxoSmithKline Consumer Healthcare in two separate deals worth a total of SEK415 million (€46.8 million).

The Swedish company gained the Geritol multivitamin, the Feosol iron supplement and another unnamed iron supplement in December, before acquiring the Contac cold and flu line and the Vivarin caffeine supplement earlier this month. The five brands had combined annual sales of around SEK180 million, Meda said, and strong profit margins.

Commenting on the deals, Anders Lönner, Meda's chief executive officer, described the acquired products as "well-known consumer brands" that would "strengthen" the company's business in the US.

The deals are Meda's fourth and fifth OTC acquisitions in recent months.

In September, Meda announced that it would be entering the US OTC market by purchasing speciality pharmaceutical company Alaven for US$350 million (€263 million) (**OTC *bulletin***, 10 September 2010, page 1).

Alaven provided Meda with a "strategic OTC platform in the US", the firm said, through which it could commercialise "strategic pipeline opportunities". About 25% of Alaven's SEK800 million annual turnover came from a portfolio of OTC brands, Meda pointed out, including the Prefera prenatal vitamin range.

Meda is well-established in the US with a portfolio of prescription brands, which generated sales of SEK2.75 billion in 2009 and accounted for a fifth of the company's SEK13.2 billion group sales. However, prior to acquiring Alaven, it had no presence in the US OTC market. Its key Betadine antiseptic brand will not be launched by it in the US as Meda does not hold the rights.

Acquired Sweden's BioPhausia

At the end of September, the company expanded its OTC business in the Nordic region by acquiring fellow Swedish firm BioPhausia's portfolio of six OTC brands for SEK190 million (**OTC *bulletin***, 29 September 2010, page 1).

In November, Meda acquired three OTC brands from the Dutch company Norgine for SEK540 million (**OTC *bulletin***, 16 November 2010, page 1).

Meda's OTC offering has grown steadily over the past few years, and now accounts for more than SEK2.0 billion of Meda's total sales. The majority of the firm's OTC sales are generated by Betadine, which had sales of SEK614 million in the opening nine months of 2010.

OTC

Product Development

New cough remedy heads towards launch

UK-based drug development firm SEEK said that its theobromine-based treatment for persistent cough could be on the market within two years.

Manfred Scheske, chief executive officer of SEEK's Consumer Health operation, said the drug containing theobromine – which is naturally present in cocoa and chocolate – had the potential to "dramatically impact the treatment of persistent cough" and could "greatly benefit the quality of life of persistent cough sufferers".

SEEK claimed that no new non-opioid treatments for persistent cough had been developed for 20 years, adding that recent safety concerns surrounding current treatments such as codeine meant patients were desperate for an alternative.

Now, following consultation with the European Medicines Agency (EMA), a single Phase III trial of theobromine was expected to begin in the UK in the first half of 2011, SEEK said.

The drug had the potential, the company pointed out, to be on the market in Europe within two years from trial commencement, subject to receiving final marketing approval.

Explaining how the drug worked, SEEK said theobromine inhibited the "inappropriate firing of the vagus nerve", which was a "key feature" of persistent cough.

This peripheral mechanism of action differentiated theobromine from codeine and other centrally-acting agents, SEEK claimed, and lessened any side effects in the lower central nervous system.

SEEK is looking for partners for the project (**OTC *bulletin***, 16 November 2010, page 26).

OTC

Mergers & Acquisitions

Omega adds brands in UK and France

Omega Pharma has boosted its weight management and parasite portfolios by acquiring five OTC brands in the UK and Ireland from Goldshield, as well as the French firm Terre Santé and its Duo LP Pro head-lice treatment. It is paying a total of €14 million.

Marc Coucke, Omega's chief executive officer, pointed out that not only did the acquisitions strengthen the Belgian company's position in two major OTC segments – parasite treatment and weight control – they also boosted its presence in France and the UK, which he described as "two key markets".

In the UK and Ireland, Omega has acquired five brands from Goldshield, including the company's Shape Smart slimming range consisting of the Appesat, Decarb and Lipobind weight-management brands.

Importantly, Omega said, the Shape Smart range provided the company with a "solid base" from which to launch its existing XLS-Medical slimming brand in the UK and Ireland.

Coucke claimed the acquired products' existing positions and listings with major UK and Irish retailers would give the XLS-Medical range an advantage when it was launched into both these markets later this year and would enable the firm to grow the brand's sales faster.

Launching XLS-Medical in the UK and Ireland is part of a wider roll-out of the brand in all markets where Omega has a presence.

XLS-Medical was currently sold in nine markets, Coucke noted, but by the end of 2011 he expected the brand to be available in all 35 countries in which the company operated.

In addition, Omega has also bought Goldshield's Kamillosan and Infaderm mother-and-baby dermatology brands, which Coucke claimed would boost the company's strategic dermatology portfolio.

Together, all five Goldshield products generated annual turnover of around €3.0 million, Coucke noted, with the majority coming from the Shape Smart products.

Meanwhile, acquiring Terre Santé and its Duo LP Pro head-lice treatment in France added a single-use treatment to Omega's existing Paranix head-lice brand, Coucke pointed out.

Sam Sabbe, Omega's chief strategy officer, said Omega would begin rolling-out Duo LP Pro as a Paranix line extension in the "near future". He noted that Paranix was already available in 28 countries across Europe.

Described as a "fast-growing brand", Duo LP Pro reported sales of almost €6.0 million in 2010, Sabbe said, €5.0 million of which had been generated in France and the remainder in a number of other western European markets.

Acquiring Duo LP Pro, along with the five brands from Goldshield, would add around €9.0 million to Omega's sales in 2011, Coucke said, but this could be higher if the company could drive-up the brands' sales in their existing markets. An additional €2.5 million would also be added to the company's earnings before interest, tax, depreciation and amortisation (EBITDA), he noted.

The latest acquisitions come less than three months after Omega agreed to pay €9.0 million for Spanish pharmaceutical company Inibsa's OTC activities (**OTC *bulletin***, 30 November 2010, page 1), €69 million for French natural products company Laboratoire de la Mer and €3.1 million for Johnson & Johnson Consumer Nordic's ACO brand of vitamins and supplements (**OTC *bulletin***, 29 October 2010, page 1).

Omega believes the market position of Goldshield's Shape Smart brands, such as Lipobind, will help it launch its XLS-Medical brand in the UK

This round of acquisitions follows Omega's announcement last March that it would consider buying innovative brands or businesses with global potential as part of its drive to become one of the world's top 10 OTC players (**OTC *bulletin***, 31 March 2010, page 2).

Acquisitions would play a part, Omega noted, in expanding its five new business categories of Classics, Cough & Cold, Derma, Multi-Locals and Parasites. Focusing on just the five business areas would enable Omega to shift away from niches with sales of €50 million to €100 million, the company said, to larger categories like dermatology and cough/cold.

Omega claims to be the 13th biggest OTC company in the world with sales of €814 million in 2009 and a presence in 35 countries (**OTC *bulletin***, 10 February 2010, page 11).

OTC

IN BRIEF

■ **SIGMA PHARMACEUTICALS**' shareholders have approved the divestment of its Pharmaceuticals business to South Africa's **Aspen Pharmacare** for A$900 million (€667 million). The deal is now expected to close on 31 January 2011, five months after Aspen first lodged its bid for the troubled Australian firm (**OTC *bulletin***, 10 September 2010, page 3). Aspen will gain Sigma's consumer healthcare brands, such as Herron, as well as its generics unit and prescription brands, orphan drugs, medical products and a contract manufacturing business. Aspen already has a A$180 million sales and marketing operation in Australia.

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Distribution Agreements

BioGaia strikes deal in Greece

BioGaia's probiotic oral-rehydration solution will soon be available in Greece after the Swedish firm signed an exclusive distribution deal with Cube Pharmaceutical.

Cube was planning to launch the product – which combines BioGaia's *Lactobacillus reuteri protectis* probiotic with zinc and an oral-rehydration solution – under the BioGaia brand name in summer 2011, the firm pointed out.

The formulation is already available in Italy and Sweden.

BioGaia claimed the product was unique in combining a probiotic, an oral-rehydration solution and zinc in one ready-mixed portion. Official guidelines for the composition of oral-rehydration solutions recommended a parallel intake of zinc for the treatment of diarrhoea, particularly in small children, added the Swedish company.

Meanwhile, BioGaia said that TwoPac – the firm in which it owns a 50% stake – would invest SEK20 million (€2.2 million) in a new manufacturing facility. TwoPac produces straws and oil drops containing probiotics for BioGaia, as well as the Life Top Cap bottle top.

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Mergers & Acquisitions

Hypermarcas to snap up Mantecorp for BRL2.52bn

Hypermarcas has agreed to buy fellow Brazilian pharmaceutical company Mantecorp Indústria Qúimica e Farmacêutica in a cash and share deal worth BRL2.52 billion (€1.12 billion).

The deal will bring a range of prescription, speciality and OTC brands to Hypermarcas' Pharma division, which houses its prescription operation and Dorsay Monange OTC business.

Hypermarcas is paying BRL600 million in cash for a 23.77% stake in Mantecorp, and issuing over 78 million of its shares to Mantecorp shareholders for the remaining 76.23% stake. Based on Hypermarcas' closing share price on 17 December 2010, the new stock was valued at BRL1.92 billion.

Established as an independent company four years ago, Mantecorp was the new name given to Mantefarma after the company's partnership with Schering-Plough came to an end in 2006 (**OTC *bulletin***, 30 June 2006, page 3). Mantefarma had marketed and distributed some Schering-Plough products in Brazil through the Quimica e Farmaceutica Schering-Plough venture, which had been established in 1991.

Founded in 2002, Hypermarcas' business strategy is built on an aggressive acquisitions policy, which has seen the company make numerous purchases across all of its business areas – Food, Home Care, Personal Care and Pharma – over the past seven years. In 2009 alone, the firm made five acquisitions totalling around BRL2.0 billion.

Acquired Neo Qúimica OTC business

Hypermarcas bought the Neo Qúimica OTC and generics business at the end of 2009 (**OTC *bulletin***, 18 December 2009, page 3), and the Luper Indústria Farmacêutica OTC company in April of last year (**OTC *bulletin***, 30 April 2010, page 9).

Over the past three months, the company has gained the oral-hygiene companies Indústria de Produtos de Higiene e Cosméticos (IPH&C), Distribuidora de Produtos de Higiene (DPH) and Comercial Maripa, as well as Colgate-Palmolive's Pom Pom baby-soap brand (**OTC *bulletin***, 30 November 2010, page 7).

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Mergers & Acquisitions

Atrium acquires Seroyal and Minami

■ *Continued from front page*

(EBITDA) of about US$14.7 million.

Seroyal operates in the Canadian and US markets, which account for 65% and 35% of its total sales respectively.

Describing Seroyal's brands as "premium" and "high margin", Atrium noted they would complement its existing portfolio, and enable the company to "surpass the important milestone" of US$100 million in EBITDA.

Seroyal's portfolio includes the Genestra Brands range, which comprises 300 nutritional, herbal and homoeopathic products, as well as the Pharmax nutraceuticals and speciality combination range, and the Unda homoeopathic line. Atrium noted that the trio of brands accounted for almost 90% of Seroyal's sales.

In addition, Seroyal owns the CoreLab health-food-store brand, which is marketed in the US, through a joint venture.

Pierre Fitzgibbon, Atrium's president and chief executive officer, said the acquisition would "provide us with a leading position in the North American healthcare-professional channel, and create a significant presence in Canada when combined with our existing operations". "Within our multi-channel strategy, we envision some cross-selling opportunities with these new brands and some operating synergies," he added.

Commenting on the acquisition of Minami, Fitzgibbon said the "high-end brand" would complement Atrium's existing wide range of omega-3 products.

Minami's portfolio of products had generated sales of €5.0 million in the past 12 months, Atrium pointed out, primarily in Belgium, Holland, Ireland and the UK.

Atrium's objective, Fitzgibbon revealed, was to leverage its own multi-channel distribution and geographic capabilities considerably to increase the penetration level of the Minami brand, so that it could achieve its full potential.

Jo Wyckmans, founder of Minami, would remain with the firm, Atrium noted, and assist with the brand's continued growth in Europe through Atrium's MCO Health operation.

In the spring of 2011, Minami would be launched in the US through the firm's Garden of Life subsidiary, Atrium said, while in Canada its Trophic subsidiary would launch the brand once product registrations had been completed.

Atrium noted that Minami had a "strategic, long-term omega-3 sourcing supply agreement" with KD-Pharma Bexbach for the European and North American markets.

The deals come soon after Fitzgibbon admitted that Atrium was back on the acquisition trail and ready to buy sooner rather than later (**OTC *bulletin***, 30 November 2010, page 3). He said that with the firm's recent purchases now integrated, it was ready to make further buys.

Atrium has made numerous acquisitions on both sides of the Atlantic over the past three years, with the majority outside of Canada. These included the US-based nutritional supplements firm Garden of Life in 2009 (**OTC *bulletin***, 30 September 2009, page 3) and the Canadian supplement manufacturer Trophic last year (**OTC *bulletin***, 31 March 2010, page 8).

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Regulatory Affairs

FDA curbs strength of acetaminophen

■ *Continued from front page*

All prescription acetaminophen products must also carry a boxed warning – the strongest warning required by the FDA – highlighting that acetaminophen overdose may cause liver failure. And a warning that highlights the potential for allergic reactions must also be added to the labels of these prescription products. The measures will be phased in over the next three years, giving manufacturers until 14 January 2014 to comply with the FDA's requirements.

Sandra Kweder, the deputy director of the FDA's Office of New Drugs, said there was no immediate danger to patients who took prescription acetaminophen products, but the risk of liver injury occurred when patients taking multiple products exceeded the current maximum dose of 4,000mg every 24 hours.

Asked whether similar moves were likely in Europe, a spokesperson for the European Medicines Agency (EMA) said the agency's pharmacovigilance working party had been working with member states to determine if any action was needed. "The safety of paracetamol is under constant monitoring throughout Europe and is regularly reviewed by the working party," the spokesperson added, noting that the amount of paracetamol per dose in prescription-only combination medicines was not harmonised within the European Union and that paracetamol-containing medicines were authorised at member-state level.

The Proprietary Association of Great Britain's (PAGB's) chief executive, Sheila Kelly, pointed out the UK had already taken action to limit general-sales list pack sizes to 16 tablets and those in pharmacy to 32 tablets.

Three FDA advisory committees voted in June 2009 in favour of reducing the maximum single adult dose for non-prescription acetaminophen medicines from 1,000mg to 650mg (**OTC *bulletin***, 31 July 2009, page 1). They also voted in favour of lowering the 4,000mg maximum daily dose, as well as for a reverse-switch to prescription-only for the 1,000mg single adult dose. However, they voted against removing non-prescription acetaminophen products from the market altogether.

Earlier that year, the FDA gave US manufacturers of OTC analgesics containing acetaminophen 12 months to ensure the active ingredients were prominently displayed on labelling of both packs and bottles and that labelling warned of the risks of severe liver damage.

OTC

Mergers & Acquisitions

Prestige buys Dramamine

Prestige Brands Holdings is set to expand its core OTC business in the US by paying US$76 million (€57 million) to McNeil-PPC for the Dramamine motion-sickness brand.

Dramamine was the number one brand in the OTC motion-sickness category in the US, Prestige said, with an estimated market share of 32%. The Dramamine line includes Dramamine Chewable, Dramamine Less Drowsy Formula and Dramamine Original Formula.

Matthew Mannelly, Prestige's chief executive officer, said that acquiring Dramamine represented a continuation of the firm's strategy to acquire OTC brands that were "broadly recognised by consumers, are important to retailers, and have strong positions in their categories".

Noting that the transaction was expected to close at the end of January 2011, Prestige said the effective purchase price was around US$62 million, as the deal would generate tax attributes with a present value of about US$14 million.

Dramamine is Prestige's second major OTC buy in the past three months, after the US$190 million acquisition of Blacksmith Brands Holdings and its range of OTC brands (**OTC *bulletin***, 29 September 2010, page 1).

At the time, Prestige described acquiring Blacksmith's OTC brands – including the Efferdent and Effergrip oral-care products, the PediaCare cough and cold remedy for infants and children, Luden's throat drops and the NasalCrom allergy products – as "transformative", and a deal that had underlined the company's commitment to increasing its OTC presence.

Ready for further acquisitions

Asked whether the company was looking to make further acquisitions or was focused on integrating Blacksmith's brands and Dramamine, a spokesperson for Prestige told **OTC *bulletin*** that if another "perfect, spot-on acquisition" became available the company would "strongly consider" making the deal.

OTC

Mergers & Acquisitions

Royal DSM to acquire Martek

Royal DSM is set to acquire US-based nutritional ingredients firm Martek Biosciences for US$1.09 billion (€0.83 billion) in cash.

Martek's board has approved the US$31.50 per share deal, which represents a 35% premium over the firm's closing share price on 20 December 2010. The transaction is expected to close in the first or second quarter of 2011.

The Dutch life sciences and material sciences group said that acquiring Martek would position it as a leader in the market for poly-unsaturated fatty acids (PUFAs) and infant nutrition, and would expand its existing platform in algal and other microbial fermentations. Furthermore, the deal would greatly increase its US presence, added Royal DSM.

Gains Amerifit Brands business

Royal DSM also pointed out that it would gain the Amerifit Brands dietary-supplement business, which would be used as an additional marketing channel for ingredients from both Royal DSM and Martek.

Martek acquired Amerifit for US$200 million in February of last year (**OTC *bulletin***, 10 February 2010, page 3). The purchase gave it a number of natural-wellness brands in the US, including the probiotic supplement Culturelle and the menopause symptom-relief product Estroven.

The bulk of Martek's sales, which rose by 32% to US$435 million in the year ended 31 October 2010, are generated by its nutritional-ingredients business. This includes Life'sDHA products, based on the omega-3 fatty acid docosahexaenoic acid (DHA), and Life'sARA products based on the omega-6 fatty acid arachidonic acid (ARA).

The two companies already have a long-standing relationship as DSM supplies Martek with base materials for its ARA product.

Royal DSM pointed out that it intended to accelerate Martek's growth using its global-reach, technology-base and application-skill capabilities, as well as its insights into the food, beverage and global dietary supplements markets, and its strength in industrial biotechnology and related applications.

Royal DSM has annual net sales of about €8.0 billion from a broad range of sectors, including human and animal nutrition and health, personal care, pharmaceuticals, coatings and paint, and housing.

OTC

Annual Results

Beiersdorf takes action to lift Consumer performance

Beiersdorf said it had not been satisfied with the overall performance of its Consumer business in 2010 and had started to restructure its operations to help improve sales growth.

The company's Consumer business – led by the Nivea and Eucerin skincare brands – had reported sales up by 6.2% to €5.32 billion in 2010, Beiersdorf said. But, with market-by-market performances varying "substantially", organic sales growth had been only 1.6%.

Strong performances had been posted in Russia and the UK, the company pointed out, whereas results had been mixed in other European markets. Elsewhere, the Consumer business had recorded "particularly strong growth" in North and Latin America, the company added, while turnover across the Africa/Asia/Australia region had increased slightly.

Earnings before interest and tax (EBIT) at the Consumer business dropped by around 14% to €482 million, due primarily to write-downs related to its Chinese business and to streamlining its product portfolio.

Commenting on the results, Thomas Quaas, chairman of Beiersdorf's executive board, said despite "clear successes in individual regions" the company was "not satisfied with the overall performance by the Consumer business segment in 2010".

As a result, the company had resolved to make significant investments in the Consumer business, Quaas noted, and had also instigated restructuring measures. He added that although the effects of these measures would impact results in the transitional phase, they would help to "systematically restore" the previous momentum of the Consumer business.

Beiersdorf announced in December that it would streamline its product portfolio and realign its regional structures in a move to boost the performance of the Consumer business (**OTC *bulletin***, 16 December 2010, page 7).

A "comprehensive package of measures and investments" had been drawn up, the company said at the time, that would help implement its new "Focus on Skin Care. Closer to Markets" consumer-business strategy.

The entire skin and body-care range had been analysed, Beiersdorf pointed out, and the decision had been made to exit the decorative-cosmetics market in Germany. All other local affiliates would decide the future of their own decorative-cosmetics businesses independently, the company noted.

As part of the streamlining process, Beiersdorf sold the skincare brand Juvena and the hair-care brand Marlies Möller for an undisclosed sum to Troll Cosmetics in Austria at the end of December.

The Consumer business accounted for 86% of Beiersdorf's total turnover in 2010, which increased by 7.7% to €6.19 billion.

The Tesa self-adhesives business contributed the remaining 14%, with sales growth of 18.3% to €872 million.

Beiersdorf's 2010 EBIT slipped back by 1.4% to approximately €579 million, due to the fall in EBIT at the Consumer business.

OTC

IN BRIEF

■ **NTC** said that its **Bigfarma** subsidiary in Portugal had merged with local Portuguese sales and marketing firm Hydrafarma. The Italian company noted that Hydrafarma was active in the mass-market sector and specialised in cosmetic products. The newly-enlarged company would keep the name Bigfarma, NTC said, and would be structured as two separate divisions, one covering the pharmacy channel and the other dealing with mass-market retailers, such as supermarkets and hypermarkets.

■ **ORIOLA-KD** is expecting its **operating profit from continuing operations to drop** by 69.4% to €20 million in 2010, due to its Russian wholesaling business reporting an operating loss. In contrast, net sales from continuing operations were expected to increase by 11.8% to €1.9 billion, the Finnish wholesaler and retailer noted.

■ **A&D PHARMA** – the Dutch holding company which operates the Mediplus wholesaling business and Sensiblu pharmacy chain in Romania – said it had secured a new **€150 million loan agreement**. The new loan would be used to refinance an existing €100 million loan, the company said, as well as fund other corporate projects.

OTC

Mergers & Acquisitions

Matrixx to go private in US$75mn deal

Matrixx Initiatives is set to be acquired by private investment firm HIG Capital in a deal which values the US-based owner of the Zicam cough and cold brand at US$75.2 million (€56.0 million).

The company said the US$8.00 per share deal had been unanimously approved by Matrixx' board of directors and recommended to shareholders. A tender offer commenced on 22 December 2010, and was expected to close on 24 January 2011.

The news came as Matrixx announced that it had agreed to pay US$15.5 million to settle a nationwide personal-injury lawsuit, which alleged that use of the Zicam Cold Remedy and other Zicam products had led to anosmia, or a loss of sense of smell.

Matrixx has been the target of numerous lawsuits over the past 18 months, after it voluntarily withdrew its Zicam Cold Remedy Nasal Gel and Zicam Cold Remedy Gel Swabs in the wake of a Warning Letter issued by the US Food and Drug Administration (FDA) (**OTC *bulletin***, 19 June 2009, page 15).

The FDA Warning Letter cited reports that the two products could cause a loss of sense of smell, and informed the company that it should file New Drug Applications (NDAs) for the two products.

Matrixx disputed that the products could cause loss of sense of smell, but was told by the FDA in November 2009 (**OTC *bulletin***, 16 November 2009, page 12) and in March 2010 (**OTC *bulletin***, 17 March 2010, page 8) that the letter would not be withdrawn and the company should file NDAs for the two products.

The US Supreme Court is currently hearing Matrixx' appeal against the re-opening of a lawsuit that accuses the company of not telling investors that its Zicam nasal sprays could cause a loss of sense of smell (**OTC *bulletin***, 30 June 2010, page 4).

A district court judge had dismissed the lawsuit in 2005, after ruling that the adverse events reported were not statistically significant enough to link the Zicam products to anosmia. However, the ninth circuit appeals court disagreed and reopened the case in 2009.

Matrixx claims that the appeal court ruling would mean that all pharmaceutical companies would have to inform investors and consumers of every adverse event reported, whether statistically significant or not.

In the six months to 30 September 2010, Matrixx' sales declined by a quarter to US$24.5 million, primarily due to the product withdrawals. However, Matrixx did report a positive operating income of US$4.63 million for the period, compared to a withdrawal-related operating loss of US$28.9 million a year earlier.

In the wake of the product withdrawals, Matrixx has been working to shift consumers to its oral Zicam products, and recently launched an advertising campaign encompassing television, print, and online media (**OTC *bulletin***, 30 November 2010, page 15).

OTC

Business Update

Futura expects CE quality mark

Futura Medical said it believed its CSD500 condom designed to help healthy men maintain an erection would be granted a European CE mark in early 2011.

The UK-based firm said that it was working with its marketing partner Reckitt Benckiser to "address a number of minor points" raised by the notified body assessing CSD500's CE-mark application and that this would be completed in a relatively short period.

CSD500 has been submitted for approval as a Class III medical device.

Once CSD500's CE mark is granted, Reckitt Benckiser plans to launch the product under the Durex brand name it gained by acquiring SSL International last year (**OTC *bulletin***, 30 July 2010, page 1). SSL gained the global marketing rights to CSD500 in 2003.

In September of last year, Futura said that almost half of non-condom users would be interested in purchasing its CSD500 condom (**OTC *bulletin***, 29 September 2010, page 8).

Market research had found that 88% of condom users in the UK would be interested in CSD500, the firm added.

OTC

Promoting Self-Medication

Germany's BAH outlines plans for brighter future

Working with statutory health insurance funds, pharmacists and doctors to create a common vision for responsible self-medication was among the key ideas outlined by Germany's medicines manufacturers' association, the BAH, during a recent press conference aimed at reversing the constant decline of the country's non-prescription market.

Noting that healthcare legislation that came into effect on 1 January this year had introduced health technology assessments (HTAs) for innovative prescription drugs, the BAH's chairman, Hans-Georg Hoffmann, insisted politicians should pay more attention to the role that self-medication could play in controlling healthcare costs and ensuring patients had access to effective treatments.

"Amid all the discussions on cost-benefit assessments, the effectiveness of OTC medicines and the role of self-care has to take a more central role," Hoffmann maintained.

Hoffmann made four key suggestions for how self-medication could play a greater role.

Firstly, he called for "a public recognition of self-medication by politicians and health insurance funds". "Only a public recognition of self-medication by these parties can adequately address the poor image and acceptance of OTC medicines," he argued.

Hoffmann laid the blame for the OTC sector's image problem largely at the door of the politicians who had in 2004 for "purely financial reasons" delisted most non-prescription medicines from reimbursement by statutory health insurance funds. Even though non-prescription status was conferred solely on the basis of a risk analysis, the delisting had implied that OTC medicines were less effective or safe than reimbursable drugs.

Secondly, Hoffmann stressed the BAH's willingness to meet with representatives of insurance funds, pharmacists and doctors to "create a united concept for encouraging responsible self-medication". The common goal should be to develop a medically and economically sensible self-medication model for the good of both the patient and the healthcare system, he said.

Among the concepts that Hoffmann proposed for discussion were 'collaborative care' and 'doctor-induced self-medication', as well as a 'self-medication budget' for consumers. The latter would see insurance funds reimburse a proportion of consumers' OTC purchases as a reward for avoiding expensive visits to the doctor when suffering from minor ailments.

Thirdly, Hoffmann appealed to the BAH's member companies to persist in their efforts to broaden the scope of self-medication, such as through switches from prescription-only to non-prescription status, or by introducing new products, line extensions and delivery forms.

And fourthly, Hoffmann called on regulatory agencies at a national and European level to make only reasonable demands on the non-prescription industry so the field of self-medication could be expanded in a rational manner.

Uwe May, head of the BAH's healthcare economics department, presented IMS Health data for the first nine months of 2010 that showed self-medication sales in Germany's community pharmacies were down by 1.2% to €3.52 billion at retail selling prices. The volume decline was 2.0% to 455 million packs.

During the same period, prescription-generated sales of non-prescription medicines declined by 3.9% to €972 million, equating to a 5.9% volume slide to 95.1 million packs (see Figure 1).

By contrast, OTC or self-medication sales through the mail-order channel were just over a tenth higher at €493 million, while a 20.6% volume rise to 51.7 million packs indicated the increasing trend towards discounting by mail-order pharmacies.

The market for prescription-only medicines grew by 3.5% to €24.7 billion, even though volume sales fell by 0.7% to 512 million packs.

While the decline in prescription-generated sales of non-prescription medicines could be explained by companies reducing marketing activities to doctors in the wake of the reimbursement delisting, May observed that the ongoing self-medication malaise had confounded several positive forecasts.

Demographic and economic factors such as an ageing population and pressure on health insurance funds to limit the range of services they funded seemed to point to an increasingly important role for self-medication, May commented. However, he added, these factors were not currently sufficient to offset the stigma surrounding OTC products in consumers' minds following the reimbursement delisting.

Trust in the efficacy of products

"Trust in the efficacy of the products is the key factor," May asserted. He suggested that industry and its partners should stress that OTC medicines met the same regulatory standards of safety, quality and efficacy as any other drug.

Insurance funds had a key role to play in educating their members on how to treat minor ailments, May continued. Furthermore, he suggested, self-care should be incorporated in the school curriculum.

Pointing out that almost every other pack sold by community pharmacies was a non-prescription medicine, May said OTC sales gave pharmacists the opportunity to position themselves as expert healthcare advisers.

Doctors, he continued, could also play a key role in promoting self-medication. May hailed the success of the 'green prescription' scheme, whereby doctors write recommendations for OTC purchases on green pads designed to resemble standard prescribing pads.

"The latest IMS Health figures show that every fifth prescription for an OTC medicine was written via a green prescription," May highlighted. Having distributed around 15 million green prescription forms in 2009, the BAH has since handed over responsibility for the project to a consortium of its member companies (**OTC *bulletin***, 17 March 2010, page 12).

OTC

	Value sales (€ millions)	Change (%)	Volume sales (million packs)	Change (%)
Sales of prescription-only medicines	24,718	+3.5	512.1	-0.7
Self-medication or OTC sales of non-prescription medicines through community pharmacies	3,520	-1.2	454.8	-2.0
Prescription-generated sales of non-prescription medicines through community pharmacies	972	-3.9	95.1	-5.9
Sales of non-prescription medicines through mail-order pharmacies	493	+10.2	51.7	+20.6

Figure 1: Breakdown of the German medicines market through pharmacies in the first nine months of 2010 at retail selling prices and in volume terms (Source – BAH/IMS Health)

Product Recalls/Business Strategy

McNeil starts new year with more recalls

McNeil Consumer Healthcare has recalled several more OTC products sold under the Benadryl, Sudafed, Sinutab and Tylenol brands in the US, the Caribbean and Brazil.

The Johnson & Johnson subsidiary stressed that the recalls, which involved products made at its Fort Washington facility in the US before April 2010, were a "precautionary measure".

The company said an "extensive review" of production records at the facility had found "instances where equipment cleaning procedures were insufficient or that cleaning was not adequately documented". However, the firm insisted that it was "very unlikely that this impacted the quality of these products".

McNeil has made a string of product recalls over the past 18 months, and production at the Fort Washington facility has been suspended since April 2010. As a result, US sales by Johnson & Johnson's OTC & Nutritionals business are expected to drop by US$600 million (€450 million) in 2010 (**OTC *bulletin***, 29 October 2010, page 4).

The latest recall includes certain lots of Tylenol 8 Hour, Tylenol Arthritis Pain and Tylenol upper respiratory products, as well as certain lots of Benadryl, Sudafed PE and Sinutab.

In addition, McNeil has recalled certain lots of Rolaids Multi-Symptom Berry tablets distributed in the US, after the production records revealed that the product's labelling did not meet regulations.

McNeil stressed that the recalls were at the wholesale level, that they had not been initiated due to adverse events, and that no action was required by consumers.

The review of the Fort Washington records, McNeil said, was part of the "Comprehensive Action Plan" on quality improvement the company had submitted to the US Food and Drug Administration (FDA) in July of last year (**OTC *bulletin***, 10 September 2010, page 31).

The plan was drawn up after the Committee on Oversight and Government Reform within the US House of Representatives launched an investigation into McNeil's voluntary recall involving over 40 OTC medicines for infants and children made at Fort Washington (**OTC *bulletin***, 14 May 2010, page 1).

This came on top of an FDA Warning Letter received by Johnson & Johnson earlier in the year about its plant in Las Piedras, Puerto Rico (**OTC *bulletin***, 10 February 2010, page 22).

The Warning Letter led Johnson & Johnson voluntarily to recall a number of its OTC brands manufactured at Las Piedras due to complaints of an "unusual mouldy, musty or mildew-like odour that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events".

As part of the action plan, McNeil had "undertaken a thorough investigation of historical records, as far back as 2007, for products sold in the US and produced in McNeil's internal manufacturing network", the company noted.

"For each product, McNeil looked at whether the right processes had been identified and followed, and evaluated whether quality standards had been met," McNeil continued. "This assessment has now been completed, representing a significant milestone in the Comprehensive Action Plan."

The assessment had identified a number of areas for improvement, McNeil said.

McNeil noted it was conducting assessments at other sites that manufactured its products.

OTC

Business Strategy

Germany's Duopharm takes the Salus name

German herbal specialist Duopharm has changed its name to Salus Pharma in a move aimed at creating a stronger umbrella brand for its parent company.

Duopharm – which markets a range of natural remedies, such as the chondroitin-based supplement Duovital – is a wholly-owned subsidiary of the Salus group.

Noting that the Salus group had historically focused largely on the health food store channel, Salus Pharma's managing director Christoph Hofstetter stated: "The Salus brand has an excellent reputation of which we intend to make better use in the pharmacy channel."

OTC

Regulatory Affairs

FDA acts against "tainted" supplements

The Food and Drug Administration (FDA) in the US has stepped up its efforts to stamp out "tainted" products that are marketed as dietary supplements.

The regulatory agency said that it was working with leading trade associations – including the Consumer Healthcare Products Association (CHPA) and the Council for Responsible Nutrition (CRN) – to "increase company vigilance and protect the public" from these "potentially dangerous" products.

A letter from the FDA to dietary supplement manufacturers expresses concern about "undeclared or deceptively-labelled ingredients in products marketed as dietary supplements". The FDA said these substances included the active ingredients in FDA-approved drugs or their analogues, or other compounds that did not qualify as dietary ingredients, such as novel synthetic steroids.

The FDA pointed out that it had alerted consumers to nearly 300 tainted products marketed as dietary supplements, and had received numerous complaints of injury associated with these products.

"These tainted products can cause serious adverse effects, including strokes, organ failure, and death," commented FDA commissioner Margaret Hamburg. "The manufacturers selling these tainted products are operating outside the law."

In its letter, the FDA emphasises that manufacturers and distributors are responsible for ensuring their products comply with the law.

The agency said it was seeking input and collaboration from dietary supplement trade associations to "educate the industry about the problem and to help develop new strategies to combat it". It noted that five major trade associations had agreed to share the letter widely within the industry.

The five associations said in a joint statement that they endorsed the FDA's actions to "use its regulatory muscle to hold accountable those who violate the law and jeopardise the public health, using tough criminal sanctions when appropriate".

In addition to the letter, the FDA has set up a new RSS feed to warn consumers more quickly about tainted products marketed as dietary supplements.

According to the FDA, tainted products fell into three main categories:

■ Weight-loss products containing substances such as sibutramine. This was the active ingredient in Abbott's Meridia, which was recently withdrawn from the market in the US due to increased risk of heart attack and stroke.

■ Body-building products containing anabolic steroids or steroid analogues. "These products can cause acute liver injury and increase the risk for heart attack, stroke and death," remarked the regulatory agency.

■ Sexual-enhancement products that contain the same active ingredient or an analogue of the active ingredient in Pfizer's Viagra (sildenafil), Lilly's Cialis (tadalafil), and Bayer's Levitra (vardenafil). "The approved products are available only by prescription, and they should not be used by people who have certain medical conditions, such as cardiovascular disease," noted the agency.

On 31 December 2010, for example, the FDA warned consumers not to take a product called either Fruta Planta or Reduce Weight Fruta Planta because it contained sibutramine. The agency said it had received multiple reports of adverse events associated with the product's use including "several cardiac events and one death". The product is marketed by PRock Marketing online as a weight-loss aid.

Also in December, the FDA warned Americans to avoid Man Up Now capsules because they contained a variation of Viagra's active ingredient sildenafil that could dangerously lower blood pressure. The agency noted that Man Up Now, which was marketed as a dietary supplement for sexual enhancement, claimed to be "herbal" and "all natural." "Consumers may mistakenly assume the product is harmless and poses no health risk," warned the FDA.

The FDA noted that Man Up Now was distributed by Synergy Distribution through internet sites, online marketplaces, and possibly retail outlets.

Michael Levy, who is director of the Division of New Drugs and Labeling Compliance at the FDA's Center for Drug Evaluation and Research, said the labeling of these tainted products may claim they are "alternatives" to FDA-approved drugs or "legal alternatives" to anabolic steroids. "Consumers should avoid products marketed as supplements that claim to have effects similar to prescription drugs," added Levy. "Consumers should also be wary of products with labelling only in a foreign language or marketed through mass e-mails."

The FDA pointed out that companies making or distributing tainted products might receive warning letters and/or face enforcement actions such as product seizures, injunctions, and criminal prosecution. "Responsible individuals may also face criminal prosecution," the agency warned.

OTC

Switches

Stronger Bazuka set for UK general sale

A stronger salicylic acid-based wart and verruca gel will soon be available on general sale in the UK, if a switch consultation from the Medicines and Healthcare products Regulatory Agency (MHRA) is given the go-ahead.

Diomed Developments is seeking to switch Bazuka Extra Strength Gel – containing 26.0% salicylic acid – from pharmacy (P) to general-sales list (GSL) status. GSL status already applies to 12.5% salicylic acid gels in the UK.

The GSL medicine would be sold under the Bazuka Extra Strength Treatment name in pack sizes containing up to 8g.

The MHRA's ARM 72 consultation document points out that Bazuka Extra Strength Gel has been available as a P medicine for the topical treatment of warts, verrucas, corns and calluses for 10 years.

Bazuka Extra Strength Treatment will be restricted to the indication of "topical treatment of warts and verrucas" only.

ARM 72 notes that there has been an "extremely low incidence of adverse reports" since Bazuka Extra Strength Gel was launched as a P medicine. "The potential for this preparation to cause significant side-effects is low and there is no reason to suggest that the product's established safety profile will be adversely affected by making it available for self-selection," explains ARM 72.

The document adds that the reclassification would allow a greater choice for consumers and reduce the reliance on healthcare professionals.

■ Comments should be sent by 7 February 2011 to Clare Hedges, Reclassification Unit, Medicines and Healthcare products Regulatory Agency, Area 3-0, 151 Buckingham Palace Road, London SW1W 9SZ (E-mail: reclassification@mhra.gsi.gov.uk).

OTC

Research & Development

Polypill for all to begin trial

A 'polypill' that is claimed to prevent more than two-thirds of heart attacks and strokes is to be the subject of a unique clinical trial in the UK that will give the combination drug to participants only on the basis of their age.

Formulated by the Indian generics producer, Cipla, the daily polypill has four components. Three off-patent antihypertensives – losartan, hydrochlorothiazide and amlodipine – are included in the pill at half their standard doses; while off-patent simvastatin is present to reduce cholesterol.

Age only criterion in trial selection

The only criterion for the 100 or so participants in the randomised crossover trial is that they should be aged over 50. Their starting blood-pressure or cholesterol levels will not be a selection factor used by researchers at the Wolfson Institute of Preventive Medicine at Queen Mary College, University of London, UK.

Claims that the polypill will prevent more than two-thirds of heart attacks and strokes are based on the effect of each component in isolation. Their doses have been selected to maximise the efficacy of the polypill in preventing cardiovascular disease while minimising its side-effects.

Claims for such a polypill were originally propounded by Professors Nicholas Wald and Malcolm Law at the Wolfson Institute more than seven years ago. Their research indicated that a similar polypill to that now being put on trial would cut heart disease by over 80% in the over 55s as well as everyone suffering from heart disease.

In a paper published in 2003 by the *British Medical Journal* (**OTC *bulletin***, 30 June 2003, page 8), they maintained that such a daily polypill containing six components – low-dose aspirin and folic acid were the other two, which have now been dropped – would prevent 88% of heart attacks and 80% of strokes. "About one in three people would directly benefit," they stated, "each on average gaining 11-12 years of life without a heart attack or stroke – or 20 years in those aged 55-64."

Less than 10% of people were expected to have any adverse-effect symptoms, mostly due to the presence of aspirin, which is not present in the latest version of the polypill.

OTC

Pricing & Reimbursement

Switzerland will pay for complementary therapies

Five key types of complementary therapies will be reimbursed in Switzerland from next year, the country's federal department of home affairs has decided.

However, the federal department plans to conduct a thorough review into whether such treatments should be reimbursed in the longer term. This will run from 1 January 2012 – when statutory reimbursement for anthroposophic, herbal, homoeopathic and traditional Chinese medicines, as well as for neural therapy, will start – until 2017.

Announcing its decision on 12 January, the federal department said it had taken account of a referendum held in 2009 that found two-thirds of Swiss voters supported the idea of placing a commitment to complementary medicine in the country's constitution (**OTC *bulletin***, 19 June 2009, page 8).

However, the department's stance is against the advice of its own advisory body on healthcare services and reimbursement, the ELGK. This body found that complementary therapies did not fulfil the necessary criteria for statutory reimbursement.

Apparently in recognition of the ELGK's advice, the federal department said the efficacy, usefulness and economic value of complementary medicine would officially be considered "somewhat disputed" between 2012 and the end of 2017.

By the end of 2015, the department intends to draw up criteria for assessing the efficacy, usefulness and economic value. An "internationally recognised institution" will be commissioned to conduct a health technology assessment of complementary medicine. Based on that assessment, the ELGK will give a revised opinion in 2016 on whether such therapies should be reimbursed.

Certain anthroposophic, herbal and homoeopathic medicines are already included in Switzerland's reimbursement formulary, or Spezialitätenliste. However, confirmation that all complementary therapies falling under the five groups will be covered is good news for many OTC companies.

A campaigning group called Ja zur Komplementärmedizin – which included manufacturers, healthcare professionals, academics and retailers – formally requested last year that complementary medicine be brought within the scope of services provided by statutory funds (**OTC *bulletin***, 31 May 2010, page 14).

In response, the ELGK created an expert group to consider the matter (**OTC *bulletin***, 29 September 2010, page 12). However, the federal department chose to ignore its advice.

To accompany the reimbursement status, the department intends to make or encourage other changes. For example, Switzerland's medicines law is to be altered to make it easier to obtain marketing authorisations for complementary and traditional medicines.

Two national diplomas – one each for complementary and alternative medicine – are to be created, while the department will also encourage Swiss cantons to set up professorial chairs in complementary medicine. Furthermore, the department wants federal funds to be made available to research into complementary therapies.

OTC

IN BRIEF

■ **REESE** Pharmaceutical Company has voluntarily **recalled** one lot of OTC cold products in the US because of mislabelling. The decongestant tablets contain 325mg acetaminophen, 5mg phenylephrine and 2mg chlorpheniramine maleate, but the labelling said they contained only 200mg guaifenesin.

■ **BAUSCH & LOMB** has voluntarily recalled its **Soothe Xtra Hydration** eye drops in the US following "a small number of consumer reports citing the presence of possible foreign matter in the tip of the bottles". The eye health specialist said initial tests had identified the matter as mould. Although there had been no adverse events reported in connection with the mould, said Bausch & Lomb, eye drops that became contaminated after being opened might cause eye infections. The company added that it would decide on the product's future distribution at the end of its ongoing investigation, which could last several months. The eye drops were launched in April of last year.

OTC

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DEALS TO DRIVE YOUR BUSINESS

Distribution

Leclerc reprises attack on France's distribution rules

Supermarket giant Leclerc has reiterated its opposition to France's pharmacy monopoly on the sale of non-prescription medicines by publishing a survey that highlights wide discrepancies between the prices of 'free access' medicines across the country.

The retailer has repeatedly campaigned for the right to sell certain non-prescription medicines through its parapharmacies.

Leclerc's survey, carried out by market researcher BIPE, compared the prices of 30 free-access medicines across a range of therapeutic categories. Prices were monitored at 118 pharmacies in five different regions of France over a 10-day period in December.

According to Leclerc, the free-access law, allowing self-selection displays for certain non-prescription medicines, should have encouraged competition between pharmacies and reduced the differences in prices of these medicines.

Instead, the survey found that the average highest price of all medicines covered by the survey was more than twice the average lowest price. This figure rose to more than three-times for certain therapeutic categories.

The findings were in line with those of another recent survey by the French consumer interest group Familles Rurales. Focusing on 11 popular medicines available through the free-access scheme, the survey compared prices in 72 pharmacies across 32 of France's regional départements in June 2010.

Prices of a 12-pack of Janssen's Imodium-caps capsules varied between €1.99 and €5.90, whilst a 2g tube of GlaxoSmithKline's Activir 5% cream could cost as little as €3.40 or as much as €9.60, the survey found. A 30-pack of McNeil's Dacryum eyewash solution could cost between €2.51 and €6.80, whilst the price of 20 Nurofen 200mg coated tablets from Reckitt Benckiser varied between €1.78 and €4.60.

Last year, French health insurer Mutualité Française called the state of free-access pricing a "jungle" and claimed that the prices of self-selection medicines seemed to be getting completely out of control (**OTC *bulletin***, 29 September 2010, page 10).

Free-access medicines could often not be found in dedicated displays, Familles Rurales said, with only one of the 11 medicines surveyed found to be available for self-selection in more than a third of pharmacies surveyed. The medicines were more often situated behind the counter or were not on display at all, the group said. However, around six out of every 10 pharmacies surveyed had dedicated a section of the pharmacy to free-access medicines.

Prices of medicines available in free-access displays were always visible to customers, Familles Rurales noted. Around half of free-access medicines had prices marked on the box, whilst prices were displayed on the shelf for the rest.

Supermarket chain Leclerc is running another consumer campaign demanding the right to sell some non-prescription medicines in its parapharmacies

Meanwhile, Leclerc said that compared to its previous survey in 2009, the overall average price had dropped by just 0.4%.

The Leclerc survey also suggested prices rose sharply when a product was dereimbursed. A magnesium-based product dereimbursed in July from a reimbursement rate of 35% had seen its average price rise by 46% to €4.69, Leclerc said. This had in effect more than doubled the cost to the consumer, the firm pointed out, because €1.13 of the earlier price of €3.22 would have previously been reimbursed.

Leclerc has also launched an advertising campaign to raise consumer awareness of the potential price discrepancies and demanding that the retailer should be able to sell certain medicines through its parapharmacies. These do not have the legal status of a pharmacy but are managed by pharmacists and sell food supplements and other health and beauty products.

An advertisement showing a cartoon of a man with a capsule stuck in his throat tells consumers: "You might have paid three-times too much for this medicine. Isn't that hard to swallow?" Summarising the results of the survey, the advertisement also claims that one in three people in France have given up buying non-reimbursable medicines due to their high prices.

Leclerc's latest campaign follows similar advertisements based on the same theme. Last year, a French court of appeal allowed the company to resume a campaign arguing that it should be able to stimulate price competition by selling a selection of medicines through its parapharmacies (**OTC *bulletin***, 16 April 2010, page 18). This echoed a similar Leclerc initiative during 2008 (**OTC *bulletin***, 29 April 2008, page 18).

OTC

Switches

Germany postpones rizatriptan decision

A decision on whether to switch the migraine medicine rizatriptan from prescription-only to non-prescription status in Germany has been postponed until a later meeting of the country's Expert Committee for Prescription.

A switch for rizatriptan – the active ingredient in Merck, Sharp & Dohme's Maxalt brand – would allow it to compete in Germany with GlaxoSmithKline Consumer Healthcare's Formigran (naratriptan) brand, which was switched more than four years ago (**OTC *bulletin***, 14 April 2006, page 1).

Almotriptan and sumatriptan have also been proposed for non-prescription status in Germany, but the switches have been held up by legal concerns about labelling raised by the federal institute for drugs and medical devices, BfArM.

Meeting at BfArM's premises on 11 January, the Expert Committee for Prescription proposed a change for orlistat – the active ingredient of GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine – that would effectively give all 60mg orlistat products, including potential generics, non-prescription status in Germany.

If approved by Germany's upper house of parliament, the Bundesrat, then the proposed changes are likely to come into effect from 1 July this year.

The Expert Committee voted against an application to raise the non-prescription limit for vitamin D3 products from 1,000 to 2,000 international units per day.

OTC

Line Extensions

Nicorette gains a mouth spray

A nicotine mouth spray is set to join McNeil Products' Nicorette range of nicotine-replacement therapy (NRT) products in the UK.

The general-sales list (GSL) medicine called Nicorette QuickMist 1mg Mouthspray is on the latest list of marketing authorisations published by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

The mouth spray will join the existing Nicorette range, which includes Gum, Icy White Gum, Inhalator, Invisipatch, Microtab and Nasal Spray variants.

McNeil recently extended its Nicorette Inhalator with black and blue mouthpieces to accompany the original white version (**OTC *bulletin***, 29 October 2010, page 15).

OTC

Hyaluronic acid forms the basis of Bausch & Lomb's BloXaphte, a new range of pharmacy-exclusive treatments for mouth ulcers in Germany.

The hyaluronic acid is said to create a protective film over aphthous ulcers, thereby promoting healing and reducing pain.

The absence of alcohol in BloXaphte's formulations avoids any burning sensation in the mouth, Bausch & Lomb claims.

A peppermint and aniseed-flavoured mouthwash that is sugar-free contains 25mg hyaluronic acid per 100ml bottle. The medical device is intended for both prophylactic use and treatment in adults and children.

The BloXaphte range also includes a 30mg/100ml mouth spray, while children aged 30 months and above are the target users of a bubblegum-flavoured 240mg/100g gel.

Recommended retail prices for BloXaphte – which was recently extended with an adult gel in France (OTC *bulletin*, 29 September 2010, page 20) – are €9.90 for each delivery form.

Launch trade-press advertising (pictured above) promises a large-scale consumer-press advertising campaign. There is also a brand website at www.bloxaphte.de.

Bausch & Lomb recently introduced eye drops containing hyaluronic acid in Germany under the brand name Artelac Rebalance (OTC *bulletin*, 16 December 2010, page 15).

OTC

Launches

Reckitt Benckiser claims Nuromol is a first in the UK

Reckitt Benckiser said its new combination pain reliever Nuromol would be available from all pharmacies in the UK from March of this year.

Currently sold exclusively at Boots, Nuromol is claimed by the company to be "the first pharmacy-only (P) fixed-dose combination of ibuprofen and paracetamol".

Reckitt Benckiser pointed out that the tablets – each containing 200mg ibuprofen and 500mg paracetamol – were formulated using Synchro-tech technology. "This releases both ibuprofen and paracetamol simultaneously," the company explained, "ensuring the active ingredients deliver a combination effect."

Nuromol comes in packs of 12 or 24 tablets. A strapline on the packaging claims the product provides "Double action pain relief".

Packaging for Nuromol is predominantly gold coloured, and carries the target logo associated with the company's Nurofen line of ibuprofen-containing pain relievers.

Nuromol is indicated for relief of backache, dental pain, headache, migraine, period pain, rheumatic and muscular pain, and pain of non-serious arthritic conditions, as well as cold and flu symptoms, and sore throat and fever.

Reckitt Benckiser's marketing for Nuromol, including the brand's website, is in line with that for Nurofen

Reckitt Benckiser is currently backing Nuromol with point-of-sale material in Boots. A website for the brand at www.nuromol.co.uk will be launched soon.

In addition, Boots is highlighting Nuromol in television advertising.

Nuromol is suitable for adults aged 18 years and over. Consumers should take a maximum of two tablets up to three times a day, and should leave at least six hours between doses.

OTC

A range of traditional herbal medicines has been launched in the UK by Higher Nature.

The 10-strong range consists of products containing black cohosh, devil's claw, echinacea, feverfew, milk thistle, passionflower, pelargonium, rhodiola, St John's wort or valerian.

Higher Nature is initially backing the newcomers with public relations activity and a consumer website at www.highernature.co.uk.

The products – which are available from the website, independent health stores, or by calling 0800 458 4747 – have recommended retail selling prices ranging from £6.70 (€8.05) to £16.75.

The 10 products have been registered using the simplified procedure introduced by European Union Directive 2004/24/EC.

OTC

Marketing Campaigns

GSK backs Alli with global advertising

GlaxoSmithKline Consumer Healthcare is backing Alli with a new global advertising campaign which urges slimmers to eat right, take exercise and use the weight-loss medicine.

The company noted that the "How healthy works" campaign, which was the first-ever global advertising for Alli, was running across Europe and in the US.

The campaign includes two television commercials from the agency TBWA\Chiat\Day: one featuring a croissant, and the other a cup of latte. A spokesperson for GlaxoSmithKline said the advertising had been adapted to meet the needs of different countries.

In the US, the croissant creative, which lasts for 30 seconds, begins with a woman sitting in an outdoor café who opts for a bread roll rather than a croissant. "Alli works when you work," explains a voiceover, "so if you go from a croissant with butter to a wholewheat roll with olive oil, you'll go from roughly 16 grammes of fat to about six. Take Alli with that, and you're down to 4.5."

A pack of Alli appears, as the voiceover continues, "Alli helps you reach a healthier weight".

The woman is then seen walking inside a giant hamster wheel, which is revealed to be one cog in a system of three. The other two are an apple and some Alli capsules. "When you get active, eat right, and take Alli," explains the voiceover, "Alli will block about 25% of the fat you eat. And for every two pounds you work to lose, Alli can help you lose one more."

The commercial ends with a pack of Alli, while the voiceover explains that the medicine is "FDA approved". "How healthy works," continues the voiceover, urging consumers to "learn more at myalli.com".

The second commercial in the US, which runs for 15 seconds, is similar to the first, but features a man who opts for a small low-fat latte rather than a large full-fat one.

GlaxoSmithKline is also backing Alli in the US with consumer-press advertising, shopper-marketing activity, and public relations.

In the UK, meanwhile, television advertising explains that Alli is "clinically proven to aid weight-loss".

Kerry O'Callaghan – vice-president of the Alli Future Team within GlaxoSmithKline's Future Group – said the campaign's key message was that "healthy works" when you eat right, are active and take Alli. "The notion of these three elements working together to help people achieve and maintain their healthy weight is being played out by enlightening people with facts about how their bodies, food and exercise can all help – or hinder – their quest for achieving their healthy weight," added O'Callaghan.

In 2009, Alli became the first non-prescription medicine to be licensed through the European Union's centralised procedure (**OTC *bulletin***, 29 January 2009, page 1). The company rapidly introduced the weight-loss medicine in virtually all 27 member states of the European Union (**OTC *bulletin***, 30 April 2009, page 22).

New television commercials for Alli explain how the weight-loss medicine works in conjunction with exercise and diet to help slimmers lose weight

Launch consumer advertising for Alli in Europe, which included a television and press campaign, focused on the relationship between a woman and her scales (**OTC *bulletin***, 30 April 2009, page 23).

When GlaxoSmithKline released its results for the third quarter of 2010, the company said Alli's sales had fallen in both Europe and the US (**OTC *bulletin***, 29 October 2010, page 6).

OTC

Advertising Complaints

P&G withdraws Prilosec OTC claim in the US

Procter & Gamble has agreed to remove a claim for its Prilosec OTC heartburn medicine from promotional material aimed at healthcare professionals in the US.

Rival heartburn medicine supplier Novartis Consumer Health lodged a complaint with the National Advertising Division of the Council of Better Business Bureaus (NAD) about several claims made in the material.

The NAD ruled that Procter & Gamble had provided "reasonable support" for claims that Prilosec OTC offered "superior acid control" compared with Novartis' Prevacid 24HR heartburn medicine.

However, it rejected the claim that "Only 10% of Prevacid prescriptions are 15mg" while "Prilosec OTC contains the same medicine at the same dose as its leading Rx formulation".

The claim, which was accompanied by the strapline "Heartburn gone.....power on", appeared separately to the other claims in a context that did not reference acid control, the NAD pointed out.

"Although literally true," said the NAD, "the claim, in a comparative context that concerned the elimination of heartburn symptoms, could be understood to mean that Prilosec OTC is superior to Prevacid 24HR at relieving heartburn symptoms in frequent heartburn sufferers."

The NAD said it had seen no "direct scientific evidence" to support this and recommended Procter & Gamble discontinued the claim.

Responding to the decision, Procter & Gamble said: "While we are disappointed that the NAD found that this claim, in the context of the "Heartburn gone.....power on" tagline, implies superior symptom relief, we are confident that the professionals to whom the advertising was directed do not take away such a message".

Procter & Gamble added it would discontinue the claim and take the NAD's decision into account in future advertising.

The promotional material is part of a wider campaign for Prilosec OTC that includes television and digital advertising based on the theme "Heartburn gone.....power on" (**OTC *bulletin***, 16 November 2010, page 21).

Launched in 2003, Prilosec OTC contains the active ingredient 20mg omeprazole (**OTC *bulletin***, 30 June 2003, page 13).

Novartis introduced Prevacid 24HR containing 15mg lansoprazole in 2009 (**OTC *bulletin***, 16 November 2009, page 1).

OTC

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Launches

Teva tackles French pain with new diclofenac spray

Two rugby players grappling with each other during a tackle is the central image of Teva's advertising for its new pain-relieving spray in France.

Pharmacy-press advertising for the diclofenac sodium-based Tevalgiespray depicts the player who is being tackled spraying himself with the product as he grimaces in pain.

Teva's advertising claims that the 4% diclofenac spray acts quickly and effectively due to its strong concentration and "innovative formulation". The product's effects are measurable within 30 minutes of use, the company claims.

Imitating the sound of the spray, the advertisement's slogan states "Dites pscchhhittt!!! à la douleur", or "Say pscchhhittt!!! to pain". The advertisement recommends Tevalgiespray for treating any pain or inflammation caused by day-to-day activities or sport. The product is also portable and easy to apply, the advertisement notes.

Suitable for adults and children over 15 years of age, Tevalgiespray is available in a 15ml or 30ml bottle. The product should be sprayed four or five times per use, up to three times a day. A doctor should be consulted if the pain persists for more than seven days.

Teva is backing its new Tevalgiespray in France with pharmacy-press advertising

OTC

Marketing Campaigns

Herbalife moves in US, Russia and India

Herbalife has set up a website to educate consumers, government agencies and scientists about "the evolving areas of foods for health and dietary supplements" in the US.

The Herbalife Nutrition Institute, which is located at www.herbalifenutritioninstitute.com, is said by the US-based direct-selling specialist to "encourage and support research and education on the relationship between good health, balanced nutrition and a healthy active life".

The institute would be headed by a "prestigious international group of leaders in nutrition science and related areas of expertise", Herbalife pointed out, who would "contribute original articles and commentary each month on a range of timely issues in nutrition".

Noting that nutrition was a rapidly changing science, Herbalife added that the institute would allow people to keep up with the latest research, and sponsor scientific conferences and symposia.

In a separate development, Herbalife is now the official nutrition sponsor of Russia's Spartak Moscow football club.

The deal, which will extend throughout the club's 2011-2012 seasons, will see Herbalife's branding appear on the players' jerseys, as well as on the club's stadium, bus, website and printed materials for home games. The US-based direct-selling specialist will also support the players with specific nutrition plans.

In addition, Herbalife is sponsoring Bollywood actress Mugdha Godse, who will front its skincare line in India. Godse starred in film director Madhur Bhandarkar's movie *Fashion*.

The Herbalife Nutrition Institute website is "dedicated to promoting excellence in the field of nutrition"

OTC

Federal Trade Commission

Vitamin claims cost NBTY US$2.1 million

NBTY and two of its subsidiaries have agreed to refund consumers US$2.1 million (€1.6 million) to settle charges that they made "deceptive" and "unsupported" health claims about their Disney and Marvel Heroes dietary supplements in the US.

According to the Federal Trade Commission (FTC), NBTY, NatureSmart and Rexall Sundown had represented on the product packaging and in print advertising that the children's multivitamin gummies and tablets contained "a significant amount of DHA". In reality, however, the products allegedly only contained a trace of DHA.

The companies had "touted the purported health benefits of 100 milligrammes of DHA", explained the FTC, and claimed that "a daily serving of the products promotes healthy brain and eye development in children".

Describing the claims as "false and unproven", the FTC pointed out that the multivitamins, which feature characters including the Disney Princesses, Spider-Man and Winnie the Pooh, actually only provided 0.1mg DHA.

The products are sold at stores including CVS Pharmacy, Kmart, Kroger, Meijer, Rite Aid, Target and Walmart, as well as online retailers such as www.drugstore.com.

OTC

Altacor has repackaged its Clinitas Hydrate eye drops in the UK in a pink and blue pack that is said by the company to be "easier to spot" in stores.

Straplines on the packaging highlight that the "Lubricating and moisturising eye drop" contains 0.2% carbomer and is "For everyday ocular use".

Clinitas Hydrate comes in a 10g tube that retails at £3.99 (€4.79).

Altacor updated its Clinitas Soothe dry-eye relief drops with purple and blue packaging last year (OTC *bulletin*, 16 April 2010, page 15).

OTC

Generics specialist Hexal says its ibuprofen suspension offers up to a 10% discount compared with Reckitt Benckiser's Nurofen Junior Fiebersaft brand in Germany.

IbuHexal Kindersaft comes in 100mg/5ml and 200mg/5ml strengths of the strawberry-flavoured ibuprofen suspension that is free from lactose, sugar and artificial colourings.

Recommended retail selling prices for the reimbursable, pharmacy-only medicines are €3.33 for the 2% strength and €4.59 for the 4% version.

Packs – which contain a dosing syringe – carry a picture of a jester. The same image appears in trade-press advertising (pictured above) for the newcomers, which highlights the 10% price difference.

OTC

IN BRIEF

■ **PADMA** – the Swiss natural remedies specialist – has obtained a marketing authorisation in its domestic market for **Padma Digestin**, a Tibetan traditional medicine containing 204mg pomegranate-seed powder (*Punicae granati seminis pulvis*) per capsule. The Swiss regulatory agency Swissmedic said pomegranate seeds were traditionally used in Tibetan medicine to alleviate digestive complaints.

■ **SEVEN SEAS** is backing its **Pure Cod Liver Oil** food supplements with a public relations campaign highlighting that consumers are seeking ongoing nutritional advice from UK pharmacy staff. Research commissioned by the company found that over a quarter of consumers would become more health conscious following advice from their pharmacist, while one in 10 wanted to "treat their body like a temple" but did not know how. Seven Seas noted that its "Your body is a temple" television commercial (**OTC *bulletin***, 15 October 2010, page 17) would return to screens from 14 February.

OTC

Marketing Campaigns

Actavis backs Cymex with a "lip-smacking" campaign

Actavis is backing its Cymex cold-sore products in the UK with a £0.85 million (€1.00 million) marketing campaign this winter.

The firm said the "lip-smacking" campaign included consumer-press advertising, sponsorship of ITV's *The Only Way is Essex* reality television show, and public relations activity.

A pair of luscious red lips puckered up for a kiss are used to grab attention in the consumer-press advertisement, which carries the strapline "Help kiss your cold sore goodbye". Above the upper lip, where cold sores often appear, are the words "Cymex was here".

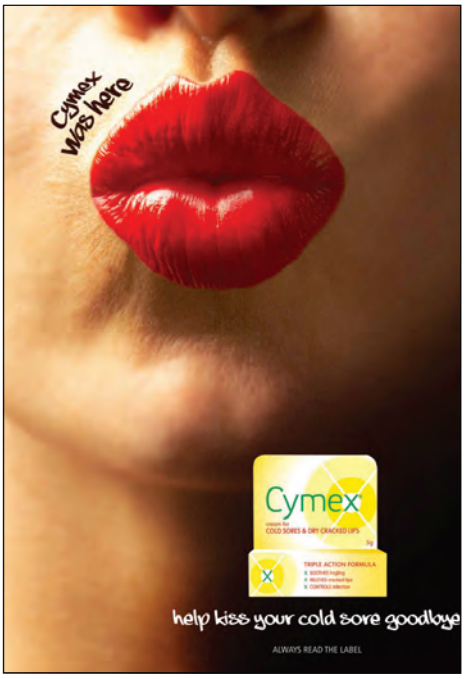
Actavis said the single-page advertisement was running in a range of women's weekly and monthly magazines including *Closer*, *Company*, *Cosmopolitan*, *Glamour* and *Reveal*.

Spots during *The Only Way is Essex*

The sponsorship deal, which commenced in October, sees a number of spots appear during commercial breaks in *The Only Way is Essex*.

One example is based around a girl dancing in a nightclub, who kisses the screen and leaves behind an imprint of her lips in bright red lipstick. "*The Only Way is Essex*. Sponsored by Cymex, cream for cold sores," says a voiceover. The creative ends with a pack of Cymex cream and the tagline "Cream for cold sores".

Meanwhile, public relations activity includes competitions in the women's magazines *Now* and *OK! Hot Stars*, offering readers the chance to win a luxury break for two.



"Help kiss your cold sore goodbye" is the theme of Actavis' press advertising for Cymex in the UK

In addition, the company has updated its website at www.cymex.co.uk to include elements of the campaign, and is supporting the brand with educational materials for pharmacists.

The Cymex range comprises Cymex Cream with 1% urea, 9% dimeticone, 0.5% cetrimide and 0.1% chlorocresol, as well as Cymex Ultra Cream containing 5% aciclovir. Both are general-sales list medicines.

OTC

Marketing Campaigns

Panadol calls for cabinet clearout

GlaxoSmithKline Consumer Healthcare is backing its Panadol Advance pain reliever with a public relations campaign urging Britons to "cough up their out of date medicines".

The company is calling for a "national medicine cabinet amnesty" after research found that more than a fifth of consumers only cleared out their cabinets once every five years or less, and almost one in 10 never did.

GlaxoSmithKline recommends "a list of everyday medicines that should be kept handy during the winter months" including pain, fever and headache relievers like paracetamol.

Noting that Panadol Advance contained paracetamol, the company said it was "gentle on the stomach and suitable for most people in the majority of situations". "What's more," added GlaxoSmithKline, "the unique Optizorb technology in Panadol Advance enables it to disperse in the stomach up to five times faster than standard paracetamol."

Other recommended products include medicines for coughs and sore throats, as well as treatments for runny and blocked noses, dry, cracked skin or lips, and indigestion.

OTC

FEBRUARY

8 February

■ **Introduction to Medicines Law**

Bonn, Germany

A one-day meeting organised by Germany's medicines manufacturers' association, the BAH, and conducted in German.

***Contact**: BAH.*
Tel: +49 228 957 45 0.
Fax: +49 228 957 45 90.
E-mail: bah@bah-bonn.de.
Website: www.bah-bonn.de.

10 February

■ **The Nutrition and Health Claims Regulation**

Brussels, Belgium

'Dealing with the present – planning for the future' is the theme of this one-day workshop from European Advisory Services (EAS).

***Contact**: Cindy Garcet, EAS.*
Tel: +32 2 218 14 70.
Fax: +32 2 219 73 42.
E-mail: workshop@eas.eu.
Website: www.eas.eu.

10 February

■ **The Pharma Summit 2011**

London, UK

'Reinventing pharma for a new generation' is the theme of this one-day meeting organised by the Economist Conferences.

***Contact**: Economist Conferences.*
Tel: +44 20 7576 8118.
Fax: +44 20 7576 8472.
E-mail: weurope_customerservice@economist.com.
Website: www.economistconferences.com.

15-17 February

■ **CIS Pharmaceutical Forum**

Moscow, Russia

Pharmaceutical markets covered by this three-day conference include Armenia, Belarus, Kazkhstan, Russia, Turkmenistan, the Ukraine and Uzbekistan.

***Contact**: Adam Smith Conferences.*
Tel: +44 20 7017 7444.
Fax: +44 20 7017 7447.
E-mail: events@adamsmithconferences.com.
Website: www.cispharmaforum.com.

17-18 February

■ **Pharmaceutical Regulatory Affairs in the Middle East**

London, UK

Countries to be discussed at this two-day conference include Bahrain, Iran, Israel, Saudi Arabia, Syria and Yemen.

***Contact:** Management Forum.*
Tel: +44 1483 730071.
Fax: +44 1483 730008.
E-mail: registrations@management-forum.co.uk.
Website: www.management-forum.co.uk.

22-23 February

■ **Variations Regulation**

Bonn, Germany

Peter Bachmann and Cornelia Nopitsch-Mai from Germany's federal institute for drugs and medical devices, BfArM will speak at this two-day conference. Each day can be booked separately.

***Contact**: Henriette Wolf-Klein, Forum Institut für Management.*
Tel: +49 6221 500 680.
Fax: +49 6221 500 555.
E-mail: h.wolf-klein@forum-institut.de.
Website: www.forum-institut.com.

24 February

■ **Hot Topics in Advertising**

This is a one-day event organised by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

***Contact**: MHRA.*
Tel: +44 20 3080 6903.
E-mail: mhraconferences@mhra.gsi.gov.uk.
Website: www.mhra.gov.uk.

28 February-1 March

■ **EuroPLX 45**

Lisbon, Portugal

A two-day partnering and licensing forum focusing on OTC medicines, nutraceuticals, branded prescription drugs and generics.

***Contact**: RauCon.*
Tel: +49 6222 9807 0.
Fax: +49 6222 9807 77.
E-mail: meetyou@europlx.com.
Website: www.raucon.com.

MARCH

10-12 March

■ **CHPA Annual Executive Conference**

Aventura, Florida, US

The Annual Meeting of the US Consumer Healthcare Products Association (CHPA) is only open to members.

***Contact:** Phyllis Taylor, CHPA.*
Tel: +1 202 429 9260.
Fax: +1 202 223 6835.
E-mail: ptaylor@chpa-info.org.
Website: www.chpa-info.org.

1-2 February

■ **What Regulation for Food Supplements and Herbal Medicinal Products in Europe?**

Brussels, Belgium

This two-day meeting is organised by the Association of the European Self-Medication Industry, the AESGP.

There will be sessions entitled: 'Implementation/enforcement of the nutrition and health claims regulation'; and 'A single market for herbal medicines in Europe?'.

Speakers will include: Dagmar Roth-Behrendt of the European Parliament; Basil Mathioudakis and Paola Testori-Coggi of the European Commission; Vittorio Silano of the European Food Safety Authority (EFSA); and Ioanna Chinou of the European Medicines Agency's Committee on Herbal Medicinal Products (HMPC).

***Contact**: AESGP.*
Tel: +32 2 735 51 30. Fax: +32 2 735 52 22. E-mail: l.gits@aesgp.be.
Website: www.aesgp.be.

17 March

■ **Phytopharmaceuticals in Europe**

Bonn, Germany

A one-day meeting organised by Germany's medicines manufacturers' association, the BAH. The meeting will be conducted in the German language.

***Contact**: BAH.*
Tel: +49 228 957 45 0.
Fax: +49 228 957 45 90.
E-mail: bah@bah-bonn.de.
Website: www.bah-bonn.de.

17 March

■ **Variations to Marketing Authorisations in the European Union**

London, UK

This one-day meeting will provide an update on mutual recognition, decentralised, centralised and national variations.

***Contact:** Management Forum.*
Tel: +44 1483 730071.
Fax: +44 1483 730008.
E-mail: registrations@management-forum.co.uk.
Website: www.management-forum.co.uk.

22-23 March

■ **Regulatory Affairs in India and China**

Frankfurt, Germany

Day one of this two-day seminar will discuss regulatory affairs, clinical trial regulation and variations in India, while day two will focus on China. Each day can be booked separately.

***Contact**: Henriette Wolf-Klein, Forum Institut für Management.*
Tel: +49 6221 500 680.
Fax: +49 6221 500 555.
E-mail: h.wolf-klein@forum-institut.de.
Website: www.forum-institut.com.

28-30 March

■ **DIA Annual EuroMeeting**

Geneva, Switzerland

A three-day conference organised by the Drug Information Association (DIA). Wider access including generics and self-care medicines will be one of the 15 parallel sessions at the conference.

***Contact:** DIA European Office.*
Tel: +41 61 225 51 51.
Fax: +41 61 225 51 52.
E-mail: diaeurope@diaeurope.org.
Website: www.diahome.org.

APRIL

11 & 12-13 April

■ **Regulatory Affairs in Central and Eastern Europe**

Prague, Czech Republic

A pre-conference symposium on 'Regulatory affairs in the CIS region' will accompany this two-day conference.

***Contact:** Informa UK.*
Tel: +44 20 7017 7481.
Fax: +44 20 7017 7823.
E-mail: registrations@informa-ls.com.
Website: www.informa-ls.org.

JUNE

8-10 June

■ **47th AESGP Annual Meeting**

Rome, Italy

The Annual Meeting of the Association of the European Self-Medication Industry, the AESGP. More details will be available soon.

***Contact:** AESGP.*
Tel: +32 2 735 51 30.
Fax: +32 2 735 52 22.
E-mail: l.gits@aesgp.be.
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Perrigo prepares to expand in Europe

US-based Perrigo intends to become a significant player in continental Europe by extending its portfolio of OTC products into the region through partnerships and acquisitions. Deborah Wilkes reports on the growth strategy of the company that describes itself as "the world's largest supplier of store-brand healthcare products".

Store-brand specialist Perrigo is busy preparing the way for its UK portfolio of OTC products, which includes more than 130 licensed medicines, to be launched in continental Europe. "Our main focus initially is on a selection of our most popular products," explains Cass Khan, who is head of European business development at Perrigo UK. "The list of non-prescription medicines that we aim to license in Europe over the next two years includes allergy medicines, analgesics, cold and flu combination products, gastrointestinal remedies and nicotine-replacement therapy products."

Using Europe's centralised procedure

Khan points out that the company's regulatory strategy encompasses the European Union's decentralised and mutual-recognition licensing procedures for medicines as well as the medical device registration procedure. In addition, the ambitious programme is making use of Europe's centralised procedure for medicines. To date, only two non-prescription medicines have been licensed via the centralised procedure: GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine containing orlistat and Nycomed's pantoprazole tablets under several brand names.

Khan points out that Perrigo's first OTC offering for sale across Europe is a medical device for relieving heartburn that is similar to existing medicines for the condition. Describing Soothing Heartburn Relief Tablets as a "unique opportunity", he says it can be "launched easily across the European Union because it is a medical device".

A number of major pharmacy and grocery retailers in the UK have already launched store-brand versions of the Soothing Heartburn Relief Tablets. Khan says the medical device is available for marketing throughout the entire European Union.

The tablets main ingredients are sodium alginate, calcium carbonate and sodium bicarbonate, notes Khan, and they are available with strengths of either 250mg or 500mg sodium alginate. Perrigo can supply packs containing 8, 12, 16 or 32 tablets, he adds, and plans to expand the range within the next few months.

Packaging highlights that the tablets have a "cool mint flavour", continues Khan, and carries the claims "Fast acting", "Long lasting" and "Sugar free". He also notes that the product is suitable for vegetarians and pregnant women.

Khan says Perrigo is seeking retailers and branded companies to distribute the Soothing Heartburn Relief Tablets – as well as the company's other OTC products – in continental Europe. "Our target clientele comprises pharmacies, drugstores and branded companies," he states, adding that "both national and international companies can successfully develop and expand their brands using Perrigo's extensive product portfolio".

He highlights the importance of "building long-term mutually-beneficial relationships" with partners.

Acquisitions are also on the agenda for Perrigo in Europe. "Our European expansion strategy has two elements," says Phil Thompson, Perrigo UK's business development director. "In addition to the organic element, whereby we will register and then market our existing products in new countries, there is an inorganic element, whereby we will seek out acquisition opportunities to establish a presence for Perrigo in appropriate countries."

"The organic strategy does not depend on acquisitions for its success, but the right transactions would accelerate and strengthen the development of Perrigo's 'Quality, Affordable Healthcare' business proposition in the region," comments Thompson, adding: "Ideally, target companies would already exhibit Perrigo's core values of quality, customer service, innovation, low cost and people."

To make European expansion more manageable, Perrigo is initially focusing on a "select" group of countries in eastern and western Europe including Russia.

Expanding into continental Europe is in line with the growth strategy outlined by US-based Perrigo in October 2009. The company, which claims to be the "world's largest supplier of store-brand healthcare products", said at that time that it planned to extend its store-brand business into the few remaining areas of the US consumer healthcare market where it had not already made its mark. Furthermore, Perrigo pointed out that it intended to "identify areas of the world that represented fertile ground for store brands" (**OTC *bulletin***, 16 October 2009, page 8).

Perrigo had just reported annual sales up by 16% to US$2.01 billion (€1.50 billion) in the year ended 27 June 2009. More than 80% of this figure came from the Consumer Healthcare division, which had pushed its turnover up by 23% to US$1.64 billion (**OTC *bulletin***, 31 August 2009, page 10).

Growth boosted by acquisitions

Consumer Healthcare's sales growth included US$140 million from acquisitions made in the 18 months leading up to 27 June 2009. In the UK, Perrigo had bought Galpharm Healthcare in January 2008 and Brunel Healthcare's OTC medicines business in June 2008 (**OTC *bulletin***, 25 January 2008, page 1; **OTC *bulletin***, 30 June 2008, page 7). In the US, the firm had acquired JB Laboratories in September 2008 and Unico Holdings in November (**OTC *bulletin***, 29 September 2008, page 2; **OTC *bulletin***, 28 November 2008, page 10). And in Mexico, it had snapped up Laboratorios Diba in October 2008 (**OTC *bulletin***, 17 October 2008, page 3).

In the year ended 27 June 2009, the vast majority of sales within the Consumer Healthcare division, 88%, were generated in the US.

Business	Annual sales (US$ millions)	Change (%)	Operating income (US$ millions)	Change (%)
Consumer Healthcare	1,833	+12	305	+30
Prescription Pharmaceuticals	238	+45	50	+73
Active Pharmaceutical Ingredients	139	+2	15	–
Other	59	-13	-33	–
Total Perrigo*	**2,269**	**+13**	**336**	**+36**

* Excluding the discontinued Israel Consumer Products business

Figure 1: Perrigo's sales and operating income in the year ended 26 June 2010 (Source – Perrigo)

Around 8% were produced in the UK, with the other 4% coming from Canada and Mexico.

Discussing new geographic markets, Joseph Papa – Perrigo's chairman, president and chief executive officer – identified Europe and South America as leading candidates for expansion. He said the company could take its portfolio of approved products and formulations to other markets, notably in Europe.

Last year, Perrigo's growth strategy took it into a new region when it acquired Australia's Orion Laboratories for approximately US$48 million in cash. The deal gave Perrigo's Consumer Healthcare division its first presence outside of its established markets of North America, Mexico and the UK (**OTC *bulletin***, 17 March 2010, page 3).

Described by Perrigo as a "leading supplier of OTC store-brand pharmaceutical products in Australia and New Zealand", Orion was expected to add around US$30 million annually to sales. Privately-held Orion also manufactured and distributed pharmaceutical products supplied to hospitals.

In terms of product categories, Consumer Healthcare's sales in the year ended 27 June 2009 came from 17 categories in the OTC medicines and nutritional products sectors. Perrigo claimed at the time to hold a 70% share of the OTC store-brand market and a 25% share of the nutritional store-brand market in the US.

As part of its growth strategy, Perrigo said it had a large pipeline of products ready to enter the US market. In October 2009, for example, the company inroduced store-brand versions of Merck Consumer Care's OTC laxative MiraLAX (polyethylene glycol 3350). It noted that MiraLAX' sales were approximately US$200 million in the year ended 28 August 2009 (**OTC *bulletin***, 16 October 2009, page 17).

In June 2010, it introduced store-brand versions of Johnson & Johnson's Monistat-1 Combination Pack for treating vaginal thrush with 180 days of generic exclusivity secured under the Hatch-Waxman legislation encouraging patent challenges (**OTC *bulletin***, 11 June 2010, page 15).

Perrigo's first OTC product offering across Europe is a medical device for heartburn relief

Perrigo aims to build "long-term, mutually-beneficial relationships" with retailers and branded healthcare companies across Europe, says Cass Khan, head of European business development at Perrigo UK

Phil Thompson, business development director at Perrigo UK, points out that a dedicated business development and regulatory team has been set up to drive the European expansion

A few months after this, Perrigo launched a store-brand version of Bayer HealthCare's Aleve Liquid Gels OTC analgesic. The store-brand specialist believed it was the first company to offer a generic OTC version of the softgels containing 220mg naproxen sodium (**OTC *bulletin***, 30 November 2010, page 12).

Perrigo is anticipating the switch of Sanofi-Aventis' allergy medicine Allegra (fexofenadine hydrochloride) from prescription-only to OTC status in the US in "early 2011". Perrigo acquired the exclusive rights to sell and market store-brand OTC Allegra and Allegra-D from Teva Pharmaceutical Industries in July (**OTC *bulletin***, 30 July 2010, page 19).

Targeting new consumer categories

Setting out the growth strategy, Perrigo said it was evaluating nine new consumer categories with a combined retail market value of US$16.7 billion in the US. These adjacent consumer categories included adult incontinence, eyecare, family planning, first-aid accessories, home diagnostic test kits, and infant nutrition.

Since the growth strategy was outlined, Perrigo has entered one of these adjacent consumer categories – infant nutrition – by paying US$808 million in cash for PBM Holdings. Described by Perrigo as a leading manufacturer and distributor of store-brand infant formulas and baby foods, PBM generated sales of approximately US$265 million in 2009 (**OTC *bulletin***, 31 March 2010, page 1).

Approximately 20% of PBM's sales were generated outside the US, said Perrigo, noting that PBM's products were available in Canada, China and Mexico as well as the US.

Acquiring PBM would give Perrigo store-brand leadership in another important product category for its US retailer customers, said Papa at the time. Furthermore, he added, PBM's presence outside of the US provided the combined business with "further opportunities to grow in key global markets".

"Just as Perrigo developed the OTC store-brand market over the past several decades, PBM created the store-brand value proposition within the highly-regulated, infant-formula space," commented Papa. "We believe that PBM's mission to provide families with high-quality, state-of-the-art formulas at sensible prices complements perfectly Perrigo's mission to deliver quality, affordable healthcare to consumers."

Perrigo has also entered another of the adjacent consumer categories, eyecare, by launching a generic version of Novartis' Zaditor antihistamine eye drops in the US. Commenting on the initiative in March of last year, Papa said Perrigo was "excited" to launch a product in the ophthalmics category (**OTC *bulletin***, 31 March 2010, page 12).

Zaditor eye drops – a 0.025% ketotifen fumarate ophthalmic solution – were approved for OTC sale in the US in 2006 by the Food and Drug Administration (FDA) with the indication of "temporary prevention of itchy eyes due to allergic conjunctivitis" caused by seasonal or perennial allergens (**OTC *bulletin***, 31 October 2006, page 11). Perrigo's store-brand versions compete with a number of other antihistamine eye drops containing the active ingredient, including Bausch & Lomb's Alaway antihistamine eye drops (**OTC *bulletin***, 25 January 2007, page 4), McNeil Consumer Healthcare's Zyrtec Itchy Eye Drops and Merck Consumer Care's Claritin Eye (**OTC *bulletin***, 31 August 2009, page 20).

As can be seen from Figure 1, these developments helped boost turnover at Perrigo's Consumer Healthcare division by 12% to US$1.83

■ *Continued on page 27*

Getting the balance right for brands

Consumer healthcare companies have plenty to say about the importance of pharmacists recommending their brands, but do their marketing plans really "walk the talk", asks Ralph Ahrbeck, consultant and former European head of Roche Consumer Health. OTC bulletin reports.

Internal communication between sales and marketing departments needs to be improved in many consumer healthcare companies, says Ralph Ahrbeck, consultant and former European head of Roche Consumer Health

"Most marketing plans for consumer healthcare brands talk about the need for pharmacist recommendation but fail effectively to walk the talk," according to consultant Ralph Ahrbeck. "How many consumer healthcare companies put as much effort into pharmacist focus groups as they do into consumer focus groups?" asks the former European head of Roche Consumer Health, observing that the "depth and precision of marketers' consumer understanding far exceeds what they know about pharmacists".

Yet in most European countries, he points out, the pharmacist is a "heavyweight middleman" in the consumer healthcare market. As a result, companies must make an important distinction, Ahrbeck says, between the customer/pharmacist and the consumer/end user.

Slowly becoming a reality

"Free choice is slowly becoming a reality, and in many cases the brand decision has been taken by the consumer before he or she enters a pharmacy," acknowledges Ahrbeck. "Nevertheless, consumers do rely on the advice of the pharmacist or the white-coated assistant."

Ahrbeck draws attention to the fact that European research conducted for one of the top consumer healthcare companies showed that one of the most powerful reasons for a consumer to purchase a brand was the advice of a healthcare professional. He also highlights a poll conducted for the Association of the European Self-Medication Industry, the AESGP, which found that 46% of people said they were influenced by the advice of a healthcare professional while only 8% said advertising had played a role.

> ***Like consumers, your customers must be segmented into groups of like-minded pharmacists to be able to speak to them differently and effectively***

This is particularly true, according to Ahrbeck, when it comes to new products or product comparisons. "Consumers are wary of what they ingest or place on their skin, and this is where the advice of the pharmacist is invaluable," he comments.

Ahrbeck is quick to point out that he is not questioning the need for effective consumer marketing. "It is essential for consumer healthcare brands, and does need to be conducted with the diligence and precision employed by fast-moving consumer goods companies," he says. "A brand always starts with the consumer, and an intimate knowledge of that target consumer is mission critical."

The issue, according to Ahrbeck, is getting the balance right within the marketing plan. "Many companies are still lagging behind when it comes to 'savvy' sales tactics, and discussions are usually based around trade discounts and the percentage of pharmacy-coverage figures," he observes.

Ahrbeck highlights internal communication barriers between sales and marketing departments, which he believes need to be improved in many companies. "When was the last time a brand manager visited a pharmacy to have a conversation with the pharmacist about the brand?" he asks. "And when was the last time a sales manager discussed the detailed marketing plans, including the target consumer, on a one-on-one basis with a brand manager?"

"If a brand-purchase decision is to be influenced effectively, there must be a balanced, integrated approach between customer-focused and consumer-focused activities," says Ahrbeck. "Furthermore, there must be a line-of-sight from the brand salesperson through the customer to the consumer. The salesperson needs to understand how he or she can help customers to understand their consumers better, and conversely how consumers can build the business of customers."

There is no one simple formula to solve this problem, acknowledges Ahrbeck, but there are five simple concepts that can be applied.

Firstly, do your consumer-marketing homework, he advises. "Get a razor-sharp understanding of the distinct group of consumers you want to talk to – not just their demographics, but their beliefs and attitudes," he says, noting "a brand lives in the mind of the consumer".

This sharpness, adds Ahrbeck, will determine what needs to be said and how it needs to be said. "Don't be lulled into employing a shotgun to blast your message to everyone with every brand benefit," he warns. "This results in a diluted message and ends up as 'me-too' positioning with no critical point-of-difference versus your competition."

"Remember the emotional hooks that drive these purchase decisions," he continues. "I do not buy a multivitamin because it gives me energy; I buy a multivitamin because this added energy allows me to play with my children after my long day at work."

Secondly, make sure that the marketing and sales teams "get up close and personal", he says. "This means more than the usual quarterly sales meeting where the marketing team inflicts "Death by Powerpoint" on the entire sales team," he remarks. "The sales team has a wealth of knowledge about pharmacists and is the eyes and ears of what happens in the 'war zone' on the pharmacy shelf. Use the power of the team to brainstorm together instead of the typical one-way communication from marketing to sales. And do this earlier in brand development."

Thirdly, get more intimate with your customers – the pharmacists, he urges. "Like consumers, your customers must be segmented into groups of like-minded pharmacists to be able to speak to them differently and effectively," he comments.

He notes, for example, the inherent difference between a health-minded pharmacist for whom scientific and medical justification is paramount and a business-minded pharmacist for whom profit and loss rule. "Once grouped, these different segments need to be addressed with different sales tactics and different mar-

Manufacturers

Herbalife gives Fleming region

Herbalife has promoted **Ibi Fleming** to senior vice-president and managing director of its North America region.

She succeeds **Tom Zimmer**, who is retiring from Herbalife after seven years with the US-based direct-selling specialist.

Fleming, who joined Herbalife in 1998, most recently served as senior vice-president of sales and marketing for the US Latin market, which represents around 65% of sales in the North America region. The company said it had been one of the fastest-growing markets under her leadership.

In her new position, Fleming will report to Herbalife president Des Walsh and will be responsible for all of the business, strategic, sales and marketing functions across the North America region, including Canada, the Caribbean, Jamaica and the US.

Commenting on the appointment of Fleming, Walsh said: "She's a talented executive and extremely experienced in working with our independent distributors, who are ultimately responsible for our success."

Zimmer, who has led Herbalife's North America region since July 2005, will remain with the company for a handover period ending on 1 March 2011.

Herbalife pointed out that Zimmer had almost doubled sales in the North America region during his time in charge.

OTC

Manufacturers

GSK makes Scarlett-Smith consumer head for Europe

GlaxoSmithKline has promoted **Roger Scarlett-Smith** to European president of its Consumer Healthcare business. He was previously North American president for the business.

Scarlett-Smith takes over from **Emma Walmsley**, who was recruited from L'Oreal a year ago as European president and worldwide president designate of GlaxoSmithKline's Consumer Healthcare business. The company said Walmsley had taken on a "broader brief" at Consumer Healthcare as she prepared to step up to worldwide president, but would retain overall responsibility for Europe. Her additional responsibilities include research and development, Future Groups – Consumer Healthcare's name for its global marketing function, strategy and business development.

Announcing the appointment of Walmsley in March 2010, GlaxoSmithKline said she would replace **John Clarke** as worldwide president of its Consumer Healthcare business within the next two years (**OTC *bulletin***, 31 March 2010, page 22).

Scarlett-Smith's replacement in North America is **Colin Mackenzie**, who was previously the vice-president oral care and customer marketing for the region.

Scarlett-Smith was promoted to president of the North American Consumer Healthcare business in 2008 (**OTC *bulletin***, 30 May 2008, page 27). He moved to the US from the UK, where he had been general manager and vice-president of the Consumer Healthcare business since October 2004. Prior to that, he headed the business in Australia and New Zealand.

Roger Scarlett-Smith

Colin Mackenzie

OTC

keting tools," he says. "For example, when detailing brand X to a health-minded pharmacist, the salesperson should use scientific and clinical data. But to a business-minded pharmacist, the salesperson must use category-management principles that demonstrate the sales potential."

Fourthly, says Ahrbeck, balance your budget and invest in choices that ultimately influence the purchase of your brand. "Where will you get the biggest 'bang for your buck' on activities that influence the purchase decision of your brand?" he asks.

"Far too often, these decisions rest with the marketing department," he observes. "And the marketing department is likely to choose direct-to-consumer activities rather than healthcare-professional activities because they know more about those activities."

Noting that financial support for brands is a scarce resource, Ahrbeck says pharmacy training and education initiatives, including clinical and scientific justification, often get left out of the marketing plan.

Finally, Ahrbeck stresses the need to measure and adjust key performance indicators. "Use unorthodox indicators," he advises. "For example, if your brand is focused on back pain, then use mystery shoppers to visit your targeted pharmacies and ask the question: 'What do you recommend for back pain?'."

"At the end of the day," concludes Ahrbeck, "building a consumer-healthcare brand is not rocket science. It is about making the right choices. This means targeting the right activities in a balanced approach to secure that essential brand-purchase decision."

■ Ralph Ahrbeck can be contacted by e-mail on ralph@ahrbeck.com.

OTC

Industry Associations

Neises leaves BAH

Professor Gudrun Neises has left the German medicines manufacturers' association, the BAH, just a few months after joining the industry association as its next chief executive.

A spokesperson for the BAH told **OTC *bulletin*** that the association and Neises had agreed to part following disagreements over the future strategy. The BAH's board would meet in the coming weeks to discuss how to proceed, the spokesperson added.

An expert in metabolic diseases, Neises joined the BAH as general manager on 1 September last year (**OTC *bulletin***, 14 May 2010, page 27). She would have taken over from **Mark Seidscheck** as chief executive on 1 July 2011.

OTC

Industry Associations

US CHPA recruits from generics body

The US Consumer Healthcare Products Association (CHPA) has recruited **Bill Head** from the Generic Pharmaceutical Association to be its vice-president of government affairs.

He takes over from **Andrew Fish**, who recently moved to AdvaMed Diagnostics as executive director.

Head led the government affairs department at the Generic Pharmaceutical Association. Before that, he was a lobbyist in the healthcare insurance and pharmaceutical benefit management industries, an adviser to governor Ben Nelson of Nebraska, and a lieutenant in the US Navy.

The CHPA has also announced that **David Spangler**, its senior vice-president for policy and international affairs, is taking on the additional role of general counsel and secretary. His new title will be senior vice-president for policy, and general counsel and secretary.

Spangler joined the CHPA in 1984 as a legislative analyst.

OTC

Retailers

Schmitz is ABDA's new chief executive

ABDA – the federal union of German pharmacy associations – has named **Sebastian Schmitz** as its chief executive from 1 March.

A lawyer, Schmitz, 51, will take over from **Hans-Jürgen Seitz**, who is stepping down.

Having joined the association – which claims to represent 57,000 German qualified pharmacists – in 1990, Schmitz has fulfilled several roles, including most recently head of ABDA's economics and contract law department.

Sebastian Schmitz

OTC

Regulatory Agencies

Sharfstein moves on from deputy post at the US FDA

The US Food and Drug Administration's (FDA's) principal deputy commissioner, **Joshua Sharfstein**, has left the regulator to become Maryland's secretary of health and mental hygiene.

Sharfstein, who took up his new role on 12 January, has been replaced at the FDA by **John Taylor** on an acting basis.

Before becoming the FDA's principal deputy commissioner in 2009 (**OTC *bulletin***, 29 May 2009, page 27), Sharfstein was commissioner of health for Baltimore. During his time in Baltimore, he was one of the signatories on a citizen petition submitted to the FDA, which expressed concerns about the safety and efficacy of non-prescription cough and cold products for use by children under six years of age (**OTC *bulletin***, 31 August 2007, page 15).

OTC

Manufacturers

Valeant names Ingram as chairman

Valeant Pharmaceuticals International has named its lead independent director **Robert Ingram** as chairman.

He replaces **William Wells**, who has resigned from the Canadian company "to pursue other interests".

Ingram has been on Valeant's board of directors since 2003. Formerly president and chief executive officer of Glaxo Wellcome, Ingram serves as a strategic adviser to Andrew Witty, GlaxoSmithKline's chief executive officer.

He is also a general partner at the venture capital company Hatteras Venture Partners, as well as a member of the board of advisers for the H Lee Moffitt Cancer Center and Research Institute.

Chief financial officer resigns

Meanwhile, Valeant has recruited former senior vice-president and corporate controller **Philip Loberg** as interim chief financial officer. He takes over from **Peggy Mulligan**, who has resigned from the company "to pursue other interests".

Valeant said it was seeking a permanent replacement for Mulligan.

OTC

IN BRIEF

■ **SANOFI-AVENTIS** has appointed **Elias Zerhouni** as president of global research and development for medicines and vaccines. Zerhouni, who has been scientific adviser to chief executive officer Chris Viehbacher since 2009, is joining the company's executive and management committees. **Marc Cluzel** has resigned as executive vice-president research and development. In addition, the French pharmaceutical company has promoted **Patrick Aghanian** to head of the Eurasia region, **Thomas Kelly** to head of the Asia region, **Heraldo Marchezini** to head of the Latin America region, and **Jeremy Moulding** to head of the Japan & Pacific region.

■ **CRN** – the US Council for Responsible Nutrition – has elected **Jim Hamilton**, president of DSM Nutritional Products, as chair of its board of directors. He takes over from **Mark LeDoux**, chief executive officer of Natural Alternatives International, who will remain on the board as immediate past chair.

■ **OGILVY HEALTHWORLD FRANKFURT** has promoted **Jürgen Veit** to managing director. Veit, 48, has been with the German advertising and public relations agency since 1992, latterly as deputy to **Wolf-Peter Witt**, 64, who has stepped down but will act as a consultant to the agency during 2011. Ogilvy Healthworld's clients in Germany include Engelhard Arzneimittel, Johnson & Johnson, Meda Pharma, Novartis and Servier.

■ **PERRIGO** in the US has promoted **Shawn McCormick** to consumer healthcare pricing and planning director. He has been with Perrigo since June 2005.

OTC

Manufacturers

J&J appoints Wu as new Consumer chief

Johnson & Johnson said **Jesse Wu** had taken over from **Colleen Goggins** as worldwide chairman of its troubled Consumer division with effect from 3 January 2011.

The company noted that Wu – who was previously group chairman of the Consumer division's global markets organisation – would work with Goggins until she retired on 1 March 2011 to ensure a smooth transition period.

Wu joined Johnson & Johnson in 1989, and has held a number of leadership positions across the Consumer division. He was appointed president for greater China in 2000, and became international vice-president with increasing responsibilities for the Asia-Pacific region in 2003.

Johnson & Johnson announced in September that Goggins, 56, would retire from the company. The news came shortly after Johnson & Johnson had revealed plans to implement a manufacturing, quality and compliance framework, which was drawn up in the wake of the product recall woes at the McNeil Consumer Healthcare subsidiary (**OTC *bulletin***, 29 September 2010, page 25).

Wu takes charge of a division that has been rocked by a series of product recalls. These have led to McNeil suspending production at its Fort Washington facility in the US (**OTC *bulletin***, 14 May 2010, page 1), and facing an investigation by the Committee on Oversight and Government Reform in the US House of Representatives (**OTC *bulletin***, 11 June 2010, page 11).

As a result, Johnson & Johnson has said it expects to report US sales at its OTC & Nutritionals business down by US$600 million (€450 million) in 2010.

Wu's appointment is one of several changes to Johnson & Johnson's senior management team, which are part of the long-term succession planning for when William Weldon, the company's chairman and chief executive officer since 2002, steps down.

Long-term succession planning

Alex Gorsky, worldwide chairman of the Medical Devices & Diagnostics division, and **Sheri McCoy**, worldwide chairman of Pharmaceuticals, have both been appointed vice-chairmen of Johnson & Johnson's executive committee. Johnson & Johnson said they had both joined Weldon in an "expanded Office of the Chairman".

Commenting on the move, Weldon pointed out that Gorsky and McCoy were both "proven leaders in driving high performance and developing talent across multiple business segments" and their appointment would ensure that the company was "well-positioned for sustainable growth into the future".

"The changes are an appropriate step," Weldon added, "in furthering our long-term succession plans, and assuring talented, experienced leaders at all levels of the organisation."

In her new role, McCoy will assume expanded responsibilities for both the Pharmaceuticals and Consumer divisions, as well as the corporate office of science and technology, and corporate affairs.

Meanwhile, Gorsky will oversee the Medical Devices & Diagnostics division, as well as the company's global supply chain, its government affairs and policy activities, and the Johnson & Johnson Development Corporation.

Joaquin Duato, former group chairman of the Pharmaceuticals division's operation in the Americas, has taken over as worldwide chairman of Pharmaceuticals with responsibility for commercial businesses and operations. And **Paul Stoffels**, previously the Pharmaceuticals division's global head of research and development, has been made worldwide chairman of Pharmaceuticals with responsibility for research and development, business development and strategic development.

Gorsky's successor as worldwide chairman of Medical Devices & Diagnostics is **Michael Mahoney** of DePuy.

In addition, **Peter Fasolo**, worldwide vice-president for human resources, has been appointed to the executive committee. Johnson & Johnson said he would "focus on talent development and succession planning at all levels of the corporation".

OTC

■ *Continued from page 23*

billion in the year ending 26 June 2010. Sales rose even faster in the fourth quarter by 18% to US$481 million (**OTC *bulletin***, 10 September 2010, page 8).

Perrigo's sales are set to get an extra boost over the next few years, as the company expands across Europe. Thompson points out that a dedicated business development and regulatory team has been set up to drive European expansion.

Perrigo is the UK's largest supplier of store-brand medicines, says Thompson, noting that each year it supplies five billion tablets, 500 million capsules, 65 million sachets and 20 million bottles and tubes. The company manufactures a total of 758 stock-keeping units, he continues, with 70% of the business coming from the production of store-brands for retailers and 30% from contract manufacturing for branded companies.

Khan notes that Perrigo's UK OTC business has a lot in common with the company's operation in the US. "It involves supplying products for sale in grocery and similar retail outlets where consumers can select the products themselves from open shelving," he observes. "And store-brands are well established in both pharmacy and non-pharmacy retail outlets."

In continental Europe, by contrast, pharmacy is still the dominant distribution channel for OTC medicines, says Khan, and store-brands are relatively insignificant in many countries. "We believe the role of the pharmacy channel will always be important, and it will remain a crucial element of our customer focus," he comments.

Noting the arrival of general-sale categories in countries such as Denmark, Norway and Sweden, Khan believes that pharmacy dominance in the sale of OTC medicines will gradually be relaxed in Europe. However, Perrigo expects this trend to be "a slow one" around Europe, he adds.

The split of sales through different distribution channels was one of the criteria Perrigo used to select its phase one countries. Other criteria included demographics; the self-medication habits of consumers; the relative ease of entering the OTC market; the size, the growth rate and the future potential of the OTC market; and the existing players.

Identified an opportunity

Khan says Perrigo has identified an opportunity to bring "quality affordable healthcare to European consumers via the pharmacy, drugstore and branded company routes". "Store-brands already exist in a number of countries, such as the Netherlands, and we are confident that the demand for them will grow as we expand our product offering with our retail partners, and as the regulatory environment continues to evolve," he says. "This is unlikely to happen overnight, but we should see some dramatic changes over the next five to 10 years."

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