20 January 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Sanofi-Aventis to pay US$1.9bn for Chattem

Sanofi-Aventis is set to enter the US OTC market by acquiring Chattem for approximately US$1.9 billion (€1.3 billion).

Chris Viehbacher, chief executive officer of Sanofi-Aventis, described Chattem as the "ideal platform in the US consumer healthcare market, which represents 25% of the current worldwide opportunity".

Chattem would provide a strong vehicle for switching some of Sanofi-Aventis' medicines from prescription to OTC status in the US, said Viehbacher, adding that the company was seeking to switch the allergy medicine Allegra (fexofenadine hydrochloride).

According to Sanofi-Aventis, the acquisition would make it the world's fifth-largest consumer healthcare company with sales of approximately €1.7 billion. Sanofi-Aventis is currently ranked number six.

Sanofi-Aventis said the price represented 4.8-times Chattem's sales in 2009 and 13.3-times its earnings before interest, tax, depreciation and amortisation (EBITDA).

In the year ended 30 November 2008, Chattem's sales increased by 7% to US$455 million. Around 93% of its turnover was generated in the US through brands such as ACT, Cortizone-10, Gold Bond, Icy Hot, Selsun Blue and Unisom.

Chattem will become the US consumer healthcare division of Sanofi-Aventis. It will continue to be led by the current management, and its headquarters will remain in Chattanooga, Tennessee.

The French pharmaceutical firm's OTC business, which is expected to record sales of €1.4 billion in 2009, does not have a direct presence in the US. Its main markets include Australia, Brazil, France, Italy, Mexico and Russia.

■ *Continued on page 22*

Europe scrutinises topical ketoprofen

Concerns over serious photosensitivity reactions have prompted Europe's Committee for Medicinal Products for Human Use (CHMP) to start a safety review of topical medicines containing ketoprofen.

The CHMP said it would assess the benefit-risk balance of these medicines, and recommend whether their marketing authorisations should be maintained, changed, suspended or revoked.

Topical ketoprofen medicines have non-prescription status in a number of European countries including Austria, Belgium, Denmark, Germany, Spain, Sweden and the UK.

The CHMP's safety review was triggered by France under Article 107 of European Directive 2001/83/EC as amended.

The French medicines agency, AFSSAPS, has suspended the marketing authorisations of all topical ketoprofen medicines in France with effect from 12 January 2010. They have prescription-only status in France.

Mergers & Acquisitions

Teva takes on Japan's Taisho

Teva has acquired a majority stake in Japanese generics player Taisho Pharmaceutical Industries through its local Teva-Towa Pharma joint venture. A definitive agreement saw Teva-Towa gain at least 66.7% of Taisho's outstanding shares for an undisclosed fee.

Taisho – which is separate from Japan's leading OTC player of a similar name – has annual sales of around ¥12 billion (€90 million) and employs almost 400 people. According to Teva, it is Japan's seventh-largest generics manufacturer.

Privately-owned Taisho manufactures a portfolio of 120 generic molecules in more than 200 presentations which it markets to pharmacies, clinics, hospitals and wholesalers through a well-established salesforce. The Japanese firm expanded its finished-dosage manufacturing facility in 2006, a year after it built a research and development centre.

Commenting on the transaction, Teva's president and chief executive officer Shlomo Yanai said it would "serve as a springboard for Teva-Kowa's operations in Japan". "Taisho will bring invaluable local expertise and know-how to support our growth plan in Japan," he insisted.

Teva created a joint venture with Japanese pharmaceuticals company Kowa in September 2008, with each party taking a 50% stake. Teva-Kowa was expected to achieve sales of US$1 billion (€0.7 billion) by 2015 through leveraging "the marketing, research and development, manufacturing and distribution capabilities of each company to become a broad-based supplier of high-quality generic pharmaceutical products for the Japanese market".

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IN BRIEF

■ **DERMA SCIENCES** has signed a three-year contract worth approximately US$15 million (€10 million) to supply an unnamed global healthcare company with **finger bandages**.

■ **ALLIANCE PHARMA** – the UK-based company that markets the Forceval multimineral-multivitamin brand and Pavacol-D cough suppressant – said trading during the last few months of 2009 had remained strong and as a result the company expected to **report sales up by 42%** to £31 million (€35 million) for the full year to the end of December.

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Licensing Agreements

GlaxoSmithKline strikes cold-sore deal in the US

GlaxoSmithKline has struck a deal that will give it access to the "next advance in the treatment of cold sores" in the US and Canada.

The company, which already markets the Abreva OTC cold-sore medicine in the US, has reached an exclusive licensing agreement with NanoBio Corporation for OTC use of NB-001. GlaxoSmithKline said that the patented compound provided "significant antimicrobial activity against the virus that causes cold sores".

Under the terms of the agreement, GlaxoSmithKline will make an upfront payment of US$14.5 million (€10.1 million) to NanoBio. It has also agreed additional milestone payments of up to US$40 million plus single-digit royalties on future sales.

Roger Scarlett-Smith, GlaxoSmithKline Consumer Healthcare's North American president, said the deal built on the company's leadership position in the cold-sore category. "With Abreva," he commented, "we have a very effective cold-sore treatment in the category and look forward to building on that platform with the new technology from NanoBio."

NanoBio pointed out that NB-001 physically killed the virus on contact. "This rapid physical mode of action significantly reduces the likelihood that resistant herpes virus strains will develop," added the company, noting that NB-001 had demonstrated "potent antiviral activity in vitro" against strains that had shown resistance to other antiviral agents including aciclovir and foscarnet.

The privately-owned biopharmaceutical company has completed two Phase 2 clinical trials for NB-001 and plans to start Phase 3 testing in the near future.

According to NanoBio, NB-001 would "rapidly capture market share from all prescription and OTC current therapies, as well as dramatically expand the market" by offering untreated sufferers a viable treatment option.

GlaxoSmithKline's Abreva cream – based on the active ingredient docosanol – is the only non-prescription cold-sore medicine that is approved by the US Food and Drug Administration (FDA) to shorten healing time and the duration of symptoms. The company pointed out that Abreva was the leading cold-sore treatment in the US with a market share of over 50%.

NanoBio's chief executive officer and founder James Baker, said GlaxoSmithKline's "leadership in developing and marketing consumer healthcare products including the leading product for treating herpes labialis makes it the ideal partner for NB-001".

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Mergers & Acquisitions

Nutrition 21 sells US retail business

Nutrition 21 has sold its retail and direct-selling businesses to contract manufacturer Nature's Products to help pay its debts.

Nature's Products is paying US$3.2 million (€2.2 million) plus the assumption of designated liabilities for the US-based businesses. The company has also agreed to buy ingredients from Nutrition 21.

Nutrition 21 said it would use approximately US$2.7 million of the proceeds to repay in full the notes that it issued in August 2006.

Commenting on the sale, Michael Zeher, president and chief executive officer of Nutrition 21, said the deal allowed the company to focus its "limited financial resources" on its profitable ingredients business. It has also retained its patent portfolio, which includes more than 30 issued and pending patents associated with chromium picolinate as well as combinations of chromium compounds with other dietary supplement ingredients.

Nutrition 21 said in October of last year that it had signed a non-binding letter of intent to sell its retail and direct-selling business to an unnamed private company to help repay its debts, after the firm's sales and profits were hit by the global economic downturn (**OTC *bulletin***, 30 October 2009, page 10).

The company was also delisted from the NASDAQ stock exchange after its share price dropped to below US$1.00.

For the year ended 30 June 2009, Nutrition 21 reported an operating loss of US$17.4 million, after it cut the goodwill valuations of its assets by US$17.5 million. Sales fell by 16% to US$39.6 million, as retail and mail order sales declined in the second half of the year.

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Mergers & Acquisitions

Thornton & Ross snaps up Metanium

Thornton & Ross has acquired the Metanium nappy-rash brand for £2.0 million (€2.2 million) from the troubled UK natural-products specialist William Ransom & Son. Thornton & Ross is also paying £0.2 million for Metanium inventory.

Comprising two licensed medicines – a cradle-cap cream and a nappy-rash ointment – the brand generated annual sales of approximately £1.05 million and a gross profit of around £0.6 million, according to Ransom. As of 11 January, the net book value of the Metanium assets was £1.1 million.

Dieno George, Thornton & Ross' chief executive officer, said Metanium would "further strengthen the company's range of paediatric medicines", which includes the Hedrin head-lice treatment, Pripsen threadworm treatment and Virasoothe product for relieving chicken-pox symptoms.

Metanium was a "long established brand in the UK", Thornton & Ross pointed out, with a "strong franchise in nappy-rash treatment", covering both the OTC and prescription sectors.

George told **OTC *bulletin*** that the company had high expectations for Metanium due to the brand's efficacy and would be backing it with "serious" promotional campaigns targeting both consumers and healthcare professionals.

He added that under the Thornton & Ross umbrella Metanium would also benefit from the company's "considerable strength and experience in the manufacture of pharmaceutical quality cream and ointment products".

The deal includes the Metanium cradle-cap cream (1.5% salicylic acid) and Metanium ointment (20% titanium dioxide, 5% titanium peroxide, 3% titanium salicylate) – which are both general sale list medicines – as well as all intellectual property, trade marks and stock relating to the brand.

An unlicensed baby moisturising cream, a soft petroleum jelly and a zinc and castor oil cream marketed by Ransom as Metanium products were not included in the deal and can no longer be marketed under the brand name.

Metanium is Thornton & Ross' fourth acquisition in a little over a year, and its second from Ransom. In December 2008, the company acquired Ransom's Radian B topical pain reliever for a total consideration of £3.4 million (**OTC *bulletin***, 18 December 2008, page 3), and a few months later snapped up the Cerumol earwax treatment from Laboratories for Applied Biology for an undisclosed sum (**OTC *bulletin***, 27 February 2009, page 3). In October, it acquired the privately-owned UK dermatology company Zeroderma (**OTC *bulletin***, 30 October 2009, page 9).

Commenting on the sale, Ivor Harrison, chief executive officer of Ransom, said the deal was consistent with the company's strategy of creating "a focused, natural consumer healthcare offering" and was also in the best interests of its shareholders.

Ransom noted that £1.0 million of the proceeds from the sale would be used to reduce the company's borrowing, while the balance would be used for working capital purposes.

The sale is part of Ransom's turnaround plan launched in September 2008 that has seen the firm put various brands and its UK contract manufacturing operation up for sale (**OTC *bulletin***, 29 September 2008, page 6).

Along with Metanium and Radian B, Ransom has also sold its Pavacol-D cough medicines brand to Alliance Pharma for £0.6 million (**OTC *bulletin***, 29 August 2008, page 3).

Despite making progress on the turnaround plan, David Suddens, Ransom's non-executive chairman, recently said that the future of the company remained uncertain as it continued to implement its new strategy under "very testing business and economic conditions" (see page 4 of this issue).

His comments came after Ransom posted an operating loss of £2.7 million for the six months ended 30 September 2009. Sales declined by 3% to £16.7 million, due mainly to the sale of Radian B and Pavacol-D.

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Business Opportunities

Avery Dennison seeks adhesive partners

Avery Dennison Specialty Tape is seeking brand owners and private-label companies worldwide to use its new proprietary adhesive technology in OTC wound-care products.

The company pointed out that the new ultra-thin hydrocolloid adhesive delivered "real consumer benefits in terms of better wear comfort, flexibility, longer wear time, less skin softening beneath the dressing, and gentle removal".

Gert Van Der Haegen, Avery Dennison's European marketing manager for medical, said the adhesive offered the possibility to "create a range of very novel consumer product designs".

Avery Dennison said companies could be supplied with rolls of a thin hydrocolloid laminate for subsequent slitting/cutting to singles; converted product for packaging; or fully-packaged consumer products to go straight into retail stores.

The company noted that a special hydrocolloid formulation with a moisturising capability was available for treating dry and cracked skin as well as callouses and corns.

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First-Half Results

Ransom faces an uncertain future

The future of William Ransom & Son remains uncertain, according to David Suddens, the company's non-executive chairman, as the troubled UK-based firm reported an operating loss of £2.7 million (€3.0 million) for the six months ended 30 September 2009.

"Much has been achieved in very testing business and economic circumstances, but the outlook remains uncertain," Suddens warned, noting that the management team was making "strenuous efforts to return the business to financial stability".

Business	First-half sales* (£ millions)	Change (%)	Operating profit (£ millions)	Change (%)
Consumer Health	10.7	-16	-1.2	–
Pharmaceuticals	4.4	+42	-0.2	–
Natural Products	1.7	+18	-0.03	–
Others	–	–	-1.3	–
Total	**16.7**	**-3**	**-2.7**	**–**

* Excludes intragroup sales

Figure 1: Ransom's sales and operating profit in the six months ended 30 September 2009 (Source – Ransom)

The majority of the operating loss during the six-month period was attributed to Ransom writing down the goodwill valuation of its business by £2.5 million.

Sales declined by 3% to £16.7 million, as the turnover at Ransom's dominant Consumer Health division dropped by 16% to £10.7 million (see Figure 1).

The lower Consumer Health sales had been caused in part by the divestment of the Radian B and Pavacol D brands during 2008, Ransom noted, which had wiped £1.2 million off the division's turnover. On a like-for-like basis, sales had actually increased by 2%.

As well as blaming Consumer Health's operating loss of £1.2 million on the goodwill write-down, Ransom also cited lower margins, due in part to product mix and an increase in cost of goods. Ransom said that it was tackling the margin erosion by reviewing the cost of goods, renegotiating prices and by working with new and existing suppliers to reduce supply chain costs.

As part of Ransom's turnaround plan introduced in September 2008 (**OTC *bulletin***, 29 September 2008, page 6), the Consumer Health division is focusing on four key areas: rebranding and communication; upgrading packaging; new product development; and distribution.

Upgrading of its core brands was "well advanced", Ransom said, noting the relaunch of Manuka Gold and Health Perception. The latter has been renamed JointFlex from Ransom.

Ransom's remaining core brands – AloeDent, AloePura and Allergenics; and the inlicensed Medibee and Kordel's – would be relaunched and on shelves from April 2010, the company noted.

A roll out of the new Ransom Naturals umbrella brand would begin in the spring of 2010, the company pointed out, adding that all major retail multiples had received the range positively. Ransom claimed the umbrella brand would cover major product categories (**OTC *bulletin***, 31 August 2009, page 12).

New "consumer friendly and modern" packaging formats would be introduced from April, Ransom revealed, while a number of recent product launches – including AloeDent with Fluoride and JointFlex – had boosted the Consumer Health business. Further launches were expected during the year.

On the distribution front, the firm's sales team had achieved considerable success over the six months, Ransom said, despite the challenging conditions. The company warned, however, that there was still "some way to go" to secure listings for the Ransom Naturals brand and to gain distribution with new customers.

Meanwhile, Ransom said it was still planning to sell its Pharmaceuticals contract manufacturing division, despite the business having reported a 42% increase in sales to £4.4 million. This included, however, £1.3 million in sales of Radian B to Thornton & Ross, which acquired the brand in December 2008 (**OTC *bulletin***, 18 December 2008, page 3). Thornton & Ross is planning to take the production of Radian B in-house.

A focus on increasing prices better to reflect raw-material costs, increasing labour efficiencies and improving manufacturing standards, narrowed the division's operating loss from £0.9 million to £0.2 million.

Natural Products turnover rose by 18% to £1.7 million. The division also edged towards breaking even after reporting an operating loss of £30,000 for the six months, an improvement on the £0.1 million operating loss reported in the same period a year earlier.

In the long term, Ransom plans to integrate Natural Products' botanical extracts know-how into the Consumer Health division.

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Business Strategy

BMS splits off from Mead Johnson

Bristol-Myers Squibb has successfully given up its majority stake in Mead Johnson Nutrition through a share-exchange offer, which saw it regain its own shares.

Through the offer – launched in November of last year (**OTC *bulletin***, 30 November 2009, page 10) – Bristol-Myers Squibb off-loaded its 170 million shares in Mead Johnson Nutrition, which represented an 83.1% stake in the company. These now publicly-held shares carry a market value in excess of US$7.3 billion (€5.0 billion), with Mead Johnson's total market capitalisation now standing at more than US$8.8 billion.

Bristol-Myers Squibb announced that it intended to give up its majority stake in Mead Johnson less than a year after it sold-off a minority 17% stake for approximately US$780 million through an initial public offering (IPO) in February 2009.

Steve Golsby, Mead Johnson's president and chief executive officer, said the result of the exchange offer – which was heavily oversubscribed – reflected a strong belief in Mead Johnson's business model, brands and strategies.

Mead Johnson offers a portfolio of nutrition products for infants and children. In the third quarter of 2009, the company reported sales down by 6% to US$700 million, while earnings before interest and tax (EBIT) fell by 2.4% to US$160 million.

Bristol-Myers Squibb sold its interest in the global Mead Johnson adult-nutrition business to Novartis in 2004 for US$385 million (**OTC *bulletin***, 23 January 2004, page 3).

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Mergers & Acquisitions

Novartis set to take control of Alcon

Novartis is set to acquire a majority stake in Alcon from Nestlé, and has proposed a deal to take full control of the global eyecare specialist.

Nestlé's 52% stake in Alcon will be added to Novartis' existing 25% holding – acquired from Nestlé two years ago – and the Swiss company will then launch an all-share offer for the remaining Alcon shares.

Once the takeover has been completed, Novartis will create a new eyecare division called Alcon, which will bring together the Alcon assets, Novartis' Ciba Vision business, and some of Novartis' ophthalmic pharmaceutical products (see Figure 1).

Proforma 2008 sales for the division would have been around US$8.5 billion (€5.9 billion), pointed out Novartis, noting that the new Alcon division would have a presence in 70% of the global vision care market, including pharmaceuticals, surgical products, contact lenses and OTC products.

Daniel Vasella, chairman and chief executive officer of Novartis, said that gaining full control of Alcon would strategically strengthen the company's healthcare portfolio and its position in eyecare. He added that the eyecare sector had "dynamic growth due to the increasing needs of an ageing population".

Just under two years ago, Novartis agreed a two-stage transaction to acquire Nestlé's majority stake in Alcon (**OTC *bulletin***, 15 April 2008, page 4). The first stage in April 2008 saw Novartis pay Nestlé US$10.4 billion for an initial 25% slice of Alcon's shares. The optional second stage gave Novartis the exclusive right to pay Nestlé US$181 per share, or US$28.1 billion, for its remaining 52% stake in Alcon between January 2010 and July 2011.

Novartis said the second stage – providing it with a 77% holding in Alcon – should be completed in the second half of 2010. The company will then launch an all-share offer to acquire the remaining 23% stake held by minority shareholders for around US$11.2 billion.

The total price tag for Alcon of US$49.7 billion represents almost 7.9-times the eyecare specialist's sales of US$6.3 billion in 2008 and 22.6-times its operating profit of US$2.2 billion.

Alcon's business is dominated by its Surgical and Pharmaceuticals divisions, which generated 87% of the company's 2008 sales. The Consumer division contributed the remaining 13%.

Alcon's Consumer division reported sales up by 8.3% to US$851 million in 2008, of which the majority came from contact-lens disinfectant products. The company offers a range of contact-lens disinfectants under the Opti-Free brand, as well as artificial tears and products for dry eyes under the Systane brand. Other consumer products include the ICaps portfolio of vitamin and mineral supplements.

International sales of US$3.5 billion accounted for just over half of Alcon's sales in 2008. The remaining US$2.8 billion was generated in the US company's domestic market.

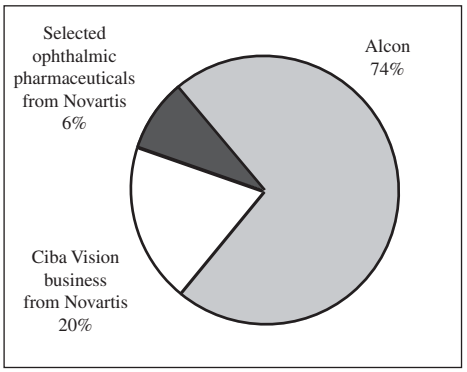

Figure 1: Breakdown of proforma 2008 sales at Novartis' proposed Alcon eyecare division – US$8.5 billion – by business (Source – Novartis)

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Mergers & Acquisitions

A&D Pharma boosts presence with CEE buys

A&D Pharma said it was set to become a "major sales and marketing player" in central and eastern Europe after striking a deal to acquire several pharmaceutical firms across five countries in the region for €23.2 million.

The company said it had agreed to acquire Bulgaria's Arishop Pharma AD and its local subsidiary, as well as the Romanian-based Ozone Laboratories' businesses in the Czech Republic, Hungary, Poland and Slovakia.

In October, A&D Pharma announced that it was in negotiations to buy the firms (**OTC *bulletin***, 16 October 2009, page 4)

A&D Pharma – the Dutch holding company which runs the Sensiblu pharmacy chain and Mediplus wholesaling businesses in Romania – noted that three of its major shareholders, Walid Abboud, Roger Akoury and Ludovic Robert, held controlling stakes in the acquired companies.

The Ozone businesses were excluded from a deal in July 2009 by Romanian firm LaborMed Pharma Group for Ozone's portfolio of branded OTC products, prescription generics and food supplements as well as the Ozone brand (**OTC *bulletin***, 31 July 2009, page 1).

LaborMed did not acquire any of Ozone's companies, which not only include the subsidiaries A&D Pharma is set to buy but also businesses in Romania and Bulgaria.

A&D Pharma said the acquisitions would turn it into a "major sales and marketing player" in the central and eastern Europe pharmaceutical market, with the ability to offer suppliers a full range of services from registration to the commercialisation of OTC products, prescription drugs and medical devices.

In addition, the acquisitions would add approximately 12% to the group's turnover, A&D Pharma noted. The company reported sales of €502 million in 2008 (**OTC *bulletin***, 31 March 2009, page 5).

Arishop and its subsidiary exclusively distributes several prescription and OTC brands in Bulgaria, including Reckitt Benckiser's Nurofen, Strepsils and Veet brands. The Ozone businesses, meanwhile, market prescription and OTC medicines, food supplements and selected medical devices.

Under the terms of the deal, A&D Pharma is paying €12.8 million for Arishop; €6.0 million for Ozone's Polish subsidiary; and €0.4 million for Ozone's businesses in the Czech Republic, Hungary and Slovakia, as well as Ozone's Polish services company.

A&D Pharma said it would pay another €4.0 million to acquire an unnamed company located in one of the target markets. A spokesperson for A&D Pharma said no further details on this acquisition were available.

The deals are expected to close at the end of February 2010, subject to approval from a consortium of five banks that granted A&D Pharma a €100 million refinancing loan in August 2009 (**OTC *bulletin***, 31 August 2009, page 13).

Meanwhile, A&D Pharma has launched a private healthcare service in Romania called Anima Specialty Medical Services.

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Bausch & Lomb has unveiled a new corporate identity, which the US-based eyecare specialist said reflected its "ongoing evolution".

Noting that both the new logo and icon (pictured above) retained the company's traditional blue and green colours, Bausch & Lomb said that introducing the "+" symbol to the design represented its "strong commitment to innovation and partnership with practitioners as a leader in eye health".

Gerald Ostrov, chairman and chief executive officer of Bausch & Lomb, said the new identity reflected the progress the company was making in growing its business for the "benefit of medical practitioners, retail partners, consumers and patients around the world".

The new identity will be phased in over the next 18-24 months as product packaging and other materials are updated.

Looking forward, Ostrov said the company expected 2010 to be a "banner year" harmonising the strong momentum built up in 2009 with product launches and marketing initiatives.

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Mergers & Acquisitions

Alberto Culver gains Simple

Alberto Culver has acquired the Simple Health & Beauty skincare business in the UK for £240 million (€268 million) from the private-equity fund Duke Street.

Described by Alberto Culver as the second largest skincare brand in the UK on a value share basis, Simple is expected to report annual sales of £65 million for 2009.

Carol Lavin Bernick, Alberto Culver's executive chairman, said the acquisition gave the company a "well-known and respected brand" in its largest foreign market. "It reaffirms our focus on beauty care and provides us with a terrific opportunity to execute our strategy of expanding and growing our skincare portfolio," Bernick added.

The scale of the business, the awareness levels of the brand and its differentiated positioning all matched the company's strategic criteria, Alberto Culver pointed out, adding that it would make the company the number two skincare manufacturer in the UK.

Alberto Culver manufacturers and markets a number of beauty care brands including the Alberto VO5 haircare brand and Noxzema skincare range.

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Business Strategy

Celesio considers future of its retailing operations

Celesio is looking closely at the future of its pharmacy operations in Ireland, Italy and the Netherlands, according to chief executive officer Fritz Oesterle.

Speaking at a press conference in Germany, Oesterle said the pan-European retailer and wholesaler was "evaluating whether to continue its pharmacy operations" in the three countries where a few months ago it had cut goodwill valuations by over €200 million for the second time this year (**OTC *bulletin***, 16 October 2009, page 1).

Generics tendering in all but name in the Netherlands had reduced the earnings power of Dutch pharmacies, Celesio said in October, while reduced reimbursement prices and a reduction in pharmacists' remuneration had had the same effect in Ireland. Government measures were also blamed in Italy for the "additional and unpredictable decline in margins".

However, a spokesperson for Celesio told **OTC *bulletin*** that the company remained committed to the retail pharmacy market. Although hundreds of pharmacies would not be added to its established chains, such as Lloydspharmacy in the UK, the spokesperson noted, stores would be opened or acquired if they benefited the business.

Celesio has ample funding available for acquisitions, as it tries to reduce its dependency on strongly government-regulated markets. The chief financial officer Christian Holzherr said the company had over €100 million available – and had placed "no limit" on raising more money – but had no immediate targets in mind.

Earlier this year, Celesio acquired Belgian wholesaler Laboratoria Flandria and a stake in Brazilian wholesaler Panpharma (**OTC *bulletin***, 31 July 2009, page 2).

Strengthening its mail-order operations was an important focus for developing Celesio's Patient and Consumer Solutions division in the future, the spokesperson added. The company currently operates the Dutch-based DocMorris mail-order pharmacy, which serves customers in Germany and the Netherlands, as well as the mail-order operations of Lloydspharmacy in the UK and its Vitusapotek chain in Norway.

Sales at Celesio's Retail Pharmacies business fell by 4.1% to €2.36 billion over the first nine months of 2009. In local currencies, sales increased by 5.5% (**OTC *bulletin***, 30 November 2009, page 5).

The Mail-Order Pharmacies business posted turnover up by 14.9% – 15.1% in local currency terms – to €187 million.

However, the €200 million goodwill write-downs on the Dutch, Irish and Italian retail business, coupled with a €71 million goodwill write-down on the DocMorris franchise business, left the Patient and Consumer Solutions division – comprising Retail Pharmacies, Mail-Order Pharmacies and Other Business – with a loss before interest and tax of €94.9 million.

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Mergers & Acquisitions

Merz fills out with BioForm Medical

Merz Pharmaceuticals – owner of the Tetesept cough and cold brand – is set to pay approximately US$253 million (€176 million) to acquire the medical aesthetics company BioForm Medical.

The German firm said the deal – which is expected to close in the first quarter of 2010 – would advance its strategy of becoming a "leading player in aesthetic medicine, a fast growing, multibillion dollar global market".

Described as a leader in the dermal filler market in the US and Europe, BioForm's portfolio of dermal-filler products is led by its Radiesse flagship brand. The company's products are designed to enhance aesthetic procedures performed in dermatology and plastic surgery practices. Once the acquisition was complete, BioForm would become a wholly-owned subsidiary of Merz and would be renamed Merz Aesthetics, the company noted.

Jochen Hückmann, the chairman of Merz' shareholders council, said that adding BioForm to the company gave it "greater potential for future growth in our worldwide, fast growing aesthetics and dermatological business".

Merz reported healthcare turnover of €590 million in the year ended 30 June 2009, an increase of 7.9% (**OTC *bulletin***, 30 November 2009, page 8).

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- OTC Brand of the Year
- OTC Launch of the Year
- OTC Brand Revitalisation of the Year
- Most Innovative New OTC Product
- Best OTC Marketing Campaign on a Big Budget
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- Best OTC Consumer Advertising on Television
- Best OTC Consumer Advertising in the Press
- Best OTC Consumer Advertising Out-of-Home
- Best OTC Consumer Advertising on the Internet
- Best OTC Public Relations Campaign for a Medicine
- Best OTC Public Relations Campaign for a Non-Medicine
- Best New OTC Packaging Design
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Annual Results

Lithuanian deal drives up Anzag

Acquiring Lithuania's Armila from 1 September 2008 helped German wholesaling group Anzag increase its turnover by 4.1% to €3.97 billion in the year ended 31 August 2009.

Armila contributed €68.7 million to Anzag's total gross sales outside of Germany, which were ahead by 83% to €280 million. The remainder came from the German firm's operations in Croatia and Romania.

Anzag said it had raised its gross margin by 0.43 percentage points to 6.39%, even though more pharmaceutical manufacturers in Germany were delivering their products directly.

Earnings before interest and tax (EBIT) improved by a quarter to €35.0 million, although Anzag said its prior-year profits had been depleted by one-off costs.

In 2010, the German group expects to raise group sales by 4% to around €4.1 billion.

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Annual Results

Ratiopharm is above forecast

Ratiopharm announced it had exceeded its profits forecast by about 20% when the firm posted earnings before interest, tax, depreciation and amortisation (EBITDA) of approximately €300 million last year.

The German OTC and generics player's group turnover stood still at around €1.6 billion, as international growth compensated for a difficult trading environment in Germany. The German firm now generates more than half of its sales outside of its domestic market.

"We have managed clearly to exceed our forecasts even though we have restructured the Ratiopharm group," insisted the group's chief executive officer Oliver Windholz.

The restructuring measures came as Ratiopharm's owners, the Merckle family, put the company up for sale (**OTC *bulletin***, 30 November 2009, page 3).

Windholz highlighted Ratiopharm's success in winning contracts in the generic tenders that were now prevalent among Germany's health insurance funds. "Our strategy remains clear – growing turnover and market share, but not at any price," he stated.

OTC

Business Strategy

Pharmacy Chain 36.6 raises RUB2.3 billion

Pharmacy Chain 36.6 has raised RUB2.3 billion (€54 million) through a new share placing to help pay the company's debt and increase working capital.

Artem Bektemirov, Pharmacy Chain 36.6's chief executive officer, said the successful placing of the additional 85.5 million shares meant the Russian pharmacy chain had "successfully overcome" one of the "most complicated periods" in its history.

Investors' continued willingness to invest funds to aid the group's development confirmed the potential of the business, Bektemirov claimed, adding that all of its efforts were now aimed at improving the company's operational results and profitability.

Cash-flow problems and a failure to refinance the firm's debt – which stood at RUB5.1 billion as of 30 September 2009 – have plagued Pharmacy Chain 36.6 over the past year as the rapidly-expanding business has suffered from the economic slowdown. The company's Retail division accounted for RUB4.4 billion of the debt, with the remainder held by its Veropharm manufacturing business.

In the past, the company admitted that its accounts payable – particularly by the Retail division – had grown as it had tried to meet other financial obligations.

This had led to some stores suffering from "stock outs", the company added (**OTC *bulletin***, 18 December 2008, page 4).

The successful share placing came after the firm had reported a double-digit decline in sales at the Retail division in the third quarter of 2009.

Retail sales fell by 29.8% to RUB3.5 billion for the three months, with the number of purchases 34.9% lower than a year earlier.

One area of growth for the Retail business was in sales of store-brand products. Store-brand turnover grew by 8.7% to RUB281 million during the third quarter, representing 8.3% of the Retail division's total sales.

Pharmacy Chain 36.6 said that with consumers looking to buy cheaper products and the company consistently making additions to its store-brand range, store-brands would contribute significantly to Retail division's profitability in the fourth quarter of 2009.

Pharmacy Chain 36.6 was operating 1,026 pharmacies across Russia as of 30 September 2009.

The Retail division accounted for 77% of Pharmacy Chain 36.6's total third-quarter sales, which fell by 26.3% to RUB4.6 billion. The Veropharm manufacturing subsidiary – where sales declined by 13.6% to €868 million – generated a further 19%.

OTC

Business Strategy

Futura talking to partners in US

Futura Medical said it had completed the modifications to its PET500 topical OTC product to delay ejaculation and was in talks over marketing the product in the US.

The UK-based firm announced last year it was modifying PET500's formulation to comply with an existing US Food and Drug Administration (FDA) monograph, so the product could be marketed in the US without any further clinical data (**OTC *bulletin***, 30 September 2009, page 5).

Futura noted studies on its topical OTC pain relief product TPR100 had been completed.

OTC

Mergers & Acquisitions

Alapis grabs 50% stake in Genesis

Alapis – the Greek healthcare group – has acquired a 50% stake in Turkish pharmaceutical firm Genesis Ilac for €1.7 million.

Genesis offered a range of prescription and OTC brands, Alapis said, which were mainly distributed to healthcare professionals. The Turkish company generated sales of €8.2 million in 2008.

Alapis' healthcare business – which consists of pharmaceuticals, OTC, veterinary and medical devices – reported sales of €708 million in the first nine months of 2009. Earnings before interest and tax were €184 million.

OTC

Mergers & Acquisitions

Kraft sweetens Cadbury takeover offer

Kraft Foods has increased the cash part of its £10 billion (€11 billion) hostile takeover bid for Cadbury, owner of the world's leading medicated confectionery, the 100 year-old Halls cough brand. But the revised terms do not increase the bid's value.

The move came as the US-based group revealed its original bid had been accepted by shareholders representing just 1.5% of Cadbury's shares by the initial acceptance deadline of 5 January 2010. The company has now given Cadbury's shareholders until 2 February to accept the offer.

Speaking as Cadbury reported sales up by 11% to £5.98 billion and operating profit ahead by 27% to £808 million for 2009, Roger Carr, the UK-based firm's chairman, urged Cadbury's shareholders to not let Kraft "steal your company with its derisory offer".

Carr maintained the revised offer exposed the "weakness" of Kraft's management, adding that the "derisory offer" had been limited by the company's "powerful" existing shareholders restricting the stock content of the bid, while its credit-rating agencies had limited the cash content of the deal.

The offer was "very significantly below all comparable transactions in the sector", Carr insisted, and exposed Cadbury's shareholders to Kraft's "low growth" business model as well as its "long history of under performance and its track record of missed targets".

Explaining the changes to its offer, Kraft said it would use the US$3.7 billion (€2.6 billion) proceeds from the agreed sale of its US frozen pizza business to increase the amount of cash it was offering Cadbury's shareholders in place of some of the new Kraft shares they would have otherwise received.

The decision had been based on the "desire expressed by some Cadbury's security holders" to have a greater proportion of the offer in cash, Kraft said, and because some of its own shareholders had expressed a desire for the company to "be more sparing" in the use of its shares as currency for the deal.

Cadbury's board flatly rejected a £10.2 billion unsolicited offer from Kraft in September (**OTC *bulletin***, 16 September 2009, page 3). However, on 9 November, Kraft took the same offer directly to Cadbury's shareholders (**OTC *bulletin***, 30 November 2009, page 3).

In December, Cadbury urged shareholders to reject Kraft's offer as it fell "well short of reflecting the value" of the firm. The UK company pointed out that due to a 5% decline in Kraft's share price since its initial offer in September, the value of the deal had actually fallen to £9.8 billion.

At the time, Carr said there was "no strategic, managerial, operational or financial merit in combining with Kraft" and that the company actually felt the reverse was true. "Whilst Kraft needs Cadbury, Cadbury does not need Kraft," Carr stressed.

Irene Rosenfeld, chairman and chief executive officer of Kraft, said that despite Cadbury's accusations, Kraft would continue with its "disciplined" pursuit of the company.

Meanwhile, Nestlé announced that it would not make, or participate in, a formal offer for Cadbury. The Swiss firm had been linked with a possible move for Cadbury in a number of media reports.

Other sources have suggested that Cadbury is discussing a merger with chocolate manufacturer Hershey. The US-based firm has not officially added to its statement issued in November when it confirmed that it was reviewing its options and could not say whether an offer would be forthcoming.

The Italian company Ferrero – owner of the Nutella brand – has also been linked with a possible bid for Cadbury.

One press report suggested that Ferrero and Hershey could make a joint bid.

Cadbury returned the Halls brand to UK ownership when it bought the Adams confectionery business from Pfizer in 2003, following the US drug firm's acquisition of Warner-Lambert (**OTC *bulletin***, 24 January 2003, page 4).

Todd Stitzer, Cadbury's chief executive officer, said Halls was one of the firm's most profitable brands and had been expanded into new functional areas and refresh segments. This had enabled the brand to move beyond its traditional cough and cold niche to a more mainstream set of consumers, Stitzer pointed out, and had driven the brand's annual sales to £450 million.

OTC

Switches

Flomax Relief to flow from March

Boehringer Ingelheim said Flomax Relief would be available without a prescription in UK pharmacies from March.

The company is backing the launch with a "high-profile" marketing campaign including consumer advertising, public relations activity and point-of-sale material, which will commence in late March or early April. A pharmacist-training programme, including a national roadshow, is already available.

Launch pharmacy-press advertising, including a fake cover to *C&D* magazine, carries the headline "Help men take control of their annoying pee problems".

A two-week trial pack of Flomax Relief containing 14 capsules has a recommended retail selling price of £8.99 (€10.19), while a four-week supply of 28 capsules costs £16.99.

In December, the UK became the first country in the world to make Boehringer Ingelheim's Flomax a non-prescription medicine for treating benign prostatic hyperplasia (BPH), or an enlarged prostate (**OTC *bulletin***, 18 December 2009, page 1). The UK's Medicines and Healthcare products Regulatory Agency (MHRA) approved the switch of 0.4mg tamsulosin hydrochloride capsules from prescription-only to pharmacy (POM-to-P) status under the Flomax Relief brand name.

Flomax Relief is indicated for treating lower urinary-tract symptoms, such as urinary hesitancy and frequent urination, in men aged between 45 and 75 years.

OTC

Switches

New Zealand agrees to switch oral famciclovir

New Zealand has given the go-ahead for oral famciclovir to be switched to non-prescription status for treating cold sores.

From this month, when the switch should be implemented, New Zealand becomes the first country in the world to give non-prescription status to oral famciclovir. Topical medicines for treating cold sores are already sold without a prescription in many countries.

Oral famciclovir is currently available in key markets around the world from Novartis Pharmaceuticals as the prescription-only drug Famvir, which is indicated for treating cold sores, genital herpes and shingles.

In neighbouring Australia, a similar switch for oral famciclovir has been turned down twice (**OTC *bulletin***, 18 December 2009, page 9).

New Zealand's Medicines Classification Committee said Novartis New Zealand could market Famvir Once as a restricted or pharmacist-only medicine. The non-prescription product will be supplied as a pack of three, 500mg famciclovir tablets.

The approval comes six months after the committee turned down a similar application from Novartis. It said at the time that a few outstanding issues needed to be resolved (**OTC *bulletin***, 30 June 2009, page 1).

Some changes were made to the application considered at the committee's 3 November meeting, for which minutes have just been released. For example, the application included a treatment algorithm to help pharmacists identify patients who might benefit from the appropriate cold-sore therapy and to screen out patients who were unsuitable for OTC treatment. Novartis also changed the proposed brand name to Famvir Once.

Lansoprazole gets the go-ahead

At its November meeting, the committee also approved an application from Douglas Pharmaceuticals to switch Solox 15mg lansoprazole capsules from prescription-only to non-prescription status as a heartburn medicine. A previous attempt to gain restricted non-prescription medicine status had been rejected.

Bayer New Zealand's application to switch Losec 20mg omeprazole tablets to non-prescription status as a restricted medicine was also approved by the committee. The 10mg strength was launched as a non-prescription medicine in New Zealand last year (**OTC *bulletin***, 31 August 2009, page 17).

In addition, the committee gave the go-ahead for Sanofi-Aventis Australia's fexofenadine-based Telfast to be reclassified from a pharmacy-only to a general-sales medicine. The switch applies to capsules containing 60mg or less and tablets with 120mg or less.

Curbs for codeine medicines

Meanwhile, the committee has recommended that codeine in combination products should be classified as a restricted medicine when each dose unit contains not more than 15mg of codeine base, the maximum daily dose is limited to 100mg codeine base, and the pack size is not more than five days' supply.

Furthermore, the committee wants New Zealand's regulatory agency, Medsafe, to require labelling for codeine-containing medicines to carry warning statements similar to those used in the UK (**OTC *bulletin***, 16 September 2009, page 1). These would read: "Do not use for more than three days" and "Codeine is an addictive substance".

Cough and cold preparations containing codeine will remain pharmacy-only medicines, but this will be reviewed in 12-18 months.

The codeine recommendations follow several years of discussions.

OTC

Switches

Australia considers pantoprazole move

An application to allow the proton-pump inhibitor pantoprazole to be advertised to Australians will be considered next month.

The country's National Drugs and Poisons Schedule Committee (NDPSC) will review the application at its next meeting to be held on 16-17 February 2010.

Last year, the NDPSC rejected a proposal to add 20mg pantoprazole to Appendix H, which would have allowed the medicine to be advertised to consumers. The committee said at the time that there was a "lack of Australian data on pantoprazole as an OTC medicine", and it was "premature" to consider an Appendix H listing (**OTC *bulletin***, 17 April 2009, page 8).

Nycomed markets 20mg pantoprazole tablets under the Somac Heartburn Relief brand as a Schedule 3, or pharmacist-only, non-prescription medicine.

Flurbiprofen will be discussed

At the February meeting, the NDPSC will also consider the legal status of flurbiprofen, including a proposal to exempt from scheduling all topical oral flurbiprofen preparations.

After referrals from New Zealand's Medicines Classification Committee, the NDPSC will also consider the status of famciclovir, fexofenadine, lansoprazole and omeprazole.

OTC

Regulatory Affairs

Germany plans to restrict pack sizes for analgesics

Non-prescription packs of popular oral analgesics including acetylsalicylic acid, diclofenac and ibuprofen will be restricted to 20 units per pack, if the German parliament follows the recommendations of its Expert Committee for Prescription.

On 12 January, the expert committee voted in favour of curbing pack sizes for non-prescription analgesics on the grounds of improving patient safety.

Packs of acetylsalicylic acid for self-medication are to contain a maximum of 10,000mg of the active ingredient, which is equivalent to a pack of 20 x 500mg-strength tablets.

Similarly, packs of 25mg diclofenac tablets are to be restricted to 20 units, with a maximum amount per pack of 500mg.

Ibuprofen will be subject to a similar restriction of 20 x 400mg-strength tablets, totalling 8,000mg per pack.

Phenazone and propyphenazone are also covered by the proposed measure, which would impose a limit of 10,000mg of each active ingredient per non-prescription pack.

At its meeting in June of last year (**OTC *bulletin***, 30 June 2009, page 1), the expert committee asked Germany's federal institute for drugs and medical devices (BfArM) to prepare a proposal on harmonising pack sizes of non-prescription analgesics. The issue was then put on the agenda for the committee's meeting this month (**OTC *bulletin***, 30 November 2009, page 11).

At present, German consumers can purchase large packs of oral analgesics from pharmacies without a prescription. For example, Bayer Consumer Care's Aspirin tablets – each containing 500mg acetylsalicylic acid – are available as 50- and 100-unit packs. It also possible to buy similar-sized packs of ibuprofen tablets for self-medication.

However, restrictions limiting paracetamol to a maximum of 10,000mg per non-prescription pack came into effect on 1 April 2009.

Meanwhile, the expert committee rejected an application to switch liquid formulations of the antidiarrhoeal loperamide to non-prescription status.

The expert committee, which is scheduled to meet again on 6 July this year, will now forward its recommendations to Germany's ministry of health. Provided a statutory order tabled by the ministry is accepted by Germany's upper house of parliament, *the Bundesrat*, any changes could come into effect from 1 June this year.

OTC

Regulatory Affairs

US FDA creates a presence in Mexico

The Food and Drug Administration (FDA) in the US has opened an office in Mexico City as part of its ongoing efforts to increase scrutiny of medical and food products outside of the US.

The office in Mexico City is the agency's third post in Latin America and its 10th outside the US.

The FDA said staff assigned to Mexico City would work with their counterparts in the Mexican government to harmonise regulations and guidance standards. Collaborations would include information-sharing on regulatory systems and joint workshops on the safety of food and medical products, commented the regulatory agency.

Murray Lumpkin, the FDA's deputy commissioner for international programmes, said the agency's staff would also work with industry in Mexico. "FDA experts in Mexico City will work closely with local industries that ship food and medical products to the US to improve their understanding of US safety and product quality expectations," he explained. "Their activities will include providing technical advice and working with government agencies and the private sector to develop certification programmes."

The FDA's two existing posts in Latin America are located in Chile and Costa Rica. The agency also has international posts in China, India and Europe.

Plans to open a series of international posts were announced by the FDA in 2008 (**OTC *bulletin***, 31 October 2008, page 14).

OTC

Regulatory Affairs

Counterfeit report exempts OTC drugs

Anti-counterfeiting measures proposed by the European Commission may not be needed for certain generic drugs and for all non-prescription medicines, according to the rapporteur on the measures for the European Parliament's influential Environment, Public Health and Food Safety committee.

Marisa Matias agrees with the Commission in her draft report for the Parliament's lead committee on the legislation (**OTC *bulletin*,** 16 November 2009, page 16) that OTC medicines should be made exempt from the new law's provisions on 'safety features', at least initially. She adds, however, that this exemption should be reviewed within five years of the directive coming into force.

Driven by economic reasons

These 'safety features' – for identifying, authenticating and tracing medicines – must be made mandatory for prescription medicines, she believes, but adds that medicines will only be falsified "if there are economic reasons for doing so".

"Because of the low cost of generic medicines, it is less profitable to falsify [them]," she says. "The performance criteria for the safety features can be waived for certain generic medicines or product categories if this is in accordance with the conclusions of a risk assessment."

Matias notes opposing industry factions: those that want to reduce intermediaries and focus on the risks presented by products; and those that would prefer efforts were made to improve the integrity of the supply chain "without taking part in the sharing of responsibilities or costs". She says both interests should be taken into account, but the overriding consideration should be patient safety.

Lack of clear definitions

The Commission is also taken to task by Matias for not providing clear definitions, both of products and actors in the supply chain, such as traders and brokers.

Ignoring internet sales, which represent "one of the main routes for falsified medicines to enter the European Union", is another major deficiency of the Commission's proposal, in her view. Matias recommends raising public awareness of the dangers of buying medicines from websites and proposes a scheme that would validate legitimate internet traders.

OTC

CONSUMER *viewpoint*

Mouth ulcers are the subject of this month's Consumer viewpoint survey of ailments suffered by Europe's consumers. The survey appears exclusively in OTC bulletin courtesy of Ipsos MORI.

British people are more likely to say they have suffered from mouth ulcers during the past year than their counterparts in France, Germany, Italy or Spain, according to our **Consumer *viewpoint*** European survey.

Of the five countries covered by the Ipsos MORI survey, the UK has the highest proportion of people who say they have suffered from mouth ulcers during the past year at 7.0%, followed by Italy at 3.0%, Spain at 2.9%, France at 1.9% and Germany at 1.2% (see Figure 1).

The low incidence of mouth ulcers in most countries means the following results should be treated with caution.

As can be seen from Figure 2, there are significant variations across the five countries in terms of the sex and age of sufferers. Younger people in the UK and France are more likely to experience mouth ulcers.

OTC remedies are the most popular treatment option for mouth ulcers in Italy, Spain and the UK (see Figure 3). The French favour prescription products, while Germans are most likely to turn to herbal remedies.

Spain has the highest proportion of sufferers who have treated the condition with an OTC remedy at 69.4% (see Figures 4 and 5).

France has the highest proportion of prescription treaters at 53.9% (see Figure 6).

Germany has the highest proportion of herbal treaters at 29.0% (see Figure 7).

OTC

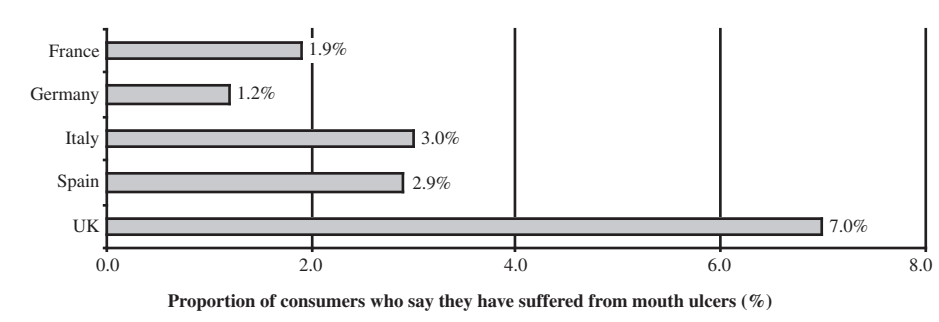


Figure 1: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers within the past year (Source – OTC *bulletin* 2010/Ipsos MORI)

	Proportion of sufferers (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	47.8	46.9	70.3	30.6	53.0	**100**	97	**144**	64	**109**
Female	52.2	53.1	29.7	69.4	47.0	**100**	**103**	58	**132**	91
18-24	23.3	7.2	2.9	11.2	21.0	**203**	81	32	93	**168**
25-34	20.1	13.3	11.3	21.4	15.5	**106**	98	64	**103**	93
35-44	6.6	32.6	10.8	26.5	22.4	34	**162**	55	**139**	**114**
45-54	19.7	28.0	19.7	18.6	19.1	**128**	**156**	**120**	**115**	**112**
55-64	11.4	8.7	32.7	17.6	7.0	67	60	**221**	**140**	48
65+	18.8	10.4	22.7	4.7	15.0	**105**	42	**122**	24	77

Figure 2: Consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers in the past year, analysed by sex and age. The index indicates the likelihood that a consumer in a specific population group will have suffered from mouth ulcers, and is the ratio of the proportion of total sufferers in a population group to the proportion of that group in the population as a whole (Source – OTC *bulletin* 2010/Ipsos MORI)

Ipsos MORI and the ailments survey

Our **Consumer *viewpoint*** ailments survey appears exclusively in **OTC *bulletin*** courtesy of Ipsos MORI. The survey is based on research conducted in February 2009 using Capibus, the market researcher's weekly European omnibus service. Ipsos MORI carried out face-to-face interviews with 1,000 plus adults in each of the survey countries – France, Germany, Italy, Spain and the UK. An OTC remedy was defined as a product purchased over-the-counter from a pharmacy or off a shop shelf.

■ For more information on the research supplied by Ipsos MORI, please contact Susan Purcell (Tel: +44 208 861 8000; Fax: +44 208 861 5515; E-mail: Susan.Purcell@ipsos-mori.com). OTC

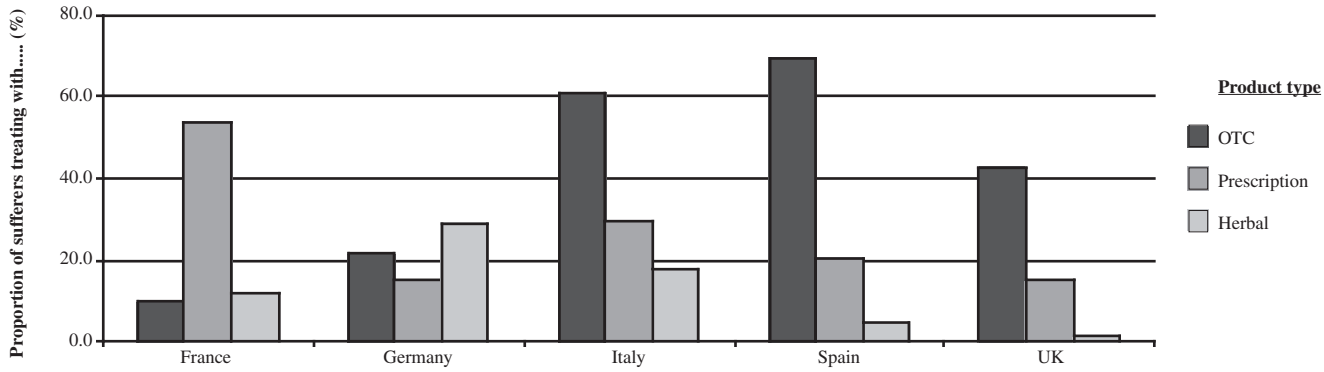


Figure 3: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers who have treated the condition with an OTC, prescription or herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

.....mouth ulcers

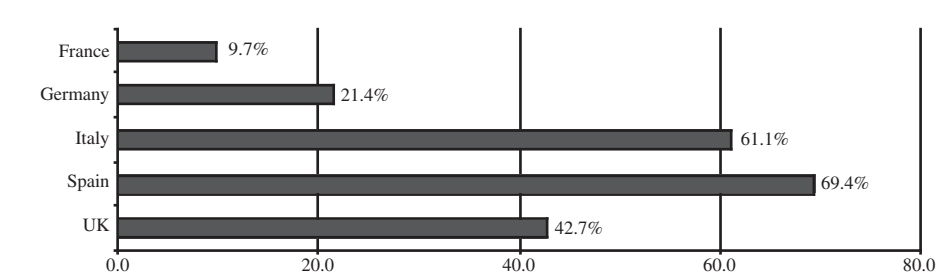


Figure 4: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers who have treated the condition with an OTC remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

	Proportion of sufferers treating with OTC (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	42.2	–	72.1	29.1	57.0	88	–	**148**	61	**117**
Female	57.8	100	27.9	70.9	43.0	**111**	**194**	54	**135**	84
18-24	–	33.5	–	13.7	17.3	–	**376**	–	**114**	**138**
25-34	–	–	–	26.0	23.4	–	–	–	**126**	**140**
35-44	–	26.0	15.0	29.6	18.1	–	**129**	76	**156**	92
45-54	57.8	–	21.5	10.9	24.2	**375**	–	**131**	67	**142**
55-64	–	40.5	35.5	12.9	5.1	–	**281**	**240**	**102**	35
65+	42.2	–	28.0	6.8	11.9	**236**	–	**151**	35	61

Figure 5: Consumers in France, Germany, Italy, Spain and the UK who have used an OTC remedy to treat mouth ulcers, analysed by sex and age. The index provides a measure of the likelihood that a consumer suffering from mouth ulcers in a specific population group will have treated the condition with an OTC remedy, and is the ratio of the proportion of total OTC treaters in a population group to the proportion of that group in the population as a whole (Source – OTC *bulletin* 2010/Ipsos MORI)

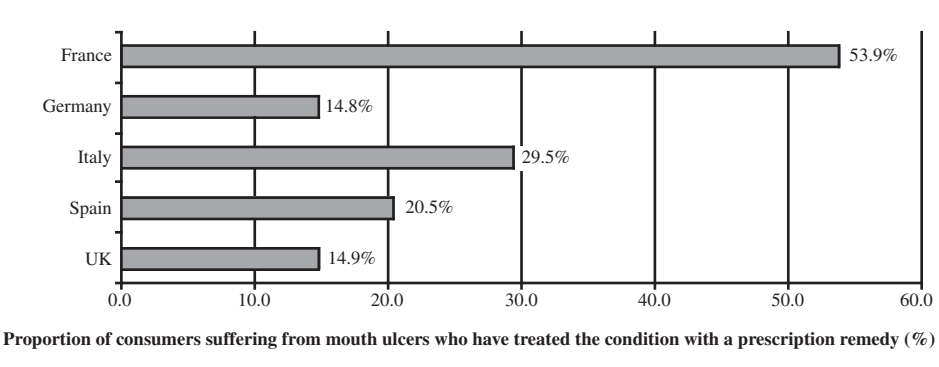


Figure 6: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers who have treated the condition with a prescription remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

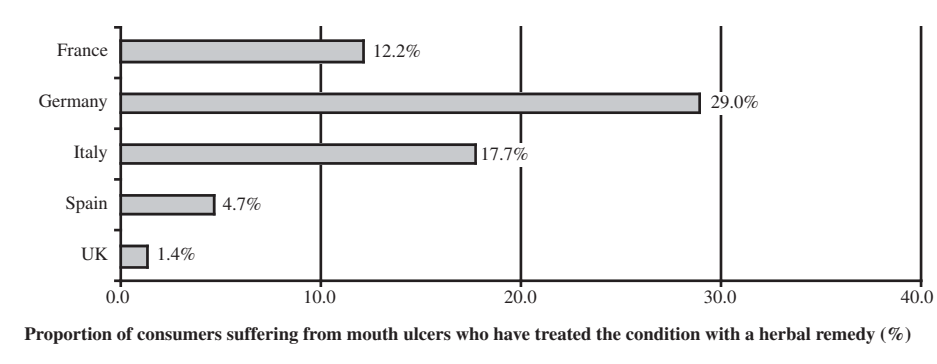


Figure 7: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from mouth ulcers who have treated the condition with a herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

Switches

Germany completes pantoprazole switch

Medicines containing 20mg pantoprazole for short-term treatment of heartburn and acid reflux now have non-prescription status in Germany.

Germany's upper house of parliament, the Bundesrat, voted on 18 December in favour of switching such formulations from prescription-only to non-prescription status. The switch took effect from 1 January.

The maximum pack size is 14 tablets or capsules, and the non-prescription version is indicated solely for adults (**OTC *bulletin***, 18 December 2009, page 11).

The proposed switch was announced soon after Nycomed introduced 20mg pantoprazole tablets in Germany as the non-prescription medicine Pantozol Control (**OTC *bulletin***, 30 September 2009, page 20).

Germany was one of the first countries where Nycomed launched Pantozol Control after the 20mg pantoprazole tablet gained non-prescription status for frequent heartburn throughout the European Union in June (**OTC *bulletin***, 19 June 2009, page 1).

According to the German ministry, switching all 20mg pantoprazole formulations with a maximum pack size of 280mg would "improve transparency" after Nycomed's switch took effect throughout the European Union.

The European Commission's Pharmaceuticals Unit says the "same medicinal product" should not, as a general rule, have both prescription-only and non-prescription status in the same member state of the European Union (**OTC *bulletin***, 29 May 2009, page 12).

The "same medicinal product" is defined as the same active substance at the same strength and in the same pharmaceutical form. The approved indications for prescription-only 20mg pantoprazole formulations in Germany include heartburn and acid reflux.

As pantoprazole lost patent protection in Germany earlier this year, the switch should see many branded and generic companies introduce non-prescription competitors to Nycomed's Pantozol Control.

OTC

IN BRIEF

■ **MHRA** – the UK's Medicines and Healthcare products Regulatory Agency – has issued new guidance on the **naming of medicines**. The regulatory body said the guidance consolidated existing requirements.

OTC

Regulatory Affairs

UK MHRA restricts sales of painkillers

Best practice for the sale of medicines for pain relief has been published by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

Retailers should not sell more than two packs in one transaction, according to the MHRA's best-practice guidance, neither should they promote offers that encourage the sale of more than one pack at a time. However, the best practice guidance does not prevent reduced price offers on single packs.

Voluntary restrictions

Described as "voluntary restrictions" by the MHRA, the best-practice guidance adds to the medicines legislation. This states that it is illegal to sell more than 100 tablets or capsules of either paracetamol or aspirin in any one retail transaction.

The maximum pack size for pain-relief medicines in a general-sale outlet is 16 tablets or capsules. A pharmacy may sell larger packs containing up to 32 tablets or capsules under the supervision of a pharmacist.

"Restricting the availability of these medicines has proved to be effective in reducing the harm from accidental or intentional overdose, estimated from number of deaths and hospital admissions," commented June Raine, the MHRA's director of vigilance and risk management of medicines.

"Clearly stating 'best practice' for sale of these medications," Raine added, "will ensure that retailers are meeting a customer's immediate need for pain relief while helping to minimise stockpiling and the risk of overdose."

The MHRA said the best-practice guidance was the result of work with stakeholders representing both large and small retailers, pharmacists, trading standards offices and the pharmaceutical industry, as well as the British Retail Consortium (BRC) and the Association of Convenience Stores (ACS).

In December, the MHRA highlighted two cases of retailers selling multiple packs of pain relievers. A Home Bargains store was warned for selling a customer six packs of 16 paracetamol tablets, while a Dips News and Off Licence ran into trouble for allegedly selling more than 100 tablets of paracetamol in one go.

The MHRA said both retailers had reviewed their policies on the sale of paracetamol and aspirin, and had restricted the sale of these products to a maximum of two packs of 16.

OTC

Switches

Austria gives OTC status to emergency contraception

Austrian women now have access to emergency contraception without a prescription, after the country's federal office for healthcare safety, the BASG, decided on 17 December 2009 to switch Vikela 1.5mg levonorgestrel tablets to pharmacy-only status.

Local company Sanova Pharma is marketing the morning-after pill in Austria for the marketing-authorisation holder, France's HRA Pharma. The recommended retail selling price for a single tablet is €11.90.

"As an emergency contraceptive, Vikela is a relatively safe method – when used correctly – to prevent an unwanted pregnancy after unprotected sex or when other contraception methods fail," the BASG stated.

The 1.5mg dose of levonorgestrel was "medically harmless", the BASG continued, but its previous prescription-only status had prevented Austrian women from gaining access to the emergency contraceptive within the necessary 72 hours after intercourse.

Up to 30% of women who were observed in clinical trials for Vikela had suffered from side-effects including bleeding and sensitive breasts, the BASG acknowledged. However, such side-effects typically abated within 48 hours, it added.

Within Europe, the BASG observed, levonorgestrel was already available without prescription in Belgium, Denmark, Estonia, Finland, France, Iceland, Latvia and Luxembourg, as well as Norway, Portugal, Slovakia, Switzerland, Sweden, the Netherlands and the UK.

Levonorgestrel was first authorised in Austria in 2005. The switched medicine is identical to Norlevo 1.5mg in France and Unofem 1.5mg in Germany.

However, whereas HRA Pharma's Norlevo 1.5mg has been available without a prescription in France since the end of 2004 (**OTC *bulletin***, 17 December 2004, page 17), German politicians have failed to act on the advice of their Expert Committee for Prescription that a switch should go ahead (**OTC *bulletin***, 31 July 2003, page 14).

OTC

Product Launches

Xerclear obtains OTC status in Sweden

A non-prescription pack of Medivir's combination cold-sore medicine, Xerclear, will be introduced in Sweden during the second quarter of this year.

The 2g tube will join the prescription-only 5g tube of Xerclear, which is set to be launched in Sweden this quarter.

Medivir said that Xerclear – a topical medicine containing 50mg/g aciclovir and 10mg/g hydrocortisone – was "the first and only topical treatment that has been demonstrated to prevent the incidence of cold sores and shorten healing times. "Current therapies shorten healing times but have not been clinically demonstrated to be able to prevent the incidence of cold sores," added the company.

Xerclear was approved in 14 countries in Europe last year through a European licensing procedure.

The medicine was also authorised in the US on 31 July 2009 as a prescription-only drug under the Lipsovir brand name.

OTC

Product Launches

DEcarb grows Goldshield's weight-loss portfolio in UK

Goldshield has expanded its portfolio of weight-management products in the UK with a "natural carbohydrate blocker", which is aimed at "people with a dietary weakness for starchy carbohydrates such as pasta, rice and noodles".

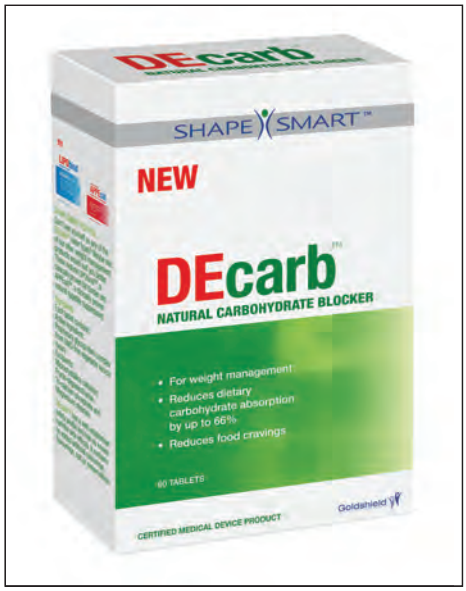
DEcarb is a medical device containing white kidney bean extract. Goldshield said the extract had been shown in clinical studies to reduce calorie intake by inhibiting the enzymes that the body uses to breakdown carbohydrates. According to Goldshield, DEcarb could block up to 66% of dietary carbohydrates eaten.

DEcarb can be purchased from the brand website at www.decarb.co.uk or the company website at www.goldshield.co.uk. Goldshield noted that DEcarb would be available from retail stores in the summer.

A pack of 60 tablets has a recommended retail selling price of £29.95 (€33.50). Packs carry straplines pointing out that the product is "For weight management", "Reduces dietary carbohydrate absorption by up to 66%", and "Reduces food cravings".

DEcarb joins Goldshield's growing portfolio of weight-management products. The company's Appesat is a medical device based on a "naturally-sourced fibre complex from seaweed", and is described on the packaging as a "Clinically-proven natural appetite suppressant". Meanwhile, LIPObind is a "natural slimming aid derived from dried cactus extract", which is said on the packaging to be a "Clinically proven fat binder".

In a separate development, Goldshield has extended its Flexeze joint-health brand in both France and the UK with Flexeze Fortify. The newcomer contains a patented collagen hydrolysate called Fortigel, and is backed by the on-pack claim "Supports the natural rebuilding of joint cartilage".



Goldshield says its new DEcarb weight-management product is aimed at "people with a dietary weakness for starchy carbohydrates"

Goldshield maintained that Flexeze Fortify was the "next step up from traditional glucosamine-based products". "It deals with the root cause of joint problems and helps rebuild cartilage that is usually damaged by the wear and tear of arthritis," explained the company, adding that glucosamine, by contrast, mostly slowed down the effects.

Flexeze Fortify is a food supplement supplied as powder to be dissolved in water. The pack of 30 one-a-day sachets sells for £29.99 in the UK.

A spokesperson for Goldshield told **OTC *bulletin*** that Flexeze Fortify would be launched in the US this summer through the company's website. Goldshield was also considering launches in other European countries, added the spokesperson, and was in discussions to make the product available from retail stores in the UK.

Existing products in the Flexeze range include: oral tablets and capsules containing glucosamine and chondroitin sulphate; a liquid containing glucosamine; and a topical gel containing glucosamine.

OTC

Available in France and the UK, Goldshield's new Flexeze Fortify joint-health supplement is described by the company as "the next step up from traditional glucosamine-based products"

Product Recalls

McNeil extends US Tylenol recall

McNeil Consumer Healthcare has expanded its voluntary recall of Tylenol Arthritis Pain caplets in the US to cover all lots of 100-count bottles with the red EZ-OPEN cap.

In November, the Johnson & Johnson subsidiary voluntarily recalled five product lots. The company commented at the time that it had identified an "uncharacteristic smell or taste associated with these lots that led to a small number of consumers reporting nausea and related symptoms" (**OTC *bulletin***, 16 November 2009, page 17).

Chemical used to treat wooden pallets

Noting the recall had been expanded as a precaution, McNeil said that the uncharacteristic smell was caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. "The source of 2,4,6-tribromoanisole is believed to be the breakdown of a chemical used to treat wooden pallets that transport and store packaging materials," explained the company. "The health effects of this compound have not been well studied, and to date all of the observed events reported to McNeil were temporary and non-serious."

OTC

The "show and tell" commercial for Canesten Duo is back on television in the UK this month.

Bayer Consumer Care is investing £1 million (€1.1 million) in a burst of advertising running nationally from 11 January until the end of March.

First shown in 2008, the animated commercial demonstrates the product's dual approach to treating vaginal thrush. With the aid of a flip chart, a woman explains how Canesten Duo's oral fluconazole capsule helps to clear the internal infection while its topical clotrimazole cream cools the external symptoms. "Cools and clears," is the sign-off message to viewers (OTC *bulletin*, 30 May 2008, page 16).

Bayer noted that the commercial had recently been modified to place greater emphasis on the "unique" double-strength 2% clotrimazole cream.

Quoting IRI data for the 52 weeks ended 3 October 2009, Bayer said Canesten was the number one brand in the thrush treatment market with a 76% share of value sales in pharmacy.

OTC

Pharmacists rate NiQuitin and Benylin

NiQuitin and Benylin are the star performers in the latest rankings for Pharmacy viewpoint – our monthly survey of UK pharmacists' attitudes to OTC sales and marketing, which is published exclusively in OTC bulletin courtesy of the Intr@PharmQ service from IMS.

Two brands dominated our closing **Pharmacy *viewpoint*** survey of 2009. GlaxoSmithKline Consumer Healthcare's NiQuitin notched up three wins and a second place, as the company alerted pharmacy staff to the introduction of the Minis line extension. Meanwhile, McNeil Products' Benylin achieved one top spot and a second position thanks to the firm's memorable launch campaign for the Mucus Cough variants.

In the trade-press advertising part of **Pharmacy *viewpoint***, NiQuitin had a small lead over Benylin. When IMS Consumer Health surveyed UK pharmacists between 1 and 17 December 2009 using its Intr@PharmQ service, 13% said the nicotine-replacement therapy was backed by the best current trade-press advertising for an OTC medicine or dietary supplement (see Figure 1). Most of these pharmacists specifically mentioned the Minis product.

A full-page advertisement for NiQuitin 4mg Minis – created by the agency TBWA/Paling Walters – points out that the lozenges provide fast craving relief within minutes. It also states that the product is "designed especially for those smokers who know they should quit, but want to do it at their own pace".

As well as highlighting the efficacy of NiQuitin Minis, the advertisement draws attention to the "discreet and portable" product packaging with an actual-size picture. The packaging also features prominently on the front cover of a sales aid, on a leave-piece and on a direct mailing.

One interesting development in the trade-press advertising section was the sixth place for AstraZeneca's Emla local anaesthetic cream. The company recently relaunched Emla in the UK with a new pharmacy campaign, fresh public relations activity, and revamped packaging (**OTC *bulletin***, 16 October 2009, page 16).

McNeil Products' memorable launch television commercial for Benylin Mucus Cough – which portrays mucus as a green character that clings to the chest – leads the television rankings for the second month in a row

Current trade-press advertising for Emla features the new OTC packaging, which carries the strapline "All you need for a less painful needle experience". The pharmacy-only medicine's formulation remains the same – 2.5% w/w lidocaine and 2.5% w/w prilocaine – but packs now contain two occlusive dressings as well as the cream.

In the television-advertising section of **Pharmacy *viewpoint***, NiQuitin had to settle for second place behind Benylin. As can be seen from Figure 2, one in five pharmacists surveyed in December said the cough medicine was backed by the best current television advertising. It is the second month in a row that Benylin has captured the top spot.

This winter, McNeil has boosted Benylin with two formulations that are claimed to thin and loosen chest mucus (**OTC *bulletin***, 30 November 2009, page 16).

Benylin Mucus Cough is a red syrup containing 100mg guaifenesin and 1.1mg levomenthol per 5ml. The general-sale list medicine has a recommended retail selling price of £4.99 (€5.55) for a 150ml bottle of the syrup.

Benylin Mucus Cough Night is a red syrup containing 100mg guaifenesin, 1.1mg levomenthol and 14mg diphenhydramine per 5ml. A

BEST CURRENT REPRESENTATIVE DETAILING

Rank	Brand	Company	Product type	Pharmacists (%)
1	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	10
2	Lemsip	Reckitt Benckiser	Cough/cold remedy	9
3	Gaviscon	Reckitt Benckiser	Indigestion remedy	5
4	Alli	GlaxoSmithKline	Weight-loss medicine	4
5=	Beechams	GlaxoSmithKline	Cough/cold remedy	3
	Benylin	McNeil Products	Cough/cold remedy	3
	HealthAid	HealthAid	Food supplement	3
	Nicotinell	Novartis	Smoking-cessation aid	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 4: Unprompted response of UK pharmacists between 1 December and 17 December 2009 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best representative detailing?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

Intr@PharmQ and Pharmacy *viewpoint*

Pharmacy *viewpoint* is a monthly survey of pharmacy attitudes to OTC marketing in the UK, which appears exclusively in **OTC *bulletin*** courtesy of the Intr@PharmQ service from IMS.

The survey highlights pharmacists' attitudes to OTC marketing campaigns – both as healthcare professionals and consumers – as well as reflecting their general feelings about particular OTC brands.

Intr@PharmQ is a rapid information-gathering service consisting of web-based interactive questionnaires on the Intr@Pharm community pharmacy portal. Questionnaires can be set up on the site quickly, and responses collated within days.

The service can be used to ask pharmacists about a range of subjects including products, company image and representatives. OTC

■ For further information contact Tai Azeez, IMS, 7 Harewood Avenue, London NW1 6JB, UK (Tel: +44 20 3075 4142; Fax: +44 20 7393 5900; E-mail: TAzeez@uk.imshealth.com).

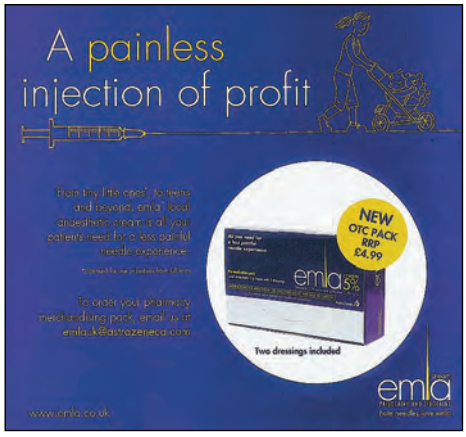
GlaxoSmithKline Consumer Healthcare's advertising for NiQuitin is top in the trade-press section

pharmacy medicine, it comes in a 150ml pack retailing at £4.99.

McNeil is backing Benylin Mucus Cough and Benylin Mucus Cough Night with an advertising spend in excess of £5 million, including extensive television air-time.

Created by the agency JWT, the television commercial for Benylin Mucus Cough portrays mucus as a green character dressed as a wrestler. It opens with a shot of a man asleep. He is woken up by the green character, which wrestles him to the floor and clings to his chest. However, the man struggles to his bathroom cabinet, takes Benylin Mucus Cough, and the green character loses its strength. "Get it off your chest with Benylin," is the sign-off.

In the sections for best current pharmacy-support package and best current representative detailing, NiQuitin came top (see Figures 3 and 4). The majority of pharmacists voting for NiQuitin mentioned the Minis variant.



AstraZeneca's relaunch of its Emla local anaesthetic cream has caught the eye of pharmacists

OTC

PHARMACY *viewpoint*

BEST CURRENT TRADE-PRESS ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	13
2	Benylin	McNeil Products	Cough/cold remedy	11
3=	Alli	GlaxoSmithKline	Weight-loss medicine	6
	Calpol*	McNeil Products	Children's analgesic	6
	Covonia	Thornton & Ross	Cough/cold remedy	6
6=	Emla	AstraZeneca	Local anaesthetic cream	4
	Nicorette	McNeil Products	Smoking-cessation aid	4
	Vicks	Procter & Gamble	Cough/cold remedy	4
9=	Nurofen	Reckitt Benckiser	Oral/topical analgesic	3
	Transvasin	Thornton & Ross	Topical pain relief	3
	Wellman	Vitabiotics	Food supplement	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

* Includes Calcold, Calpol and Calprofen

Figure 1: Unprompted response of UK pharmacists between 1 December and 17 December 2009 when they were asked the question: "In your opinion, what is the best current trade-press advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT TELEVISION ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Benylin	McNeil Products	Cough/cold remedy	20
2	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	11
3	Gaviscon	Reckitt Benckiser	Indigestion remedy	8
4=	Covonia	Thornton & Ross	Cough/cold remedy	7
	Lemsip	Reckitt Benckiser	Cough/cold remedy	7
6	Beechams	GlaxoSmithKline	Cough/cold remedy	6
7	Alli	GlaxoSmithKline	Weight-loss medicine	5
8	Nurofen	Reckitt Benckiser	Oral/topical analgesic	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 2: Unprompted response of UK pharmacists between 1 December and 17 December 2009 when they were asked the question: "In your opinion, what is the best current television consumer advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT PHARMACY-SUPPORT PACKAGE

Rank	Brand	Company	Product type	Pharmacists (%)
1	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	14
2	Alli	GlaxoSmithKline	Weight-loss medicine	12
3	Lemsip	Reckitt Benckiser	Cough/cold remedy	11
4	Gaviscon	Reckitt Benckiser	Indigestion remedy	6
5	Benylin	McNeil Products	Cough/cold remedy	4
6=	Beechams	GlaxoSmithKline	Cough/cold remedy	3
	Covonia	Thornton & Ross	Cough/cold remedy	3
	Emla	AstraZeneca	Local anaesthetic cream	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 3: Unprompted response of UK pharmacists between 1 December and 17 December 2009 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best pharmacy-support package (consumer/trade advertising, bonus deals, profit margin, training, etc)?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

Product Recalls

Dendron recalls Dentinox in UK

Dendron has recalled several batches of its Dentinox Teething Gel in the UK due to the presence of very small amounts of the contaminant glyoxal.

The Medicines and Healthcare products Regulatory Agency (MHRA) stressed that the recall was "precautionary". "There is currently no evidence of harm and no suspected adverse drug reactions have been reported," said the MHRA.

The regulatory body noted that glyoxal was an organic compound that occurred naturally, and was found in the environment and some foods at very low levels.

OTC

Product Recalls

DayQuil LiquiCaps recalled in the US

A packaging problem has forced Procter & Gamble to recall Vicks DayQuil Cold & Flu 24-Count LiquiCaps in the US.

Procter & Gamble said the product did not have a child-resistant backing for the blister packs in the box, despite label statements that it was supplied in child-resistant packaging. "The lack of child-resistant packaging means it is possible that a child could gain access to the medicine," added the company.

However, Procter & Gamble stressed that "no accidental ingestion by children" had been reported.

No other DayQuil or Vicks products are affected by the recall.

OTC

IN BRIEF

■ **LLOYDSPHARMACY** in the UK is piloting a **weight-management service** in 20 of its pharmacies in Scotland. As the name suggests, the Lloydspharmacy Tailored Weight Loss Solutions service provides a personalised weight-loss programme. Customers would be given a free consultation in a private room, said the retailer, adding that weight-loss experts would take height and weight measurements, calculate the body-mass index and discuss the most appropriate weight-loss solution based on the individual's goals.

OTC

Litigation

German court controls use of the suffix 'akut'

Including the suffix 'akut' in the name of a medicine in Germany implies that the medicine is effective within an hour, according to a Munich regional court.

The court reached the decision in a case brought by a body dedicated to "honest competition" against a pharmaceutical company that used the 'akut' suffix for a non-prescription heartburn remedy.

Earlier this year, Hexal launched 20mg omeprazole capsules under the Omep Akut brand name following a switch of the active ingredient from prescription-to-non-prescription status (**OTC *bulletin***, 31 August 2009, page 21).

The generics specialist continued to sell Omep Akut even after litigation over its suffix was initiated (**OTC *bulletin***, 30 October 2009, page 12). However, Hexal has now dropped the 'akut' suffix and is marketing its non-prescription omeprazole capsules under the Omep brand name.

In the case, the competition body claimed the non-prescription medicine became effective several hours after it was taken, so the 'akut' suffix gave a misleading impression of acute relief.

However, the pharmaceutical company insisted that its product could alleviate symptoms within an hour of being taken. Furthermore, the product was effective at the latest within one-and-a-half to three hours of having been taken.

Judges at the Landgericht München found the competition body's arguments more persuasive. Consumers targeted by advertising for the OTC heartburn medicine would be led to believe through the 'akut' suffix that the remedy offered rapid relief, they ruled. Such rapid relief, they said, would require an onset of action within 20 to 60 minutes.

No more information on the court case was available as **OTC *bulletin*** went to press.

OTC

Two liquid products for controlling mucus are the latest additions to Procter & Gamble's Vicks brand in the US.

Vicks DayQuil Mucus Control and Vicks DayQuil Mucus Control DM both contain 200mg of the expectorant guaifenesin in each 15ml tablespoon. The DM version also provides 10mg of the cough suppressant dextromethorphan hydrobromide.

DayQuil Mucus Control is claimed to "help loosen phlegm from your bronchial passageways to help you breathe easier", while the DM version is formulated "for temporary cough relief and to help loosen phlegm from your bronchial passageways". Both products work for four hours.

The products are available in a choice of 6 fl oz or 10 fl oz bottles with an average retail selling price of US$6.49-US$7.29 (€4.49-€5.00).

OTC

FEBRUARY

10 February

■ **Basics of Regulatory Affairs**

London, UK

A one-day course organised by The Organisation for Professionals in Regulatory Affairs (TOPRA).

***Contact**: TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ, UK. Tel: +44 20 7510 2560. Fax: +44 20 7537 2003. E-mail: meetings@topra.org. Website: www.topra.org.*

11 February

■ **The Pharma Summit**

London, UK

Ornella Barra from Alliance Boots, David Brennan from AstraZeneca, and Jeff George from Sandoz will be three of the speakers at this one-day conference.

***Contact**: Economist Conferences, 26 Red Lion Square, London WC1R 4HQ, UK. Tel: +44 20 7576 8118. Fax: +44 20 7576 8472. E-mail: weurope_customerservice@economist.com. Website: www.economistconferences.co.uk.*

18-19 February

■ **CIS Pharmaceutical Forum**

Moscow, Russia

This two-day conference will look at the pharmaceutical markets in Armenia, Belarus, Georgia, Kazakhstan, Russia, the Ukraine and other CIS countries.

***Contact**: Adam Smith Conferences, 6th Floor, 29 Bressenden Place, London SW1E 5DR, UK. Tel: +44 20 7017 7444. Fax: +44 20 7017 7447. E-mail: events@adamsmithconferences.com. Website: www.cispharmaforum.com.*

22 February

■ **The Borderline Between Cosmetics and Drugs**

London, UK

This one-day conference will be chaired by Ronald Marks.

***Contact:** Management Forum, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK. Tel: +44 1483 730071. Fax: +44 1483 730008. E-mail: registrations@management-forum.co.uk. Website: www.management-forum.co.uk.*

23 February

■ **Marketing Authorisation in the European Union**

Bonn, Germany

Topics to be covered at this one-day meeting include variations and the centralised procedure.

***Contact**: Forum Institut für Management, Postfach 10 50 60, 69040 Heidelberg, Germany. Tel: +49 6221 500 680. Fax: +49 6221 500 555. E-mail: h.wolf-klein@forum-institut.de. Website: www.forum-institut.com.*

MARCH

1 March

■ **Marketing Authorisation in the CIS countries**

Berlin, Germany

This one-day meeting will cover Belarus, Kazakhstan, Russia, the Ukraine and other CIS countries.

***Contact**: Forum Institut für Management, Postfach 10 50 60, 69040 Heidelberg, Germany. Tel: +49 6221 500 680. Fax: +49 6221 500 555. E-mail: h.wolf-klein@forum-institut.de. Website: www.forum-institut.com.*

1-2 March

■ **EuroPLX 42**

Valletta, Malta

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

***Contact**: RauCon, Kurfürstenstrasse 1A, 69234 Dielheim, Germany. Tel: +49 6222 9807 0. Fax: +49 6222 9807 77. E-mail: europlx@raucon.com. Website: www.raucon.com.*

2 March

■ **Variations Regulation**

Cologne, Germany

Peter Bachmann and Susanne Winterscheid from the German federal institute for drugs and medical devices, BfArM will speak at this one-day conference.

***Contact**: Forum Institut für Management, Postfach 10 50 60, 69040 Heidelberg, Germany. Tel: +49 6221 500 680. Fax: +49 6221 500 555. E-mail: h.wolf-klein@forum-institut.de. Website: www.forum-institut.com.*

4 March

■ **Variations to Marketing Authorisations**

London, UK

A one-day conference focusing on mutual recognition, decentralised, centralised and national variations to marketing authorisations with emphasis on the UK and Ireland.

***Contact:** Management Forum, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK. Tel: +44 1483 730071. Fax: +44 1483 730008. E-mail: registrations@management-forum.co.uk. Website: www.management-forum.co.uk.*

8-10 March

■ **DIA Annual EuroMeeting**

Larvotto, Monaco

'The challenges of switching from prescription to non-prescription status through the centralised procedure' is one of 13 themes at the annual EuroMeeting of the Drug Information Association (DIA).

***Contact**: DIA, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland. Tel: +41 61 225 5151. Fax: +41 61 225 5152. E-mail: diaeurope@diaeurope.org. Website: www.diahome.org.*

APRIL

16 April

■ **Medicines Variations Regulation**

London, UK

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

***Contact**: Conferences and Learning Centre, MHRA, 16th Floor, Market Towers, 1 Nine Elms Lane, London SW8 5NQ, UK. Tel: +44 20 7084 2903. Fax: +44 20 7084 3522. E-mail: conferences@mhra.gsi.gov.uk. Website: www.mhra.gov.uk.*

19, 20-21 & 22 April

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

Budapest, Hungary

A pre-conference symposium entitled 'Regulatory affairs in the CIS region' and a post-conference workshop on 'Practical application of pharmacovigilance in regulatory affairs' will accompany this two-day meeting.

***Contact**: Informa UK, PO Box 406, Byfleet KT14 6WL, UK. Tel: +44 20 7017 7481. Fax: +44 20 7017 7823. E-mail: registrations@informa-ls.com. Website: www.informa-ls.com.*

MAY

18-19 May

■ **Regulatory Affairs in Africa**

London, UK

This two-day event will focus on pharmaceutical regulatory affairs in Africa, including South Africa.

***Contact:** Management Forum, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK. Tel: +44 1483 730071. Fax: +44 1483 730008. E-mail: registrations@management-forum.co.uk. Website: www.management-forum.co.uk.*

18-20 May

■ **Vitafoods**

Geneva, Switzerland

A three-day exhibition and conference focusing on nutraceuticals, cosmeceuticals, functional foods and functional drinks.

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Sanofi-Aventis reshapes its OTC business

2009 saw Sanofi-Aventis set about transforming its OTC business into a global operation through local acquisitions, including most recently Chattem in the US. Deborah Wilkes reports on the strategy.

"Sanofi-Aventis probably has one of the most interesting portfolios of prescription-to-OTC switch candidates in the business," according to Chris Viehbacher, chief executive officer of the French pharmaceutical company. But before making a move for Chattem, it lacked access to the OTC market offering the largest potential to exploit the opportunity, namely the US.

Noting that innovation is hard to come by in the OTC market, Viehbacher maintains that the growth and dynamism of the US OTC market is driven by switches. Schering-Plough's Claritin, Procter & Gamble's Prilosec OTC and Johnson & Johnson's Zyrtec have all brought "electric" growth, he observes.

Switch pipeline at Sanofi-Aventis

The switch pipeline at Sanofi-Aventis includes the acne medicine BenzaClin (clindamycin/benzoyl peroxide), the corticosteroid Nasacort (triamcinolone), and the antifungal Penlac (ciclopirox), says Viehbacher. But switching the antihistamine Allegra (fexofenadine hydrochloride) in the US is the priority, he adds.

Viehbacher points out that the opportunity to switch Allegra in the US is the driving force behind Sanofi-Aventis' proposed US$1.9 billion (€1.3 billion) purchase of Chattem, whose board's approval for the move was announced on 21 December (see front cover). Although the existing OTC business at Sanofi-Aventis is ranked number six in the world, it has no direct presence in the US.

Allegra is a well-recognised brand with both physicians and consumers in the US, says Viehbacher, and major OTC players have expressed an interest in switching the allergy remedy on behalf of Sanofi-Aventis.

"However, if you do this with someone else, then you play a completely passive role," he comments. "That would not allow us to build an OTC presence in the US, and we would be giving away a significant chunk of profit to the other company."

Viehbacher explains that Sanofi-Aventis decided to look around for a company that had the skills and competency to help it launch an OTC version of Allegra itself. "We found Chattem," he says, adding: "We believe our ability to convert prescription medicines to OTC products will be enhanced by Chattem's leading sales, marketing and distribution channels."

Successfully launching an OTC version of Allegra in the US will not be easy. Key competitors, such as Claritin and Zyrtec, are already well-established in the OTC market for allergy medicines. Furthermore, Allegra already faces generic competition in the prescription sector, and store-brand players will be keen to capitalise on the OTC opportunity.

Hanspeter Spek, president of global operations at Sanofi-Aventis, says Allegra has one of the best safety and efficacy profiles in the antihistamine category. There were around 23 million prescriptions in total for fexofenadine – including generics – in the US in 2008, he says, of which more than five million were for the Allegra brand.

Viehbacher, meanwhile, stresses that there is "significant brand awareness" of Allegra in the US, despite the generic competition.

A successful US switch of Allegra would make a big difference to Sanofi-Aventis' OTC business. Acquiring Chattem will create the world's fifth-largest consumer healthcare company with sales of around €1.7 billion, says Viehbacher, adding that switching Allegra has the potential to move the business up the rankings "pretty significantly".

The news that Sanofi-Aventis had agreed to acquire Chattem came at the end of a year that saw the French pharmaceutical firm set about transforming its existing OTC business into a global operation through local acquisitions.

The first sign that the OTC business was moving up the agenda at Sanofi-Aventis came in 2008. In July of that year, the company agreed to buy Symbion Health's consumer healthcare business from Australia's Primary Health Care for A$560 million (€360 million). The acquired business had sales of A$190 million in 2007 (**OTC *bulletin***, 31 July 2008, page 1).

The deal gave Sanofi-Aventis a portfolio of nutraceutical and OTC brands in Australia and New Zealand, including the Bio-organics, Cenovis, Golden Glow, Microgenics and Nature's Own brands, and a share of around a fifth of the Australian consumer healthcare market. Sanofi-Aventis said the deal would provide "a platform to launch a nutraceutical offering throughout the Asia-Pacific region".

At the start of 2009, the OTC industry was waiting to see how Sanofi-Aventis would develop under the leadership of Viehbacher, who had taken over as chief executive officer on 1 December 2008. Despite being one of the top 10 global OTC players, Sanofi-Aventis was a sleeping OTC giant with a low profile (**OTC *bulletin***, 29 January 2009, page 24).

The industry did not have to wait long. In February, Sanofi-Aventis said it intended to double the size of its OTC business to around €3 billion within the next five years through acquisitions and geographic expansion. The company added that it expected to see repeated opportunities to acquire OTC businesses with sales of around €100 million over the next five years (**OTC *bulletin***, 27 February 2009, page 1).

At the time, Viehbacher acknowledged that Sanofi-Aventis was "clearly not a serious OTC player" in the way its global ranking would suggest. Nobody oversaw the OTC business as a whole, he said, and it was run "as a kind of product portfolio" within individual countries.

Developing the OTC business is part of Viehbacher's strategy to transform Sanofi-Aventis into a "diversified global healthcare leader". The OTC business is one of the company's five key growth drivers together with diabetes prod-

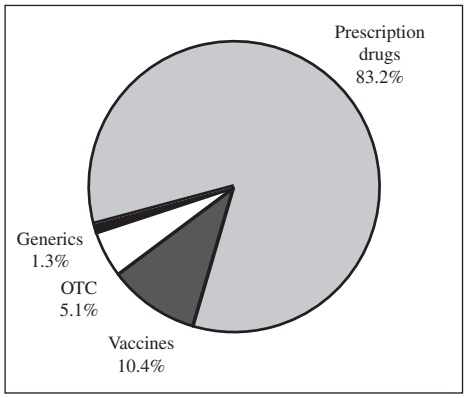

Figure 1: Sanofi-Aventis' sales in 2008 – €27.6 billion – broken down by business (Source – Sanofi-Aventis)

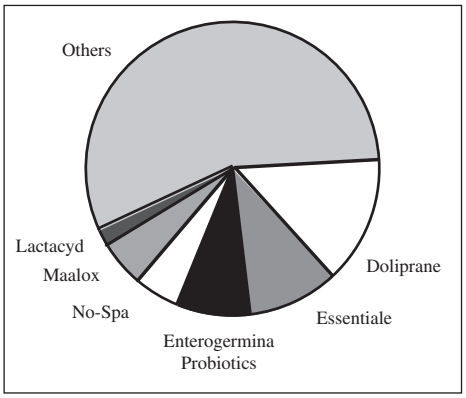

Figure 2: Sanofi-Aventis' OTC sales in 2008 – €1.42 billion – by brand (Source – Sanofi-Aventis)

Chris Viehbacher, chief executive officer of Sanofi-Aventis, says the Chattem deal will give Sanofi-Aventis' OTC business a global presence but it will still be a collection of regional businesses

ucts, emerging markets, new products and vaccines. It is also one of the five pillars of Sanofi-Aventis' diversified healthcare business model, which will reduce the company's dependence on blockbuster prescription drugs and patents. The other four pillars are animal health, generics, prescription medicines and vaccines.

Announcing the Chattem deal, Viehbacher stresses that "consumer healthcare is a strategic opportunity". "It offers prospects for sustainable growth and helps offset the more volatile nature of the prescription drugs market," he comments. "Bringing Chattem into the Sanofi-Aventis family is absolutely consistent with our strategy."

External growth opportunities

Outlining the external growth opportunities, Viehbacher points out that the global OTC market is highly-fragmented. "The top 10 companies represent only around a third of sales, and there are few really global players," he says, adding that "although there are a number of global brands, the majority of the business is driven regionally".

According to Viehbacher, there are opportunities for "local or category acquisitions". "You have to look carefully for them, and you have to be very vigilant," he says, "but there are opportunities for companies like Sanofi-Aventis."

Sanofi-Aventis is building on an OTC business with sales up by 5.3% to €1.42 billion in 2008 (**OTC *bulletin***, 27 February 2009, page 2). OTC sales accounted for 5.1% of total turnover at the group (see Figure 1).

Five countries – Brazil, France, Italy, Mexico and Russia – were responsible for almost two-thirds of the annual OTC total. And 44% of OTC sales came from six flagship brands (see Figure 2). Sales of these six – Doliprane, Essentiale, Enterogermina Probiotics, Lactacyd, Maalox and No Spa – grew by 14.1% on a comparable basis to around €623 million in 2008.

Over the past 15 months, Sanofi-Aventis has made four local OTC acquisitions. In addition to Symbion, which was completed on 1 September 2008, the company has snapped up Gramon in Argentina, Kernpharm in the Netherlands, and Oenobiol in France (**OTC *bulletin***, 16 November 2009, page 1).

Described by Sanofi-Aventis as the French leader for nutritional, health and beauty supplements, Oenobiol has annual sales of €57.2 million. Around 85% of this figure is generated in France, with the rest coming mostly from Belgium, Italy, Poland, Portugal and Spain.

In addition, the OTC business has also been boosted by the acquisition of a number of generics companies. During 2009, Sanofi-Aventis expanded its generics operation by buying the Czech firm Zentiva – which had substantial OTC interests in central and eastern Europe – Mexico's Laboratorios Kendrick and Brazil's Medley (**OTC *bulletin***, 17 April 2009, page 7).

Another interesting development was the firm's agreement to set up a joint-venture company with Minsheng Pharmaceutical Group to produce vitamin and mineral supplements for the Chinese OTC market. Sanofi-Aventis said the initiative would give it access to one of the largest categories in the Chinese OTC market worth approximately US$10 billion last year (**OTC *bulletin***, 30 October 2009, page 10).

Acquisitions helped drive up OTC sales at Sanofi-Aventis by 18.7% to €356 million in the third quarter of 2009. At constant exchange rates, growth was even faster at 26.3% (**OTC *bulletin***, 16 November 2009, page 2).

Viehbacher notes that at the end of the first nine months of 2009 Sanofi-Aventis' OTC business had a strong presence in six local markets – Australia, Brazil, France, Italy, Mexico and Russia – which accounted for 77.4% of OTC sales. But the company had "no direct presence in the all-important US consumer healthcare market", he adds.

If Sanofi-Aventis' tender offer is successful, Chattem will become the US consumer healthcare division of Sanofi-Aventis. The corporate brand of Chattem will be maintained, the company will continue to be led by the current management, and its headquarters will remain in Chattanooga, Tennessee. Sanofi-Aventis said it was committed to Chattem's "current operations and entrepreneurial spirit".

Sanofi-Aventis said it would retain both of Chattem's manufacturing facilities and would continue constructing a third.

Zan Guerry, chairman and chief executive officer of Chattem, commented: "We bring a lot to the table with our 130-year history of managing and growing brands."

"Sanofi-Aventis' commitment to preserving our corporate culture and investing in the business and our community demonstrates a clear understanding of the qualities that have enabled Chattem to succeed for five generations," continued Guerry.

The two companies expect that the transaction, which has been unanimously approved by Chattem's board, will close during the first quarter of 2010.

Chattem's sales were up by 7% to US$455 million in the year ended 30 November 2008. Around 93% of sales were generated in the US (**OTC *bulletin***, 12 February 2009, page 2).

Spek is keen to point out that Chattem has had a compound annual growth rate (CAGR) of 12.3% between 2004 and 2009. Turnover in 2007 was boosted by the acquisition of five OTC brands from Johnson & Johnson and Pfizer.

Well-concentrated portfolio of brands

He also draws attention to the fact that Chattem is the largest "pure-play company in the US consumer healthcare market". Spek says Chattem has a "well-concentrated portfolio of 26 brands, of which six are billed as core". The top six brands – ACT, Cortizone-10, Gold Bond, Icy Hot, Selsun Blue and Unisom – generate 70% of sales, he adds, and are market leaders in their respective categories across food, drug and mass merchandisers.

As Figure 3 shows, medicated skincare is the biggest category for Chattem, accounting for 33.4% of sales in the nine month ended 31 August 2009. Its key brands in the category are Gold Bond, Cortizone-10 and Balmex.

Viehbacher describes Chattem's operating margin of 34.7% in the first nine months of 2009 as "best-in-class". "Chattem has a very unique system of rotational promotional performance, and the team has been able to figure out how to turn on and off the promotion

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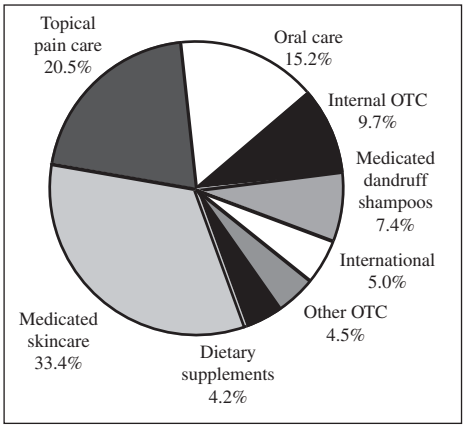

Figure 3: Chattem's sales in the nine months ended 31 August 2009 – US$353 million – broken down by category (Source – Sanofi-Aventis)

■ *Continued from page 21*

for certain brands without wasting a lot of money," he says, adding that the margins are down to "good management".

According to Viehbacher, Chattem is the "ideal platform in the US consumer healthcare market, which represents 25% of the current worldwide opportunity". "Chattem will provide a strong platform for switching some of Sanofi-Aventis' medicines from prescription to non-prescription status in the US," he adds.

Discussing the potential to take Chattem's products into new countries, Viehbacher says the focus is likely to be on emerging markets rather than western Europe. Spek notes that Canada and Mexico will be early targets.

It is unlikely that Sanofi-Aventis' existing OTC products will be introduced in the US, says Viehbacher, as the launch marketing costs would be prohibitive. But Spek notes that Sanofi-Aventis will explore potential synergies between Dermik Laboratories, its US dermatology business, and Chattem.

The Chattem deal will give Sanofi-Aventis' OTC business a global presence, says Viehbacher, although he acknowledges that it will still be "a collection of regional businesses".

Viehbacher comments that it is "fairly true in this industry that there is no single transaction that you can do to transform the business". Sanofi-Aventis is "slowly and surely" building its five growth platforms, he adds.

Another part of the strategy recently fell into place, when Sanofi-Aventis announced on 8 January that it had recruited Hans Regenauer – the worldwide head of Boehringer Ingelheim's Consumer Health Care division – to develop its OTC business (see this page).

OTC

Manufacturers

Sanofi-Aventis recruits Regenauer

Sanofi-Aventis has recruited **Hans Regenauer**, worldwide head of Boehringer Ingelheim's Consumer Health Care division, to develop its OTC business.

Hans Regenauer

Regenauer takes up the newly-created post of vice-president, Consumer Health Care, Europe, and global development at Sanofi-Aventis. He reports to **Belen Garijo**, who is senior vice-president for European Pharmaceutical operations at the French company.

Regenauer moves to Sanofi-Aventis from Boehringer Ingelheim, where he was worldwide head of the German company's Consumer Health Care business. Before joining Boehringer Ingelheim in 1997, Regenauer held various marketing, sales and general management positions at Bayer.

Boehringer Ingelheim said Regenauer had not been replaced, and it was evaluating options.

Sanofi-Aventis said further announcements regarding appointments at its Consumer Health Care business would be made in the near future.

News of Regenauer's appointment comes soon after Sanofi-Aventis announced it would enter the US OTC market by acquiring Chattem for around US$1.9 billion (€1.3 billion).

OTC

Mergers & Acquisitions

Sanofi-Aventis to pay US$1.9bn for Chattem

■ *Continued from front page*

The deal has been unanimously approved by Chattem's board, and is expected to close in the first quarter of 2010.

On 11 January 2010, Sanofi-Aventis launched a tender offer for all outstanding shares of Chattem at US$93.50 per share in cash, having said in December that it had the support of Chattem's board for the move. The tender offer runs until midnight on 8 February.

The offer price represented a 34% premium on the closing price of Chattem's shares on 18 December 2009, according to Sanofi-Aventis.

Several law firms have said that they are investigating whether the offer price is fair.

Sanofi-Aventis said earlier this year that it intended to double the size of its OTC business to around €3 billion within the next five years through a combination of acquisitions and geographic expansion.

OTC