31 May 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Sanofi-Aventis is set to buy Poland's Nepentes

Sanofi-Aventis is set to acquire Nepentes in a deal that values the Polish OTC company at PLN420 million (€105 million).

A joint statement issued by the two companies said Nepentes and its controlling shareholders – who hold a combined stake of around 63% in the Polish company – had agreed to sell all their shares to Sanofi-Aventis and would not accept any competing offers.

The two companies noted Sanofi-Aventis would seek to buy all the outstanding shares in Nepentes through a public tender offer.

Nepentes reported sales up by nearly a quarter to PLN135 million in 2009 from its portfolio of pharmaceuticals and dermocosmetics, including the Emolium and Iwostin brands. The majority of this figure was generated in Poland, but Nepentes also has affiliates in Bulgaria and Romania.

The founders of Nepentes – Lukasz Butruk and Marek Orlowski – have agreed to act as consultants to Sanofi-Aventis for three years.

Under the terms of the agreement, Sanofi-Aventis will pay PLN26.00 per share to the main shareholders and PLN28.00 per share to any other minority shareholders. The public tender will run until 10 August 2010.

The deal is conditional on Sanofi-Aventis gaining at least 90% of the outstanding shares of Nepentes, as well as approval by the Polish competition authority.

The Nepentes deal is the latest in a series of OTC acquisitions by Sanofi-Aventis, which helped push up sales by the French company's Consumer Health Care business by 44.8% – 42.5% at constant exchange rates – to €491 million in the first quarter of 2010 (**OTC *bulletin***, 14 May 2010, page 8).

Sanofi-Aventis says it is the "fifth-largest consumer healthcare player in the world".

FDA issues PPI fracture warning

The Food and Drug Administration (FDA) in the US has issued a Drug Safety Communication on proton-pump inhibitors (PPIs), citing a possible increased risk of fractures of the hip, wrist and spine with their use.

As a result, the FDA said that the labelling for both prescription and OTC medicines con-

■ *Continued on page 7*

Aspen Pharmacare makes bid for Sigma

South Africa's Aspen Pharmacare has made a non-binding takeover bid worth A$1.49 billion (€979 million) for Australia's Sigma Pharmaceuticals.

Sigma's board said it was considering Aspen's "non-binding, indicative and conditional proposal" for all of the company's issued share capital at a price of A$0.60 per share. The deal

■ *Continued on page 7*

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Mergers & Acquisitions

GSK takes a 9.9% stake in South Korea's Dong-A

GlaxoSmithKline is set to pay £73.9 million (€87.0 million) for a 9.9% stake in South Korea's Dong-A Pharmaceutical.

The purchase is part of a strategic alliance that will see the two companies co-promote a range of products in South Korea. A spokesperson for GlaxoSmithKline told **OTC *bulletin*** they would initially co-promote prescription pharmaceuticals but could work together on consumer healthcare products at a later date.

The two companies will share profits generated by the co-promoted products. A new business unit will be created within Dong-A to manage the collaboration.

Asked whether GlaxoSmithKline intended to raise its stake in Dong-A, the spokesperson declined to comment.

Described by GlaxoSmithKline as the "number one pharmaceutical and OTC company in South Korea", Dong-A generated sales of £414 million in 2009 from its range of prescription and OTC medicines, as well as energy drinks, consumer products, active pharmaceutical ingredients and biologicals.

GlaxoSmithKline noted that its own South Korean business, which marketed consumer healthcare brands as well as prescription pharmaceuticals, currently ranked number five in the country's pharmaceutical market with sales of £225 million in 2009.

Christophe Weber, GlaxoSmithKline's senior vice-president and regional director for Asia-Pacific, said Dong-A's market-leading position and expertise in Korea gave GlaxoSmithKline a significant opportunity to expand its commercial footprint and build operational scale in the fast-growing Asian market.

Korea's pharmaceutical market had "consistently enjoyed double-digit growth", GlaxoSmithKline pointed out, adding that market researcher IMS had forecast the market would achieve a compound annual growth rate of approximately 10% through to 2012.

Won-Bae Kim, president of Dong-A, said the collaboration would improve his company's competitiveness in the "fast-changing domestic and global pharmaceutical markets".

The deal would also enable Dong-A to accelerate its transformation into a "true global player", he remarked, by taking advantage of GlaxoSmithKline's product pipeline and global marketing and operational expertise.

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Editor & Publisher: Deborah Wilkes
Associate Editors: Aidan Fry, Mike Rice
Senior Assistant Editor: Matt Stewart
Assistant Editors: Joanne Grew, Jenna Lawrence, Dave Wallace
Advertising Controller: Debi Minal
Marketing Manager: Val Davis

Editorial, Subscription and Advertising enquiries should be addressed to: **OTC *bulletin,*** OTC Publications Ltd, 54 Creynolds Lane, Solihull, West Midlands B90 4ER, UK.
Tel: +44 1564 777550. *Fax:* +44 1564 777524.
E-mail: info@OTC-bulletin.com.

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IN BRIEF

■ **ABBOTT** is set to acquire **Piramal Healthcare's Indian branded generics business** in a deal worth US$3.72 billion (€3.00 billion). India's Piramal said it would retain its other businesses, including its OTC operations. US-based Abbott claimed the deal would make it the number one pharmaceutical firm in India.

OTC

Mergers & Acquisitions/First-Quarter Results

Church & Dwight gets Simply Saline

Church & Dwight is set to acquire the Simply Saline brand of nasal saline solutions in the US from Blairex Laboratories for an undisclosed sum.

Simply Saline had the potential to be even bigger, said Church & Dwight, even though it was already the number one nasal saline solution brand in the US, with annual turnover of around US$20.0 million (€15.9 million).

Church & Dwight added that the acquired brand would complement its existing Sterimar nasal saline solution brand in Europe and other parts of the world.

Built on a line of saline-based "nasal mist" products, the Simply Saline offering includes Simply Saline Nasal Mist, Baby Simply Saline Nasal Mist, Simply Saline Nasal Mist Allergy & Sinus Relief, Simply Saline Nasal Mist Cold Formula and Simply Saline Nasal Mist Cold Formula with Menthol. The Simply Saline Nasal Moist Gel and Simply Saline Sinus Wash products complete the line up.

The Simply Saline brand offers a range of "nasal mist" products in the US

The US-based company said the deal should close in the second quarter of 2010.

Meanwhile, Church & Dwight has reported sales up by 9.2% to US$635 million in its first quarter ended 2 April 2010.

Personal Care sales in the US grew by 6.1% to US$164 million, aided by higher sales of Orajel oral analgesics and Trojan condoms.

The rise in Personal Care sales – combined with a 6.8% increase in US Household Products sales to US$303 million – lifted Church & Dwight's Consumer Domestic turnover by 6.5% to US$467 million.

International sales of Church & Dwight's Consumer brands rose by 24.0% to US$103 million over the period. Specialty Products sales grew by 8.6% to US$65.2 million.

OTC

Annual Results

Alliance Boots breaks £1bn profit mark

Focusing on customer service and rebranding its community pharmacies in the UK boosted OTC sales at Alliance Boots in its year ended 31 March 2010, as the company overcame a difficult retail environment and pressures on dispensing margins to report a trading profit of over £1.00 billion (€1.16 billion) for the first time.

The privately-held wholesaler and retailer reported a trading profit of £1.01 billion for the year – a rise of 12.7% – from total sales which increased by 9.6% to £22.5 billion. Alliance Boots is only the third UK-based retailer – after supermarket chain Tesco and clothing firm Marks & Spencer – to achieve a profit of over £1.00 billion in a single year.

Alliance Boots said that its sales of non-prescription medicines and healthcare products in the UK – which are grouped under the Retail Health banner within Boots UK – increased by 5.6% to £798 million for the year. The gross margin from these sales had also improved, the company noted, thanks to a better product mix and more effective use of promotions.

Alex Gourlay, chief executive of Alliance Boots' Health & Beauty division, said the growth of Retail Health sales had been aided by a focus on customer service, which had led to over 90% of the company's UK pharmacy staff accessing e-learning training programmes to help provide better advice to customers.

This focus had contributed to the growth of Boots' share of the UK retail health market, Gourlay insisted.

The impact of the swine flu outbreak in the summer and autumn of 2009 had also lifted Retail Health turnover, Gourlay noted, along with new product development. He added that the relaunch of Boots' own-branded vitamin range last year had boosted sales of non-prescription healthcare products.

Meanwhile, Retail Health and the firm's dispensing business benefited from Alliance Boots rebranding its UK community pharmacies with the 'your local Boots pharmacy' format.

The £65 million rebranding of around 1,000 Boots community pharmacy stores (**OTC *bulletin***, 30 March 2007, page 1) had been completed at the end of 2009, Gourlay noted.

Stores that had been converted had seen "substantial increases" in both retail sales and dispensing volumes, Gourlay noted, adding that higher sales of Boots own-brand products had been recorded in converted stores.

Retail Health accounted for 13% of sales by the firm's Boots UK unit, which increased by 2.6% to £6.32 billion (see Figure 1).

Dispensing and related income, which represented 37% of Boots UK's turnover, finished ahead by 1.7% to £2.35 billion. Alliance Boots noted that good dispensing volume growth and a strong rise in related income had been partially offset by a lower average revenue per prescription mainly as a result of lower generic reimbursement prices.

In the Beauty & Toiletries category, turnover jumped by 6.1% to £2.18 billion, with sales of cosmetics, fragrances, accessories and toiletries all increasing year-on-year.

Sales in Boots UK's Lifestyle category, however, dropped back by 4.6% to £991 million.

Boots UK accounted for 95% of the company's UK Health & Beauty sales, which grew by 4.7% to £6.64 billion (see Figure 2). The Boots Opticians chain contributed the remaining £320 million. Health & Beauty's like-for-like UK sales advanced by 2.4%.

The UK Health & Beauty trading margin rose by 0.3 percentage points to 10.2%, as UK trading profit grew by 7.8% to £677 million.

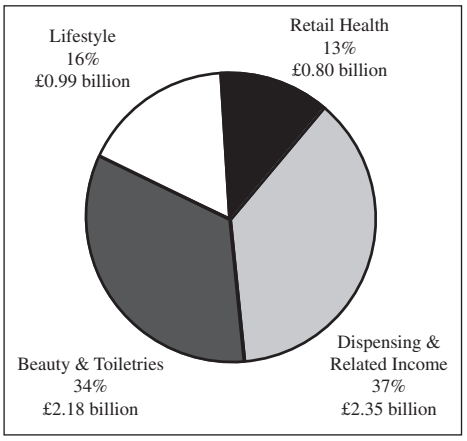


Figure 1: Sales by Boots UK in the year ended 31 March 2010 – £6.32 billion – broken down by product category (Source – Alliance Boots)

As of 31 March 2010, Alliance Boots was operating 2,473 Boots health and beauty stores in the UK, of which 2,380 included a pharmacy. During the year, 10 new stores had been opened, the company said, while 46 had been relocated. The company also had 671 Boots Opticians stores.

Continue to expand UK chain

Andy Hornby, chief executive officer of Alliance Boots, said the company would continue to expand its UK chain when opportunities arose and prices were realistic.

He added that Alliance Boots' target for store openings in its UK chain was approximately 10-20 outlets each year.

Away from its standalone Boots stores, the company recently rebranded 13 pharmacies within Waitrose supermarkets in the UK as Boots outlets. The company has also begun a trial where Boots health and beauty products are sold in selected Waitrose locations and Waitrose food products are sold in selected Boots stores.

Gourlay said that although the trial had only been running for four weeks, the immediate customer reaction had been "very encouraging". He cautioned that it may be a year before the results of the trial became clear. However, if they were good, the scheme could be expanded quite rapidly, he said.

Outside of the UK, international Health & Beauty sales improved by 9.2% to £878 million. At constant currencies, the increase was a more modest 2.7%, while like-for-like sales slipped back by 0.3%.

International trading profit jumped by 17.8% – 9.4% at constant currencies – to £53 million,

Country	Annual sales (£ millions)	Change (%)	Number of stores
Health & Beauty – UK*	6,642	+4.7	3,144
Norway	*373*	*+10.4*	*153*
Republic of Ireland	*235*	*+7.8*	*55*
The Netherlands	*174*	*+6.1*	*74*
Thailand	*68*	*+19.3*	*165*
Italy	*25*	*+8.7*	*21*
Russia	*3*	*-25.0*	*9*
Health & Beauty – International	878	+9.2	477
Total Health & Beauty	**7,520**	**+5.2**	**3,621**

* Including Boots Opticians

Figure 2: Sales by Alliance Boots' Health & Beauty division in the year ended 31 March 2010 and the number of stores at 31 March 2010, broken down by country (Source – Alliance Boots)

pushing up the trading margin by 0.4 percentage points to 6.0%.

As of 31 March 2010, Health & Beauty's international portfolio consisted of 477 stores in six countries, along with 43 franchise stores across Bahrain, Kuwait, Qatar, Saudi Arabia and the United Arab Emirates (UAE).

Norway remained Health & Beauty's biggest market outside of the UK, with sales growing by 10.4% to £373 million. In constant currencies, the growth was 4.7%.

Converting existing Norwegian pharmacies to the new 'Boots apotek' format – which features a higher proportion of Boots-branded beauty and toiletry products than unconverted stores – had helped offset a fall in dispensing income and lift like-for-like sales by 1.3%, Alliance Boots said.

Norwegian rebranding finished this year

Over 100 of the company's 153 Norwegian pharmacies had been converted to the 'Boots apotek' format as of 31 March, Alliance Boots noted, with the rebranding process expected to be completed by the end of this year.

The fragile state of the local economy had impacted on retail sales in Ireland, Alliance Boots said, but this had been more than offset by "excellent" dispensing growth, as turnover increased by 7.8% – 1.1% on a constant-currency basis – to £235 million. However, on a like-for-like basis, the lower retail sales hit home, with turnover declining by 3.9%.

The decline in like-for-like revenue and lower gross margins were blamed for a drop in profitability at Alliance Boots' Irish stores.

Ireland's poor economic climate does have an upside for the company, with Alliance Boots claiming the current environment would allow it to "secure attractive store locations on competitive leases".

In the Netherlands, turnover improved by 6.1% to £174 million, but constant-currency sales declined by 0.6% and like-for-like sales fell by 0.2%. Profits had increased, Alliance Boots said, due to the adverse effect of government measures on profits in the prior year.

Following promising results from the initial test of a new 'Boots apotheek' pharmacy concept – which offered a broader range of products than most Dutch pharmacies, including Boots-branded health and beauty products – the trial had been expanded to five stores, Alliance Boots said. A decision on whether to roll-out the concept in more Dutch stores will be taken in the next few months.

A net 15 stores were added to Alliance Boots' portfolio in Thailand during the year, as turnover grew by nearly a fifth to £68 million. On a constant-currency basis, the rise was 9.3%, while like-for-like revenue was up by 5.1%.

Business	Annual sales (£ millions)	Change (%)
Pharmaceutical Wholesale	*12,424*	*+10.3*
Health & Beauty	*7,520*	*+5.2*
Contract Manufacturing & Corporate Costs	*252*	*–*
Intra Group	*-1,474*	*–*
Total Group	18,722	+8.9
Associates & Joint Ventures	3,791	+13.2
Total Alliance Boots	**22,513**	**+9.6**

Figure 3: Sales by Alliance Boots in the year ended 31 March 2010 by business (Source – Alliance Boots)

Asked about expansion into new countries, Stefano Pessina, executive chairman of Alliance Boots, said the company remained open-minded about the issue, but added that it would need to find a partner that was "on the same page" as Alliance Boots for a deal to be done.

Commenting on the market for pharmacies in Europe, Pessina said he was not sure that now was the "best time to invest in pharmacy".

It was a "difficult period for pharmacists", Pessina admitted. However, sellers were still "thinking of the good times when they could ask foolish prices", he added, and this had made buying pharmacies "really difficult".

Alliance Boots is considering entering the newly-liberalised Swedish pharmacy market, having signed a letter of intent to establish a joint venture with the Swedish Association of Pharmacists, Sveriges Farmacevtförbund (**OTC *bulletin***, 10 February 2010, page 3).

Under the terms of the deal, the joint venture would allow independent pharmacies in Sweden to operate as franchise stores under the Boots brand name.

However, Pessina said it did not intend to invest a lot of money in the country as Swedish pharmacies were not particularly profitable.

Pessina explained that this lack of profitability had been why the company had not made a substantial bid for any of the state-owned Apoteket pharmacies that the Swedish government had put up for sale last year (**OTC *bulletin***, 29 May 2009, page 1).

Country	Annual sales (£ millions)	Change (%)
France	4,780	+5.8
UK	2,544	+10.1
Spain	1,358	+8.0
Italy	1,162	+8.1
The Netherlands	822	-2.8
Russia	657	+40.1
Czech Republic	442	+11.3
Germany	343	+130.2
Norway	334	+21.0
Other	43	+2.4
Intra-segment	-61	–
Total Wholesale	**12,424**	**+10.3**

Figure 4: Sales by Alliance Boots' Pharmaceutical Wholesale division in the year ended 31 March 2010, broken down by country (Source – Alliance Boots)

Total sales at Alliance Boots' Health & Beauty retail division rose by 5.2% to £7.52 billion over the 12 months (see Figure 3). At constant currencies, this represented an improvement of 4.5%. Boots said like-for-like sales had finished ahead by 2.1%.

Trading profit by the division as a whole rose by 8.5% – 8.0% on a constant currency basis – to £730 million, with a trading margin improved by 0.3 percentage points to 9.7%.

Wholesaling delivers double-digit profit rise

Meanwhile, the company's Pharmaceutical Wholesale division had delivered double-digit trading profit growth, Alliance Boots said, despite facing difficult market conditions. This had been thanks to a combination of organic growth, the initial benefits of a restructuring plan instigated a year ago, and the full-year impact of acquisitions made during 2008/2009.

Pharmaceutical Wholesale's turnover grew by 10.3%, or 5.6% at constant currencies, to £12.4 billion (see Figure 4). Like-for-like turnover increased by 3.7%.

Alliance Boots estimated that the wholesale markets in which it operated had grown by 4% – up from 3.5% a year earlier – thanks to higher volume and price growth in Russia.

The trading profit from wholesaling jumped by 17.2% – 13.3% on a constant-currency basis – to £252 million, pushing up the trading margin by 0.1 percentage points to 2.0%. Like-for-like trading profit – adjusted for acquisitions and disposals – increased by 9.0%, reflecting good profit growth in all markets except for France, Germany and the Netherlands.

The division-wide restructuring programme, launched last year with the aim of reducing operating costs by £55 million per year by 2011/2012, was now almost complete, Alliance Boots said, noting efficiency gains of just over £30 million had been achieved in 2009/2010.

OTC

Annual Results

Cold remedies drag down sales at Taisho

Japan's Taisho Pharmaceutical blamed a steep decline in sales of cold remedies in the second half of the year and the "sluggish" performance of more potent OTC products for a 2.6% decline in its OTC sales to ¥144 billion (€1.26 billion) in the 12 months ended 31 March 2010.

The company said there had been a "significant drop" in the market for cold remedies in the final six months of its financial year, in contrast to the first half, when sales had grown strongly due to an outbreak of H1N1 swine flu (**OTC *bulletin***, 16 November 2009, page 11).

Compounding the fall in sales of cold and flu products had been the weak market for what are termed 'category 1 products' – OTC medicines, such as switch products, deemed to hold the highest degree of adverse-event risk.

As a result of the lower OTC sales, turnover by Taisho's Self-Medication division declined by 1.4% to ¥159 billion for the year (see Figure 1). However, the division's operating income increased by 4.2% to ¥30.5 billion.

Looking ahead, Taisho said its Self-Medication business faced difficult market conditions due to the "sluggish" Japanese economy – which had been hit by a decline in consumer spending due to the worsening employment environment – as well as an increase in competition and the ongoing impact of changes to the rules governing OTC medicine distribution.

In June last year, Japan reclassified OTC drugs into three categories according to the degree of risk attached to their active ingredient, which in turn impacted on how and where they could be sold.

To combat these difficulties, Taisho said it planned to broaden its range of category 1 drugs by switching more ingredients from prescription-only to OTC status, as well as "aggressively" developing new product categories, such as treatments for metabolic conditions. In-store promotion would also be strengthened, Taisho added, to highlight the value of its products and drive sales.

With these measures in place, Self-Medication's sales were expected to increase by 5.3% to ¥167 billion in the year ending 31 March 2011, Taisho said.

A 5.3% fall in sales of the company's core Lipovitan brand of energy and tonic drinks to ¥70.8 billion (see Figure 2) reflected the impact of the tough economic environment, more competition and unfavourable weather conditions in the key summer period.

Although sales of some Lipovitan products had increased, Taisho noted, the leading Lipovitan D product had slipped back, resulting in the overall turnover decline.

Business	Annual sales (¥ billions)	Change (%)	Forecast sales (¥ billions)	Change (%)
Livita brand	*3.1*	*+19.6*	*3.5*	*+12.9*
Overseas drinks	*5.7*	*-3.8*	*6.2*	*+8.8*
Others	*1.6*	–	–	–
Foods for specified health use	10.4	+5.2	11.3	+8.2
OTC products	144.3	-2.6	151.3	+4.8
Others	4.1	+36.7	4.6	+12.5
Total Self-Medication	**158.9**	**-1.4**	**167.2**	**+5.3**
Prescription operations	**99.6**	**+4.8**	**94.8**	**-4.8**
Total for Taisho	**258.4**	**+0.9**	**262.0**	**+1.2**

Figure 1: Taisho Pharmaceutical's sales in the year ended 31 March 2010. Forecasted sales are for the year ending 31 March 2011 compared with actual sales in the previous 12 months (Source – Taisho Pharmaceutical)

Business	Annual sales (¥ billions)	Change (%)	Forecast sales (¥ billions)	Change (%)
Lipovitan D	*49.4*	*-6.3*	*50.0*	*+1.2*
Other Lipovitan	*21.4*	*-2.9*	*21.8*	*+1.9*
Total Lipovitan brand	70.8	-5.3	71.8	+1.4
Zena brand	3.5	-10.5	3.6	+2.9
Other drinks	1.4	–	–	–
Total tonics and nutrient drinks	**75.7**	**-5.3**	**–**	**–**
Cold remedies (Pabron brand)	**24.9**	**-1.7**	**25.0**	**+0.4**
Hair treatments (RiUP brand)	**12.7**	**+11.9**	**13.5**	**+6.3**
Analgesics (Naron brand)	**4.4**	**+0.1**	**4.7**	**+6.8**
Gastrointestinal treatments	**4.3**	**-2.0**	**4.3**	**±0.0**
Laxatives (Colac brand)	**3.9**	**+0.1**	**4.0**	**+2.7**
Cold remedies (Vicks brand)	**2.9**	**+2.2**	**2.9**	**±0.0**
Other OTC products	**15.5**	**–**	**–**	**–**
Total OTC products	**144.3**	**-2.6**	**151.3**	**+4.8**

Figure 2: Breakdown of Taisho Pharmaceutical's OTC sales in the year ended 31 March 2010. Forecasted sales are for the year ending 31 March 2011 compared with actual sales in the previous 12 months (Source – Taisho Pharmaceutical)

Sales of all Taisho's tonic and nutrient drinks dropped by 7.0% through drug channels and by 3.6% through food channels (see Figure 3).

Although category 1 OTC drugs had generally struggled during the year, the RiUP X5 minoxidil product for hair regrowth – launched in March last year (**OTC *bulletin***, 17 March 2009, page 17) – had helped drive up turnover of the RiUP brand by 11.9% to ¥12.7 billion.

Sales of Naron analgesics – boosted by a new Naron Ace R product – and Colac laxatives both edged up by 0.1% to ¥4.4 billion and ¥3.9 billion respectively. Meanwhile, the new topical analgesic Diclotect – available as a tape, gel or lotion containing diclofenac – was meeting its sales targets.

In the 'foods for specified health use' category, sales increased by 5.2% to ¥10.4 billion, driven by a double-digit rise in sales of the Livita brand.

	Annual sales (¥ billions)	Change (%)
Food channels	38.5	-3.6
Drug channels	37.1	-7.0
Total	**75.7**	**-5.3**

Figure 3: Breakdown by distribution channel of Taisho Pharmaceutical's sales of tonics and nutrient drinks in Japan in the year ended 31 March 2010 (Source – Taisho Pharmaceutical)

During the year, Taisho expanded its Self-Medication division's presence outside of Japan by paying US$310 million (€250 million) for Bristol-Myers Squibb's OTC assets in the Asia-Pacific region, excluding China and Japan (**OTC *bulletin***, 30 September 2009, page 1).

OTC

Mergers & Acquisitions

Aspen Pharmacare bids to buy Sigma

■ *Continued from front page*

would also see Aspen assume Sigma's debts of A$785 million.

However, Sigma advised shareholders to take no action at this stage, and that further announcements would be made in due course.

The South African firm's approach comes shortly after Sigma – which has interests in OTC products, generic pharmaceuticals, pharmacy retailing and drug wholesaling – reported a net loss of A$389 million for the year ended 31 January 2010. Sigma reported the net loss after cutting goodwill valuations by A$424 million. Sales increased by 4.5% to A$3.22 billion (**OTC *bulletin***, 16 April 2010, page 2).

Aspen's existing Australian subsidiary generates annual sales of around A$180 million from an Ethicals division and an OTC/Grocery division, which currently markets the Andrews Tums indigestion and Bio-Oil skincare products, as well as the Murine eye drops range and Tixylix cough and cold brands.

In the wake of the poor financial performance, Sigma is looking for a new chief executive officer and chief financial officer.

The company said chief financial officer Mark Smith had resigned "to pursue other interests" on 13 May, less than one month after chief executive officer Elmo de Alwis handed in his resignation after 33 years at the company (**OTC *bulletin***, 30 April 2010, page 23).

However, while Smith has already left his post, de Alwis will remain in place until a successor is recruited.

Sigma said KPMG partner Mark Watson would take over as chief financial officer until a replacement for Smith was found.

The company will also have a new chairman from 21 June, when Brian Jamieson replaces John Stocker, who is retiring from the company's board of directors. Jamieson was appointed to Sigma's board of directors in December 2005.

Sigma's cuts to its goodwill valuations included a reduction of A$49.1 million for its Herron range of OTC products following a poor performance in the grocery channel. Another A$375 million came from the A$819 million goodwill valuation placed on the Arrow generics business Sigma bought in 2005.

Excluding the goodwill impairment charges of A$424 million, Sigma said its annual underlying net profit had decreased by 15.5% to A$67.7 million.

OTC

First-Quarter Results

Nycomed's OTC sales rise despite decline in Europe

Nycomed's total OTC sales moved forward by 4.7% to €103 million in the first quarter of 2010. In local currencies, however, this represented a decline of 1.6%.

Strong sales outside of Europe had driven the growth, the Swiss company noted, although this advance had been offset by a 12.7% fall in European turnover during the period.

European sales had been hit by pharmacies destocking flu products acquired at the end of 2009 in anticipation of a flu pandemic, Nycomed said. This had then been compounded by a "relatively mild" cough and cold season in some European markets.

Meanwhile, total OTC turnover had risen by 9.2% in Latin America, Nycomed said, while sales in Russia and the Commonwealth of Independent States (CIS) had grown by 16.4%. The fastest OTC sales growth was reported in the Asia-Pacific, Africa and Middle East region, where sales increased by 50.2%.

Nycomed's OTC sales excluding calcium OTC and pantoprazole OTC – which are reported as part of its Specialty Products and Gastrointestinal businesses respectively – slipped back by 1.0% to €87.3 million. In local currencies, the fall was a more dramatic 8.8%.

The company said sales of its OTC calcium products had been strong in Russia and the CIS, while the company had launched OTC pantoprazole products in 14 countries to date.

Novartis Consumer Health has just introduced Nycomed's Pantoloc Control OTC pantoprazole product in the UK, as part of the co-marketing agreement signed between the two companies in February (**OTC *bulletin***, 14 May 2010, page 22).

Novartis Consumer Health will launch the product in 14 European countries during 2010, using the Pantoloc Control brand name – one of the five names Nycomed can use in Europe along with Pantozol Control, Pantecta Control, Somac Control and Controloc Control.

OTC sales – excluding OTC calcium and OTC pantoprazole – accounted for 11.2% of Nycomed's total group sales, which declined by 7.6% as reported and 8.9% in local currencies to €776 million.

OTC

Regulatory Affairs

FDA warns on PPIs

■ *Continued from front page*

-taining PPIs would be changed to reflect the new safety information.

Procter & Gamble's Prilosec OTC and Merck & Co's Zegerid OTC heartburn medicines – both of which are based on the PPI omeprazole – will be affected by the labelling change, as will Novartis Consumer Health's lansoprazole-based Prevacid 24HR.

The FDA said it had taken action following a review of seven epidemiology studies, six of which had reported an increased risk of fractures of the hip, wrist, and spine with PPI use. The greatest risk seemed to be associated with high doses or long-term use of PPIs.

However, it was "not clear at this time" if the use of PPIs was the cause of the increased risk of fractures seen in some studies, the agency pointed out. Most of the studies had evaluated individuals 50 years of age or older, the FDA noted, and the increased risk of fracture was seen mainly in this age group.

OTC

First-Quarter Results

Podravka sees OTC sales drop

Croatia's Podravka said a drop in consumer demand caused by the economic crisis had led to a 26% decline in sales of its domestic OTC products in the first quarter of 2010.

Consumer spending power in Croatia had been weakened by the economic crisis, Podravka said, which had led people to stop buying what they viewed as "unnecessary drugs".

The fall in sales of OTC products – combined with a 7% drop in sales of domestic prescription-only drugs – pushed turnover at the company's Pharmaceuticals division down by 5% to CrK156 million (€21.5 million).

Podravka's performance in Croatia offset the 5% gain the Pharmaceuticals division made in international markets, which was driven by a 22% growth in sales of prescription-only drugs.

Pharmaceuticals' earnings before interest and tax (EBIT) grew by 2% to CrK13.9 million.

OTC

Annual Results

Acquisitions add £123mn to SSL's sales

Acquiring a controlling stake in eastern European condom distributors Beleggingsmaatschappij Lemore BV (BLBV) and Gainbridge added £123 million (€143 million) to SSL International's sales during the year ended 31 March 2010.

The UK-based firm said adding Russia's BLBV on 1 June 2009 and Gainbridge in the Ukraine on 1 October 2009 had helped lift total group sales by 24.9% to £803 million. Operating profit had advanced even quicker, growing by 40.8% to £126 million, the company noted, thanks primarily to the two acquisitions.

As Figure 1 shows, SSL's turnover through BLBV in Russia and the Commonwealth of Independent States (CIS) – excluding Ukraine – stood at £116 million for the 10-month period, driven by £49.6 million in sales from the Contex and Durex condom brands. In the Ukraine, the Gainbridge business posted sales of £7.3 million for the six months, again led by the Contex and Durex brands, which generated sales of £4.8 million in the country.

BLBV and Gainbridge contributed a combined operating profit of £29.3 million, SSL noted, at an operating margin of 23.8%.

SSL has built up its stake in BLBV – which distributes condoms and medical products – over the past two years. Having taken a 50% plus one share stake in BLBV in 2009 (**OTC *bulletin***, 17 April 2009, page 2), SSL lifted its holding to 75.3% earlier this year, with an option to purchase the remaining shares in 2011 (**OTC *bulletin***, 26 February 2010, page 11).

The company took complete control of Gainbridge Investments on 1 October 2009 after exercising an option agreed in 2008 to acquire the business (**OTC *bulletin***, 30 May 2008, page 7).

Following the close of the year, SSL expanded its presence in Eastern Europe further with the acquisition of the Polish condom brand Rosetex for £3.9 million on 11 May. Annual sales of Rosetex were approximately £2.1 million, the company noted.

	Russia/CIS* (£ millions)	Ukraine** (£ millions)
Contex and Durex	*50*	*5*
Locally owned brands	*12*	*1*
Scholl footcare	*1*	–
Branded consumer	63	6
Medical gloves/others	53	2
Total sales	**116**	**7**

* Sales in the 10 months ended 31 March 2010
** Sales in the 6 months ended 31 March 2010

Figure 1: Contribution of Beleggingsmaatschappij Lemore BV in Russia and the Commonwealth of Independent States (CIS) – excluding Ukraine – and Gainbridge in Ukraine to SSL International's sales in the year ended 31 March 2010 (Source – SSL International)

	Annual sales* (£ millions)	Actual growth (%)	Adjusted growth** (%)
Durex	*294*	*+10.0*	*+4.8*
Scholl footcare	*168*	*+17.5*	*+4.6*
Scholl footwear	*106*	*+13.6*	*+7.4*
Locally-owned brands	*65*	*-14.1*	*-4.4*
Branded consumer	632	+9.4	+4.1
Other consumer	47	-26.9	-22.3
Total SSL	**679**	**+5.7**	**+1.8**

* Excluding £123 million in sales from Beleggingsmaatschappij Lemore BV (BLBV) and Gainbridge Investments
** Adjusted to constant exchange rates

Figure 2: SSL's sales – excluding BLBV and Gainbridge – in the year to 31 March 2010 (Source – SSL International)

Meanwhile, SSL said that its core Durex and Scholl global brands had driven up group sales – excluding BLBV and Gainbridge – by 5.7% to £679 million for the 12 months. On a currency-adjusted basis, the growth was a more modest 1.8%.

Turnover by SSL's Durex brand increased by a tenth – 4.8% when adjusted for currency effects – to £294 million (see Figure 2), driven by strong growth in Austria, China, Germany, the Middle East, Poland and Switzerland.

Durex condoms enjoyed "robust performances" across all product types, SSL noted, with sales growing by 4.1% on a currency-adjusted basis to £244 million. China had been a key growth driver, the company pointed out, backed up by "solid" gains in eastern Europe, the Middle East and Switzerland.

Sales of the Durex Play range of personal lubricants and vibrators advanced by 8.4% on an adjusted basis to £49.3 million. The "excellent" performance had been driven by Spain, SSL remarked, where turnover had grown in excess of 50%, despite the difficult economic conditions. The Benelux and eastern Europe regions had also made positive contributions, the company said.

Good performances in France, Germany and Japan boosted Scholl Footcare sales, which increased by 4.6% when adjusted for currency effects to £168 million. The gains in those three markets managed to offset the adverse effects of pharmacy destocking in Italy and a difficult trading environment in the UK.

SSL noted that its Scholl Cracked Heel Repair Cream had now generated sales of nearly £20 million since its global launch in 2008 and was regularly recommended by doctors and footcare professionals around the globe.

Scholl Footwear, meanwhile, reported turnover up by 7.4% at constant exchange rates to £106 million, thanks to good performances in France, Germany and Italy.

Sales of SSL's locally-owned brands – including the company's OTC offering in the UK – declined by 14.1% to £65 million. On an adjusted basis, the decline was less severe at 4.4%.

SSL blamed the fall on pharmacy destocking in Italy and the difficult UK market environment. Successfully launching its head-lice treatment Full Marks in new territories – such as Germany, where it had been launched under the K Laus name – had offset some of the decline, the company added.

OTC

IN BRIEF

■ **RELIV** said its **sales had fallen by 4.5% to US$22.7 million** (€17.8 million) in the first quarter of 2010, as turnover at the company's US business dropped by 9.0%, due to the effects of the economic recession. By contrast, international sales jumped by 36.1%, although approximately half of the rise was thanks to positive currency effects.

■ **VALEANT PHARMACEUTICALS** said its first-quarter **sales had increased by 30% to US$232 million** (€189 million). Turnover at its Specialty Pharmaceuticals division – including OTC brands – grew by 40% to US$121 million. Sales of branded generics in Latin America rose by 35% to US$42.1 million and in Europe by 18% to US$41.7 million. Royalties, alliances and services added US$27.5 million.

OTC

Business Strategy/First-Quarter Results

Stada shuns Poland due to high prices

Over-inflated prices for local pharmaceutical companies mean it is unlikely that Stada Arzneimittel will expand in Poland via acquisitions in the near future, the German group's executive chairman Hartmut Retzlaff told investors.

Retzlaff's comments came shortly before Sanofi-Aventis announced that it was set to acquire Polish OTC company Nepentes in a deal worth €105 million (see front page). The price represents a multiple of around three-times Nepentes' annual sales.

Stada set up a sales subsidiary in Poland two years ago, but in the first quarter of 2010 its sales of €1.27 million represented just 0.3% of the group's turnover, which grew by 5% to €396 million. The German firm's total sales in eastern Europe advanced by 11% to €86.8 million, while turnover in western Europe was 3% higher at €291 million. Asia added €12.4 million and other markets €5.1 million.

Sales at the Branded Products division were up by a tenth to €101 million (see Figure 1). Adjusted for currency effects, as well as acquisitions and disposals, the division's sales had grown by 7%, the company noted. Around two-thirds of the division's sales are generated by non-prescription products.

Operating profit at Stada's Branded Products division moved ahead faster than sales, rising by 32% to €23.5 million. This lifted the operating margin from 19.3% to 23.2%.

Business	First-quarter sales (€ millions)	Change (%)	Operating profit (€ millions)	Change (%)
Generics	278	+3	37.8	-3
Branded Products	101	+10	23.5	+32
Commercial	15	+22	1.7	+36
Group/other	2	-40	-11.6	–
Total Stada	**396**	**+5**	**51.4**	**+6**

Figure 1: Stada's sales and operating profit in the first quarter of 2010 by business (Source – Stada)

Branded Products accounted for just over a quarter of Stada's total group sales, but 46% of the company's total group operating profit, which increased by 6% to €51.4 million.

Stada said sales of Branded Products in Germany had grown by 6% to €36.4 million, aided by acquiring the Eunova nutritional supplement at the end of 2009, which had contributed €1.1 million. Branded Products accounted for 25% of Stada's total domestic sales, which slipped back by 3% to €143 million.

Retzlaff said the company would be supporting its Grippostad OTC cold medicine and Ladival sun-care brand in Germany with television advertising during the year.

Sales of Branded Products in Russia improved by 43% to €22.2 million, representing around half of Stada's total sales in the country. These jumped by 23% – 17% at constant exchange rates – to €44.7 million. Stada added that its local Nizhpharm unit had agreed to pay €0.2 million for a 50% share in Hetmak, a purchasing company based in Dubai.

A 22% turnover decline for Branded Products in Italy to €9.9 million was in contrast to the double-digit sales growth by the Generics division, which helped drive up Stada's total sales in the country by 8% to €32.0 million.

In Belgium, Branded Products' sales grew by 67% to €1.5 million, accounting for 5% of Stada's total sales in the country. These grew by 13% to €30.0 million.

Stada's Branded Products business in Spain posted sales up by 11% to €2.1 million, as total group sales in the country increased by a quarter to €23.4 million.

Branded Products generated 7% of Stada's total sales in Serbia, with turnover growing by 50% to €1.5 million. Total group turnover in the country jumped by 27% – 34% at constant exchange rates – to €21.3 million.

OTC

First-Quarter Results

Acquisition boosts Atrium Innovations

Acquiring the US-based nutritional supplements firm Garden of Life, along with organic growth, helped lift sales at Canada's Atrium Innovations by 27.5% to US$90.1 million (€73.0 million) in the first quarter of 2010.

The company said buying Garden of Life in September last year (**OTC *bulletin***, 30 September 2009, page 2) had driven a double-digit rise in turnover at its US branded products business.

Total sales of the Wobenzym enzyme brand had fallen slightly, Atrium said, due to a shift to a different version of the product in Germany.

Earnings before interest, tax, depreciation and amortisation (EBITDA) jumped by 19.5% to US$21.2 million.

OTC

First-Quarter Results

Krka sees self-medication gains

Slovenia's Krka said sales of its self-medication products had risen by 9% to €27.4 million in the first quarter of 2010, driven by "positive trends" in south-eastern and eastern Europe.

The biggest increases had been seen in the company's eastern European markets, Krka pointed out, where self-medication turnover had grown by a fifth. The growth had been led by a 65% increase in sales in Ukraine and a 28% jump in Russia, the company noted.

Self-medication sales in south-eastern Europe had increased by 4%, Krka commented. This was thanks to a 35% advance in Romania and a 15% gain in Macedonia.

These gains had been partially offset, Krka noted, by lower sales in central Europe and the company's home market of Slovenia.

During the quarter, Krka extended its Pikovit and Duovit vitamin and supplement brands in Russia with the Pikovit Omega 3 and Pikovit Prebiotik products and Duovit Elegance skincare supplement. The Duovit range was also boosted in Ukraine with the caffeine-based Duovit Sila chewable tablet.

Krka's Orsoslim weight-management brand had gained approvals in Kazakhstan and Ukraine, the firm noted, while the Septolete Plus honey and lime sore-throat pastilles had been approved in Bulgaria and Czech Republic.

Sales of self-medication products were responsible for 11% of Krka's total first-quarter group sales, which edged forward by 0.4% to €246 million. The dominant prescription pharmaceuticals business generated 83% – €205 million – of total group turnover.

OTC

Regulatory Affairs

J&J's Weldon asked to testify at hearing

Johnson & Johnson's chairman and chief executive officer, William Weldon, has been "invited" to testify at a hearing of the US Committee on Oversight and Government Reform about the company's recent recall of medicines for infants and children.

A spokesperson for Johnson & Johnson said that Weldon would be unable to testify at the hearing on 27 May 2010, as he was recovering from back surgery. However, Colleen Goggins, worldwide chairman of Johnson & Johnson's Consumer division, would testify, the spokesperson added.

The congressional committee announced on 6 May that it was investigating the company's recall of 44 OTC medicines for infants and children (**OTC *bulletin***, 14 May 2010, page 1). The liquid products are sold under the Motrin, Tylenol and Zyrtec brands in a number of countries, including the US.

The move was the sixth significant recall in North America by Johnson & Johnson's McNeil Consumer Healthcare subsidiary in an eight-month period.

The recalls pointed to "a major problem in the production of McNeil products", maintained the committee's chairman Ed Towns and ranking member Darrell Issa. "We are deeply concerned about the recall of popular paediatric medications that millions of families have grown to rely on and stocked in their medicine cabinets," they remarked. "The American people deserve answers and we intend to get to the bottom of this matter."

According to McNeil, the latest recall had been initiated because "some of these products may not meet required quality standards". The recall was not due to adverse medical events, the company stressed.

"Some of the products included in the recall may contain a higher concentration of active ingredient than is specified; others may contain active ingredients that may not meet internal testing requirements; and others may contain tiny particles," explained McNeil, insisting that the "potential for serious medical events is remote".

The company added that it had temporarily suspended production at its plant in Fort Washington, Pennsylvania.

Commenting on the recall, the US Food and Drug Administration (FDA) said its inspectors had found grime and contaminated ingredients at the plant. McNeil's manufacturing deficiencies could affect "quality, purity or potency" of products, the agency noted.

Representatives Towns and Issa felt that the FDA's "most alarming finding" was that "raw materials used to make these infant and children's products were contaminated with potentially harmful bacteria". They noted, however, that the FDA had not found the bacteria in any finished product.

The congressional committee has also invited FDA commissioner Margaret Hamburg to testify at the hearing.

The hearing comes soon after Johnson & Johnson revealed that product recalls had cut the US sales of its OTC & Nutritionals business by 25.3% to US$542 million (€444 million) in the first three months of this year (**OTC *bulletin***, 30 April 2010, page 1).

OTC

First-Quarter Results

Entering Sweden hits Celesio's profits

Establishing its DocMorris pharmacy chain in Sweden, coupled with government cost-cutting measures, produced a 19.4% decline in earnings before interest, tax, depreciation and amortisation (EBITDA) at Celesio's Retail Pharmacies business in the first quarter of 2010.

Retail Pharmacies' EBITDA had declined to €59.2 million over the three months (see Figure 1), the pan-European wholesaler and retailer pointed out, in part due to healthcare spending cuts in various countries, but also because of start-up costs in Sweden.

Celesio opened its first Swedish DocMorris pharmacy in February (**OTC *bulletin***, 26 February 2010, page 2), and by the end of the quarter had opened six branches across the country.

Fritz Oesterle, chairman of Celesio's management board, confirmed the fledgling Swedish chain's success had prompted the company to aim for 30-40 pharmacy openings in 2010, up from the 20-30 originally planned (**OTC *bulletin***, 14 May 2010, page 3).

Oesterle added that the company's move into Sweden reflected the fact that "direct access to end users" was, and would remain, "very important to the company".

Establishing an entirely new pharmacy chain in Sweden – as opposed to acquiring some of the state-owned Apoteket pharmacies that the Swedish government had put up for sale when it liberalised the country's pharmacy market (**OTC *bulletin***, 31 July 2009, page 3) – had demonstrated how Celesio would expand its own chains in a way that conserved capital and goodwill, Oesterle insisted.

Over the past year, Celesio has scaled back pharmacy acquisitions in favour of opening entirely new stores. The firm has also closed or sold stores with the aim of boosting efficiency.

As a result, the Retail Pharmacies business was operating a total of 2,301 outlets as of 31 March 2010, which was 31 fewer than a year earlier. Despite the reduction, Retail Pharmacies' sales increased by 3.3% to €783 million in the first quarter of the year. In local-currency terms, the rise was 0.2% (see Figure 2).

Business	EBITDA (€ millions)	Change 2009/2010 (%) €	Local currencies
Retail Pharmacies	*59.2*	*-19.4*	*-22.0*
Mail-Order Pharmacies	*0.6*	–	–
Other Business Areas	*-0.4*	–	–
Patient and Consumer Solutions	59.4	-17.5	-20.1
Pharmacy Solutions	107.9	+22.5	+21.6
Other	-14.1	–	–
Total Celesio	**153.2**	**+6.0**	**+4.1**

Figure 1: Celesio's earnings before interest, tax, depreciation and amortisation (EBITDA) in the first quarter of 2010 broken down by business (Source – Celesio)

"Robust development" at the group's biggest pharmacy chain – Lloydspharmacy in the UK – helped drive the rise in sales at the Retail Pharmacies business. However, government adjustments to the pharmacy margin for dispensing generic drugs had damaged Lloydspharmacy's profit, Celesio pointed out.

Cost cutting impacts Irish pharmacies

Highlighting the situation in Ireland, Celesio pointed out that its 72 pharmacies in the country had been impacted by cuts to the reimbursement prices of prescription medicines, lower remuneration for Irish pharmacies and a 40% cut in the prices of off-patent products, which had made some originator products less expensive than their generic counterparts.

On a brighter note, Celesio said in March that it had opened a second DocMorris-branded pharmacy in Ireland after the success of a trial pharmacy opened in 2009 (**OTC *bulletin***, 31 March 2010, page 5). Oesterle remarked recently that once the company was sure the "resounding success" of the trial pharmacy could be sustained, it would decide on the best way to roll out the brand in Ireland.

Away from the Retail Pharmacies business, Celesio's mail-order operations enjoyed a strong start to the year, with sales rising by 20.2% – 20.1% in local currencies – to €70.1 million. The firm's largest mail-order business, DocMorris in Germany, had "considerably" increased its turnover, Celesio said.

The smaller Lloydspharmacy and Vitusapotek mail-order operations continued to show promise, the company said, which reflected the growth potential of mail-order pharmacy businesses in international markets.

Mail-Order Pharmacies achieved a positive EBITDA this time of €0.6 million, compared with a loss of €0.6 million in the prior-year quarter due to higher advertising spending (**OTC *bulletin***, 29 May 2009, page 9).

In the Other Business Areas unit – which is dominated by the Apotheke DocMorris franchise business in Germany – turnover edged up by 1.0% to €1.1 million. Celesio said it was working to optimise the range of products, marketing support and retail services offered to DocMorris franchise members.

Last October, Celesio wiped €71.0 million off the goodwill valuation of the DocMorris franchise business, following operating failures (**OTC *bulletin***, 16 October 2009, page 1).

Celesio had intended to sign up 500 pharmacies to the virtual pharmacy chain by 2011, but this will not now happen until 2015 at the earliest. As of the 31 March 2010, 154 pharmacies had signed up to the scheme.

During the first quarter, Celesio's Patient and Consumer Solutions division posted turnover up by 4.5% – 1.6% in local currencies – to €854 million. However, the division's EBITDA fell by 17.5% – 20.1% in local currencies – to €59.4 million.

At the dominant Pharmacy Solutions division, which includes Celesio's Wholesale business, sales grew by 10.8% – 10.1% in local currencies – to €4.66 billion. EBITDA increased by 22.5% to €108 million, which in local currencies was a rise of 21.6%.

Business	First-quarter sales (€ millions)	Change 2009/2010 (%) €	Local currencies
Retail Pharmacies	*783*	*+3.3*	*+0.2*
Mail-Order Pharmacies	*70*	*+20.2*	*+20.1*
Other Business Areas	*1*	*+1.0*	*+1.0*
Patient and Consumer Solutions	854	+4.5	+1.6
Pharmacy Solutions	4,660	+10.8	+10.1
Other	154	–	–
Total Celesio	**5,668**	**+10.8**	**+9.7**

Figure 2: Celesio's sales in the first quarter of 2010 broken down by business (Source – Celesio)

OTC

Business Strategy

Pfizer mulls outsourcing OTC product production

Pfizer may seek contract manufacturers to produce a number of the OTC brands that it gained through acquiring Wyeth, as the company overhauls the manufacturing network of its Consumer Healthcare division.

The company said it had decided to cease production of a number of its freshly-acquired consumer healthcare brands at two former Wyeth facilities in the US.

Brands like Anbesol, ChapStick, Dimetapp, Preparation H and Robitussin would be phased out of Pfizer's Richmond, Virginia, plant over the next two to three years, the company said. Packaging of Advil products would also end at the plant, which was obtained when Pfizer bought Wyeth last year (**OTC *bulletin***, 30 October 2009, page 3).

However, Consumer Healthcare's research and development unit would remain at the Richmond facility, Pfizer said.

Its Pearl River, New York, facility would cease to be the primary US supplier of Centrum dietary supplements by the first half of 2014, Pfizer added.

Approximately 550 Consumer Healthcare jobs would be affected at Richmond and a further 330 would go at the Pearl River facility, commented Pfizer.

In the wake of the changes, the Richmond facility's packaging and production activities would be transferred either to other Pfizer manufacturing sites or to "external supply partners", the company said, adding that it would also expand production of Consumer Healthcare's products at its Guayama facility located in Puerto Rico.

Once the restructuring is complete, Consumer Healthcare's manufacturing network will comprise the Guayama plant and Pfizer's facilities in Montreal, Canada; Suzhou, China; Aprilia, Italy; Hsinchu, Taiwan; and Albany, Georgia in the US.

The move is part of a wider restructuring of Pfizer's newly-enlarged manufacturing network, which the company said would result in the loss of 6,000 jobs worldwide.

Pfizer explained that by the end of 2015 it planned to have ceased operations at eight sites globally, and to have reduced operations at a further six.

OTC

Business Strategy

Amway shifts some manufacturing out of US

Amway plans to shift production of a number of its products to Asia and Europe in the next three years to reflect the US-based company's growth in international markets.

Steve Van Andel, chairman of the direct-selling specialist, pointed out that "more than 80%" of the company's customers bought its products outside of the US.

Amway's parent, Alticor, reported sales of US$8.4 billion (€6.9 billion) in 2009.

OTC

Sales & Distribution Agreements

Perrigo obtains Delsym generic

Perrigo has acquired from Tris Pharma the exclusive US sales and distribution rights to the store-brand equivalent of Reckitt Benckiser's Delsym (dextromethorphan polistirex) 12-hour OTC cough liquid.

Tris is currently engaged in US patent litigation with Reckitt Benckiser over the only patent listed against Delsym in the US Food and Drug Administration's (FDA's) Orange Book – US patent 5,980,882, expiring on 16 April 2017.

The company believes that it holds first-to-file status in the US, entitling it to 180 days of generic market exclusivity.

Quoting Information Resources data, Perrigo said annual US sales of Delsym were approximately US$125 million (€101 million).

Under the terms of the licensing agreement, Perrigo and Tris will share profits and Perrigo will also pay Tris certain milestone payments.

Reckitt Benckiser gained the Delsym brand, along with the guaifenesin-based cough medicine Mucinex, when the UK-based company acquired Adams Respiratory Therapeutics for US$2.3 billion in 2008 (**OTC *bulletin***, 17 December 2007, page 1).

Perrigo is currently awaiting approval from the FDA for its store-brand version of Mucinex 600mg guaifenesin extended-release tablets, after a federal court rejected Reckitt Benckiser's patent-infringement complaint against Perrigo in February (**OTC *bulletin***, 26 February 2010, page 13).

Perrigo's chairman and chief executive officer, Joseph Papa, said the deal was another example of the firm "making quality healthcare more affordable to Americans".

OTC

Pricing & Reimbursement

Switzerland could pay for complementary medicines

Complementary medicines – such as herbal remedies, homoeopathic and anthroposophic products, and traditional Chinese medicine – could be reimbursed by Swiss statutory health insurance funds from the end of this year if health authorities accede to industry demands.

Switzerland's federal health authority, the Bundesamt für Gesundheit, said that it had received formal requests from industry associations to bring complementary medicines within the scope of services provided by the statutory funds. The country's federal department of home affairs is expected to make a decision by the end of this year.

The health authority said it would review the formal requests for completeness, but the assessment of efficacy and cost/benefit ratio would be the task of a federal commission that could call on expert advice. The commission would then pass its recommendations on to the department of home affairs.

Last year, a Swiss referendum found that two-thirds of voters supported the idea of placing a commitment to complementary medicine in the country's constitution (**OTC *bulletin***, 19 June 2009, page 8).

A campaigning group called Ja zur Komplementärmedizin – which included manufacturers, healthcare professionals, academics and retailers – insisted that therapies such as herbal medicines and homoeopathy had been "politically marginalised" in Switzerland over the past few years.

"Anthroposophic medicine, homoeopathy, neural therapy, herbal medicine and traditional Chinese medicine should become a definitive part of basic healthcare insurance," the group maintained.

Switzerland's federal council, the Bundesrat, has already passed a motion to support measures that would integrate complementary medicine in education for doctors, chiropractors, dentists and pharmacists. A consultation period is scheduled to open at the end of this year.

Meanwhile, Switzerland's medicines regulatory agency, Swissmedic, last year created an expert pharmacopoeia committee for complementary medicines (**OTC *bulletin***, 30 October 2009, page 11).

Furthermore, legislation to simplify the marketing authorisation process for complementary medicines could come into effect by the end of this year, providing the federal council approves.

OTC

IN BRIEF

■ **FDA** – the US Food and Drug Administration – said its **Transparency Task Force** had released 21 draft proposals for public consultation. The drafts cover public disclosure policies aimed at helping consumers, stakeholders and others understand how the agency operates and makes decisions. The FDA said the task force would review the comments received and decide which proposals would be implemented. The task force was set up a year ago (**OTC *bulletin***, 19 June 2009, page 12).

OTC

Regulatory Affairs

Europe's list of herbals grows to seven

Five entries have been added to the Community list of herbal substances, preparations and combinations for use in traditional herbal medicinal products since the beginning of this year, according to the European Commission.

The new additions have lifted the total number of entries on the Community list of herbal substances to seven (see Figure 1).

Peppermint oil is the latest herbal substance to join the list. Four others – aniseed, calendula flower, eleutheroccus root and purple coneflower herb – were added in January. Bitter-fennel fruit and sweet-fennel fruit were already present.

All seven were proposed for inclusion by Europe's Committee on Herbal Medicinal Products (HMPC), which has not yet submitted any further entries to the European Commission for consideration.

The European Medicines Agency's (EMA's) latest Annual Report, which has just been published, points out that the HMPC did not submit any entries for the Community list of herbal substances to the European Commission during 2009. This compared with five in 2008 and two in 2007 (see Figure 2).

Furthermore, the report notes that the HMPC only published one list entry for public consultation in 2009. A total of three draft list entries are currently under active public consultation.

The report adds that the HMPC finalised 17 Community herbal monographs in 2009, which was exactly the same number as in 2008. In addition, 16 draft Community herbal monographs were published by the HMPC.

The number of Community herbal monographs finalised by the HMPC had reached 60 as **OTC *bulletin*** went to press (see Figure 3). The most recent herbal monographs finalised by the HMPC at its March 2010 meeting were for java tea leaf and purple coneflower root.

The EMA's Management Board has expressed concern about the slow progress with herbals.

Anisi fructus (aniseed)
Calendulae flos (calendula flower)
Echinaceae purpureae herba (purple coneflower herb)
Eleutherococci radix (eleutherococcus root)
Foeniculi amari fructus (bitter-fennel fruit)
Foeniculi dulcis fructus (sweet-fennel fruit)
Menthae piperitae aetheroleum (peppermint oil)

Figure 1: Current entries in Europe's Community list of herbal substances, preparations and combinations for use in traditional herbal medicinal products

Community herbal monographs for traditional and well-established herbal medicinal products are not legally binding on member states of the European Union, but they should be taken into account. By contrast, entries on the Community list of herbal substances, preparations and combinations for use in traditional herbal medicinal products are legally binding.

However, the European Parliament's influential Environment, Public Health and Food Safety (ENVI) committee recently endorsed a proposal that would make Community herbal monographs legally binding on member states. If the proposal is adopted, directive 2001/83/EC would be amended to state that Community herbal monographs "shall be complied with" by member states.

The proposal, which focuses on pharmacovigilance, has been forwarded to the European Parliament for a full plenary vote in June.

OTC

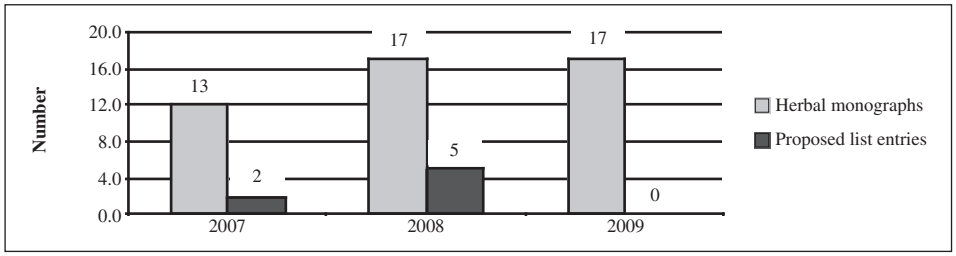


Figure 2: The number of Community herbal monographs finalised by Europe's Committee on Herbal Medicinal Products (HMPC) together with the number of entries for Europe's Community list of herbal substances proposed to the European Commission by the HMPC (Source – European Medicines Agency)

Absinthii herba (wormwood herb)
Aloe (barbados aloes, cape aloes)
Althaeae radix (marshmallow root)
Anisi aetheroleum (anise oil)
Anisi fructus (aniseed)
Avenae fructus (oat fruit)
Avenae herba (oat herb)
Betulae folium (birch leaf)
Boldi folium (boldo leaf)
Calendulae flos (calendula flower)
Centaurii herba (centaury herb)
Curcumae longae rhizoma (tumeric root)
Echinacea pallidae radix (pale coneflower root)
Echinaceae purpureae herba (purple coneflower herb)
Echinaceae purpureae radix (purple coneflower root)
Eleutherococci radix (eleutherococcus root)
Equiseti herba (horsetail)
Foeniculi amari fructus (bitter-fennel fruit)
Foeniculi amari fructus aetheroleum (bitter-fennel fruit oil)
Foeniculi dulcis fructus (sweet-fennel fruit)
Frangulae cortex (frangula bark)
Gentianae radix (gentian root)
Hamamelidis cortex (hamamelis bark)
Hamamelidis folium (hamamelis leaf)
Hamamelidis folium et cortex aut ramunculus destillatum (hamamelis leaf and bark distillate and twig distillate)
Harpagophyti radix (devil's claw root)
Hippocastani semen (horse chestnut seed)
Hyperici herba (St John's wort)
Juniperi psuedo-fructus (juniper berry)
Linum semen (linseed)
Lupuli flos (hop strobiles)
Meliloti herba (melilot)
Melissae folium (melissa leaf)
Menthae piperitae aetheroleum (peppermint oil)
Menthae piperitae folium (peppermint leaf)
Orthosiphonis staminei folium (java tea leaf)
Passiflorae herba (passion flower)
Plantaginis ovatae semen (ispaghula seed)
Plantaginis ovatae seminis tegumentum (ispaghula husk)
Polypodii rhizoma (polypody rhizome)
Primulae flos (primula flower)
Primulae radix (primula root)
Psyllii semen (psyllium seed)
Rhamni purshianae cortex (cascara)
Rhei radix (rhubarb)
Rusci aculeati rhizoma (butcher's broom)
Salicis cortex (willow bark)
Salviae officinalis folium (sage leaf)
Sambuci flos (elder flower)
Sennae folium (senna leaf)
Sennae fructus (senna pods)
Solidaginis virgaureae herba (European goldenrod)
Taraxaci folium (dandelion leaf)
Taraxaci radix cum herba (dandelion root and herb)
Thymi aetheroleum (thyme oil)
Thymi herba (thyme herb)
Urticae folium (nettle leaf)
Urticae herba (nettle)
Valerianae radix (valerian root)
Verbasci flos (mullein flower)

Figure 3: Community herbal monographs finalised to date by Europe's Committee on Herbal Medicinal Products (HMPC) (Source – HMPC)

Herbal Medicines

Most Germans use herbals for children

The vast majority of German parents give their children herbal remedies, according to a study published in the medical journal *Deutsche Medizinische Wochenschrift*.

The study was conducted by a team from the paediatric departments of university hospitals in Leipzig and Munich. They asked 413 parents of children attending either the outpatient department of two hospitals or two paediatricians to fill out a questionnaire about the usage of herbal remedies by their children.

Of the parents, 353, or 85.5%, had given their children one or more herbal products, with chamomile and fennel the most popular choices ahead of eucalyptus.

In terms of herbal medicine brands, Bionorica's thyme-based Bronchipret and Engelhard's ivy-based Prospan cough remedies were equally popular. They were named by 43% of the parents surveyed.

"Parents who gave phytotherapies to their children were significantly more often women living in large cities who had a good educational background and were better off financially," the researchers commented.

OTC

IN BRIEF

■ **ASA** – the UK's Advertising Standards Authority – has upheld a complaint about an online advertisement for a weight-loss product from **LB CyberNet Entertainment**. The authority has also upheld a complaint about a reference to cycling teams in Zipvit's press advertisement for its vitamin supplements.

OTC

Market Research

German pharmacists favour generic OTC manufacturers

German pharmacists favour generic companies over other manufacturers of OTC products, according to recent market research conducted by management consultancy Sempora Consulting.

Sempora asked 133 German pharmacists in March and April to name unprompted the three OTC manufacturers with which they best liked working.

As can be seen from Figure 1, three of the top four places were filled by generics companies – Ratiopharm, Hexal and Stada. Top ranking Ratiopharm was named by around one in two pharmacists.

Bayer broke up the dominance of the generics companies, ranking second after having been named by a third of pharmacists.

Hexal was identified as a preferred partner by almost one out of three German pharmacists, but only one in 10 named its parent company Novartis. Stada's low-cost Aliud business found favour with 8% of pharmacists, the same proportion that liked the Heumann generics unit of Indian generics firm Torrent.

German OTC divisions of Johnson & Johnson and Boehringer Ingelheim ranked fifth and sixth, with 24% and 19% respectively, ahead of non-prescription specialist Klosterfrau, which was named by 17% of pharmacists.

Global generics leader Teva was eighth.

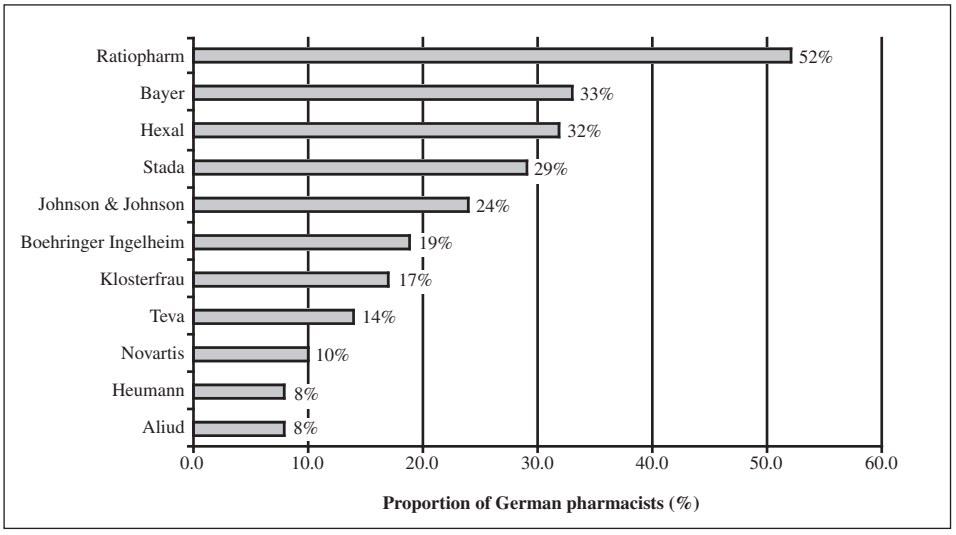


Figure 1: Response of German pharmacists when they were asked to name the three OTC manufacturers with which they best liked working (Source – Sempora Consulting)

OTC

Regulatory Affairs

PGEU warns about internet pharmacy logos

A "false sense of security" could be created by a Europe-wide scheme for internet pharmacy certification, warns the Pharmaceutical Group of the European Union (PGEU).

The pharmacy body says the ease with which certification can be counterfeited exposes the limitations of such schemes.

It points out The Canadian Neighbor Pharmacy – a website registered in Russia – had recently stated that it was supported by the PGEU, claiming that all drugs sold on the website were "considered to be approved by the PGEU". If visitors clicked on a PGEU logo on the website, they were taken to a certificate allegedly issued by the PGEU and carrying the signature of PGEU president Filip Babylon.

A scheme for internet-pharmacy certification was recently proposed by the European Parliament's influential Environment, Public Health and Food Safety (ENVI) committee as part of anti-counterfeiting measures for pharmaceuticals. ENVI wants internet pharmacies to obtain a special authorisation, which would be displayed as a European Union logo on their homepages. The committee also said online retailers should be listed in a European database (**OTC *bulletin***, 14 May 2010, page 20).

"Patients should not be put in a position where they have to discriminate between fake and real certification," remarked John Chave, secretary general of the PGEU. "We need to explore technological options which put certification beyond the counterfeiters."

The PGEU noted The Canadian Neighbor Pharmacy website at http://www.cancarepharmacy.com was no longer on the internet.

However, a Canadian Neighbor Pharmacy website at http://canadianneighborpharmacy.com was available on the internet at the time of writing. It carried a certificate said to be from the Royal Pharmaceutical Society of Great Britain (RPSGB).

OTC

Advertising Complaints

Mentholatum's Regenovex runs into trouble in the UK

Claims made by The Mentholatum Company in newspaper advertising for its Regenovex range of joint-health products have been thrown out by the UK Advertising Standards Authority (ASA).

The ASA ruled that the company's efficacy claims for the products' ingredients – hyaluronic acid and the green-lipped mussel extract Bionovex Oil – were "breakthrough claims" and should be supported by "robust scientific evidence". The authority insisted that such evidence should consist of "product-specific, controlled, double-blind clinical trials conducted on people".

The advertisement described the products as "An advanced formulation for joint health" and "A new generation of joint-care products". It included the claims "Unique dual-action formulation hyaluronic acid strengthens, lubricates and cushions by improving the quality of synovial fluid in your joints" and "Natural marine Bionovex Oil soothes and eases discomfort in joints by providing a rich source of specialist nutrients".

A report provided by Mentholatum was "not a clinical trial, but an uncontrolled, unblinded consumer-use study", said the ASA. "Participants used the advertised products over specific periods of time, and then gave their opinion as to the joint-care products' effectiveness via a self-completion questionnaire," said the authority, adding that the "consumer-use trial was not sufficient substantiation to support the type of claims being made in the advertisement".

Furthermore, the ASA said supporting literature for the efficacy of hyaluronic acid and green-lipped mussel extract consisted of general information about their use in joint health. Concluding that the evidence was not product-specific, the ASA said it did not demonstrate that there were sufficient quantities of the ingredients in the products, or that they would be absorbed and utilised by the body to produce the claimed effects.

The ASA also highlighted that some of the studies had been conducted on frogs and rats, and were "not appropriate to support a claim relating to humans".

The advertisement was "misleading", according to the ASA, as the claims could not be substantiated.

A spokesperson for Mentholatum told **OTC *bulletin*** that the company was "extremely disappointed" at the ruling. Regenovex products were backed by "health-maintenance claims", commented the company, adding that "extensive laboratory studies, as well as large-scale consumer trials, provided superior evidence to that of many other products already on the market and exceeded the regulatory requirements for a food supplement".

Although Mentholatum accepted the ASA's ruling, it disagreed that placebo-controlled double-blind clinical trials were meaningful to support the joint-health-maintenance claims. "Non-medicines – including cosmetics, cosmeceuticals and other consumer wellness products – use consumer studies as a method of supporting claims," the company said.

The advertisement is part of the £1.0 million (€1.2 million) UK launch campaign for the Regenovex range, which consists of oral capsules, topical gel and a patch (**OTC *bulletin***, 30 April 2010, page 15).

OTC

"Complete mouth ulcer care" is the theme of Reckitt Benckiser's launch campaign for the latest addition to its Bonjela brand in the UK.

The company is backing Bonjela Complete Plus with television and press advertising as well as public relations activity.

Consumer-press advertising (pictured left) points out that the medical device forms a "fast-acting protective barrier over the ulcer which lasts for up to four hours". This "soothes the pain" and "aids healing", it adds.

Reckitt Benckiser said Bonjela Complete Plus was applied with a soft applicator which allowed "accurate and hygienic application". The company noted that the applicator could be put straight back into the bottle after use with no need for rinsing or sterilising.

A pack containing 100 applications has a recommended retail selling price of £7.99 (€9.25).

It joins Bonjela, Bonjela Cool and Bonjela Teething Gel.

OTC

A dietetic food for people with osteoporosis is the latest addition to Sandoz' range of vitamin and mineral products in Germany.

Each Vitamin D-Sandoz Osteo Complex capsule provides not only 1,000 international units of vitamin D, but also folic acid and vitamins B6, B12 and K.

The predominantly yellow packs of 45 capsules – which have a recommended retail price of €6.30 – carry a strapline stating the product is for dietetic treatment of osteoporosis where there is vitamin D deficiency.

Launch trade-press advertising (pictured above) describes the newcomer as "Das Sonnenvitamin für die Knochen", or "The sun vitamin for your bones".

OTC

Launches

Stada Austria targets joints

The strong combination of glucosamine and chondroitin is how Stada Arzneimittel is positioning the latest addition to its OTC portfolio in Austria.

Each two-a-day KnorpelPlus capsule contains 750mg glucosamine sulphate and 400mg chondroitin sulphate, along with 100mg vitamin C and 2.5mg manganese sulphate.

Stada said that glucosamine was vital for strengthening cartilage, tendons and ligaments, while chondroitin acted as a protective film and a "shock absorber" for joints.

A month's supply of 60 tablets of the pharmacy-exclusive food supplement has a recommended retail selling price of €26.90. A strapline on tubs says the supplement "encourages movement and reduces sensitivity of joints".

OTC

Marketing Campaigns/Launches

Scholl is 'Keeping Britain on its Feet'

SSL International is investing more than £3.0 million (€3.5 million) in the "first overarching brand campaign" for its Scholl footcare products in the UK.

The campaign – which is based around the message "Keeping Britain on its Feet" – includes television, press, radio and online advertising as well as public relations and social marketing activity.

"As the leading brand in footcare and with the breadth of products that Scholl covers, we believe we are Keeping Britain on its Feet," said Scholl marketing director Mark Critchley. "The campaign aims to celebrate the ordinary hardworking British people who are keeping this country going."

SSL pointed out the campaign was a way of engaging with people in both their workplace and community, and at key times when they were with their peers, friends and family. "Virtually every adult in the UK will see and/or hear some communication from Scholl this summer," noted the company.

The campaign, which is running nationally from 26 April until 14 June, kicked off with television, press and online advertising for SSL's Scholl Hard Skin range. Launched earlier this year, the range comprises softening cream, softening pen, instant hard skin remover, and a file for hard skin and calluses (**OTC *bulletin***, 16 April 2010, page 14).

The television commercial, which explains how Scholl Hard Skin products can give "Visibly softer skin in seven days", is based around a woman on a beach with friends. She is initially embarrassed by the hard skin on her feet, but regains her confidence after using Scholl Hard Skin products.

Meanwhile, consumer-press advertising targets women with the message "Are you ready to bare your soles?", and online banners reach out to men with a humorous creative carrying the headline "Want strokably soft balls?".

In mid-May, the emphasis shifted to television, press and online advertising for SSL's Orthaheel orthotic inserts. Aimed at men and women aged 35-55 years, the advertising is based around the message "Walk away from pain" and highlights that the products are backed by a 30-day money-back guarantee.

The campaign will end with a burst of television advertising for Scholl Cracked Heel products, which highlights that Scholl Cracked Heel Repair Cream K+ is now available in a larger 120ml pack priced £9.99. It also draws attention to the new Scholl HydraStep sandals, which are claimed to "moisturise your feet with every step".

SSL explained that the sandals contained a built-in gel footbed that "slowly releases softening ingredients to the skin on your feet while you go about your daily routine". The top layer comprised natural emollients, vitamin E and a "delicate" fragrance, while the insole underneath was made of "a soft and breathable bamboo and charcoal textile", the company noted.

Scholl HydraStep sandals come in three colours – black, fuchsia and white – and have a recommended retail selling price of £24.99. SSL said the sandals should be worn for one to two hours a day.

The sandals are available exclusively from selected Boots stores as well as the websites www.boots.com and www.scholl.com.

According to SSL, television advertising for Scholl Cracked Heel products and Scholl HydraStep Sandal was aimed at women aged 35-65 years who used footcare for wellbeing, confidence and beauty.

"Keeping Britain on its Feet" is the unifying theme for SSL International's marketing initiatives for its broad portfolio of Scholl footcare products in the UK

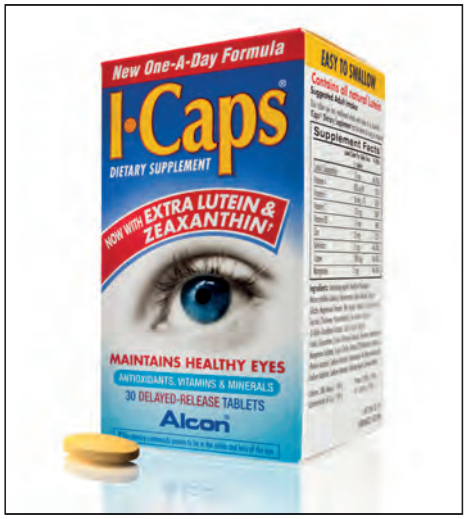
SSL said five of its product categories that were not covered by the television and press initiatives – athlete's foot, blister, insoles, nail-care and odour – would be supported by radio advertising. This runs for three weeks from 7 May on Bauer Media's radio stations, including Forth 1, Radio City and Rock FM.

In addition, there will be a nationwide competition to find "Britain's Hardest Working Feet" via 11 radio stations.

In the blister category, SSL has launched "improved" Scholl Clear Gel Blister Plasters. The company said visibility through the HydraGel pad had been improved to allow more precise application, the adhesive border had been made larger, and the application method had been simplified. Five-plaster packs – containing either five large plasters or three large and two small plasters – are priced £4.39.

New Scholl HydraStep sandals are claimed to "moisturise your feet with every step"

SSL International has just launched "improved" blister plasters in the UK



Alcon is relaunching its ICaps food supplement for healthy eyes in the UK as a one-a-day formulation with extra lutein and zeaxanthin.

While the original version of ICaps provided 4mg lutein/zeaxanthin per daily dose of two tablets, the newcomer contains 10mg lutein/zeaxanthin in each delayed-release tablet.

Commenting on the revamp, Chris Miller, Alcon business unit manager, said: "The new one-a-day formula is certain to aid patient compliance, particularly in those above the age of 50."

A yellow bar on the side of the pack highlights that the product is "easy-to-swallow", while straplines on the front point out that ICaps now comes with "extra lutein and zeaxanthin" and contains "antioxidants, vitamins & minerals".

Alcon said recent research had found that ophthalmologists "considered lutein and zeaxanthin to be the most important nutrients in relation to age-related macular degeneration problems and ocular supplementation".

Current pharmacy-press advertising describes ICaps as the "First choice ocular supplement of UK ophthalmologists".

ICaps has a recommended retail selling price of £11.49 (€13.55).

OTC

Regulatory Affairs

FDA warns Americans about topical Benadryl

Americans have been warned about the dangers of mistakenly ingesting McNeil Consumer Healthcare's topical OTC medicine, Benadryl Extra Strength Itch Stopping Gel.

The Food and Drug Administration (FDA) in the US said it had received reports of "serious side-effects" in people who had mistakenly swallowed the product. "People swallowing the gel can ingest a dangerous amount of the active ingredient, diphenhydramine," insisted the FDA, adding: "Large doses of diphenhydramine can result in serious side-effects such as unconciousness, hallucinations and confusion."

Noting that some OTC Benadryl products were intended to be swallowed, the FDA advised consumers and pharmacies to store products for the skin separately from products that should be swallowed.

To address the FDA's concerns, McNeil has changed the packaging for its Benadryl Extra Strength Itch Stopping Gel to help consumers recognise that the product is for use on the skin. Labelling now includes the prominent statement "For skin use only", and the cap now carries a sticker stating "For skin use only".

In addition, the company has initiated studies to understand better the factors that may contribute to consumers mistakenly swallowing the product.

New packaging for Benadryl Extra Strength Itch Stopping Gel in the US carries prominent warnings that the topical product is "For Skin Use Only"

The FDA is urging manufacturers of similar products to make similar changes to their labelling and packaging.

The Benadryl warning follows a series of product recalls by Johnson & Johnson's McNeil Consumer Healthcare subsidiary affecting North American markets (**OTC *bulletin***, 14 May 2010, page 1).

In April, Johnson & Johnson revealed that product recalls had cut the US sales of its OTC & Nutritionals business by 25.3% to US$542 million (€444 million) in the first three months of 2010 (**OTC *bulletin***, 30 April 2010, page 1).

OTC

Business Strategy

P&G puts PharmacyCare online in UK

Procter & Gamble has launched an online version of its PharmacyCare programme to make it more accessible to independent pharmacies across the UK.

The company said more than 500 stores had now signed up to PharmacyCare, which was launched two years ago to help independent pharmacies improve their merchandising and increase retail sales (**OTC *bulletin***, 13 June 2008, page 14).

Quoting data from IRI, Procter & Gamble said value sales of Beauty & Baby Care products in pharmacy had dropped by 13% in the year ended 31 March 2010 compared with the same period a year earlier. The company added, however, that stores that had implemented the PharmacyCare programme had bucked this trend with sales rises of between 7% and 20% in three key health and beauty categories.

The new online service – available at www.pharmacycare-online.co.uk – includes information on products, promotions and campaigns as well as downloadable point-of-sale material, planograms and modules from the Retail Skills Made Easy training programme.

Pharmacists and assistants visiting Procter & Gamble's new PharmacyCare website can download planograms, point-of-sale material and training modules

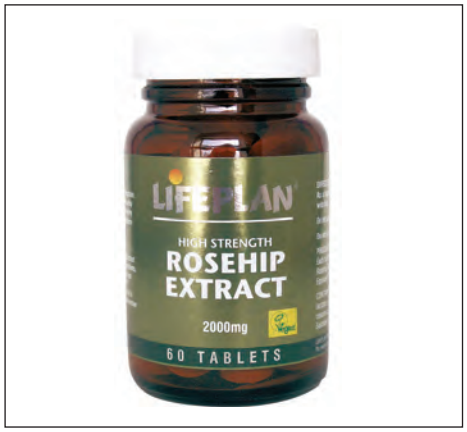
In addition, the company has introduced an online forum for pharmacists and their staff "to share best practice with their counterparts in the profession".

Procter and Gamble said it wanted "pharmacists and their assistants to take a look, download the planograms, start implementing the plans at store level, and see the results for themselves". The company hoped that they would then "share their stories in the PharmacyCare online forum".

Meanwhile, Procter & Gamble noted that 133 stores had signed up to its recently-launched personal support programme for Retail Skills Made Easy, which coaches staff through the initiative either in store or by telephone.

The company noted that its future plans included the launch of Retail Skills Made Easy Bitesize – documents containing hints and tips to "get the best out of the front of store area" – as well as new category management cards.

OTC



Lifeplan Products has extended its offering in Europe with the launch of two food supplements.

The company is introducing the newcomers – Lifeplan Rosehip Extract and Lifeplan Pumpkin Seed Extract – to Cyprus, Ireland, Italy, Latvia, Lithuania, Malta, Portugal, Spain and the UK.

According to Lifeplan, the food supplements contained "superior quality, ethical ingredients in high-strength formulations that are registered with the Vegan Society". The products were competitively priced and free of artificial colours, flavours and preservatives, added Lifeplan.

The company said Lifeplan Rosehip Extract was a "2,000mg" strength product for consumers who had joint problems and wanted to maintain a healthy heart as well as lower high cholesterol levels. It added that the "300mg" strength Lifeplan Pumpkin Seed Extract helped urinary problems including incontinence and benign prostatic hyperplasia.

In the UK, Lifeplan Rosehip Extract has a recommended retail selling price of £8.99 (€10.49) for 60 tablets, while Lifeplan Pumpkin Seed Extract retails at £6.99 for 60 tablets. Users should take up to two tablets a day.

Earlier this year, the company launched the Lifeplan Acai Berry, Lifeplan Aloedophilus, and Lifeplan Pine Bark Extract food supplements in Europe.

OTC

Lloydspharmacy is touring the UK with an inflatable heart-shaped sofa to raise awareness of the effects of high blood pressure.

As part of its Heart Health campaign, the pharmacy chain is offering shoppers a free blood-pressure check at shopping centres in Birmingham, Cardiff, Leeds and Southampton during May.

Lloydspharmacy said it aimed to encourage people to monitor their blood pressure regularly in between doctors' appointments.

The retailer pointed out that it had offered free blood-pressure checks in its pharmacies since 2003, and had conducted more than 1.5 million checks to date. It also sells a range of blood-pressure monitors.

OTC

Line Extensions

Novartis adds three to Savlon selection in UK

Novartis Consumer Health said a newcomer to its Savlon range of antiseptics would bring the brand into "daily usage" in the UK and Ireland.

Savlon Hand Gel – one of three new line extensions – made the brand "more accessible", pointed out the company, and could encourage impulse purchases to "increase basket spend from the first-aid fixture".

The company said the antibacterial hand gel, which is claimed to kill 99% of bacteria, had been launched following the outbreak of swine flu last year. It could be used to "complement traditional hand washing or to cleanse and sterilise the hands before treating minor wounds", the company added.

Packaging highlights that the product provides "clean hands on the go".

Meanwhile, Novartis has introduced Savlon Anti-Bacterial Surface Spray following a surge in demand for antibacterial cleansers. The company claimed the trigger spray killed 99.9% of bacteria and viruses including MRSA.

Novartis maintained that its third newcomer – Savlon Spray Plaster – brought "credibility and differentiation to the spray plaster category", adding it had been launched to "create new interest in spray plasters and revitalise the premium sector".

The product produces a flexible film when sprayed onto cuts, making it particularly good for use on knees and elbows. The film seals out water, dirt and germs, before wearing off after two to three days.

The company noted that, unlike competing products, Savlon Spray Plaster was antiseptic upon application and had a "unique non-drip formula for a fuss-free treatment". The 40ml bottle was "excellent value", added Novartis.

A spray-on plaster that is antiseptic upon application is one of three new additions to Novartis Consumer Health's Savlon brand in the UK and Ireland

Packaging highlights the product "aids natural healing" and "reduces the risk of infection".

Novartis said that it was backing the Savlon brand with consumer advertising, public relations and in-store activity throughout 2010.

The 100ml bottle of Savlon Hand Gel has a recommended retail selling price of £2.30 (€2.70), the 500ml bottle of Savlon Anti-Bacterial Surface Spray is priced at £1.99, and Savlon Spray Plaster is priced at £6.19.

OTC

"Slim while you sleep" is Power Health's promise to consumers for a new food supplement in the UK.

Power Health claimed that Slim-Nite, which contains l-arginine, l-carnitine and l-ornithine, harnessed the power of sleep to give "you incredible results fast".

The "unique blend" of ingredients helped convert food into energy for the body to repair itself and boost metabolism, added the company.

Available from the website www.powerhealth.co.uk and selected independent healthfood stores, Slim-Nite comes in a pack of 45 capsules and has a recommended retail selling price of £10.60 (€12.50). Consumers should take three capsules every evening before going to sleep.

A strapline on the packaging states that Slim-Nite is "A food supplement of particular amino acids".

OTC

JUNE

14-15 June

■ **EuroPLX 43**

Berlin, Germany

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

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

14 & 15-16 & 17 June

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

Budapest, Hungary

A pre-conference symposium on 'Regulatory affairs in the CIS region' and a post-conference workshop on pharmacovigilance will accompany this two-day event.

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

17 June

■ **Building a Regulatory Strategy for Marketing Food Supplements in Europe**

Brussels, Belgium

This one-day conference is subtitled 'The key steps to a successful product launch'.

***Contact**: Cindy Garcet,*
European Advisory Services (EAS).
Tel: +32 2 218 1470.
Fax: +32 2 219 7342.
E-mail: workshop@eas.eu.
Website: www.eas.eu.

17 June

■ **Medicines and Medical Devices Borderline**

Bonn, Germany

A one-day meeting organised by Germany's medicines manufacturers' association, the BAH, and conducted in the German language. Speakers will include Guido Middeler and Ralf Sibbing from Diapharm.

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

21-23 June

■ **Pharmacovigilance**

London, UK

A three-day training course covering drug safety monitoring in Europe, Japan and the US.

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

22-23 June

■ **Pharmaceutical Regulatory Affairs in Canada**

London, UK

This two-day seminar will focus on Canada's regulatory environment for pharmaceuticals.

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

9-11 June

■ **46th AESGP Annual Meeting**

Dubrovnik, Croatia

'Connecting with self-care. The future of self-medication in the new Europe' will be the theme of the 46th Annual Meeting of the Association of the European Self-Medication Industry, the AESGP.

The three-day meeting will include a session entitled 'How to be successful in self-care', featuring presentations from Etienne de Laroullière, vice-president and head of global business unit OTC at Nycomed; Brian McNamara, region head Europe OTC for Novartis Consumer Health; Luc Massart, chief operating officer of HRA Pharma; and James Hallatt, UK general manager of GlaxoSmithKline Consumer Healthcare.

Speakers at the meeting will also include: Martin Terberger and Basil Mathioudakis of the European Commission; Thomas Lönngren of the European Medicines Agency (EMA); Dagmar Roth-Behrendt of the European Parliament; and Catherine Geslain-Lanéelle and Vittorio Silano of the European Food Safety Authority (EFSA).

***Contact**: Association of the European Self-Medication Industry, the AESGP.*
Tel: +32 2 735 51 30. Fax: +32 2 735 52 22.
E-mail: info@aesgp.be. Website: www.aesgp.be.

24 June

■ **Pharmaceutical Quality of Herbals**

Bonn, Germany

A one-day meeting organised by Germany's medicines manufacturers' association, the BAH, and conducted in German. Speakers will include Klaus Reh from Germany's federal institute for drugs and medical devices, BfArM.

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

JULY

7-8 July

■ **Marketing Authorisation in the Middle East**

Frankfurt, Germany

Countries to be discussed at this two-day meeting include Jordan, Lebanon and Saudi Arabia.

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

8-9 July

■ **Pharmaceutical Regulatory Affairs in Russia, Belarus, Ukraine and Former Soviet States**

London, UK

This two-day meeting will cover recent and expected regulatory development and pharmacovigilance requirements, as well as specific issues relating to Belarus, Ukraine and the former Soviet States.

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

14 July

■ **Marketing Authorisation in Japan**

Frankfurt, Germany

Speakers at this one-day conference on Japan will include Bettina Fiedler from Bayer Schering Pharma.

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

AUGUST

4 August

■ **Basics of Regulatory Affairs**

London, UK

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

***Contact**: TOPRA.*
Tel: +44 20 7510 2560.
Fax: +44 20 7537 2003.
E-mail: meetings@topra.org.
Website: www.topra.org.

OCTOBER

4-6 October

■ **The 7th TOPRA Annual Symposium**

London, UK

A three-day meeting organised by The Organisation for Professionals in Regulatory Affairs (TOPRA) together with the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

***Contact**: TOPRA.*
Tel: +44 20 7510 2560.
Fax: +44 20 7537 2003.
E-mail: meetings@topra.org.
Website: www.topra.org.

25-26 October

■ **Nutraceuticals and Functional Foods**

London, UK

Topics for discussion at this two-day meeting include global perspectives and evolution of functional foods, marketing opportunities, nutrition and health claims, nanotechnology, and probiotics.

***Contact**: Samantha Graves,*
SMi Group.
Tel: +44 20 7827 6000.
Fax: +44 20 7827 6001.
E-mail: sgraves@smi-online.co.uk.
Website: www.smi-online.co.uk.

NOVEMBER

8-9 November

■ **EuroPLX 44**

Barcelona, Spain

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

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

A tale of two companies

2010 is turning out to be a tale of two companies. Sanofi-Aventis is surging ahead with a string of OTC acquisitions, while Johnson & Johnson is struggling to defend the reputation of its key brands in North America in the wake of a series of product recalls. Deborah Wilkes follows the leading firms.

"It was the best of times, it was the worst of times," was how Charles Dickens chose to begin *A Tale of Two Cities*. And that sums up the fortunes of two of the world's leading consumer healthcare companies – Sanofi-Aventis and Johnson & Johnson – during the opening few months of 2010.

Sanofi-Aventis has just announced plans to acquire Polish OTC company Nepentes. Meanwhile, as **OTC *bulletin*** went to press, Johnson & Johnson was busy preparing to testify at a hearing of the US Committee on Oversight and Government Reform about its recent recall of medicines for infants and children.

The Nepentes deal is the latest in a string of local OTC acquisitions that are transforming Sanofi-Aventis into a global OTC player.

Ideal platform in the US

The big news at the beginning of this year was that Sanofi-Aventis intended to enter the US OTC market by acquiring Chattem for approximately US$1.9 billion (€1.5 billion). Chris Viehbacher, the chief executive officer of the French pharmaceutical firm, described Chattem as the "ideal platform in the US consumer healthcare market, which represents 25% of the current worldwide opportunity" (**OTC *bulletin***, 20 January 2010, page 1).

Announcing the deal, Viehbacher pointed out that Chattem would provide a strong vehicle for switching some of Sanofi-Aventis' medicines from prescription-to-OTC status in the US. "Sanofi-Aventis probably has one of the most interesting portfolios of prescription-to-OTC switch candidates in the business," he insisted, adding that the company was seeking to switch the allergy medicine Allegra (fexofenadine hydrochloride) in the US.

Sanofi-Aventis was keen to point out that acquiring Chattem would make it the world's fifth-largest consumer healthcare company with sales of approximately €1.7 billion. At the time, Sanofi-Aventis ranked number six.

Before the deal was completed in early February, Sanofi-Aventis' Consumer Health Care business did not have a direct presence in the US. Its main markets included Australia, Brazil, France, Italy, Mexico and Russia.

Chattem, by contrast, generated around 93% of its turnover in the US through a portfolio of brands that includes ACT, Cortizone-10, Gold Bond, Icy Hot, Selsun Blue and Unisom. In the year ended 30 November 2008, the company increased its sales by 7% to US$455 million.

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

If Allegra is switched successfully in the US, then the premium price tag will be good value. According to Viehbacher, switching Allegra had the potential to move Sanofi-Aventis' Consumer Health Care business up the rankings "pretty significantly".

Earlier this year, Viehbacher forecasted that an OTC version of Allegra could double Chattem's annual sales of more than US$450 million. He highlighted that established OTC allergy brands in the US, like Merck & Co's Claritin (loratadine) and McNeil Consumer Healthcare's Zyrtec (cetirizine), generated a similar figure on their own (**OTC *bulletin***, 26 February 2010, page 5).

However, successfully launching an OTC version of Allegra in the US will not be easy. Capturing market share from Claritin and Zyrtec will be tough. Furthermore, Allegra already faces generic competition in the prescription sector, and store-brand players, such as Perrigo, are queuing up to capitalise on the OTC opportunity.

> ***Nepentes is the latest in a string of local OTC acquisitions that are transforming Sanofi-Aventis into a global OTC player***

Sanofi-Aventis submitted its switch application to the US Food and Drug Administration (FDA) at the end of March. The company is confident that Allegra will be an OTC medicine in the US by early 2011 (**OTC *bulletin***, 14 May 2010, page 8).

In addition to entering the US OTC market, Sanofi-Aventis recently agreed to form a joint-venture company with Minsheng Pharmaceutical Group to produce vitamin and mineral supplements for the Chinese OTC market. Hanspeter Spek, president of global operations at Sanofi-Aventis, said that entering the "world's second-largest consumer healthcare market" was an important strategic move (**OTC *bulletin***, 10 February 2010, page 2).

Furthermore, Sanofi-Aventis has just announced that it plans to acquire Nepentes in a deal that values the Polish OTC company at PLN420 million (€105 million). The two companies said in a joint press statement that Sanofi-Aventis would seek to acquire all the outstanding shares in Nepentes through a public tender offer (see front page).

Affiliates in Bulgaria and Romania

Nepentes reported sales up by nearly a quarter to PLN135 million in 2009 from its portfolio of pharmaceuticals and dermocosmetics, including the Emolium and Iwostin brands. The majority of this figure was generated in Poland, but Nepentes also has affiliates in Bulgaria and Romania.

The past two years have seen Sanofi-Aventis set about transforming its Consumer Health Care business from a sleeping giant with a low profile into a rapidly-growing player that is never far from the headlines. The company intends to double the size of its Consumer Health Care business to around €3.0 billion within the next five years through a combination of acquisitions and geographic expansion (**OTC *bulletin***, 20 January 2010, page 20).

In the run up to obtaining Chattem, Sanofi-Aventis acquired Symbion Health's consumer healthcare business in Australia and New Zealand, Zentiva in the Czech Republic, Gramon in Argentina, Kernpharm in the Netherlands, and Oenobiol in France.

These bolt-on acquisitions helped push up sales by the company's Consumer Health Care business by 18.9% – or 26.8% at constant exchange rates – to €1.43 billion in 2009 (see Figure 1). On a constant-structure and exchange-rate basis, the rise was still a strong 8.1%.

Growth in the first quarter of this year was even more rapid, as Chattem came on board for about half of the period. Turnover at Sanofi-Aventis' Consumer Health Care business grew by 44.8% – 42.5% at constant exchange rates – to €491 million (see Figure 2 on page 25). Sales growth on a constant-structure and ex-

Parent group	OTC business	Annual sales of OTC business	Change as reported (%)	% of group	Comments
Bayer HealthCare	Consumer Care	€3.08 billion	+2	19.3	–
Boehringer Ingelheim	Consumer Health Care	€1.26 billion	+6	9.9	–
GlaxoSmithKline	OTC Medicines	£2.32 billion (€2.67 billion)	+20	8.2	–
Herbalife	Herbalife	US$2.32 billion (€1.85 billion)	+1	100.0	Includes some sales of personal care products
Johnson & Johnson	OTC & Nutritionals	US$5.63 billion (€4.48 billion)	-4	9.1	Launched OTC Zyrtec in the US at the end of January 2008
Merck & Co	Consumer Care	US$1.28 billion (€1.02 billion)	–	2.8	Merck & Co bought Schering-Plough for US$41 billion on 3 November 2009
Merck KGaA	Consumer Health Care	€467 million	+6	6.0	–
Nycomed	Total OTC	€418 million	-5	1.3	–
Novartis	OTC	US$3.00 billion (€2.39 billion)	–	6.8	Approximate figure
Omega Pharma	Omega Pharma	€814 million	±0	100.0	Majority of sales are generated in Europe
Perrigo	Consumer Health Care	US$1.64 billion (€1.31 billion)	+23	81.7	Figures are for the year ended 27 June 2009. Made several acquisitions in the financial year. Majority of sales come from store-brands in the US
Pfizer	Consumer Healthcare	US$663 million (€527 million)	–	4.0	Figures are for first quarter of 2010 only, as no figure was reported for the year 2009. Pfizer acquired Wyeth, including its Consumer Healthcare business, for US$68 billion in 2009
Procter & Gamble	Health Care	US$13.6 billion (€10.9 billion)	-7	17.2	Figures for the year ended 30 June 2009. Health Care sales included Feminine Care, Oral Care and Pharmaceuticals businesses as well as Personal Health Care
Reckitt Benckiser	Health & Personal Care	£2.08 billion (€2.39 billion)	+24	26.8	Acquired Adams Respiratory Therapeutics in the US on 30 January 2008
Sanofi-Aventis	Consumer Health Care	€1.43 billion	+19	4.9	Made a series of local OTC acquisitions in 2009
Taisho	Self-Medication	¥159 billion (€1.41 billion)	-1	61.5	Figures for the year ended 31 March 2010. Acquired Bristol-Myers Squibb's OTC assets in the Asia-Pacific region, excluding China and Japan

Figure 1: Performance of selected OTC businesses in 2009 (unless otherwise stated) as reported by the parent groups. Changes in sales are as reported in the parent group's chosen currency and include the effect of acquisitions/divestments and currency translations, and they are compared to the same period a year earlier. Currency conversions to euros are at rates on 21 May 2010. The range of products covered by OTC business units in this table varies from one company to another and may include personal-care products (Source – OTC *bulletin*)

change-rate basis, however, was 3.4%.

Meanwhile, the world number one, Johnson & Johnson, is having a really tough time, following a series of product recalls in North America by its McNeil Consumer Healthcare subsidiary. As **OTC *bulletin*** went to press, the US-based company was about to testify at a hearing of the US Committee on Oversight and Government Reform about its recent recall of medicines for infants and children.

Johnson & Johnson's chairman and chief executive officer, William Weldon, has been invited to testify but will not put in an appearance as he is recovering from back surgery (see page 11). However, Colleen Goggins, worldwide chairman of Johnson & Johnson's Consumer division, was expected to testify.

FDA commissioner Margaret Hamburg has also been invited to address the hearing.

The congressional committee is investigating the company's recall of 44 OTC medicines for infants and children. These are sold under the Motrin, Tylenol and Zyrtec brands in a number of countries, including the US. Announcing the recall, McNeil said it had temporarily suspended production at its plant in Fort Washington, Pennsylvania (**OTC *bulletin***, 14 May 2010, page 1).

According to McNeil, the latest recall had been initiated because "some of these products may not meet required quality standards". The recall was not due to adverse medical events, the company stressed.

Nevertheless, the FDA said its inspectors had found grime and contaminated ingredients at the plant. McNeil's manufacturing deficien-

cies could affect "quality, purity or potency" of products, the agency noted.

The recall is the sixth significant such move in North America by McNeil in an eight-month period. In January of this year, the FDA sent McNeil a warning letter about another manufacturing facility at Las Piedras in Puerto Rico, where a number of the company's OTC medicines are produced (**OTC *bulletin***, 10 February 2010, page 22).

It remains to be seen how the latest product recall and congressional committee hearing will affect Johnson & Johnson's sales and the reputation of its brands.

Last year, Johnson & Johnson's OTC & Nutritionals business saw its worldwide sales decrease by 4.5% to US$5.63 billion. The company put the fall down to a tough year-on-year comparison in the US following the launch of OTC Zyrtec in early 2008, and from negative currency effects. Excluding currency effects, the fall was only 1.1% (**OTC *bulletin***, 10 February 2010, page 6).

It remains to be seen how the latest product recall and hearing will affect Johnson & Johnson's sales and the reputation of its brands

However, in the first three months of this year – before the latest product recall and congressional committee hearing – US sales of its OTC & Nutritionals business dropped by 25.3% to US$542 million. The company blamed the earlier product recalls, which affected the flagship Tylenol analgesic brand amongst others. The US slump meant worldwide turnover by the business fell by 10.5% – 15.0% excluding currency effects – to US$1.21 billion in the period (**OTC *bulletin***, 30 April 2010, page 1).

The problems in the OTC & Nutritionals business had a knock-on effect at Johnson & Johnson's Consumer division. It experienced a 9.6% US sales decrease to US$1.56 billion during the first quarter.

Commenting on the first-quarter results, Dominic Caruso, Johnson & Johnson's chief financial officer, claimed that the recalls had "not really impacted physician recommendation or consumer preferences" for the company's OTC products. Caruso acknowledged, however, that second-quarter sales would also be hit by the recalls.

Meanwhile, the OTC business of another US giant, Procter & Gamble, is also going through a challenging period. The company does not release detailed sales figures for its OTC operation, but during the first three months of this year its Personal Health Care business recorded a mid-single-digit fall in worldwide volume sales (**OTC *bulletin***, 14 May 2010, page 9).

Procter & Gamble explained that the drop was due to a mild cold and flu season, which had reduced shipments of Vicks products, as well as declining volume sales of its Prilosec OTC heartburn medicine containing the proton-pump inhibitor omeprazole. Prilosec OTC has now only recorded one quarter of volume sales growth in the two years since it lost market exclusivity in the US in March 2008, and store-brand competition began to eat away at the brand's sales.

In addition to store-brand versions, Prilosec OTC now has to compete with Merck & Co's Zegerid OTC brand, which combines omeprazole with sodium bicarbonate. Merck claims the product's "unique dual-ingredient formulation" protects the omeprazole from stomach acids and allows the medicine to be absorbed quickly. A heavyweight consumer-advertising campaign for Zegerid OTC urges Americans to "Discover the Difference" (**OTC *bulletin***, 16 April 2010, page 14).

Prilosec OTC also faces stiff competition in the US from Novartis Consumer Health's recently-launched Prevacid 24HR, based on rival proton-pump inhibitor lansoprazole (**OTC *bulletin***, 16 November 2009, page 1).

Procter & Gamble's total Health Care sales – including its Feminine Care and Oral Care businesses as well as Personal Health Care – rose by 5% to US$2.8 billion in the quarter.

Reckitt Benckiser's performance in the first quarter of 2010 compared favourably with its OTC industry peers, but the UK-based company is accustomed to better.

In 2009, Reckitt Benckiser's Health & Personal Care division pushed its worldwide sales up by 24% to £2.08 billion (€2.39 billion). At constant exchange rates, the rise was still an impressive 14% (**OTC *bulletin***, 26 February 2010, page 4).

Reckitt Benckiser's performance in the first quarter of 2010 compared favourably with its OTC industry peers, but the UK-based company is accustomed to better

Chief executive officer Bart Becht said that Health & Personal Care had posted "very good growth", driven by its Healthcare powerbrands Gaviscon, Nurofen and Strepsils, as well as the Personal Care powerbrand Dettol. The company's strategy of rolling out the division's powerbrands into new markets had continued during 2009, he noted.

By the first quarter of this year, however, sales growth at Reckitt Benckiser's Health & Personal Care division had slowed down to 4% – both as reported and at constant exchange rates. A weak cold and flu season in Europe and North America had held back worldwide sales growth at the Healthcare unit, said the company, but Personal Care had recorded a "strong performance".

Becht was keen to point out that the Healthcare unit had increased its market share during the quarter. The Healthcare powerbrands Gaviscon, Mucinex, Nurofen and Strepsils had all improved their respective market shares in the period, he said.

Dark clouds on the horizon

Some dark clouds, however, lie on the horizon for Reckitt Benckiser. In the UK, for instance, the company has been accused by the Office of Fair Trading (OFT) of abusing its dominant position in the supply of alginate and antacid heartburn drugs. The watchdog has alleged that the firm limited generic competition through the UK's National Health Service (NHS) to its Gaviscon brand (**OTC *bulletin***, 17 March 2010, page 5).

In the US, meanwhile, store-brand specialist Perrigo recently moved a step closer to introducing a generic version of Reckitt Benckiser's Mucinex cough medicine, when a federal court threw out the UK-based company's patent-infringement complaint (**OTC *bulletin***, 26 February 2010, page 13).

The Michigan district court granted Perrigo summary judgement in litigation over its 600mg guaifenesin extended-release tablets. The court said Perrigo's generic did not infringe the Mucinex patent.

Perrigo is now waiting for the Abbreviated New Drug Application (ANDA) for its generic product to be approved by the FDA. At the start of February, Perrigo's chairman and chief executive officer, Joseph Papa, said the company expected approval from the FDA for its store-brand Mucinex in the next 30-60 days, and that the product would be available before the close of the company's financial year ending June 2010. However, Papa said more recently that the company had now removed the estimated impact of a store-brand Mucinex from its fourth-quarter forecast (**OTC *bulletin***, 14 May 2010, page 11).

Quoting data from AC Nielsen, Perrigo said Mucinex 600mg extended-release tablets had generated sales of approximately US$162 million through food, drug and mass merchandiser retail outlets in the US during the 12-month period ended January 2010.

Perrigo filed an ANDA with a patent challenge against Mucinex in 2007, but Adams

Respiratory Therapeutics – which is now part of Reckitt Benckiser – responded by suing Perrigo for patent infringement (**OTC *bulletin***, 12 October 2007, page 9).

Earlier in 2007, Adams had settled a patent challenge to the Mucinex brand from URL/Mutual, which potentially kept URL/Mutual's 600mg guaifenesin product off the market in the US until 2012 (**OTC *bulletin***, 30 March 2007, page 11).

Perrigo's victory, however, means that URL/Mutual may soon be in a position also to launch its extended-release 600mg guaifenesin product, as the company's settlement with Adams allowed it to launch if a third party was in a position to introduce its own generic guaifenesin product before 1 July 2012.

Reckitt Benckiser is also defending its Mucinex, Mucinex D (pseudoephedrine hydrochloride/guaifenesin) and Mucinex DM (dextromethorphan/guaifenesin) products from patent challenges made by the generics company Watson Pharmaceuticals (**OTC *bulletin***, 19 June 2009, page 12).

Turnover at Perrigo's Consumer Healthcare division moved ahead by 10% to US$1.35 billion in the nine months ended 27 March 2010. Johnson & Johnson's loss during the first three months of this year was Perrigo's gain, as the store-brand specialist reported that sales of its analgesics had been boosted by the recall of the Tylenol products (**OTC *bulletin***, 14 May 2010, page 10).

Perrigo has struck some significant deals this year, including the acquisition of store-brand infant formula and baby food specialist PBM Holdings for US$808 million in cash. Perrigo said PBM, which generated sales of around US$265 million in 2009, took the firm into another important product category in the US (**OTC *bulletin***, 31 March 2010, page 1).

The deal for PBM was announced less than a month after Perrigo said it would expand its Consumer Healthcare division into Australia by acquiring Orion Laboratories for approximately US$48 million in cash (**OTC *bulletin***, 17 March 2010, page 3).

Acquiring Orion is part of the geographical expansion plan that Perrigo laid out for its Consumer Healthcare division last year (**OTC *bulletin***, 15 May 2009, page 6). At that time, Consumer Healthcare generated the majority of its sales in the US, but also had a presence in Mexico and the UK as well as "relationships" in Canada.

However, as **OTC *bulletin*** went to press the news had just broken that Perrigo had received a warning letter from the FDA about its manufacturing plant in Allegan, Michigan.

Elsewhere in the OTC industry, companies such as Bayer, Boehringer Ingelheim, Merck KGaA, Novartis, Omega Pharma and Taisho felt the effects of the difficult economic environment, currency fluctuations and poor cough/cold seasons to a greater or lesser degree. The growing threat from retailers' own-label products remains an ongoing challenge.

OTC business	Change in sales in the first three months of 2010 as compared to the same period a year earlier (%)	
	As reported	Constant currencies
Bayer's Consumer Care unit	+6	+6
GlaxoSmithKline's OTC Medicines unit	+8	+11
Herbalife	+19	+13
Johnson & Johnson's OTC & Nutritionals unit	-10	-15
Merck & Co's Consumer Care unit*	-2	NP
Merck KGaA's Consumer Health Care unit	±0	NP
Nycomed's total OTC sales	+5	-2
Omega Pharma	+4	NP
Perrigo's Consumer Healthcare unit**	+4	NP
Procter & Gamble's Health Care unit***	+5	+1
Reckitt Benckiser's Health & Personal Care unit	+4	+4
Sanofi-Aventis' Consumer Health Care unit	+45	+43

* Sales in the US and Canada only. Merck & Co's International Consumer Care sales are reported in a different unit
** First quarter of 2010 is the third quarter of Perrigo's financial year
*** First quarter of 2010 is the third quarter of Procter & Gamble's financial year
NP Not provided

Figure 2: Performance of selected OTC businesses in the first quarter of 2010, both as reported and excluding currency effects. Changes in sales include the effect of acquisitions/divestments, and they are compared to the same period a year earlier. The range of products covered by OTC business units in this table varies from one company to another and may include personal-care products (Source – OTC *bulletin*)

Taisho Pharmaceutical, for instance, reported Self-Medication turnover down by 1.4% to ¥159 billion (€1.41 billion) in the year ended 31 March 2010. The Japanese company mentioned the "sluggish" economy in its home market, and a significant drop in sales of cold remedies (see page 6).

During the year, Taisho expanded its Self-Medication division's presence outside of Japan by acquiring Bristol-Myers Squibb's OTC assets in the Asia-Pacific region – excluding China and Japan – for US$310 million. Taisho said the deal – which included the Tempra analgesic and the Counterpain topical analgesic brands – meant the company could now enter the Asian OTC drug business "in earnest" (**OTC *bulletin***, 30 September 2009, page 1).

Meanwhile, Boehringer Ingelheim recently strengthened its position in the Japanese consumer healthcare market by acquiring the 40% stake in its Japanese OTC subsidiary, SSP, that it did not already own (**OTC *bulletin***, 26 February 2010, page 3). The company has held a majority stake in SSP since 2001 (**OTC *bulletin***, 16 November 2001, page 1).

SSP generates annual sales of around ¥48 billion from a portfolio of brands including the S-Cup tonic drinks, S-Tac cough and cold medicines and Hythiol-C vitamin C products.

Boehringer Ingelheim's Consumer Health Care business saw its sales rise by 5.9% – 2.7% on a currency-adjusted basis – to €1.26 billion last year. Nevertheless, the German firm said Consumer Health Care had been "considerably weakened" by the global economic crisis.

Less fortunate on the acquisition front

Merck KGaA was less fortunate on the acquisition front. Earlier this year, the German firm admitted plans for its Consumer Health Care business had been dealt a blow in 2009. Chairman Karl-Ludwig Kley said the company had missed out on two unnamed acquisition targets (**OTC *bulletin***, 17 March 2010, page 1).

Just over a year ago, Merck KGaA said it intended to turn its Consumer Health Care business into "one of the top-10 global OTC players by doubling annual sales to €1.0 billion over the next three years", via a combination of acquisitions and organic growth (**OTC *bulletin***, 29 May 2009, page 20).

"I was extremely confident of closing one of the acquisitions when I mentioned the €1.0 billion target," Kley revealed, "but it slipped through our fingers at the last minute."

Merck KGaA's Consumer Health Care business produced sales growth of 6% in 2009 to €467 million, but sales were static during the first quarter of this year (**OTC *bulletin***, 14 May 2010, page 2).

Following its US$41 billion purchase of

■ *Continued on page 31*

CEE growth masks mixed trends

Strong sales growth in local currencies in the non-prescription market of Central and Eastern Europe is the tip of the iceberg, with mixed trends lying beneath the surface. Deborah Wilkes reports on new data from IMS.

Central and Eastern Europe (CEE) continues to provide good growth opportunities for the OTC industry, says Andy Tisman, IMS Consulting's senior principal for Consumer Health, noting that the region remains the "key growth driver" in Europe.

Tisman points out, however, that the strong growth in sales of non-prescription products recorded in the region last year in terms of local currencies was only part of the picture. "Value growth in local currencies dropped back significantly in many CEE countries as the economic crisis took its toll," says Tisman, adding that Poland and Ukraine were notable exceptions to this trend. "In addition, devaluation of CEE currencies against the euro meant local-currency growth hid a significant reduction in sales at the euro level."

Tisman also highlights that volume sales actually declined in the CEE region last year. "Russia, Ukraine and Romania were the biggest drivers of the volume declines in the region," he observes.

Nevertheless, Tisman believes there is further growth potential in some CEE countries, as the per capita expenditure on non-prescription products is relatively low compared to other European countries. Furthermore, he maintains that multinational companies are "failing to leverage fully the growth potential of the CEE region".

Based on local-currency comparisons, sales of non-prescription products in the CEE region increased by 15.3% to €8.53 billion at manufacturers' selling prices in 2009 compared to the previous year, according to data from IMS OTC Review Plus. The strong performance of the CEE region last year followed value sales growth of 20.1% in 2008 and 19.2% in 2007 (see Figure 1).

Countries included in the data are Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Slovakia and Ukraine. Data for Croatia and Slovenia are not included in the total for the CEE region, but are included in some of the figures that appear in this article.

The data cover both prescription-generated and self-medication or OTC sales of non-pre-

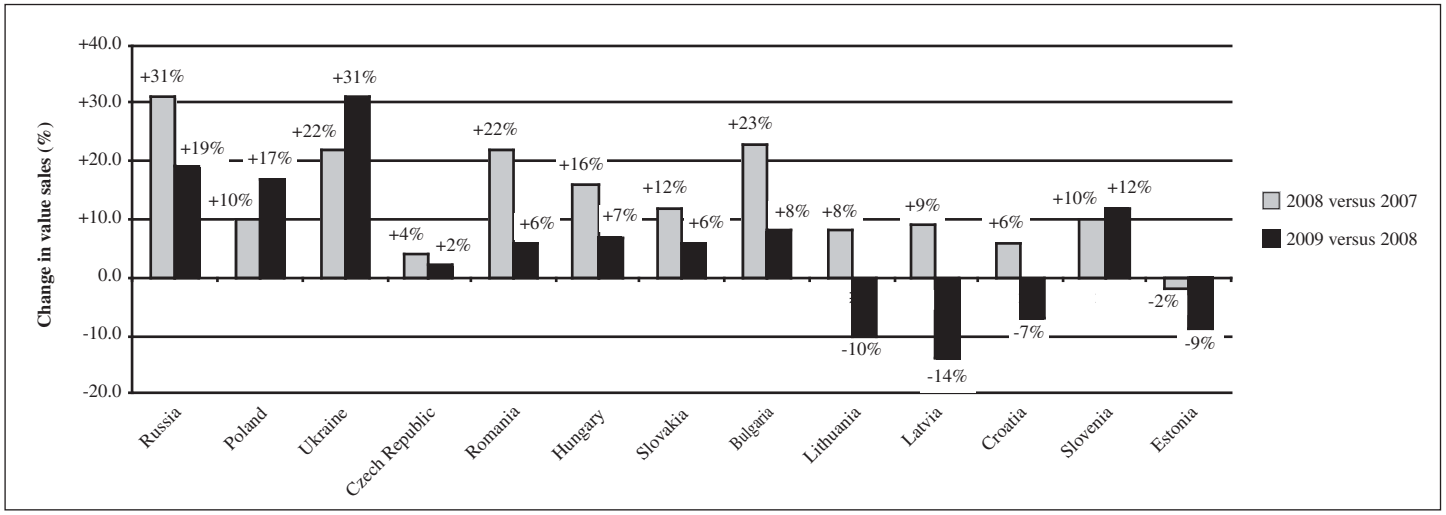


Figure 3: Comparison of the change in value sales of non-prescription products in Central and Eastern European markets in 2008 and 2009. Growth/decline figures are based on local-currency comparisons (Source – IMS Consumer Health's IMS OTC Review Plus)

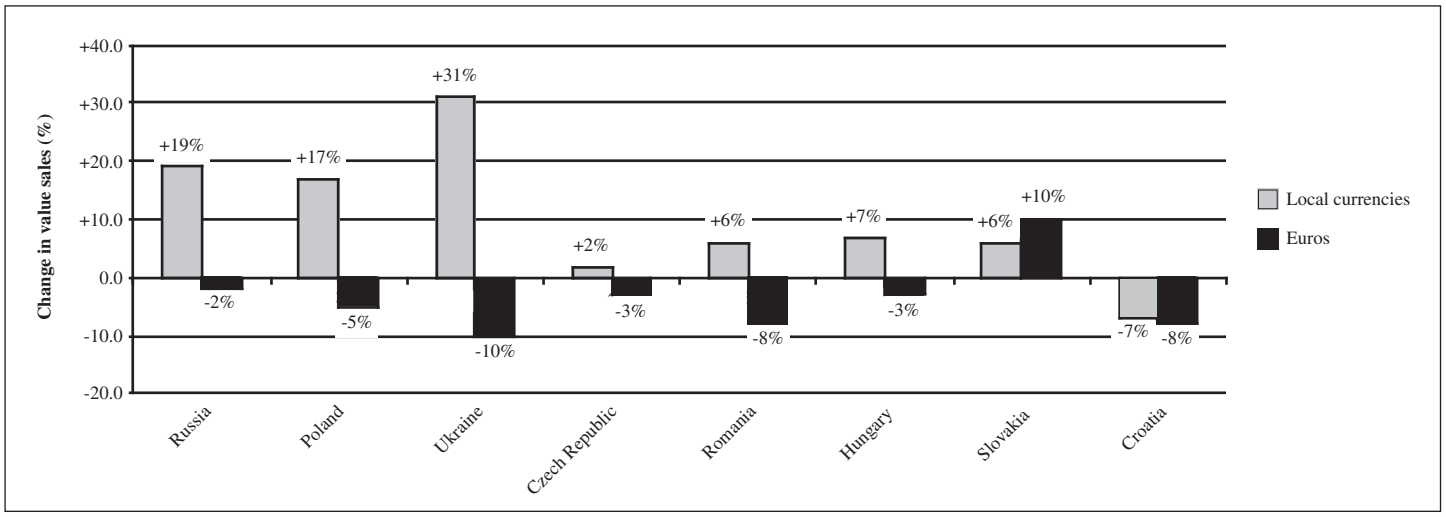


Figure 4: Comparison of the change in value sales of non-prescription products in Central and Eastern European markets in 2009, measured in local currencies and in euros (Source – IMS Consumer Health's IMS OTCims)

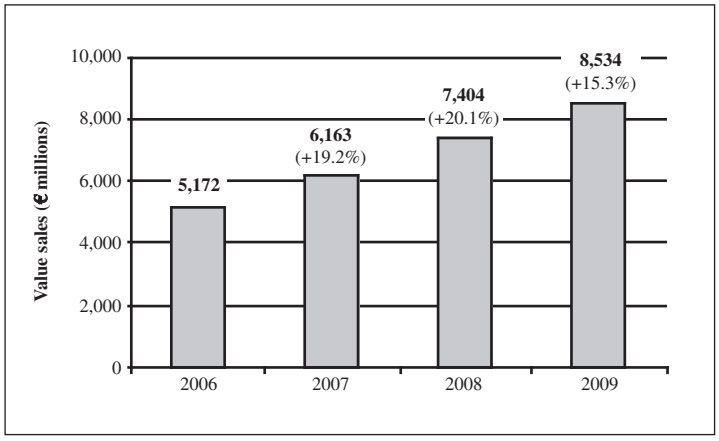


Figure 1: Value sales of non-prescription products in Central and Eastern Europe in 2009 at manufacturers' selling prices. Growth figures are based on local-currency comparisons (Source – IMS Consumer Health's IMS OTC Review Plus)

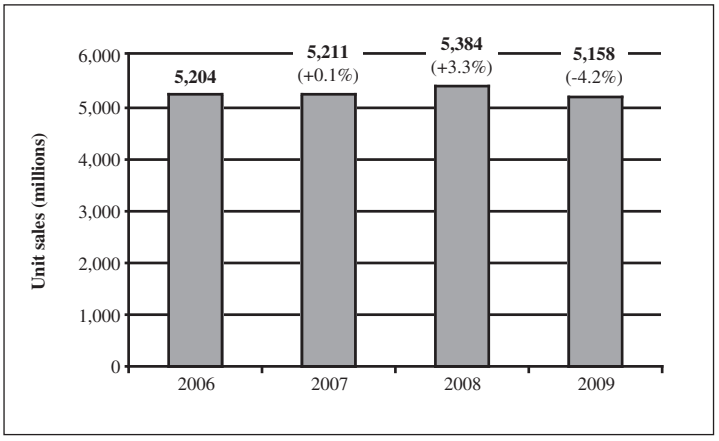


Figure 5: Volume sales of non-prescription products in Central and Eastern Europe in 2009 measured in millions of units (Source – IMS Consumer Health's IMS OTC Review Plus)

scription products. Growth rates use the latest exchange rate for all countries across all time periods.

Tisman points out Europe's non-prescription market consists of three distinct groups of countries. The CEE region was the "key growth driver" in 2009, while western Europe's "de-reimbursed markets" – France and Germany – underperformed compared with the European average. Other European markets sat between the two extremes with value sales growth of around 6% in 2009.

Within the CEE region, he notes, countries outside of the European Union performed better than those that are member states.

Tisman also highlights that the CEE region continues to be a significant contributor to the growth of the global non-prescription market. As can be seen from Figure 2, the CEE region only generated 9.2% of global non-prescription sales but accounted for 18.1% of global non-prescription sales growth in 2009.

Taken together, the developing regions of the world – CEE, Latin America, and South-East Asia/China – generated around a third of global non-prescription sales, but accounted for more than two-thirds of global non-prescription sales growth in 2009.

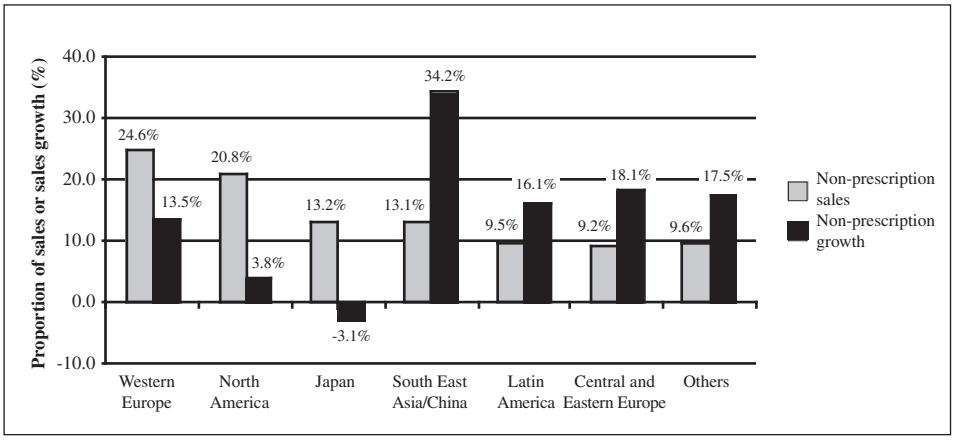


Figure 2: Contribution to global non-prescription sales and sales growth by region of the world in 2009. Figures are based on sales in euros at manufacturers' selling prices. Growth figures are based on local-currency comparisons (Source – IMS Audits plus estimates)

Looking in more detail at the CEE region, Tisman comments that value growth in local currencies fell significantly in many countries, although Poland, Ukraine and Slovenia bucked the trend.

As can be seen from Figure 3, the biggest market in the CEE region – Russia – recorded non-prescription sales up by 19% in local currencies in 2009 compared with the previous year, but this was down on the 31% growth in sales seen in 2008. Similarly, the fourth-largest market in the region – the Czech Republic – recorded 2% growth in 2009, following a 4%

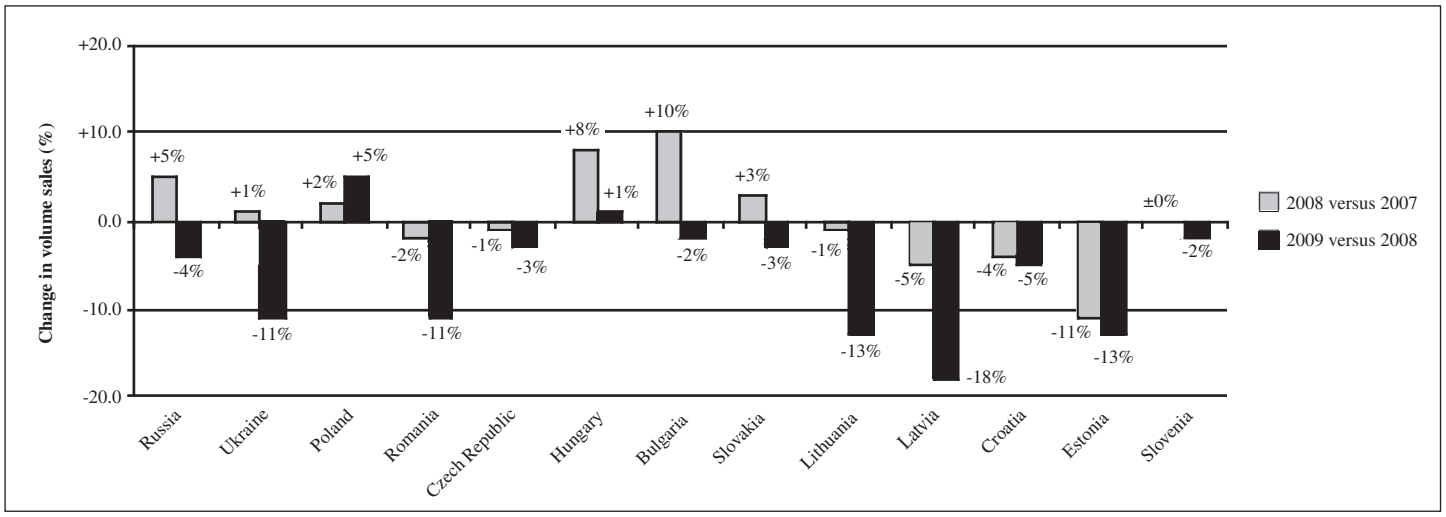


Figure 6: Comparison of the change in volume sales of non-prescription products in Central and Eastern European markets in 2008 and 2009 (Source – IMS Consumer Health's IMS OTC Review Plus)

rise in 2008. And the equivalent figures for the fifth-largest market – Romania – were 6% and 22% respectively.

By contrast, Poland – the second-largest market in the CEE region – saw sales growth in local currencies increase from 10% in 2008 to 17% in 2009. Similarly, the Ukraine – the third-largest market – saw sales growth rise from 22% in 2008 to 31% in 2009.

Tisman points out that devaluation of CEE currencies against the euro meant sales rises in local currencies translated into significant sales reductions in euros. Russia's 19% sales growth in local currencies, for example, translated into a 2% decline in euros. Similarly, Ukraine's 31% sales growth in local currencies became a 10% decrease in euros (see Figure 4 on page 26).

He adds, however, that this effect was most marked in the first quarter of 2009, and there has been some recovery since then.

In terms of volume, sales of non-prescription products in the CEE region declined by 4.2% to 5.16 billion units last year compared with 2008. The decline followed a period of relative stability, with volume sales rising by 3.3% in 2008 and by 0.1% in 2007 (see Figure 5 on page 27).

Tisman says that the biggest drivers of this decline were Russia, Ukraine and Romania, which recorded falls in volume sales of 4%, 11% and 11% respectively (see Figure 6 on page 27).

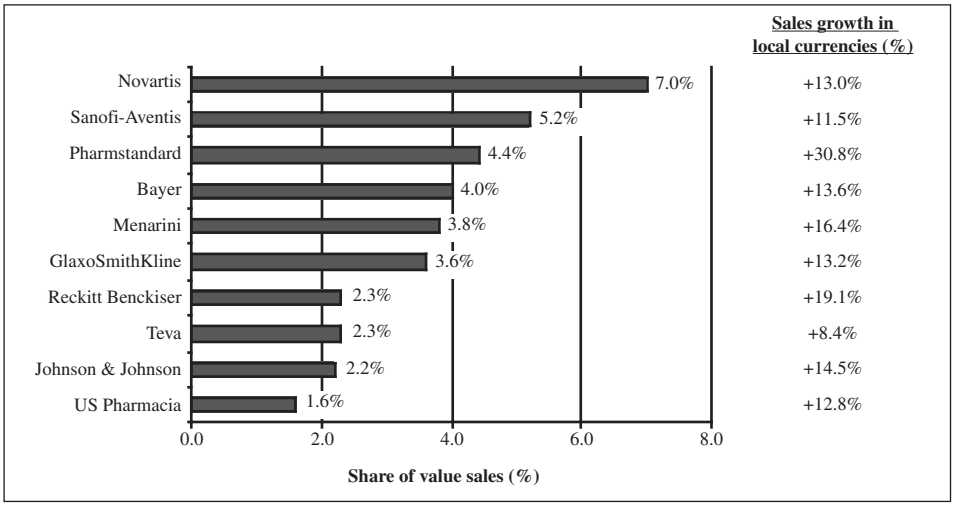


Figure 8: Top 10 companies in Central and Eastern Europe ranked by sales of non-prescription products in 2009, together with sales growth in local currencies for the year. Figures are based on sales in euros at manufacturers' selling prices (Source – IMS Consumer Health's IMS OTC Review Plus)

According to Tisman, there is still potential for further growth in annual per capita expenditure on non-prescription products in some of the CEE countries. As can be seen from Figure 7, annual per capita expenditure was €16 at public prices in both Romania and the Ukraine in 2009. This figure was below the CEE average of €28, and well below the Western European average of €68.

Tisman also maintains multinational companies are not capitalising fully on the growth opportunities offered by the CEE region.

As can be seen from Figure 8, Pharmstandard was the fastest-growing of the top 10 non-prescription companies in the CEE region in 2009. The Russian company pushed sales up by 30.8% in local currencies, which was more than double the 15.3% growth in the CEE region as a whole.

Of the eight multinational companies in the top 10, only two – Menarini and Reckitt Benckiser – outperformed the overall CEE market in terms of sales growth in local currencies. Reckitt Benckiser did best with a 19.1% rise.

The leading company in the CEE region last year was Novartis Consumer Health with a 7% share of value sales. It achieved growth of 13.0% in local currencies.

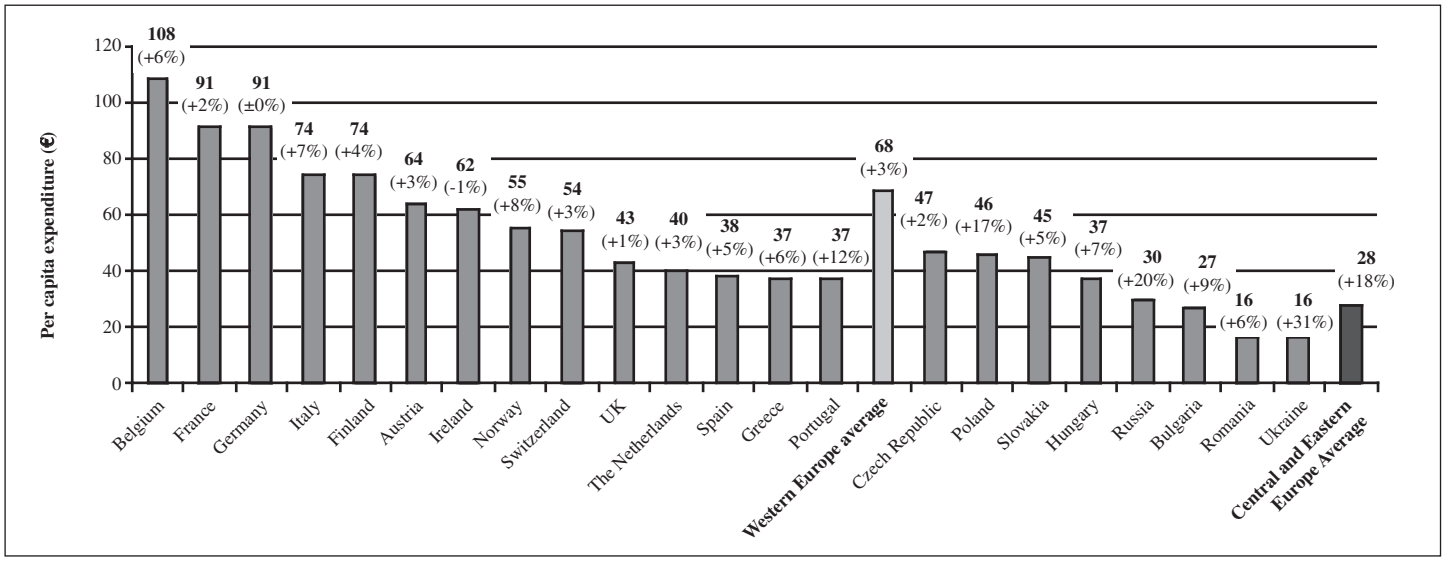


Figure 7: Per capita expenditure in euros on non-prescription products at public prices in selected European countries in 2009 (Source – IMS Consumer Health's OTCims)

IN BRIEF

■ **DAIICHI SANKYO's** strategy of becoming a "global pharma innovator" by 2015 that saw it buy Indian firm Ranbaxy in 2008 has seen the Japanese firm name a new chairman and president. **Takashi Shoda** is moving up to chairman from president and chief executive officer, while **Joji Nakayama** is promoted from executive vice-president to president and chief executive officer. Their appointments should be approved at a shareholders' meeting on 28 June 2010. Current chairman **Kiyoshi Morita** will become corporate adviser.

■ **PHAGRO** – the association of German pharmaceutical wholesalers – has re-elected Anzag's **Thomas Trümper** as its chairman for a further two years. He has led the association since 2006. **Ralph Schüller** from Ebert + Jacobi has been elected deputy chairman.

■ **MATRIXX INITIATIVES** has promoted **William Barba** to vice-president of finance and accounting, and treasurer. Barba has been with the US-based company since 2004.

OTC

Manufacturers

Procter & Gamble names new PharmacyCare team

Procter & Gamble has promoted UK pharmacy channel team leader **Adam Bishop** to commercial manager of UK consumer healthcare and pharmacy. He replaces **Joanna Dee**, who has joined the firm's laundry division.

Adam Bishop

Dee played a central role in the launch two years ago of the company's PharmacyCare initiative, which aims to help independent pharmacists improve their merchandising and retail skills (see page 19).

Bishop will work closely with associate director of UK pharmacy **Liz Caton** – who succeeded **Andy Mill** on 1 March 2010 – to drive the initiative forward.

Caton has spent 15 years with Procter & Gamble, focusing mainly on its Femcare and Babycare businesses. She was previously responsible for market strategy and planning for Procter & Gamble's western European Femcare business in Geneva, Switzerland. Mill has been appointed non-food sales director for western Europe. He is based in Geneva.

OTC

Manufacturers

Germany's Stada drops its production director

Stada Arzneimittel's supervisory board has decided not to extend the contract of the German company's chief production and development officer, **Christof Schumann**.

The board wants someone else to implement the German firm's 'Build the Future' restructuring and rationalisation project, details of which are currently being finalised. The project aims to save over €10 million per year.

Schumann, 47 – who stepped up onto Stada's board in 2006 (**OTC *bulletin***, 26 January 2006, page 26) – will continue to fulfil his responsibilities "until further notice". His contract expires on 31 December 2010.

Schumann's departure continues the recent run of changes at Stada's senior management team. About 21 months ago, chief legal officer Alexander Oehmichen and chief procurement, production and logistics officer Hans-Martin Schwarm stepped down, reducing Stada's executive board from five to three members (**OTC *bulletin***, 29 August 2008, page 27).

Furthermore, chief financial officer Wolfgang Jeblonski quit last year (**OTC *bulletin***, 31 August 2009, page 31).

Christof Schumann

Jeblonski was replaced from the start of this year by Helmut Kraft (**OTC *bulletin***, 16 November 2009, page 27), who took over responsibility for procurement from Schumann. On 1 March 2010, executive chairman Hartmut Retzlaff assumed Schumann's previous oversight of logistics.

Stada's executive board comprises Kraft, Retzlaff and, until he leaves, Schumann.

OTC

Manufacturers

Goldshield appoints new chief executive

John Beighton – former vice-president of global business optimisation at the generics company Teva Pharmaceutical Industries – has replaced **Rakesh Patel** as chief executive officer of the UK-based healthcare company Goldshield.

Goldshield said that Beighton had been appointed after Patel decided to step down from the role to focus on other business interests. Patel would continue to advise the board of Goldshield, the company added, and would remain a shareholder.

Part of management buyout team

Patel was part of the team behind a £179 million (€209 million) management buyout of Goldshield in December of last year (**OTC *bulletin***, 18 December 2009, page 6).

Prior to joining Goldshield, Beighton spent 13 years at Teva, helping to build the Israeli company's generics and branded pharmaceuticals businesses. Beighton became managing director of Teva UK in October 2002, a position he held until February 2009, when he was named Teva's vice-president of global business optimisation.

OTC

Retailers

Merlo to succeed Ryan as CVS chief

Larry Merlo, 54, is set to become the chief executive officer of CVS Caremark when **Thomas Ryan**, 58, steps down from the position at the US pharmacy chain's meeting of shareholders in May 2011.

As part of the succession plan, Merlo, who has spent 20 years with the company, has been immediately promoted to president and chief operating officer. In his new role, he will join the company's board of directors and take responsibility for human resources, legal, corporate compliance and government relations.

Merlo will remain president of the company's CVS/pharmacy retail operations – overseeing a portfolio of over 7,000 CVS/pharmacy locations and sales of US$55 billion plus (€45 billion) – until a successor is found.

Ryan is now chairman and chief executive officer but no longer president.

OTC

A tale of two companies

■ *Continued from page 25*

Schering-Plough last year, US-based Merck & Co did not release a full set of figures in 2009 for its newly-acquired Consumer Care business. In the first quarter of this year, sales by the business in the US and Canada dropped by 2% to US$379 million, as Claritin OTC sales fell by 26% (**OTC *bulletin***, 14 May 2010, page 11).

Merck & Co's chairman and chief executive officer, Richard Clark, reiterated that the Consumer Care business would play a critical part in the group's strategy going forward. Earlier this year, Bridgette Heller – former president of Johnson & Johnson's global Baby business unit – joined Merck as executive vice-president and president of Consumer Care (**OTC *bulletin***, 26 February 2010, page 1).

Similarly, Pfizer has not reported a full set of figures for its freshly-acquired Consumer Healthcare business, following the company's US$68 billion purchase of Wyeth last year. Jeffrey Kindler, Pfizer's chairman and chief executive officer, has stressed that the Consumer Healthcare business would not be divested like its predecessor (**OTC *bulletin***, 30 October 2009, page 3).

Ending with a positive note, GlaxoSmithKline's OTC Medicines business continues to buck the trend and report relatively strong increases after the pan-European OTC launch of its Alli weight-loss medicine containing orlistat (**OTC *bulletin***, 30 April 2009, page 1).

Worldwide turnover at the OTC Medicines business improved by 8% – 11% at constant exchange rates – to £617 million in the first quarter of 2010. Sales of Alli doubled to £63 million, and the company's smoking-control business recorded a strong improvement of 16% at constant exchange rates (**OTC *bulletin***, 14 May 2010, page 6).

Europe accounted for the majority of Alli's turnover, with sales of £34 million. In the year since Alli's pan-European launch, the brand has now generated total sales for GlaxoSmithKline of £139 million in Europe.

OTC