30 April 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Johnson & Johnson recall cuts OTC sales by quarter

Voluntarily recalling Tylenol and other OTC products in response to regulatory concerns slashed US sales by Johnson & Johnson's OTC & Nutritionals business unit by a quarter in the first three months of this year.

Sales by the business in the US had slumped by 25.3% to US$542 million (€404 million) in the period, revealed Dominic Caruso, Johnson & Johnson's chief financial officer, who admitted that second-quarter sales would also be hit by the recall. He claimed, however, that the action had "not really impacted physician recommendation or consumer preferences" for the company's OTC products.

In February, the US Food and Drug Administration (FDA) sent Johnson & Johnson's McNeil Consumer Healthcare business a warning letter about the unit's Las Piedras plant in Puerto Rico.

The firm immediately initiated a voluntary recall of certain lots of its Benadryl, Motrin, Rolaids, Simply Sleep, St Joseph Aspirin and Tylenol products made at the facility (**OTC *bulletin***, 10 February 2010, page 22). The recall applied to the Americas, the United Arab Emirates (UAE) and Fiji.

Consumer reports of "an unusual mouldy, musty or mildew-like odour that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events" had already prompted McNeil to carry out two recalls of Tylenol Arthritis Pain caplets in January of this year and in November 2009.

Zegerid OTC could face store brands

Zegerid OTC could face generic competition in the US, after a Delaware district court found that five patents protecting Santarus' Zegerid (omeprazole/sodium bicarbonate) capsules and powder for oral suspension until 2016 were invalid due to obviousness.

Par Pharmaceutical currently holds tentative approval for 20mg/1,100mg and 40mg/1,100mg capsules.

Santarus, which plans to appeal, said it was not aware of any companies other than Par that had filed an Abbreviated New Drug Application (ANDA) for omeprazole/sodium bicarbonate products.

Perrigo has expressed an interest in producing a store-brand version of Zegerid OTC but has not yet stated publicly whether it has filed an ANDA.

Schering-Plough Healthcare Products, which is Santarus' partner in the OTC market, has just started a major consumer advertising campaign for Zegerid OTC, which is available as capsules for treating frequent heartburn containing 20mg omeprazole and 1,100mg sodium bicarbonate (**OTC *bulletin***, 16 April 2010, page 14). A spokesperson for Schering-Plough's parent company Merck & Co told **OTC *bulletin*** that the "court decision does not change Merck Consumer Care's commitment to the launch and

■ *Continued on page 12*

Business Strategy

Ransom has no plans to sell more brands

William Ransom & Son said it did not plan to sell any more brands after securing a new long-term financing agreement.

The UK-based natural products specialist has made a series of divestments to help reduce its bank debt and provide working capital, as part of the turnaround plan introduced in September 2008 (**OTC *bulletin***, 29 September 2008, page 6).

This year alone, Ransom has sold its Metanium nappy-rash brand (**OTC *bulletin***, 20 January 2010, page 3), its honey-based Manuka Gold brand (**OTC *bulletin***, 10 February 2010, page 13) and its Snufflebabe and Easy Breathe brands (**OTC *bulletin***, 31 March 2010, page 8). It has also terminated its supply and licensing agreement for the Medibee honey brand (**OTC *bulletin***, 26 February 2010, page 11).

Ransom pointed out that selling these brands had helped reduce its bank debt to £2.6 million (€3.0 million) as of 31 March 2010. This compared with £3.8 million a year earlier.

The company also sold the Pavacol-D and Radian B brands in 2008 for £3.1 million (**OTC *bulletin***, 18 December 2008, page 3).

A spokesperson for Ransom told **OTC *bulletin*** that although the company did not plan to divest more brands it was still pursuing the sale of its Pharmaceuticals contract manufacturing division.

Under the new financing agreement with KBC Business Capital, Ransom said its existing debt facilities had been replaced by asset-based facilities comprising an accounts receivable finance facility, stock facility and a plant and machinery long-term loan. The new facilities would provide the company with the additional working capital required to build on the progress it had made since launching its turnaround plan, Ransom noted.

The new financing agreement was announced as Ransom revealed that it expected to report a reduced underlying operating loss – before exceptional costs, non-recurring items and goodwill impairment – of approximately £0.5 million for the year ended 31 March 2010. This compared with £1.9 million in the same period a year earlier.

Ransom said better performances by its manufacturing divisions and cost-reduction initiatives had helped cut the underlying loss, but progress had been hindered by "challenging market conditions and brand disposals".

The first products in the Ransom Naturals range are now available in selected Tesco outlets in the UK

Exceptional costs – excluding goodwill impairment, financing costs and gains on asset disposals – were expected to be around £1.1 million for the year, said Ransom, adding that this reflected the cost of refinancing the company's debt and restructuring costs associated with the turnaround plan.

Ivor Harrison, Ransom's chief executive, noted that the company had just introduced the first products in its Ransom Naturals range. Two digestive juice products are now available in selected outlets of supermarket chain Tesco in the UK, and more products will be launched in the near future.

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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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Mergers & Acquisitions

Valeant expands with Brazil deal

Valeant Pharmaceuticals International is set to expand its presence in Brazil still further by acquiring another unnamed branded generics and OTC company for BRL97.0 million (€41.4 million).

The US-based company said the Brazilian firm had generated annual sales of approximately BRL49.0 million in 2009 from a product portfolio that largely comprised branded generics, but also included topical OTC lines.

Michael Pearson, Valeant's chairman and chief executive officer, said the unnamed company's product sales had grown in excess of 30% over the past year and it had achieved operating margins greater than 20%.

The deal was expected to close in the second quarter of 2010, Valeant said.

This latest acquisition came after Valeant said in March that it had agreed to acquire for US$28 million (€21.0 million) another unnamed Brazilian firm, which has now been named as branded generics and OTC company Instituto Terapeutico Delta. It also acquired a manufacturing plant in Brazil for the same price (**OTC *bulletin***, 31 March 2010, page 3).

Pearson pointed out that the deals provided Valeant with expanded opportunities for growth in Brazil and enhanced the company's Latin American franchise.

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First-Quarter Results

Recall not only reason for J&J's slump

McNeil Consumer Healthcare's voluntary recall of Tylenol and other OTC products made at its Puerto Rico facility (see front page) had not been the only reason for the 25.3% first-quarter fall in US sales of Johnson & Johnson's OTC & Nutritionals business unit said Louise Mehrotra, the firm's vice-president of investor relations. The impact of the product recall had been compounded, she said, by a less severe cold and flu season than had been anticipated.

She added that a more positive note had been struck by the strong growth achieved by the cetirizine allergy medicine Zyrtec OTC, thanks to the launch of Zyrtec Liquid Gels.

But with international OTC & Nutritional sales also slipping back by 2.7% at an operating level, worldwide turnover as reported slumped by 10.5% to US$1.21 billion (€0.91 billion). This represented a decline of 15.0% on an operational basis, partially offset by a positive currency effect of 4.5% (see Figure 1).

International OTC & Nutritional sales increased by 6.9% to US$665 million as reported, but this growth was solely down to a positive currency effect of 9.6%.

Consumer sales slip back

Some sales declines in other parts of Johnson & Johnson's Consumer division meant that the McNeil recall translated into the total Consumer result. Operationally, the division slipped back by 3.7%, although a positive 5.2% currency effect meant it was ahead in dollar terms by 1.5% to US$3.77 billion.

US Consumer turnover dropped back by 9.6% to US$1.56 billion, while international sales increased by 11.1% to US$2.21 billion. Positive currency effects of 9.7% bolstered the international operational growth of 1.4%.

Dominic Caruso, Johnson & Johnson's chief financial officer, pointed out that Consumer's sales would have been flat on an operational basis had the impact of the recall been excluded.

The product recall responsible for the drop in OTC & Nutritionals' sales was initiated in January (**OTC *bulletin***, 10 February 2010, page 22). This was when Johnson & Johnson's McNeil Consumer Healthcare operation received a warning letter from the US Food and Drug Administration (FDA), which said processes at its Puerto Rico facility deviated from current Good Manufacturing Practice (cGMP).

An earlier recall of Tylenol Arthritis Pain caplets had occurred in December (**OTC *bulletin***, 10 January 2010, page 15), and a recall of five lots of the same product had been initiated in November 2009 (**OTC *bulletin***, 16 November 2009, page 17).

Consumers had complained of "an unusual mouldy, musty or mildew-like odour", which McNeil said had been caused by trace amounts of a chemical called 2,4,6-tribromoanisole. This can result from the breakdown of a wood-treatment chemical used on the wooden pallets that

Business	First-quarter sales (US$ millions)	Change (%)	Operational change (%)	Currency effect (%)
Medical Devices & Diagnostics	6,227	+12.5	+8.1	+4.4
Pharmaceutical	5,638	-2.5	-5.7	+3.2
Consumer	3,766	+1.5	-3.7	+5.2
Total Johnson & Johnson	**15,631**	**+4.0**	**-0.1**	**+4.1**

Figure 2: Johnson & Johnson's sales in the first quarter of 2010 (Source – Johnson & Johnson)

Business	First-quarter sales (US$ millions)	Change 2009/2010 (%)	Operational change (%)	Currency effect (%)
OTC & Nutritionals – US	*542*	*-25.3*	*-25.3*	–
OTC & Nutritionals – International	*665*	*+6.9*	*-2.7*	*+9.6*
Total OTC & Nutritionals	1,207	-10.5	-15.0	+4.5
Skin Care – US	*452*	*+6.9*	*+6.9*	–
Skin Care – International	*468*	*+11.7*	*+2.4*	*+9.3*
Total Skin Care	920	+9.3	+4.6	+4.7
Baby Care – US	*103*	*+1.0*	*+1.0*	–
Baby Care – International	*426*	*+10.1*	*+1.2*	*+8.9*
Total Baby Care	529	+8.2	+1.2	+7.0
Women's Health – US	*146*	*-2.0*	*-2.0*	–
Women's Health – International	*323*	*+17.9*	*+7.8*	*+10.1*
Total Women's Health	469	+10.9	+4.4	+6.5
Oral Care – US	*174*	*-7.4*	*-7.4*	–
Oral Care – International	*207*	*+16.9*	*+5.1*	*+11.8*
Total Oral Care	381	+4.4	-1.3	+5.7
Woundcare/Other – US	*143*	*+3.6*	*+3.6*	–
Woundcare/Other – International	*117*	*+10.4*	*±0.0*	*+10.4*
Total Woundcare/Other	260	+6.6	+2.1	+4.5
Total Consumer	**3,766**	**+1.5**	**-3.7**	**+5.2**
Consumer – US	1,560	-9.6	-9.6	–
Consumer – International	2,206	+11.1	+1.4	+9.7

Figure 1: Breakdown of sales by Johnson & Johnson's Consumer division in the first quarter of 2010 (Source – Johnson & Johnson)

transport and store products.

However, the FDA said McNeil had failed to investigate first reports of the uncharacteristic smell thoroughly, including examining other batches and alerting the authorities, despite numerous complaints.

Responding to the warning letter a month later, McNeil said it had enhanced its quality system, made organisational changes and introduced greater oversight by senior managers (**OTC *bulletin***, 31 March 2010, page 11).

Johnson & Johnson's Skin Care business generated 24.4% of Consumer's turnover, with worldwide sales growing by 9.3% to US$920 million, thanks to the Aveeno, Neutrogena, Johnson's Adult and Le Petit Marseillais brands. The business had also been boosted by new products containing new Cytomimic anti-ageing technology, Mehrotra noted.

US Skin Care sales finished ahead by 6.9% to US$452 million. International sales grew even faster by 11.7% to US$468 million, due mostly to positive currency effects.

Sales at the Baby Care business jumped by 8.2% to US$529 million, driven by a 10.1% rise in international sales to US$426 million – thanks to an 8.9% positive currency effect – and aided by a 1.0% increase in the US to US$103 million.

The Women's Health business posted sales up by 10.9% to US$469 million, thanks to a 17.9% improvement in international sales to US$323 million. The rise in international sales offset a 2.0% drop in the US to US$146 million.

Listerine grows strongly outside US

Strong growth of the Listerine mouthwash brand outside the US helped push up worldwide Oral Care sales by 4.4% to US$381 million. Listerine's performance, coupled with positive currency effects, lifted international Oral Care sales by 16.9% to US$207 million. This offset a 7.4% fall to US$174 million in the US, caused by the sale of the Efferdent and Effergrip brands in the fourth quarter of 2009.

Woundcare/Other posted worldwide sales up by 6.6% to US$260 million, with both international and US sales growing. The 10.4% international growth to US$117 million came entirely from positive currency effects, while US sales improved by 3.6% to US$143 million.

The Consumer division represented 24.1% of Johnson & Johnson's worldwide sales in the first quarter of 2010, which increased by 4.0% to US$15.6 billion (see Figure 2). The rise was driven entirely by a 4.1% positive currency effect, which offset a 0.1% decline on an operational basis. Pre-tax profits increased by 35.3% to US$6.28 billion, thanks to a US$1.59 billion gain from a legal settlement.

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Trading Update

Omega Pharma sees sales rise by 4% to over €200mn

Omega Pharma reported sales up by 4% to €202 million in the first quarter of 2010, despite turnover at its French business dropping back by a tenth.

The Belgian firm has now reported sales growth for three consecutive quarters. It maintained that its "tighter" strategy – involving strengthened management structures, decisive innovation, more centralised brand management and greater focus on emerging markets – could "guarantee continued growth".

Marc Coucke, Omega's chief executive officer, pointed out that it was the first time the company had posted first-quarter sales of over €200 million. The performance represented a strong start to what he believed was a "promising year" ahead.

As Figure 1 shows, sales growth was driven by Omega's Emerging Markets region, where turnover finished up by 31% to €21.3 million. Coucke said the result had been aided by the "strong local structures" the company had put in place, which had been fuelled by innovative new products and the company's centrally-managed brands.

Omega highlighted its good returns from Australia, the Czech Republic, Hungary, Romania, Russia and Turkey, adding that it had also done well in other "Omega-growth countries" by combining successful local OTC products with the company's centralised brands.

Omega's performance in its home market had been "pleasantly surprising" once again, Coucke said. Sales in Belgium had grown by 11% to €57.4 million in the first quarter, thanks to both OTC turnover and the generics business, which had posted sales up by 9%.

Although boosted by "strong growth" in the UK for the first time in two years, turnover by the Western Europe business – Omega's biggest market in terms of sales – only edged ahead by 2% to €86.5 million. Good performances had been recorded in the Nordic countries, Spain and Switzerland, Omega said, but these had been partially offset by weaker showings in Germany and Greece.

Commenting on the French business – with sales down by 10% to €36.8 million – Coucke said a new management team had "performed the necessary analyses" and was now "implementing vigorous brand management" to stabilise quarterly revenues.

Looking ahead, Omega said it believed that its "energetic innovation projects" and presence in growth markets would enable the company to sustain over the full year the 4% growth achieved in the first quarter.

Commenting on Omega's strategy going forward, Coucke said the company had virtually completed strengthening its management structure – having recruited experienced country managers and regional managers – and had also finished expanding its innovation, brand management and supply departments.

Organised to execute strategy

He added that the company was now well organised to execute a "sustainable and viable" strategy focused on its five new core-business categories – Derma, Classics, Cough & Cold, Multi-Locals, and Parasites.

In March, Omega unveiled a new corporate strategy that focused the company on broader business categories rather than individual 'starbrands', with the aim of becoming one of the top 10 OTC players in the world (**OTC *bulletin***, 31 March 2010, page 2).

Omega said at the time it would switch its focus from its starbrands – which represented only 15% of Omega's total sales – to brands representing 50% of its sales.

These, it said, would be managed via the five new business categories.

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	First-quarter sales (€ millions)	Change 2009/2010 (%)	Proportion of total (%)
Western Europe	86.5	+2	43
Belgium	57.4	+11	28
France	36.8	-10	18
Emerging markets	21.3	+31	11
Omega Pharma	**202.0**	**+4**	**100**

Figure 1: Breakdown of Omega Pharma's sales in the first quarter of 2010 (Source – Omega Pharma)

Annual Results

Boehringer OTC goes up despite economic crisis

Boehringer Ingelheim's Consumer Health Care business reported sales up by 5.9% – 2.7% on a currency-adjusted basis – to €1.26 billion in 2009. Nevertheless, the German firm said Consumer Health Care had been "considerably weakened" by the impact of the global economic crisis.

Engelbert Tjeenk Willink, who is responsible for pharma marketing and sales on Boehringer Ingelheim's board of managing directors, said the Consumer Health Care business had performed well in all three of its geographic regions over the 12 months despite negative market trends (see Figure 1).

The strongest growth was recorded in the Asia, Australasia, Africa (AAA) region, where turnover increased by 19.7%, or 6.6% on a currency-adjusted basis, to €436 million. As Figure 2 shows, the AAA region generated 34% of Consumer Health Care's net sales in 2009.

Japan generated 72.6% of Consumer Health Care's sales in the AAA region, Tjeenk Willink said, but the business' expansion in China, Turkey and countries in the Middle East had also helped to drive up sales and would remain a focus for the company.

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).

European sales slipped back slightly to €476 million, Tjeenk Willink said, due to the economic crisis. The impact of the difficult trading environment had been most evident in Spain – where sales fell by 5.9% – and Eastern Europe, where turnover dropped by 11.4% as reported.

One bright spot in Europe had been Germany, Boehringer Ingelheim pointed out, where sales had improved by 3.4% to €133 million.

Sales in the Americas region had been held back by a 14.9% fall in Mexico, Boehringer Ingelheim said. This had led to turnover growth of just 0.7% – 2.0% on a currency-adjusted basis – to €349 million.

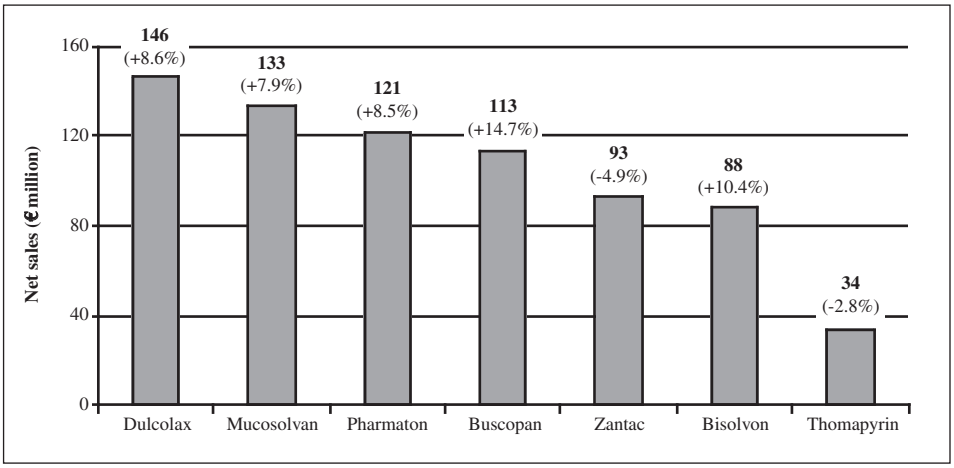


Figure 3: Net sales achieved by Boehringer Ingelheim's most important international Consumer Health Care brands in 2009. Change is on a currency-adjusted basis (Source – Boehringer Ingelheim)

Business	Annual sales (€ millions)	Change 2008/2009 (%) Actual	Currency-adjusted	Proportion of total (%)
Prescription Medicines	10,058	+10.4	+7.1	79
Consumer Health Care	1,261	+5.9	+2.7	10
Industrial Customer	786	-4.1	–	6
Animal Health	610	+30.6	+29.4	5
Other	6	–	–	–
Boehringer Ingelheim	**12,721**	**+9.7**	**+6.7**	**100**

Figure 4: Breakdown of Boehringer Ingelheim's sales in 2009 (Source – Boehringer Ingelheim)

Four of Consumer Health Care's most important brands – the laxative Dulcolax, the cough medicine Mucosolvan, the vitamin and mineral product Pharmaton, and Buscopan for abdominal cramps – had each generated sales of over €100 million in 2009 (see Figure 3), Tjeenk Willink pointed out. Growth was led by Buscopan, which reported currency-adjusted sales up by 14.7% to €113 million.

It is the first time that Buscopan – which is sold in more than 100 countries – has recorded sales in excess of €100 million.

Boehringer Ingelheim recently extended the brand in the UK by introducing the Buscopan Cramps product (**OTC *bulletin***, 31 March 2010, page 15).

Described as the UK's "first specialist treatment for abdominal pain and cramps", Buscopan Cramps contains the same active ingredient – 10mg hyoscine butylbromide – as the established Buscopan IBS relief product for irritable bowel syndrome.

Expanding the Buscopan brand

Boehringer Ingelheim said it aimed to make Buscopan the leading OTC brand worldwide for abdominal problems. The company noted that it had already launched a heartburn remedy – Buscogast/Buscasan 24 (20mg omeprazole) – in Argentina, Germany and the Netherlands, as well as a menstrual-pain line extension called Buscofem in Brazil.

Rolling out the Dulcolax Balance constipation remedy into new markets helped the Dulcolax brand retain its position as Consumer Health Care's biggest seller, with turnover up by 8.6% to €146 million.

Launched in Germany in 2007 (**OTC *bulletin***, 28 September 2007, page 16), Dulcolax Balance – which contains macrogol 4000 – had been unveiled in South Korea and the US during 2009, the company noted, and had recently been introduced into the UK under the Dulcobalance name (**OTC *bulletin***, 31 March 2010, page 15).

A "global television commercial" for Dulcolax Balance has been produced, which Boehringer Ingelheim hopes will not only boost the product's sales in Germany, but also act as a "great launch platform" in new markets as well as underpinning the "global brand positioning" of Dulcolax.

Commenting on the status of the Consumer Health Care business within Boehringer Ingelheim, Tjeenk Willink said that "from an entrepreneurial viewpoint" the business would be of "ever-growing importance" to the company. The need to control costs, he said, would see healthcare systems increasingly turn to switching prescription-only medicines to non-prescription status.

An example of this trend, Tjeenk Willink

Region	Annual sales (€ millions)	Change 2008/2009 (%) Actual	Currency-adjusted	Proportion of total (%)
Europe	476	-0.8	-0.1	38
Asia, Australasia, Africa	436	+19.7	+6.6	34
Americas	349	+0.7	+2.0	28
Consumer Health Care	**1,261**	**+5.9**	**+2.7**	**100**

Figure 1: Sales by Boehringer Ingelheim's Consumer Health Care business in 2009 (Source – Boehringer Ingelheim)

said, was the recent switch in the UK of its Flomax product for treating the symptoms of benign prostatic hyperplasia, or enlarged prostate, from prescription-only to pharmacy status (**OTC *bulletin***, 18 December 2009, page 1).

The UK was the first country in the world to switch Flomax (0.4mg tamsulosin hydrochloride), which is now available to men aged between 45 and 75 years from UK pharmacies under the Flomax Relief brand name.

Described by Boehringer Ingelheim as a "big opportunity" to obtain "significant new growth" in the UK market, Flomax Relief is backed by a £5.0 million plus (€5.5 million plus) consumer marketing campaign including television, radio and press advertising (**OTC *bulletin***, 31 March 2010, page 13).

Consumer Health Care accounted for 9.9% of Boehringer Ingelheim's group net sales in 2009, which increased by 9.7% – 6.7% on a currency-adjusted basis – to €12.7 billion. The dominant Prescription Medicines business – which saw sales rise by 10.4%, or 7.1% currency-adjusted – generated 79.1% of the group total (see Figure 4).

Andreas Barner, chairman of Boehringer Ingelheim's board of managing directors, said the company had been the fastest-growing of the top 15 pharmaceutical companies worldwide, and had expanded faster than the pharmaceutical market for the tenth year in a row.

Favourable currency effects added €330 million, or 3%, to the company's sales, Barner noted, before pointing out that the majority of its 6.7% currency-adjusted growth had been organic and had not come from acquisitions.

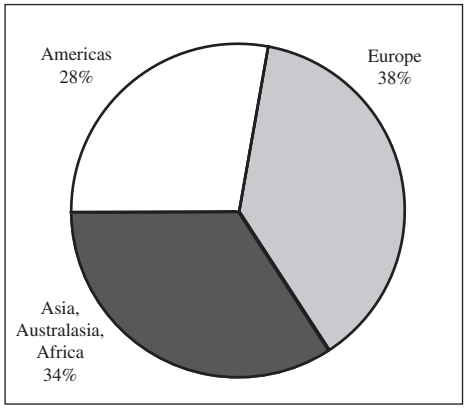


Figure 2: Sales by Boehringer Ingelheim's Consumer Health Care business in 2009 broken down by region (Source – Boehringer Ingelheim)

This performance demonstrated the success of Boehringer Ingelheim's policy of focusing on organic growth, Barner said. He pointed out, however, that "targeted acquisitions" would be made for individual business areas where the company saw "specific opportunities to make sensible additions" to its product portfolio.

Operating income increased by 13.1% to €2.24 billion, while the firm's operating margin improved from 17.1% to 17.6%.

Boehringer Ingelheim pointed out that its good performance in 2009 had been reflected in its net cash flow, which had increased by 20.6% to €2.41 billion.

Licensing Agreements

HemCon signs Japanese agreement

Woundcare specialist HemCon Medical Technologies has signed up Zeria Pharmaceuticals to market, distribute and sell its entire range of products in Japan.

The US-based company said the agreement gave it the opportunity to break into the Asian market, which had not been a focus for HemCon until now.

Under the terms of the deal, Japan's Zeria has the right to launch HemCon's full range of products, including its OTC nasal plugs, which use m.doc technology to stop bleeding, and its KytoStat Bandage. The latter product, the firm said, was "30-times more effective than other OTC blood-stopping technology solutions".

Zeria already offered a range of prescription and consumer healthcare brands in Japan, HemCon noted, and would establish a new division to manage the HemCon product line.

The Japanese firm held a strong position in the gastroenterology field, HemCon added, and also marketed dermatology and cardiovascular brands.

Business Strategy/Annual Results

Pharmstandard snaps up stake

Russia's Pharmstandard has acquired an 11.3% stake in Latvian pharmaceutical manufacturer Grindeks for an undisclosed sum.

Igor Krylov, the chief executive officer of Pharmstandard, said the decision to buy into Grindeks had been based on the long-term relationship between the two companies.

A Pharmstandard spokesperson told **OTC *bulletin***, that the company had no plans to increase its stake in Grindeks any further. However, if it were to be offered shares by other Grindeks shareholders, then it would consider taking them up.

In January 2008, Pharmstandard gained the exclusive rights to distribute Grindeks' prescription-only cardiovascular drug Mildronate in Russia. Since signing the agreement, Mildronate had generated sales of over RUB2.3 billion (€59.2 million) in Russia, Pharmstandard pointed out.

Janis Romanovskis, chairman of Grindeks, said that having Pharmstandard as one of the company's largest shareholders would strengthen its position in Russia and provide new business opportunities.

However, Grindeks has resigned from Latvia's employers' confederation, the LEC, in protest at the body's president selling the shares to the Russian firm. Pointing out that the LEC was charged with promoting Latvian industry, Grindeks accused the confederation's president Vitalijs Gavrilovs of "essentially breaching business ethics" by selling his 11.3% stake – 1.08 million shares – to Pharmstandard.

Grindeks generated sales of LVL53.6 million (€75.8 million) in 2009 – a fall of 13.7% compared to 2008 – from a range of prescription drugs, generics and active pharmaceutical ingredients, as well as a portfolio of OTC brands. The company's OTC range includes analgesic, cough and cold, and gastrointestinal brands, as well as a line of ointments, tonics and natural health products.

Almost all of Grindeks' sales – 96% – were achieved through exports to more than 40 countries. The company's main export markets are the Baltic States, Japan, Russia and other Commonwealth of Independent States (CIS) countries, and the US.

Grindeks said it was aiming to lift sales to LVL70 million in 2010 by building its position in its existing markets, entering new territories and increasing its range of generic products.

First-Quarter Results

Novartis OTC grows ahead of market

Worldwide OTC sales by Novartis Consumer Health grew ahead of the market in the first quarter, according to the Swiss company, as it recovered from the challenges posed by the global economic crisis in 2009.

This time last year, the company's worldwide OTC sales had fallen as growth in some emerging markets had slowed and demand for branded OTC products in the US had dropped (**OTC *bulletin*,** 30 April 2009, page 12).

Novartis said its pain-reliever brands, particularly Voltaren in Europe and Excedrin in the US, had been key contributors to the first-quarter rise in its OTC sales. Their performance, however, had been offset by a weaker cough and cold season.

Launching the OTC proton-pump inhibitor Prevacid 24HR in the US last November (**OTC *bulletin***, 16 November 2009, page 1) had also boosted the OTC business, the company added.

A strong advertising and promotional campaign had seen the lansoprazole-based Prevacid 24HR grab a 30% share of the US OTC proton-pump inhibitor market – including branded and private-label products – in the week ending 21 March 2010, Novartis told **OTC *bulletin***.

In the weeks that followed, Prevacid 24HR's share had remained steady, standing at 29.6% for the week ended 28 March 2010 and 29.9% in the week ended 4 April 2010.

Prevacid 24HR competes with Procter & Gamble's established omeprazole-based Prilosec OTC as well as Merck & Co's recently launched Zegerid OTC, which combines 20mg omeprazole with 1,100mg sodium bicarbonate (**OTC *bulletin***, 16 April 2010, page 14).

As the first-quarter results were announced, Novartis revealed that it was seeking a new worldwide head for its OTC business. The company said the current worldwide head, Dirk Van de Put – who only took up the role in September of last year (**OTC *bulletin***, 31 July 2009, page 29) – would step down at the end of April to become chief operating officer of McCain Foods (see page 23).

George Gunn, worldwide head of Novartis' Consumer Health division, would take on the responsibility for the day-to-day running of the OTC business until a replacement had been appointed, Novartis said.

Region	First-quarter sales (US$ millions)	Change 2009/2010 (%) US$	Change 2009/2010 (%) Local currencies
Europe	668	+14	+5
US	468	+11	+11
Asia/Africa/Australasia	219	+13	+3
Canada and Latin America	123	+22	+4
Novartis Consumer Health*	**1,478**	**+13**	**+7**

* Continuing operations

Figure 2: Breakdown of Novartis Consumer Health's sales in the first quarter of 2010 (Source – Novartis)

Sales at Novartis' Consumer Health division increased by 13% – 7% in local currencies – to US$1.48 billion (€1.11 billion), as turnover improved at the division's Ciba Vision and Animal Health businesses as well as at its OTC unit (see Figure 1).

Novartis noted that all three of its Consumer Health businesses had achieved faster growth than their respective markets.

Canada and Latin America was the best performing region for Consumer Health, with sales rising by 22% – 4% in local currencies – to US$123 million (see Figure 2).

Robust growth – especially in France, Germany and Spain – led to a 14% rise in European turnover to US$668 million. In local currency terms, the growth was a more modest 5%.

In the US, strong performances from the OTC, Ciba Vision and Animal Health businesses had helped drive up sales by 11% to US$468 million, the company noted.

Net sales in Consumer Health's top six emerging markets had increased by 27% – 11% in local currencies – led by double-digit growth in India, Russia and Turkey. Russian growth had come despite price controls.

Operating income at the Consumer Health division increased by 12% to US$264 million (see Figure 3). Consumer Health's operating margin fell from 18.0% to 17.9% as a result.

OTC

	First-quarter of 2010 (US$ millions)	Change 2009/2010 (%)
Net sales	**1,478**	**+13**
Gross profit	**991**	**+14**
Marketing & sales	-540	+15
Research & development	-86	+13
General & administration	-96	+19
Other income & expenses	-5	-17
Operating income	**264**	**+12**

Figure 3: Novartis Consumer Health's continuing operations in the first quarter of 2010 (Source – Novartis)

Division	First-quarter sales (US$ millions)	Change 2009/2010 (%) US$	Change 2009/2010 (%) Local currencies	Operating income (US$ millions)	Change 2009/2010 (%)	Operating margin (%)
Pharmaceuticals	7,291	+13	+7	2,327	+13	31.9
Sandoz	2,001	+16	+9	310	+7	15.5
Consumer Health*	1,478	+13	+7	264	+12	17.9
Vaccines and Diagnostics	1,361	+451	+436	839	–	61.6
Corporate	–	–	–	-229	+32	–
Novartis	**12,131**	**+25**	**+18**	**3,511**	**+50**	**28.9**

* Continuing operations

Figure 1: Breakdown of financial performance of Novartis in the first quarter of 2010 (Source – Novartis)

Annual Results

Economic crisis hits turnover at Krka

Krka said sales of its self-medication products had declined by a tenth in 2009, as the global economic crisis hit the spending power of the public in two of its biggest markets.

Self-medication sales dropped to €89.6 million over the 12 months, with turnover in Russia and the Ukraine falling due to the economic conditions. This had been enough to offset the gains made in the company's other markets, Krka said, most notably Albania, Bosnia and Herzegovina, the Czech Republic, Germany, Poland, Romania, Slovakia and Slovenia.

As can be seen from Figure 1, two product categories – vitamin and mineral brands, and herbal products – accounted for 60% or €53.8 million of the company's total self-medication sales in 2009.

Krka said that its key herbal brand Bilobil (ginkgo biloba) had been expanded during the year with Bilobil Intense – which has 120mg of ginkgo biloba in just two capsules – and Bilobil Aktiv, which combines ginkgo biloba with ginseng.

Bilobil was the leading ginkgo biloba product in Romania and Slovenia, and also held leading positions in Poland, Russia and the Ukraine, Krka claimed.

Krka's core Duovit range of vitamin/mineral products for adults had seen a successful 2009, the company said, with the new Duovit for Men and Duovit for Women variations selling well in key markets.

Meanwhile, the children's vitamin/mineral brand Pikovit had maintained leading market shares in Romania, Russia, the Ukraine and Uzbekistan, Krka noted.

Cough and cold products – led by the Septolete sore-throat brand and Herbion cough syrup – accounted for another 19% of Krka's self-medication sales, with products for diseases of the alimentary tract and metabolism contributing 10% and analgesics 7%.

Self-medication products generated 9% of Krka's total sales in 2009 (see Figure 2), which edged up by 0.3% to €953 million. Earnings before in interest and tax (EBIT) fell back by 0.8% to €235 million.

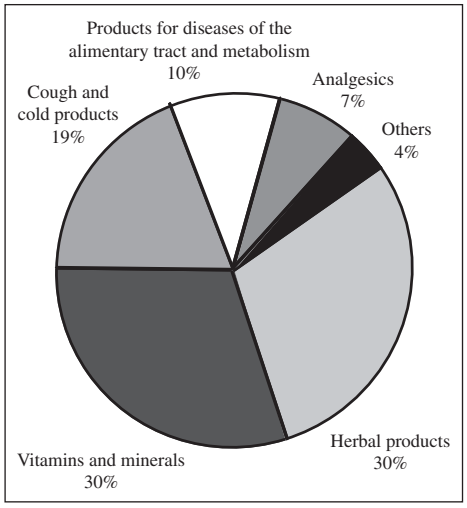


Figure 1: Krka's self-medication sales in 2009 – €89.6 million – by product category (Source – Krka)

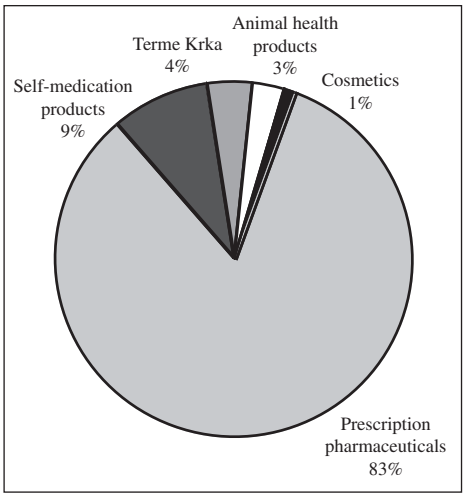


Figure 2: Krka's sales in 2009 – €953 million – allocated by product category (Source – Krka)

OTC

IN BRIEF

■ **HYPERMARCAS** has completed its acquisition of fellow Brazilian firm **Luper Indústria Farmacêutica** for BRL52.2 million (€22.0 million). Luper markets a range of OTC brands including the Ambroflux and Bequidex cough/cold products and Cetafrin paracetamol line (**OTC *bulletin***, 17 March 2010, page 2).

■ **BIOGAIA's probiotic drops** will be available in Indonesia under the BioGaia brand name from 2011, after the Swedish firm reached a distribution agreement with Interbat.

OTC

Annual Results

36.6 restructures as turnover declines

Difficulties raising capital and a decline in consumer demand due to the global economic crisis led to a 23.3% drop in retail sales by Russia's Pharmacy Chain 36.6 in 2009, according to Valeria Solok, chief executive officer of the management company.

An overhaul of certain areas of the company had been required, she said, noting that the company had had to restructure its long-term financial obligations, completely rebuild its relations with suppliers, reduce 'stock-out' levels and become much more efficient.

By the final quarter of the year, she added, the changes had slowed the decline in sales.

Retail sales decreased to RUB16.0 billion (€412 million) in 2009 (see Figure 1), accounting for 75.9% of Pharmacy Chain 36.6's total sales, which fell by 19.1% to RUB21.1 billion.

The company's Veropharm manufacturing business generated a further 20.9% of the sales total with the remainder coming from other businesses. Veropharm's sales increased by 2.2% to RUB4.40 billion (**OTC *bulletin***, 16 April 2009, page 6).

Business	Annual sales (RUB millions)	Change 2008/2009 (%)	Proportion of sales (%)
Retail	15,989	-23.3	75.9
Veropharm	4,395	+2.2	20.9
Other	682	-24.6	3.2
Pharmacy Chain 36.6	**21,065**	**-19.1**	**100.0**

Figure 1: Breakdown of Pharmacy Chain 36.6's sales in 2009 (Source – Pharmacy Chain 36.6)

Region	Number of pharmacies	Share of sales (%)
Moscow Central	349	47.1
South Urals	217	16.8
South	163	12.8
Volga	128	9.4
North Urals	86	6.6
Siberia	52	4.2
North West	24	3.1
Total	**1,019**	**100.0**

Figure 2: Number of pharmacies operated by Pharmacy Chain 36.6 as of 31 December 2009, broken down by region of Russia (Source – Pharmacy Chain 36.6)

Cash-flow problems and a failure to refinance the firm's debt – which stood at RUB7.62 billion at the end of 2009 – have plagued Pharmacy Chain 36.6 in the past year as the rapidly-expanding business suffered from the economic slowdown. The company's Retail division accounted for RUB6.67 billion of the debt, with the remainder held by Veropharm.

Accounts payable – particularly by the Retail division – grew as the company tried to meet its other financial obligations. This had led to some stores suffering from "stock outs" (**OTC *bulletin***, 18 December 2008, page 4).

In January, however, Pharmacy Chain 36.6 raised RUB2.3 billion through a share placing to help pay the debt and increase working capital (**OTC *bulletin***, 20 January 2010, page 8). A month later, Russian pharmaceutical wholesaler SIA International acquired a 25% stake in the business for an undisclosed sum (**OTC *bulletin***, 10 February 2010, page 2).

A spokesperson for Pharmacy Chain 36.6 declined to comment on media reports that the deal had been struck to settle the company's debts with SIA.

The number of pharmacies operated by the company were also cut as it closed underperforming outlets. As of the 31 December 2009, Pharmacy Chain 36.6 was operating 1,019 pharmacies in 29 regions of Russia (see Figure 2). This was down from the 1,127 a year earlier.

Pharmacy Chain 36.6 noted that the number of purchases made in its stores had dropped by 29.9% to 70.9 million in 2009, but the average amount spent had risen by 12.5% to RUB236.

Earlier this month, the company announced that it would cut prices of the most popular products by an average of 20% in its Moscow stores in an attempt to increase customer traffic (**OTC *bulletin***, 16 April 2010, page 2).

Branded OTC and prescription drugs, as well as cosmetics and private-label products, had been included in the price cuts, a spokesperson for Pharmacy Chain 36.6 told **OTC *bulletin***, noting that the scheme might be rolled out into other regions in the future.

To help increase traffic further and boost profitability, the company would also build its range of private-label products, Solok noted.

In 2009, sales of private-label products had risen by 29.5% to RUB1.13 billion, Pharmacy Chain 36.6 said, accounting for 7.1% of Retail sales. Its private-label range had grown from 698 at the end of 2008 to 821 a year later.

OTC

Development Agreements

Oxford Nutrascience signs Chewitab deal

Oxford Nutrascience has signed a development deal with the contract manufacturer Surepharm Services to scale up and validate manufacturing processes for its Chewitab delivery systems.

The UK-based company plans to license its Chewitab technology to OTC healthcare companies as well as launch its own products based on Chewitab technology including a chewable calcium supplement and a chewable multivitamin supplement.

Prototype tablets had performed well, Oxford Nutrascience said, and Surepharm would now be responsible for demonstrating that manufacturing processes could be scaled-up.

Chewitabs are said to be suitable for convenience-driven OTC medicines – such as analgesics, allergy treatments and digestive aids – and medicines for the elderly. They produce a light 'crunch' when bitten and then form a soft chew that dissolves quickly in the mouth, allowing them to be taken without water (**OTC *bulletin***, 26 February 2010, page 8).

OTC

IN BRIEF

■ **CELESIO** has raised around **€500 million** through its first corporate bond placement with private and institutional investors in Germany and selected other countries. The pan-European wholesaler and retailer said the placement set the group's finances on an "even more stable and broader footing" and the proceeds would be used primarily to reduce its bank debt.

■ **STADA ARZNEIMITTEL** said it had raised **€350 million** through a bond placement. The German firm said it would use the proceeds for general business purposes.

OTC

Regulatory Affairs

EMA recommends bufexamac withdrawal

Topical medicines containing the active ingredient bufexamac should be withdrawn in Europe, according to the European Medicines Agency (EMA).

The EMA said last week that bufexamac was associated with a "high risk" of contact allergies, and there was "very limited" data to support effectiveness of the medicine.

Earlier this year, Europe's Committee for Medicinal Products for Human Use (CHMP) started a safety review of topical medicines containing bufexamac (**OTC *bulletin***, 10 February 2010, page 15).

The move came soon after Germany's federal institute for drugs and medical devices, BfArM, proposed withdrawing haemorrhoid treatments and dermatological medicines containing bufexamac (**OTC *bulletin***, 18 December 2009, page 13).

Following its safety review, the CHMP has concluded that the "benefits of these medicines do not outweigh their risks for patients in any of their indications".

The EMA pointed out the CHMP's scientific review had identified a high risk of sometimes serious contact allergic reactions with bufexamac. "The risk was even higher in patients with pre-disposing conditions such as certain forms of eczema, for which bufexamac is frequently prescribed," the agency said.

Similar to disease being treated

The EMA added that the allergic reactions caused by bufexamac were very similar to the disease being treated, which might lead to a potential delay in correct diagnosis and treatment of patients.

"It is also likely that the difficulty to differentiate between a treatment failure and an allergic reaction has led to the cases of contact allergic reaction being under-reported," maintained the EMA.

Bufexamac-containing medicines have been sold in European Union member states since the 1970s. The non-steroidal anti-inflammatory drug (NSAID) is used in topical formulations to treat dermatological diseases such as eczema and dermatitis, as well as proctological conditions such as haemorrhoids and anal fissure.

Marketing authorisations for bufexamac-containing medicines have been issued in Austria, Bulgaria, the Czech Republic, France, Hungary, Italy, Latvia, Lithuania, Luxembourg, Portugal, Romania and Slovakia. The products are non-prescription medicines in some countries.

It had been known for some time that bufexamac may trigger contact allergic reactions. This has led to restrictions on the use of the medicines in some European Union countries over the years.

OTC

IN BRIEF

■ **TGA** – Australia's Therapeutic Goods Administration – has announced the membership of its new **Advisory Committee on Non-prescription Medicines** (ACNM). Formed in January 2010, the ACNM supersedes the Medicines Evaluation Committee, and will advise and make recommendations to the TGA regarding the entry of non-prescription medicines on the Australian Register of Therapeutic Goods.

■ **MELDEX INTERNATIONAL** has signed up **MJT Holdings/Majeton** to sell and distribute its Menoflavon range of products in Singapore. The deal may be extended to other countries in South-East Asia.

OTC

Patent Challenges

Schwabe patent ruling published

The European Patent Office (EPO) has published its reasons for revoking Dr Willmar Schwabe's patent, EP1,429,795, which covers a method for deriving extracts from pelargonium plants.

Following oral opposition hearings in January of this year, the EPO announced that it would revoke the German company's '795 patent, which is entitled 'Method for producing extracts of *Pelargonium sidoides* and/or *Pelargonium reniforme*' (**OTC *bulletin***, 10 February 2010, page 17).

Four parties had brought the opposition proceeding – herbal extracts providers Alpinamed, Finzelberg and Frutarom, as well as the African Centre for Biosafety. Their grounds of opposition included a lack of novelty, lack of inventive step and patentability, as well as insufficient disclosure.

The EPO decided that the patent did not represent an inventive step, although Schwabe said it intended to appeal. In particular, the EPO found, a two-stage maceration process was not inventive, because a person skilled in the art would have known how to follow this route to improve yields.

OTC

Switches

Zegerid OTC may face store brands

■ *Continued from front page*

promotion of the Zegerid OTC brand".

According to the US Food and Drug Administration's (FDA's) Orange Book, Zegerid OTC's only protection from generics is the patents covered by the court case. It has no switch marketing exclusivity.

The Delaware court found that the five patents at issue – all of which expire on 16 July 2016 – were obvious in light of prior art. That prior art included US patent 5,840,737, which covered "a method for treating gastric acid disorders" with an aqueous solution or suspension of omeprazole and sodium bicarbonate.

"The prior art at the time of the filing of the provisional application includes buffered, non-enteric-coated solutions or suspensions containing omeprazole and sodium bicarbonate," the court stated, highlighting two articles published in gastrointestinal journals in 1985.

Noting that the articles referred to aqueous solutions rather than the solid formulations covered by the patents that Santarus licensed from the University of Missouri, the court said the distinction did not render the articles irrelevant to considering obviousness. A skilled person would be well aware of how to convert liquids into solid-dosage forms, it stated.

While the two articles – which taught that a sodium bicarbonate buffer could be used as an alternative to an enteric coating to protect omeprazole from degrading in the stomach – were enough to render the five patents obvious, the court said two prior-art US patents further supported that finding.

Furthermore, the antacid properties of sodium bicarbonate had been well-known for many years, the court added, citing Alka-Seltzer as an example. "The idea of combining an acid-secretion inhibitor with an antacid was not new at the time of invention," it asserted, highlighting a similar finding by a New York district court in Perrigo's 2007 victory over McNeil regarding Pepcid Complete.

OTC

IN BRIEF

■ **FDA** – the US Food and Drug Administration – has announced draft guidance that would expand transparency and disclosure when the agency grants a **conflict of interest** waiver to permit an individual's participation at an FDA advisory committee meeting.

OTC

Retailing

Germany's BAH fears the rise of mail-order pharmacy

The growing importance of mail-order pharmacies in Germany threatens to trivialise the status of non-prescription medicines in consumers' minds, according to the country's medicines manufacturers' association, the BAH.

Noting that self-medication sales of non-prescription medicines and unlicensed healthcare products through mail-order pharmacies had risen by 32% to just over €600 million at retail selling prices during 2009 (**OTC *bulletin***, 16 April 2010, page 8), the BAH said the mail-order channel now accounted for around one in 10 self-medication purchases.

The BAH noted its members in the non-prescription sector viewed this development with concern. "Selling non-prescription medicines through mail-order tends to trivialise them and pushes them closer towards normal consumer goods," the association maintained. "It is thus logical to fear that consumers will use them in an indiscriminate manner."

However, the BAH welcomed the pledge contained in the pharmaceuticals action plan recently unveiled by Germany's ruling coalition to ban 'pick-up points'. These are kiosks within drugstores at which consumers can collect prescription and non-prescription medicines ordered through a mail-order pharmacy.

The BAH's reservations about mail-order pharmacies appear to be supported by the findings of a recent study conducted by German consumer watchdog *Stiftung Warentest*.

The study compared levels of service, advice and price at 50 pharmacies – 27 community pharmacies and 23 mail-order pharmacies. On the whole, community pharmacies fared significantly better than mail-order pharmacies.

None of the seven pharmacies considered to be "good" were mail-order operations, but eight of the 11 "deficient" businesses were.

Celesio's DocMorris pointed out that it had ranked seventh among the 23 mail-order pharmacies, and one of its franchise stores in Berlin had come third among the community outlets.

Last year, the DocMorris mail-order operation reported double-digit turnover growth to more than €250 million. The brand's first television advertising campaign had taken its customer base above 1.3 million people and had achieved brand recognition in Germany of 60%, the retailer said.

However, parent group Celesio blamed the advertising campaign for the DocMorris mail-order operation making a €3.6 million loss in earnings before interest, tax, depreciation and amortisation (EBITDA) loss in 2009.

OTC

Market Research

Global pharma market to grow 5%-8%

Global pharmaceutical sales will pass US$1 trillion (€0.74 trillion) at manufacturers' selling prices by 2014, according to a new report from market researcher IMS Health.

Over the next five years, forecasts the report entitled IMS Market Prognosis, a compound annual growth rate of 5%-8% will add sales of nearly US$300 billion to a global pharmaceutical market worth US$837 billion in 2009.

Strong overall growth in the world's emerging markets, says the report, will be partly offset by the impact of leading products losing patent protection in developed markets.

"In developed markets with publicly-funded healthcare plans, pressure by payers to curb drug spending growth will only intensify," says Murray Aitken, senior vice-president of healthcare insight at IMS Health. "But that will be more than offset by the ongoing, rapid expansion of demand in the pharmerging markets including Egypt, Brazil and Poland."

"Net growth over the next five years is expected to be strong," adds Aitken, "even as the industry faces the peak years of patent expiries for innovative drugs introduced 10-15 years ago and subsequent entry of lower-cost generic alternatives."

IMS Market Prognosis says the US will remain the world's largest pharmaceutical market, with growth of 3%-6% annually pushing sales up to US$360-US$390 billion in 2014.

Global pharmaceutical sales in 2010 are expected to increase by 4%-6%, compared with 7% in 2009 and 5% in 2008.

The IMS Market Prognosis report includes pharmaceutical sales in both audited and unaudited markets.

OTC

IN BRIEF

■ **TONGJITANG CHINESE MEDICINES COMPANY** said it had established a special committee to **evaluate a proposal** from Hanmax Investment and Fosun Industrial that would see the two firms acquire all of its outstanding shares. Tongjitang produces a number of "modernised traditional Chinese medicines" for the Chinese market, including an OTC product for osteoporosis sold under the Xianling Gubao brand. The company also owns a number of retail stores in China.

■ **ORIOLA-KD** has cut its operating profit forecast for 2010 because of **"difficult market conditions in Russia"**. The Finnish wholesaler and retailer said it now expected its operating profit to be lower in 2010 than it had been in 2009. Group net sales were still expected to be higher than last year. In the first quarter of 2010, operating profits dropped by 66% to €4.2 million due to the Russian business. The Russian pharmaceutical market had declined by around 10% in Ruble terms, the company noted, while pricing regulation had led to "fierce competition". Group sales rose by 11% to €449 million in the first quarter.

■ **CEPHALON** has completed its SFr662 million (€462 million) acquisition of Swiss generics player **Mepha** (**OTC *bulletin***, 10 February 2010, page 2).

OTC

Switches

German committee to consider orlistat switch

Switching all 60mg formulations of orlistat to non-prescription status is one of the points on the agenda for the next meeting of Germany's Expert Committee for Prescription on 6 July 2010.

GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine, which is based on 60mg orlistat, was granted non-prescription status in all 27 member states of the European Union, plus Norway, on 21 January 2009 via the centralised procedure (**OTC *bulletin***, 29 January 2009, page 1).

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

By switching all 60mg orlistat capsules to non-prescription status, Germany would comply with the Pharmaceuticals Unit's edict.

Germany recently switched all 20mg pantoprazole medicines for short-term treatment of heartburn and acid reflux to non-prescription status just months after Nycomed had introduced Pantozol Control. Supplied as a 20mg pantoprazole tablet, Pantozol Control gained non-prescription status for heartburn throughout the European Union in June (**OTC *bulletin***, 20 January 2010, page 13).

Provided the expert committee supports the orlistat switch, the proposal will be forwarded to Germany's upper house of parliament, the Bundesrat, for approval. The switch should come into effect early in 2011.

Other items on the agenda include an application to increase the maximum single dose of nicotine-replacement therapy (NRT) products from 10mg to 15mg.

The committee will also be asked to review a proposed reverse-switch to prescription-only status for pancreatin in doses of at least 20,000 units per dosage form.

Clarifying the rules on selling pseudoephedrine is also on the agenda.

OTC

Switches

Boehringer rejects bad press for Flomax

Boehringer Ingelheim has rejected suggestions by a UK newspaper that switching Flomax Relief to non-prescription status could put lives at risk.

The UK recently became the first country in the world to switch the 0.4mg tamsulosin hydrochloride capsules from prescription-only to pharmacy (POM-P) status for treating benign prostatic hyperplasia or an enlarged prostate (**OTC *bulletin***, 18 December 2009, page 1). Pharmacists can now sell Flomax Relief to men aged between 45 and 75 years with lower urinary-tract symptoms, such as urinary hesitancy and frequent urination.

Article ran in the *Daily Mail*

Earlier this month, however, the *Daily Mail* newspaper claimed that switching Flomax Relief could discourage older men from visiting a doctor with potentially serious consequences.

"Instead of having to visit a general practitioner, who may decide his symptoms warrant further investigation for conditions such as prostate cancer," said the newspaper, "someone suffering from the symptoms of benign prostatic hyperplasia will be able to visit a pharmacy."

A doctor quoted in the newspaper pointed out that a minority of men visiting their pharmacist may be suffering from a more serious problem. "There is a risk that they could not receive treatment as quickly as they may have if they had gone directly to their general practitioner," said the doctor.

Much later on, the newspaper does briefly mention that research shows many men suffering from lower urinary-tract symptoms do not visit their general practitioner anyway, so pharmacists are providing some healthcare intervention for this group of patients.

Responding to the *Daily Mail* article, Boehringer Ingelheim stressed that the pharmacy model used when recommending Flomax Relief was not "instead of having to visit a general practitioner".

"The pharmacy supply protocol presents numerous opportunities to encourage the man to see his general practitioner," noted Boehringer Ingelheim, "and all men will be referred to the general practitioner within six weeks of presenting to pharmacy for diagnosis of benign prostatic hyperplasia and to exclude any serious underlying conditions."

Any additional supply of Flomax Relief would be withheld if the man failed to comply with the pharmacist's advice to see a general practitioner, the firm continued, adding that further treatment would only be supplied by the pharmacist if a doctor had diagnosed the man with benign prostatic hyperplasia.

Boehringer Ingelheim also pointed out that pharmacists would encourage men to have an annual prostate health review with their general practitioner.

Describing pharmacists as "highly trained and educated healthcare professionals", the company said they were "well placed to be responsible for the first-line management of the symptoms of this condition" with the support of a symptoms-check questionnaire.

OTC

World kickboxing champion Christine Theiss has become a brand ambassador for Novartis Consumer Health's Voltaren analgesics in Germany. In return, Voltaren is now her main sponsor.

Theiss – who is also a qualified doctor – wears Voltaren-branded clothing in the ring and includes prominent links to the brand website at www.voltaren.de on her official website.

She is also supporting promotional events for the diclofenac-based brand, including the recent press launch of Voltaren Spray (40mg/g diclofenac sodium) for treating acute pain and inflammation around small- to medium-sized joints (OTC *bulletin*, 10 February 2010, page 21).

Line Extensions

Spanish firm Cinfa offers allergy spray

Spanish OTC and generics firm Cinfa is taking its market-leading Respibien nasal congestant brand into the allergy market by launching a nasal spray that combines oxymetazoline with chlorphenamine.

Respibien Antialérgico is indicated for relieving allergic rhinitis and nasal congestion.

Cinfa says the oxymetazoline in the spray unblocks the nose while the chlorphenamine reduces excess mucus.

Furthermore, the firm adds, the spray format helps to ensure the product does not leave an unpleasant taste by reaching the mouth.

A 15ml bottle has a retail price of €4.40.

IN BRIEF

■ **HERBALIFE** has become the official nutrition adviser to the **Pumas** football team in Mexico. The US-based direct-selling specialist said that together with Pumas it would educate its distributors and consumers about the benefits of exercise and adequate nutrition to promote a healthy and active lifestyle. In addition, the Pumas club has become involved with the Herbalife Family Foundation's Casa Herbalife programme, which helps provide good nutrition to disadvantaged children. The programme will now also cover regular exercise.

Line Extensions/Marketing Campaigns

Reckitt Benckiser revamps E45 Endless Moisture offer

Reckitt Benckiser has refreshed its E45 Endless Moisture skincare brand in the UK by streamlining the existing range and launching a body lotion containing gold particles.

The company is backing the relaunch with a £1.5 million (€1.7 million) consumer campaign including television and press advertising. New creatives use a blue ribbon to represent moisture.

Reckitt Benckiser pointed out that the new addition – E45 Endless Moisture Radiance – was enriched with "radiance boosters". The newcomer should attract customers looking for a good moisturiser with a cosmetic effect on the skin, the company told **OTC *bulletin***, adding that it would "broaden and re-emphasise the beauty credentials of E45".

E45 Endless Moisture Radiance body lotion is supplied in a 200ml bottle with a recommended retail selling price of £4.49.

Reckitt Benckiser has also reduced the existing E45 Endless Moisture range from six stock-keeping units to just two 300ml body lotions in lightly fragranced and fragrance-free formulations. The company noted that the £4.49 price tag was "more attractive" to customers.

Reckitt Benckiser's E45 Endless Moisture skincare range in the UK now comprises the new Radiance variant (pictured left) and the revamped Daily Care products (pictured right)

A blue ribbon represents moisture in Reckitt Benckiser's new television commercial for its E45 Endless Moisture range

The revamped products have been renamed E45 Endless Moisture Daily Care to "reinforce their daily moisturising role".

Meanwhile, the television commercial is built around the new claim: "In a clinical test, 100% of women should improve moisturisation from morning till evening."

"Endless Moisture, only from E45," states a female voiceover at the start of the commercial, as a woman wearing a towel applies the product to her body while sitting in the bathroom.

"Endless vibrancy, as you keep that just moisturised feeling all day long," continues the voiceover, while the blue ribbon that represents moisture wraps itself around the woman's arms and follows her to various locations including her flower shop.

As she sets out for a party in the evening, the blue ribbon forms "100%" in the air and the voiceover reads the new claim.

Near the end of the commercial, the voiceover states "Endless Moisture from Dermatological E45 – the expert touch for healthy feeling skin", and the packs of E45 Endless Moisture Daily Care body lotion appear on the screen.

The commercial ends with a woman placing a bottle of E45 Endless Moisture Radiance next to the two Daily Care packs.

IN BRIEF

■ **BAUSCH & LOMB** has launched its **Renu Sensitive** multi-purpose contact lens solution in Australia, Hong Kong, India, Malaysia and Singapore. The US-based eye health specialist said it had also revamped the packaging of Renu Sensitive and Renu Fresh in selected Asian markets, including China, Japan and Korea, to give the brand a "fresher and more contemporary look". Renu Sensitive is positioned as a "gentle formula for sensitive eyes", while Renu Fresh offers "fresh lens comfort" and "removes protein daily". Bausch & Lomb recently repackaged Renu Fresh in the US in a clear bottle, allowing consumers to see how much solution is left (**OTC *bulletin***, 31 March 2010, page 13).

Launches

Mentholatum puts £1m behind Regenovex in UK

The Mentholatum Company is putting £1.0 million (€1.2 million) behind Regenovex in the UK, as it widens distribution for the range of joint-health products.

Regenovex oral capsules, topical gel and patch – which up until recently were only available in Boots' stores – will be supported by television advertising, public relations activity and sampling initiatives over the coming months. "Because movement should be a pleasure," will be a key message to consumers.

The UK is the first market where Mentholatum has launched Regenovex, but the products will soon be available in other countries including the US.

Mentholatum is positioning Regenovex in the UK as an "advanced formulation for joint health" and higlighting the product's dual action. "This new generation of dual-action products contains active ingredients which work together to relieve joint discomfort and help the joint restore and maintain itself," comments the company.

According to the company, existing joint-care offerings either relieve pain and inflammation or help restore the joint. None has a formula designed to do both of these," insists the company.

All three Regenovex products contain hyaluronic acid which is a component of synovial fluid and cartilage. Mentholatum notes that as people get older their bodies produce less hyaluronic acid and it is of poorer quality. The products also contain the green-lipped mussel extract Bionovex Oil, which has an anti-inflammatory action.

Mentholatum points out that the range includes products for both long- and short-term relief. The one-a-day capsules – described as "small" and "easy-to-swallow" – are for people requiring "daily joint health", while the two topical products provide "targeted action for problem joints".

The pack of 30 capsules has a recommended retail selling price of £22.47. Users should take two capsules a day for the first 10 days, followed by one capsule a day as a maintenance dose.

One Regenovex patch is priced £2.34, while a 40ml pack of Regenovex fast-acting gel sells for £10.21.

According to Mentholatum, the products are useful for men and women over 40 years of age, active sports players and those who prefer a more natural approach.

A double-blind, placebo-controlled clinical trial involving Regenovex is due to start in the US this year.

Mentholatum's Regenovex range comprises oral capsules for "daily joint health", and two topical products for "targeted action for problem joints"

Marketing Campaigns

SSL pushes Durex with floating condom

A floating condom that prompts people to "get it on" is the cheeky advertising concept SSL International has devised to launch three condoms in the UK.

The company said the commercial – which highlighted that "it is everyone's right to have a happy, healthy and fulfilling sex life" – was the first television advertising for Durex condoms in the UK for six years.

Built around the slogan "Feeling is everything", the commercial begins with a couple kissing on a bed. A condom in its wrapper floats away from their bedside table and then hits the window of another bedroom, grabbing the attention of a young couple sat inside studying. The man then touches the woman's leg.

The condom continues on its journey, catching the eye of a middle-aged woman on a balcony, who then turns to a man sitting inside and lowers her top.

It then floats past a woman standing in a window. She smirks, looks back at a couple drinking champagne and closes the curtains.

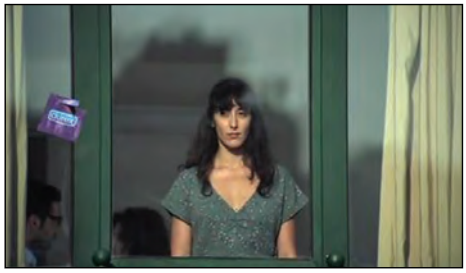
The condom's final stop is the windscreen of a police car, leading two policemen sat inside to look at each other and grin.

A female voiceover then states "Feel like never before with the enhanced range of condoms from Durex" as packs of Durex Deluxe, Durex RealFeel and Durex Fetherlite Ultra appear on the screen. "Feeling is everything," is the sign-off message.

SSL International said a similar commercial had already been aired in France.

The five-week burst of advertising started on 22 April. The commercial appears on ITV1 and Channel 4 each Thursday from 9pm-10pm.

SSL recently launched the three condoms in the UK, claiming they were the "thinnest" ever produced by the Durex brand (**OTC *bulletin***, 16 April 2010, page 14).



"Feeling is everything" is the theme of SSL International's launch television commercial for its Durex Deluxe, Durex RealFeel and Durex Fetherlite Ultra condoms in the UK

Flomax flows to the top of the rankings

Boehringer Ingelheim's new Flomax Relief dominates the rankings in Pharmacy viewpoint – our monthly survey of UK pharmacists' attitudes to OTC sales and marketing, which is published exclusively in OTC bulletin courtesy of the Intr@PharmQ service from IMS.

Boehringer Ingelheim's humorous launch campaign for Flomax Relief is proving a hit with pharmacists, judging by the results of our **Pharmacy *viewpoint*** survey for April. The pharmacy-only medicine for benign prostatic hyperplasia achieved a clean sweep of wins in all four sections of the survey.

In December of last year, the UK became the first country in the world to make Flomax a non-prescription medicine for treating benign prostatic hyperplasia, or an enlarged prostate, (**OTC *bulletin***, 18 December 2009, page 1). The Medicines and Healthcare products Regulatory Agency (MHRA) approved the switch of 0.4mg tamsulosin hydrochloride capsules from prescription-only to pharmacy (POM-to-P) status for treating lower urinary-tract symptoms in men aged between 45 and 75 years.

The challenge facing Boehringer Ingelheim and its advertising agency TBWA\Paling Walters is to drive men – a patient group that has historically been hard to reach – into pharmacies. Their solution is a humorous campaign in which an animated letter 'P' represents annoying pee problems.

Boehringer Ingelheim's initial activity focused on pharmacy training – including a national roadshow, distance learning and CPD training – public relations activity, and advertising in the pharmacy press. The last of these urged pharmacy staff to "Help men take control of their annoying pee problems", and showed a product pack dropping onto the letter 'P'.

One in four voted for Flomax

When IMS Consumer Health questioned pharmacists between 1 April and 21 April 2010 using its Intr@PharmQ service, one in four of them said Flomax Relief was backed by the best current trade-press advertising for an OTC medicine or dietary supplement (see Figure 1). Flomax Relief attracted over twice as many votes as GlaxoSmithKline Consumer Healthcare's NiQuitin brand in second place.

BEST CURRENT REPRESENTATIVE DETAILING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	24
2	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	7
3	Nurofen	Reckitt Benckiser	Oral/topical analgesic	6
4	Lemsip	Reckitt Benckiser	Cough/cold remedy	5
5	Alli	GlaxoSmithKline	Weight-loss medicine	4
6	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	3

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

Figure 4: Unprompted response of UK pharmacists between 1 April and 21 April 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best representative detailing?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

More recently, Boehringer Ingelheim started a £5.0 million plus (€5.5 million plus) consumer campaign for Flomax Relief. This is based around a television commercial that appeals to older men with the straightforward message "Take control of your annoying pee problems" (**OTC *bulletin***, 31 March 2010, page 13).

The letter 'P' represents the symptoms of benign prostatic hyperplasia, which include frequent urination and weak flow. The annoying letter P distracts one man from his game of golf by repeatedly shouting "pee"; irritates a second man trapped in a traffic jam by activating his windscreen washer; and keeps another awake at night by pouring water into a glass.

"One in four men over the age of 40 suffers from pee problems – ranging from difficulty getting started to a frequent urge to go, particularly at night-time," says a voiceover. "Fortunately, there is now a simple and effective treatment. New once-a-day Flomax Relief can ease all of these symptoms within one week."

A pack of Flomax Relief drops on top of the letter P, which is last seen wildly waving its

Intr@PharmQ and Pharmacy *viewpoint*

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

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

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

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

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

An animated letter 'P' represents annoying pee problems in Boehringer Ingelheim's launch marketing campaign for Flomax Relief in the UK. Trade initiatives include pharmacy-press advertising (pictured above), while the consumer campaign is based around a television commercial (pictured left)

arms and legs around in an attempt to escape. "Ask your pharmacist for Flomax Relief and take control of your annoying pee problems," is the sign-off message at the end of the 30-second commercial.

Two versions of the television commercial – the full 30-second execution and a cut-down 10-second spot – are running for three months now and again in September and October.

As can be seen from Figure 2, nearly one in four pharmacists surveyed thought Flomax Relief was backed by the best current television advertising.

In addition to television advertising, Flomax Relief will benefit from radio spots as well as press advertising in national newspapers and other relevant publications such as *Saga Magazine*. Boehringer Ingelheim is also planning a washroom-poster campaign in motorway service stations.

The brand's online presence includes a website at www.flomaxrelief.co.uk, as well as advertising on the NetDoctor and 50connect sites.

Flomax Relief also tops the rankings for best current pharmacy-support package (see Figure 3) and best current representative detailing (see Figure 4).

Reckitt Benckiser's new advertising for its Nurofen pain relievers – which was created by the agency Mother and depicts the brand as a superhero called Nuro (**OTC *bulletin***, 10 February 2010, page 18) – also did well in the April survey. As can be seen from Figure 2, Nurofen came second behind Flomax Relief in the television section, after attracting 12% of the best-advertising vote.

Nurofen also ranked second for best pharmacy-support package (see Figure 3).

OTC

PHARMACY *viewpoint*

BEST CURRENT TRADE-PRESS ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	25
2	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	12
3	Dulcobalance	Boehringer Ingelheim	Laxative	9
4	Gaviscon	Reckitt Benckiser	Indigestion remedy	8
5	Nurofen	Reckitt Benckiser	Oral/topical analgesic	6
6	Alli	GlaxoSmithKline	Weight-loss medicine	4
7=	Nicorette	McNeil Products	Smoking-cessation aid	3
	Vitabiotics	Vitabiotics	Food supplement	3
	Wellman	Vitabiotics	Food supplement	3

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

Figure 1: Unprompted response of UK pharmacists between 1 April and 21 April 2010 when they were asked the question: "In your opinion, what is the best current trade-press advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT TELEVISION ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	24
2	Nurofen	Reckitt Benckiser	Oral/topical analgesic	12
3	Gaviscon	Reckitt Benckiser	Indigestion remedy	9
4	Alli	GlaxoSmithKline	Weight-loss medicine	7
5=	Canesten	Bayer Consumer Care	Antifungal	4
	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	4
	Optrex	Reckitt Benckiser	Eyecare	4
8	Bio-Oil	Keyline Brands	Skincare	3

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

Figure 2: Unprompted response of UK pharmacists between 1 April and 21 April 2010 when they were asked the question: "In your opinion, what is the best current television consumer advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT PHARMACY-SUPPORT PACKAGE

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	27
2	Nurofen	Reckitt Benckiser	Oral/topical analgesic	9
3	Alli	GlaxoSmithKline	Weight-loss medicine	8
4	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	6
5=	Canesten	Bayer Consumer Care	Antifungal	3
	Covonia	Thornton & Ross	Cough/cold remedy	3
	Gaviscon	Reckitt Benckiser	Indigestion remedy	3
	Meltus	SSL International	Cough/cold remedy	3

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

Figure 3: Unprompted response of UK pharmacists between 1 April and 21 April 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best pharmacy-support package (consumer/trade advertising, bonus deals, profit margin, training, etc)?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

MAY

13-14 May

■ **Changing Channels in the OTC Environment**

Bethesda, Maryland, US

This two-day regulatory and scientific conference is organised by the US Consumer Healthcare Products Association (CHPA).

***Contact**: CHPA, 900 19th Street, NW, Suite 700, Washington DC 20006, USA.*
Tel: +1 202 429 3545.
Fax: +1 202 223 6835.
E-mail: msarabia@chpa-info.org.
Website: www.chpa-info.org.

16 & 17-19 May

■ **2nd DIA China Annual Meeting**

Beijing, China

'Priming China for drug innovation and development: from strategy to execution' is the theme of this three-day meeting organised by the Drug Information Association (DIA). The meeting will be accompanied by three pre-conference workshops.

***Contact:** Drug Information Association (DIA) China Office, 11F/1177, Block A, Gateway Plaza, No.18, XiaGuangLi, North Road East 3rd Ring, Chaoyang District, Beijing 100027, China.*
Tel: +86 10 5923 1109.
Fax: +86 10 5923 1090.
E-mail: dia@diachina.org.
Website: www.diahome.org.

18-19 May

■ **Regulatory Affairs in Africa**

London, UK

A two-day event covering pharmaceutical regulatory affairs in Africa, including South Africa.

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

18-20 May

■ **Vitafoods**

Geneva, Switzerland

This three-day global exhibition and conference will focus on nutraceutical, cosmeceutical, functional food and functional drink products.

***Contact:** Vitafoods Conference 2010, Data House, Curriers Close, Tile Hill, Coventry CV4 8AW, UK.*
Tel: +44 845 218 7266.
E-mail: conferencedepartment@melville.co.uk.
Website: www.vitafoods.eu.com.

19-21 May

■ **Russian Pharmaceutical Forum**

St Petersburg, Russia

This three-day conference focusing on the Russian pharmaceutical market will include sessions on regulation; distribution; legal issues; healthcare goods and OTC products; and pricing, reimbursement and market access.

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

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 Emma Walmsley, president of GlaxoSmithKline Consumer Healthcare for Europe; and Etienne de Laroullière, who is vice-president and head of global business unit OTC at Nycomed.

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; Catherine Geslain-Lanéelle and Vittorio Silano of the European Food Safety Authority (EFSA); and Marisa Matias, who is a member of the European Parliament.

***Contact**: AESGP, 7 Avenue de Tervuren, 1040 Brussels, Belgium.*
Tel: +32 2 735 51 30. Fax: +32 2 735 52 22. E-mail: info@aesgp.be.
Website: www.aesgp.be.

30-31 May

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

Dubai, United Arab Emirates

Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Libya, Palestine, Qatar, Saudi Arabia and other countries in the Middle East will be discussed at this two-day meeting.

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

JUNE

13-17 June

■ **46th DIA Annual Meeting**

Washington DC, US

With more than 350 sessions, the 46th Annual Meeting of the Drug Information Association (DIA) will cover a range of topics including outsourcing and advertising.

***Contact:** Drug Information Association (DIA), 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA.*
Tel: +1 215 442 6100.
Fax: +1 215 442 6199.
E-mail: dia@diahome.org.
Website: www.diahome.org.

14-15 June
8-9 November

■ **EuroPLX 43 & 44**

Berlin, Germany
Barcelona, Spain

Two-day partnering and licensing forums focusing on OTC medicines, nutraceuticals, branded prescription drugs and generics.

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

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 German. Speakers will include Guido Middeler and Ralf Sibbing of Diapharm.

***Contact**: BAH, Ubierstrasse 71-73, 53173 Bonn, Germany.*
Tel: +49 228 957 45 0.
Fax: +49 228 957 45 90.
E-mail: bah@bah-bonn.de.
Website: www.bah-bonn.de.

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, Ubierstrasse 71-73, 53173 Bonn, Germany.*
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

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

8-9 July

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

London, UK

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

14 July

■ **Marketing Authorisation in Japan**

Frankfurt, Germany

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

Centralised route requires passion and perseverance

Changes in the day-to-day practice of regulatory agencies – both at the European and national level – are top of the wishlist for Manfred Scheske, former president of GlaxoSmithKline Consumer Healthcare Europe. Deborah Wilkes reports.

If you want to switch a medicine to non-prescription status using Europe's centralised procedure, remarks Manfred Scheske, you need "a lot of passion backed up by a lot of hard work".

Scheske – who up until recently was president of GlaxoSmithKline Consumer Healthcare Europe (**OTC *bulletin***, 16 April 2010, page 1) – points out that the centralised procedure is "no easy walk in the park" for an applicant. "It brings together the wide variations in European understanding of non-prescription medicines in one decision-making round," he says, adding that "the result tends towards the lowest common denominator".

"Even when all the participants have a constructive approach," he continues, "the procedure still demands a lot of perseverance from the applicant."

Efficacy is not typically the problem when switching medicines to non-prescription status, notes Scheske, but it is essential for applicants to have a "complex understanding" of safety management within the non-prescription setting. "Any concerns about safety will make the switch a no-go area," he warns.

Scheske advises applicants to ensure they supply Europe's Committee for Medicinal Products for Human Use (CHMP) with the right quantity and quality of data. "A negative vote by the CHMP is very, very difficult to overcome," he comments.

Scheske stresses that the CHMP is "data-driven". "Applicants must generate data and use data to make their case," he advises. "If safety issues cannot be addressed persuasively with the support of data, then the switch application will not succeed."

In January of last year, GlaxoSmithKline's Alli became the first non-prescription medicine to be licensed through the centralised procedure (**OTC *bulletin***, 29 January 2009, page 1). The company rapidly introduced the weight-loss medicine containing 60mg orlistat in virtually all 27 member states of the European Union (**OTC *bulletin***, 30 April 2009, page 22).

Following the consumer launch in April, Alli recorded sales in excess of £100 million (€115 million) in Europe during the rest of 2009. GlaxoSmithKline's chief executive officer Andrew Witty highlighted that Alli was the third best-selling OTC brand in Europe during 2009 (**OTC *bulletin***, 10 February 2010, page 1).

Manfred Scheske, former president of GlaxoSmithKline Consumer Healthcare Europe, says self-care and self-medication will enter territory that was unthinkable in the past

Only one other medicine – Nycomed's 20mg pantoprazole formulation for frequent heartburn – has managed to gain non-prescription status through the centralised procedure (**OTC *bulletin***, 27 February 2009, page 1).

However, two applications involving non-prescription medicines have been withdrawn. The first was announced in late 2008, when Pfizer pulled the plug on its application to switch the erectile dysfunction drug Viagra (sildenafil citrate) from prescription to non-prescription status (**OTC *bulletin***, 28 November 2008, page 1). The second came at the start of this year, when Wyeth Consumer Healthcare – now part of Pfizer – decided not to pursue its application to licence a new combination containing the existing non-prescription medicines ibuprofen and diphenhydramine hydrochloride (**OTC *bulletin***, 10 February 2010, page 1).

Scheske observes that the door to Europe's centralised procedure is "open" to non-prescription medicines, but it is "not yet wide open".

He describes the centralised procedure as a "high maintenance route" with some "severe hurdles". All stakeholders must work together to make it the default pathway for non-prescription medicines in the same way that it has become the default pathway for prescription drugs, he insists.

Scheske believes the centralised procedure is "absolutely critically important to the OTC industry". "If we talk about competitiveness, then we have to talk about European business and we have to talk about European brands," he says. "If we want more pan-European brands in the self-medication industry, then the centralised procedure is the pathway to get there."

One problem area for the non-prescription industry, according to Scheske, is access to the centralised procedure. "Eligibility is still very narrowly defined," he remarks, noting that "only a few candidates are let through the door".

Non-prescription medicines have two possible entry points to the centralised procedure. The first is automatic entry for switching centrally-authorised prescription medicines, which was the route taken by Alli and Viagra. The second – taken by pantoprazole – is non-automatic entry for medicines that have not been authorised through the centralised procedure.

In January of this year, Patrick Le Courtois – head of the European Medicines Agency's (EMA's) human medicines development and evaluation unit – said that there had been 11 requests for eligibility through the second point, of which only five had been accepted (**OTC *bulletin***, 10 February 2010, page 24).

A second important issue raised by Scheske is that decision-makers have a limited understanding of issues relating specifically to non-prescription medicines. "Before the approval of Alli, the CHMP had only ever had to make decisions about complex and sophisticated new prescription-only drugs," says Scheske. "Committee members had little experience of OTC labelling, pharmacy distribution and communicating with consumers."

Agencies need more OTC expertise

According to Scheske, the time has come to consider how the necessary non-prescription expertise could be incorporated into the EMA and its procedures. The Food and Drug Administration (FDA) in the US, for instance, has an Office of Nonprescription Drug Products that plays an important role, he says, and some regulatory agencies in Europe have introduced either OTC offices or OTC champions.

A third issue raised by Scheske is the lack of a "commonly-defined role across Europe for pharmacists in self-medication".

Speaking in January, the EMA's Le Courtois acknowledged that this had been "a main issue for the small number of products that have been looked at by the CHMP". "The role

of the pharmacist has been a breaking point in one of the procedures," he remarked.

"There is little harmonisation at the European Union level in terms of the role of the pharmacist," Le Courtois observed, adding that "the practice is different, the culture is different, the perceptions are different, and the healthcare systems are organised differently".

As well as having to negotiate hurdles within the centralised procedure, GlaxoSmithKline's Alli faced barriers at the national level.

The company's launch campaign for Alli achieved a high level of consistency in consumer advertising and pharmacy communications throughout Europe. However, some nationally-imposed restrictions did cause problems for the company.

In Italy, for instance, Alli was placed in the country's controversial category of non-advertisable, non-prescription medicines. This stopped GlaxoSmithKline advertising Alli to consumers (**OTC *bulletin***, 19 June 2009, page 1).

Italy's move came despite the fact that there is no legal basis for a ban on consumer advertising of non-prescription medicines that are not reimbursable.

A European Court of Justice (ECJ) ruling in 2007 clearly stated that member states could not add to Europe's advertising directive (**OTC *bulletin***, 16 November 2007, page 1). Member states could ban consumer advertising for reimbursable medicines, said the ECJ, because they were expressly permitted to do so by the directive. But the same was not true for non-reimbursable medicines.

In France, meanwhile, GlaxoSmithKline was not allowed to run television advertising for Alli for a year, but the company could use posters and press advertisements to reach consumers.

Scheske maintains there is an urgent need for change within regulatory agencies, both at the national and the European level. "When it comes to day-to-day regulatory practice, some agencies do not reflect the important role of self-medication within healthcare systems," he says, adding that the problem is particularly apparent in southern Europe.

"Although non-prescription medicines account for half of the packs of medicines sold in most developed countries," adds Scheske, "some regulatory staff classify non-prescription medicines somewhere between a necessary and an unnecessary evil, based on the assumption that the control of the doctor is the only meaningful way to protect consumers."

"Such attitudes are based on the need to manage safety," acknowledges Scheske, "but they also include an element of protectionism for doctors and their role in society."

Scheske points out that the political will already exists in some countries to promote greater self-care and self-medication. In the UK, for instance, it exists at the highest levels of both the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA). "A lot of effort is made in the UK to get things moving and challenge the status quo," he observes.

Consumer healthcare will have to play an increasingly important role in all countries in future, maintains Scheske. "The ageing population means the worst is still to come in terms of rising healthcare costs," he says. "Neither the infrastructure nor the budgets of healthcare systems will be able to cope with the surge in demand unless changes are made."

According to Scheske, the OTC industry needs to engage at a strategic level with governments and regulatory agencies around Europe. "It is not just about the next analgesic or the next haemorrhoid treatment," he states. "It is about extending the boundaries of self-medication beyond the treatment of minor ailments to encompass management of certain chronic conditions."

To have a meaningful impact on the infrastructure and budgets of healthcare systems, remarks Scheske, self-care and self-medication will have to enter territory that was unthinkable in the past. This means that both industry and regulators, he continues, will need to "redefine how safety can be managed in the non-prescription setting".

Scheske points out that the trend towards greater self-care and self-medication will create a bigger role for pharmacists in consumer healthcare. Noting that "pharmacists hold the key to the success of the next big switches in Europe", he stresses that individual pharmacists and trade associations need to pave the way for change.

He emphasises that "European pharmacists must play a vital and pivotal role in driving this shift". "The role of pharmacists has to a certain extent diminished in recent decades, and they have turned into dispensers of high-margin drugs," he notes. "But this is set to change, and pharmacists will once again be first-line healthcare professionals, providing consumers with advice on minor ailments and manageable chronic conditions like doctors do today."

According to Scheske, the Pharmaceutical Group of the European Union (PGEU) and national pharmacy associations generally understand that the role of pharmacists has to change. "Pharmacists accept that they will have to play a wider role, and that they will have to become more involved in consultations and in services beyond distribution," he says.

There is more consistency in pharmacy care across Europe, he says, than would appear at first glance. "Most countries still have independent pharmacies rather than chains, and the classical community pharmacies are present in almost every European country," he says. "The pharmacy infrastructure is there to be grabbed and utilised by industry and governments."

Commenting on the response of pharmacists in Europe to Alli, Scheske says it has been "positive with very, very few exceptions".

Scheske points out that the future of self-medication in Europe depends on the "ability of all stakeholders to see and accept the role that self-care can play in European healthcare". "If self-care and self-medication is to reach its full potential in Europe, then pharmacists must evolve into trusted and trustworthy first-line healthcare professionals," he states. "Furthermore, consumers will need help to understand and manage their health conditions, and product labelling will need to enable consumers to choose the right product and to use that product correctly."

He urges regulators to accept "unreservedly" the need for self-medication products to be supported by consumer marketing campaigns. "OTC companies cannot manage safety, support correct selection of products, elevate the role of pharmacists and drive commercial success without the ability to communicate directly with consumers," he stresses.

Industry needs incentives

Scheske also calls for the issue of incentives for industry to be addressed. European legislation allows innovative switches to obtain a one-year period of data exclusivity, but this is proving very difficult to get in practice and neither of the two centralised switches have been successful. In any case, industry would prefer three years rather than one.

"Most European switches, including those before the centralised procedure became available, have not broken even or paid back regulatory and launch expenses," he insists, asking: "Why would anybody invest millions when there is an almost absolute certainty that the investment will never be recouped?"

Set against this background, Scheske urges governments and regulators to "take these commercial risks into consideration, and start discussing ways of providing incentives to balance the risks".

"The centralised procedure is a long and winding road, and is an expensive option as well," remarks Scheske. "It absorbs huge resources and not every stakeholder – particularly small- and mid-sized entities – can afford the investment."

■ Manfred Scheske can be contacted by e-mail on scheske@mac.com.

OTC

Manufacturers

Bayer places Reinhardt in charge of HealthCare

Bayer has recruited **Jörg Reinhardt** – former chief operating officer of Novartis – to lead its HealthCare division with effect from 15 August.

Arthur Higgins – the current chief executive officer of Bayer HealthCare – will move on from the company at the end of April. Bayer announced in September of last year that Higgins had decided to "leave the company during the first half of 2010 for personal reasons".

From 1 May until 15 August, the HealthCare division will be overseen by **Marijn Dekkers**, who is set to replace **Werner Wenning** as chief executive officer of the overall Bayer group later this year.

In January, Novartis said its chairman and chief executive officer Daniel Vasella was handing over his role as chief executive officer to Joe Jimenez with effect from 1 February 2010 (**OTC *bulletin***, 10 February 2010, page 27). The Swiss group noted Reinhardt – who had been up against Jimenez for the position of chief executive officer – had left the company.

Bayer has appointed Reinhardt – who is a 54 year-old German national – as chairman of the Board of Management of Bayer HealthCare and chairman of the Bayer HealthCare Executive Committee from 15 August 2010.

"Reinhardt is an acknowledged expert with many years of experience in the healthcare industry," commented Wenning. "We are convinced of his ability to provide a decisive impetus to our global HealthCare business and further expand our strong competitive positions."

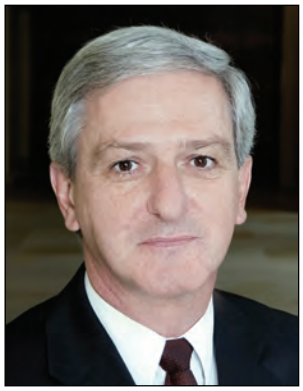
Reinhardt started his career with Sandoz – a predecessor company to Novartis – in 1981. After holding a series of managerial positions in research and development, he was appointed head of corporate development in 1994.

After the formation of Novartis in 1996, Reinhardt served as head of preclinical development and project management before being appointed global head of development in 1999.

At the end of 2005, he was appointed chief executive officer of the Vaccines & Diagnostics division in the US.

Reinhardt returned to Switzerland at the end of 2008 to become chief operating officer of Novartis, and a member of the company's Executive Committee.

Bayer's HealthCare division – which houses the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals businesses – reported sales up by 3.8% to €16.0 billion in 2009. Earnings before interest and tax (EBIT) grew by 21.0% to €2.64 billion (**OTC *bulletin***, 17 March 2010, page 6).



Jörg Reinhardt

Arthur Higgins

Marijn Dekkers

Dekkers, 51, will replace Wenning, 62, as the Bayer group's chief executive officer on 1 October. He was previously president and chief executive officer of the laboratory equipment manufacturer Thermo Fisher Scientific. A chemist, Dekkers has worked for a number of companies including General Electric, GE Plastics and Allied Signal.

OTC

Manufacturers

Herbalife appoints Peru country head

Herbalife has appointed **Jose Ramón Hernández Gallego** as its new country director for Peru.

The US-based direct-selling specialist noted that Hernández brought almost three decades of direct-selling experience to Herbalife.

He joins from the Brazilian cosmetics company Natura Cosmeticos, where he had been general manager of its Peruvian operations for two years. Before that, he spent more than 20 years at Avon.

At Herbalife, Hernández reports to the company's managing director of its South and Central America region, **Patricio Cuesta**.

The company said Hernández would be responsible for the growth and profitability of its business in Peru and working with its independent distributors. Herbalife started doing business in Peru in December 2006.

OTC

IN BRIEF

■ **PROCTER & GAMBLE** said **Charles Lee** and **Ralph Snyderman** had left the Board of Directors after reaching the company's retirement age of 70. Both men had been directors for over 15 years. Director **Patricia Woertz** has taken Lee's role as chair of the firm's Audit Committee, while director **Scott Cook** now has Snyderman's position as chair of the Innovation & Technology Committee.

OTC

Manufacturers

Connors leaves Matrixx and joins Prestige Brands

Prestige Brands has recruited its new chief marketing officer, **Timothy Connors**, from fellow US OTC company Matrixx Initiatives.

Connors was vice-president of marketing at Matrixx with responsibility for increasing market share of the Zicam Cold Remedy and introducing the firm's new products. He joined Matrixx in 2005 as director of national sales.

Before joining Matrixx, Connors worked for a number of other consumer-products companies, including Benckiser, The Clorox Company and Nestlé.

Matthew Mannelly, Prestige's president and chief executive officer, said Connors brought a "terrific combination of consumer and customer focus" to the team. "His marketing expertise, strategic thinking, and entrepreneurial spirit will serve our iconic brands as we continue to build them in the marketplace," he commented.

Connors said he would bring "innovation, energy and creative marketing" to the company's brand names.

In October of last year, Prestige divested its three shampoo lines to Ultimark Products to focus on its OTC Healthcare Products and Household Products divisions and pay down its debt (**OTC *bulletin***, 16 November 2009, page 8).

The company received an upfront payment of US$8.0 million (€6.0 million) for the Prell, Denorex Dandruff and Zincon Dandruff shampoo brands, as well as a subsequent payment of US$1.0 million.

Prestige noted that the three brands represented around 2%-3% of its annual sales.

In the firm's third quarter ended 31 December 2009, Prestige reported sales from continuing operations 3% lower at US$75.4 million.

The OTC Healthcare Products division saw sales drop by 3% to US$46.2 million. Prestige noted that an increase in sales of the Chloraseptic, Clear Eyes and Little Remedies brands had been offset by declines for the Allergen Block and Murine lines.

Sales of Household Products were down by 3% to US$27.3 million, and Personal Care Products experienced a 10% decline in turnover to US$2.0 million.

Prestige's operating income from continuing operations was 22% higher at US$23.7 million in the quarter, thanks in part to lower advertising and promotional expenditure.

Meanwhile, Matrixx Initiatives posted sales down by more than a quarter to US$28.5 million for its third quarter ended 31 December 2009 (**OTC *bulletin***, 10 February 2010, page 8).

Just under a year ago, Matrixx withdrew two of its core products, Zicam Cold Remedy Nasal Gel and Zicam Cold Remedy Gel Swabs, after receiving a warning letter from the US Food and Drug Administration (FDA).

OTC

Manufacturers

Novartis loses OTC unit head

Dirk Van de Put is leaving Novartis just eight months after becoming worldwide head of the company's OTC business unit.

A company spokesperson said that Novartis had not yet found a replacement for Van de Put, who departs at the end of April. **George Gunn**, worldwide head of Novartis' Consumer Health division, is taking day-to-day command of the business.

Van de Put becomes chief operating officer of McCain Foods with effect from 17 May.

Joined Novartis eight months ago

He joined Novartis on 1 September 2009 from Groupe Danone, where he was executive vice-president of Groupe Danone and president of its Americas division, as well as a member of the company's Executive Committee (**OTC *bulletin***, 31 July 2009, page 29).

OTC

Retailers

Smith parts from Lloydspharmacy

Richard Smith is stepping down as managing director of Lloydspharmacy in June. The UK's second-largest pharmacy chain said that Smith's successor would be announced in due course.

Smith, who is moving to Integrated Dental Holdings as chief executive officer, has been managing director of Lloydspharmacy for two years (**OTC *bulletin***, 29 February 2008, page 19). He was previously chief operations and commercial director.

Richard Smith

OTC

Manufacturers

De Alwis resigns as chief of Sigma Pharmaceuticals

The board of the Australian company Sigma Pharmaceuticals has accepted the resignation of its chief executive officer and managing director, **Elmo De Alwis**. However, De Alwis will remain in the post while the board searches for a successor.

De Alwis, 56, has spent 33 years with the Australian group, which has interests in OTC products, generic pharmaceuticals, pharmacy retailing and wholesaling. He was appointed managing director in February 2001 and oversaw the merger with generics firm Arrow Pharmaceuticals in 2005 (**OTC *bulletin***, 16 September 2005, page 5).

Sigma has just reported a net loss of A$389 million (€270 million) during the year ended 31 January 2010, after the company cut goodwill valuations by A$424 million (**OTC *bulletin***, 16 April 2010, page 2).

The company said this figure included a reduction of A$49.1 million in the goodwill valuation of its Herron range of OTC products following a poor performance in the grocery channel. In addition to the Herron write-down, Sigma cut A$375 million off the A$819 million goodwill valuation placed on the Arrow business after the two companies merged in 2005.

Excluding the goodwill impairment charges of A$424 million, Sigma said its underlying net profit had dropped by 15.5% to A$67.7 million. Sales increased by 4.5% to A$3.22 billion.

At the end of February, Sigma asked for trading in its shares to be suspended ahead of a profits warning.

When the firm eventually revealed its annual results a week late on 31 March, its share price immediately fell by more than 50%.

Rumours of takeover bid

There has been speculation in the financial press that the private-equity owners of iNova Pharmaceuticals – Archer Capital and Ironbridge Capital – could make a bid for Sigma Pharmaceuticals.

OTC

Retail Associations

CCA names Duncanson as chairman

Murray Duncanson will become chairman of the UK's Company Chemists' Association (CCA) in May.

He will take over from **Digby Emson**, who is retiring after 12 years in the post (**OTC *bulletin***, 26 February 2010, page 22).

Duncanson has extensive experience within the UK's National Health Service (NHS), where his most recent job was interim director of organisational development and workforce planning for NHS Medway. He has held a number of other senior positions within the NHS, including the chief executive of Barnet Healthcare NHS Trust, chief executive of Lothian Primary Care NHS Trust, and non-executive director of NHS Education Scotland.

Commenting on his role at the CCA, Duncanson said 2010 was "proving a pivotal year for community pharmacy and presents a real opportunity for the CCA to build upon the excellent work achieved throughout 2009".

Rob Darracott, the CCA's chief executive, said: "The wide-ranging experience and skills set that Duncanson brings to the CCA will be of considerable benefit to the association and its members in what looks like being a difficult few years for healthcare."

Murray Duncanson

The CCA represents the interests of leading multiple pharmacy groups in the UK. The association's full members – Asda Walmart, Boots UK, The Co-operative Pharmacy, Lloydspharmacy, Rowlands Pharmacy, Sainsbury's, Superdrug Stores, Tesco, and Wm Morrison Supermarkets – between them own more than 6,000 pharmacies in the UK. In addition, Day Lewis Pharmacy is an associate member.

OTC