

OTC *bulletin*

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

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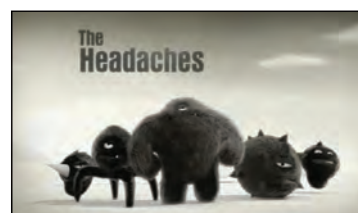
Nurofen's advertising targets paracetamol

“Nurofen provides faster and longer relief from headaches than standard paracetamol tablets” is Reckitt Benckiser's new claim for its ibuprofen-based brand in the UK market.

Reckitt Benckiser pointed out that head-to-head comparisons between Nurofen 200mg ibuprofen tablets and standard paracetamol tablets had demonstrated that Nurofen provided “both faster and longer pain relief than paracetamol for headaches”.

The company said that the new claim would

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Nurofen's superhero Nuro takes on “The Headaches” in Reckitt Benckiser's new television commercial

Trimethoprim switch is stopped in the UK

Actavis has given up on its application to switch the antibiotic trimethoprim from prescription-only to pharmacy (POM-to-P) status in the UK.

The decision comes nearly five years after the UK's Medicines and Healthcare products Regulatory Agency (MHRA) started consulting on the application to switch 200mg trimethoprim oral tablets under the Cysticlear brand name. The P medicine would have been indicated for recurrent urinary tract infections in women (*OTC bulletin*, 29 July 2005, page 9).

The company's bid to switch trimethoprim was hit from the start by concerns about in-

■ Continued on page 13

Scheske leaves GlaxoSmithKline

Manfred Scheske, 58, president of Consumer Healthcare Europe with GlaxoSmithKline has left the company to pursue other opportunities. His decision follows the appointment of Emma Walmsley, 40, in his role.

Paying tribute to Scheske's “highly successful” 25-year career with the company, Consumer Healthcare president John Clarke said: “His career comprises many highlights, including building Odol from a tiny brand to a leading position in oral care in Germany; creating the Dr Best brand in that market; and most recently the pan-European launch of [weight-loss

■ Continued on page 16

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NEW COST-EFFECTIVE RATES APPLY FOR 2010

Business Strategy

36.6 cuts prices of OTC products

Russia's Pharmacy Chain 36.6 said its decision to cut prices of the most popular products by an average of 20% at its stores in Moscow should increase customer traffic.

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 future.

Increased sales due to higher customer traffic would offset any profit shortfalls caused by the price cuts, insisted Pharmacy Chain 36.6. Incremental profit gains would also be made, the company added, through new deals with distributors, further direct-supply contracts with manufacturers, and an increase in the amount of private-label products sold.

The move comes after Russian pharmaceutical wholesaler SIA International acquired a 25% stake in Pharmacy Chain 36.6 for an undisclosed sum in February (**OTC bulletin**, 10 February 2010, page 2).

At the time, Igor Rudinsky, general director of SIA, said the partnership would make Pharmacy Chain 36.6 more competitive with consumers, as synergies would allow the retailer to cut costs, and reduce/stabilise prices.

A month earlier, Pharmacy Chain 36.6 raised RUB2.3 billion (€57.5 million) through a new share placing to help pay its debts and increase working capital (**OTC bulletin**, 20 January 2010, page 8).

As of 30 September 2009, Pharmacy Chain 36.6 was operating 1,026 pharmacies across Russia. This was down from the 1,168 stores the company was operating a year earlier, as it closed underperforming stores.

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IN BRIEF

■ **ALKALOID's** OTC sales grew by 3.3% to €17.2 million in 2009, accounting for 22.9% of the Macedonian company's pharmaceuticals turnover, which improved by 16.1% to €75.0 million. Alkaloid's OTC portfolio includes the Bil-ol, Caffetin, Diprol and Primulin brands as well as various herbal drops. Group sales, including other business segments as well as pharmaceuticals, grew by 15.7% to €89.2 million. Operating profit finished up by 2.5% to €10.9 million.

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Annual Results

Goodwill cuts result in massive loss at Sigma

Sigma Pharmaceuticals reported a net loss of A\$389 million (€270 million) in the year ended 31 January 2010, after cutting goodwill valuations by A\$424 million.

The Australian 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.

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.

The goodwill write-down was divided into A\$184 million for its Pharmaceuticals division, which houses the Herron brand, and A\$240 million for the Healthcare division.

Trading in Sigma's shares on the Australian Securities Exchange had been suspended for around five weeks prior to the results announcement, after the firm admitted it would have to make adjustments to its previous earnings guidance. Sigma may now face legal action from shareholders in the wake of the impairment-related loss and cancelled dividend payments.

Commenting on the reasons why it reduced the goodwill valuation of its Herron brand – which has products covering 16 healthcare categories – Sigma admitted that additional investment to raise brand awareness in the grocery channel had not paid off, and this had adversely affected the company's cash-flow forecasts for the brand.

Sigma pointed out that sales of Herron products in the pharmacy channel, by contrast, had grown. Herron had primarily been sold through grocery retailers, but more recently Sigma has moved to strengthen its appeal to pharmacists by introducing pharmacy-exclusive products (**OTC bulletin**, 17 October 2008, page 16).

Other OTC brands – including Chemists' Own – had experienced a strong year, Sigma

noted, and had strengthened their positions in the pharmacy channel. Looking ahead, the company said that it was planning to launch 25 OTC products during 2010 and 2011.

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 (**OTC bulletin**, 16 September 2005, page 5).

Of this figure, A\$135 million took the form of a write-down on the generics part of Sigma's Arrow business within the Pharmaceuticals division. The company said it had made the cut due to the aggressive discounting in the generics market and the expected impact of government cuts to generic reimbursement prices.

The combined A\$184 million write-down for Herron and the generics business meant Sigma's Pharmaceuticals division – which comprises Medical and Manufacturing as well as the Arrow generics and Consumer units – posted a loss before interest and tax of A\$125 million in 2009 (see Figure 1).

The equivalent loss by Sigma's Healthcare distribution division was A\$175 million after taking A\$240 million in goodwill impairment charges. Sigma said synergies expected from the merger with Arrow had not been achieved.

Sigma's reported loss before interest and tax was A\$309 million. Of this figure, the Pharmaceuticals and Healthcare divisions accounted for A\$300 million of the loss. The remainder was attributed to unallocated costs.

Excluding the goodwill impairment charges and other adjustments, the underlying earnings before interest and tax (EBIT) at the Pharmaceuticals division stood at A\$105 million, down by 23.7% compared to the same period a year earlier. Sales fell by 5.6% to A\$671 million.

Healthcare's underlying EBIT declined by 4.0% to A\$67.9 million.

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Business	Annual sales (A\$ millions)	Change (%)	EBIT (A\$ millions)
Pharmaceuticals	671	-5.6	-125
Healthcare	2,550	+7.5	-175
Sigma Pharmaceuticals	3,220	+4.5	-309*

* Includes A\$9.43 million of unallocated losses

Figure 1: Breakdown of Sigma Pharmaceuticals' sales and losses in earnings before interest and tax (EBIT) in the year ended 31 January 2010 (Source – Sigma)

Joint Ventures

Mead Johnson moves into Gulf with Almarai

Mead Johnson Nutrition is set to enter the member states of the Gulf Cooperation Council (GCC) by forming a paediatric nutrition joint-venture company with Saudi Arabian dairy foods firm Almarai.

Steve Golsby, president and chief executive officer of Mead Johnson, said the 50:50 joint venture would give the US-based firm a "great entry point into the GCC" and a "tremendous opportunity to enhance nutritional offerings and

increase consumer choice in the region".

Expansion into the GCC member states – Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates – had been prioritised by Mead Johnson due to their size and "attractive demographics", Golsby said, noting the group's "strong birth rates, above-average income levels and potential for growth".

Described as the "largest integrated dairy foods company in the world", Almarai would provide the joint venture with "extraordinary knowledge of the local market", an "excellent dairy supply" and an "extensive distribution network", Mead Johnson pointed out.

The two companies both had "tremendously well-known brands", Mead Johnson said, which had led to the decision that products sold by the joint venture would be co-marketed under Mead Johnson's 'Enfa' brand and Almarai's own brand names.

The joint venture will lease a new paediatric nutrition manufacturing facility that Almarai is currently constructing in Saudi Arabia. A management team sourced from both companies will oversee the facility and run the business on a day-to-day basis, reporting to the board of the joint venture that will also be composed of representatives from Mead Johnson and Almarai.

Mead Johnson – which has a portfolio of nutrition brands for infants and children – said it expected the joint venture would be profitable during 2012, adding that the impact of the project on the company's earnings per share in 2010 and 2011 would be minimal.

Bristol-Myers Squibb gave up its majority stake in Mead Johnson in January of this year (**OTC bulletin**, 20 January 2010, page 4).

Mergers & Acquisitions

Abbott suffers nutrition blow

Abbott Laboratories and Wockhardt have terminated an agreement signed in July 2009 that would have seen US-based Abbott buy Wockhardt's Indian nutrition businesses.

Abbott said the joint decision had been taken after India's Wockhardt had been "unable to resolve debt-restructuring issues with some of its lenders".

If the agreement had been successfully implemented, Abbott would have paid US\$130 million (€97.5 million) for the nutrition businesses of Wockhardt, Carol Info Services and certain Wockhardt subsidiaries.

The deal would have given Abbott a range of paediatric and adult nutrition products in India, including the Farex, Dexolac and Nusobee infant-formula brands as well as the Farex weaning cereal. The company would have also gained the leading adult protein supplement Protinex.

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www.OTC-bulletin.com**IN BRIEF**

■ **FUTURA MEDICAL** said its CSD500 condom had now been submitted for a **European CE mark**. The UK-based company added that it expected approval later in 2010. CSD500 is set to become Futura's first commercially available product. SSL International will launch CSD500 – which incorporates an erectogenic compound to help men maintain a firmer erection during intercourse whilst wearing a condom – under its Durex brand name.

Mergers & Acquisitions

Poland's Adamed grows OTC reach

Product development-focused pharmaceutical company Adamed has expanded its reach into the Polish OTC and food supplements market by acquiring Agropharm for an undisclosed sum.

The company commented that acquiring Agropharm fitted with its aim of becoming a more diversified pharmaceutical firm.

Agropharm offers a number of food supplement brands, as well as the Nervomix herbal medicine. All Agropharm products, Adamed noted, would be handled by a new division called Adamed Consumer Healthcare.

The deal is Adamed's second in less than two months, after it agreed to buy the state-owned Polish pharmaceutical firm Polfa Pabianice in February.

Acquiring Polfa Pabianice will give Adamed a range of OTC ibuprofen products sold under the Ibutar brand name, along with the Natrax range of naproxen painkillers.

The Agropharm and Polfa Pabianice deals would double the company's workforce to 1,700, Adamed noted.

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Stada's board open to takeover offers

Stada Arzneimittel's board is open to takeover offers or partnership deals involving "significant capital investment", according to the German group's executive chairman and chief executive officer Hartmut Retzlaff.

Retzlaff insisted that Stada had received no contact from either Actavis or Pfizer after they lost out to Teva on acquiring Ratiopharm (OTC *bulletin*, 31 March 2010, page 1). But he said it would not be surprising if parties interested in strengthening their presence in Germany looked at Stada.

The company's board, he added, was obliged to consider any serious offer and make a recommendation to shareholders. All Stada's shares are in free float, with about 55% of the firm's equity in the hands of institutions, such as pension funds, and another 14% owned by German pharmacists and doctors.

Meanwhile, Retzlaff said Stada intended to capitalise on the potential offered by its OTC portfolio this year. He acknowledged the OTC business had produced mixed results in 2009.

Although Stada did not release figures for its OTC business, Retzlaff said some of its OTC brands had enjoyed a successful 2009, but others had lost market share. Furthermore, he add-

ed, some smaller brands had not been actively promoted last year.

Retzlaff pointed out that advertising had been stepped up in 2010, and Stada had decided to re-establish a separate OTC pharmacy salesforce in Germany. Combining the company's generics and OTC salesforces had led to some products not receiving the German representation they deserved, Retzlaff admitted. Both the company and pharmacists agreed that Stada's OTC brands needed their own representatives, he added.

Internationalisation was a "buzzword" at Stada's OTC business, Retzlaff stated, noting its NeoCare unit had been marketing Stada's OTC and other Branded Products in countries outside of Germany without creating new costs.

Retzlaff did not comment on how acquisitions might help the development of Stada's OTC business, but he did highlight the addition of the Eunova nutritional supplement brand in Germany. Stada acquired Eunova for €12.0 million from GlaxoSmithKline in November 2009. The brand generated sales of €6.9 million in the previous year.

Non-prescription products generated around 62% of sales by Stada's Branded Products division in 2009. These increased by 6% as report-

ed to €393 million (see Figure 1). Adjusted for portfolio changes and currency effects, sales improved by 15%.

Difficult trading conditions caused by the global economic crisis had failed to influence significantly demand for the company's Branded Products, Stada noted.

Operating profit grew even quicker than sales, rising by 39% to €74.9 million, with the operating margin rising from 14.6% to 19.1%.

Sales of the Grippostad cold medicine had increased by 21% to €34.1 million, Stada said, adding that the Hirudoid brand for blunt injuries had reported sales up by 8% to €16.2 million. The smaller Mobilat brand for the same type of injuries, however, suffered an 11% fall in turnover to €15.2 million.

In Stada's home market of Germany, sales by Branded Products were flat at €103 million, representing 19% of the group's sales in the country which fell by 6% to €532 million (see Figure 2).

Branded Products carrying the Stada label posted sales up by 0.5% to €97.4 million, the company noted, thanks in part to the strong performances by Grippostad and the Ladival sunscreen range. The German Hemopharm label posted sales up by 22% to €3.8 million, Stada said, adding that the Eunova acquisition would boost Hemopharm's sales further in 2010.

Turnover by Branded Products in Russia – Stada's second-biggest market in terms of sales – increased by 7.5% to €105 million, representing over half of Stada's sales in the country, which finished up by 5% to €192 million.

Stada continued to build its Branded Products business in Belgium, with sales growing by a tenth to €5.5 million. However, faster growth at Stada's Belgian generics business meant that Branded Products generated just 4% of the company's total sales, down from a 5% share a year earlier. Total sales in Belgium increased by 14% to €126 million.

In Serbia, Branded Products' turnover jumped by 34% to €9.0 million, boosting its share of total sales from 5% to 8%. Stada's group sales in Serbia were down by 18% to €119 million. In local currencies, sales grew by 6%.

Acquisitions and disposals impacted Branded Products' performance in Italy, where sales increased by 10% to €49.5 million. The division contributed 42% of Stada's total Italian sales, which slipped back by 6% to €117 million.

The majority of Stada's sales in the UK – 66% – were generated by the Branded Products division, with generics in niche product cate-

Business	Annual sales (€ millions)	Change (%)	Operating profit (€ millions)	Change (%)
Generics	1,116	-3	156.3	+14
Branded Products	393	+6	74.9	+39
Commercial	52	-12	2.7	-54
Group/other	9	-86	-41.9	-
Total Stada	1,569	-5	191.9	+9

Figure 1: Stada's sales and operating profit in 2009 broken down by business (Source – Stada)

Country	Stada's sales (€ millions)	Change (%)	Branded Products' sales (€ millions)	Branded Products' sales in Stada (%)
Germany	532	-6	103	19
Russia	192	+5	105	54
Belgium	126	+14	6	4
Serbia	119	-18	9	8
Italy	117	-6	50	42
France	82	-10	5	6
Spain	74	+12	7	9
UK	51	-49	34	66
Netherlands	38	-8	14	37
Denmark	26	+40	1	4
Others	212	-	60	28
Total Stada	1,569	-5	393	25

Figure 2: Breakdown of sales by Stada and its Branded Products division in 2009, together with the proportion of group sales accounted for by Branded Products (Source – Stada)



Stada intends to capitalise on the potential offered by its OTC portfolio during 2010, according to chairman and chief executive officer Hartmut Retzlaff

gories accounting for the remainder. UK Branded Products sales fell back by 3.7% to €33.8 million, while total sales dropped by 49% – 44% in local currencies – to €51.3 million due to the sale of the Forum Products business.

The Branded Products division accounted for 25% of Stada's group sales and 39% of its operating profit in 2009. Group sales declined by 5% to €1.57 billion as reported, but increased by 4% when adjusted for currency effects and portfolio changes.

Group operating profit increased by 9% to €192 million. Earnings before interest, taxes, depreciation and amortisation (EBITDA) were 10% higher at €280 million.

According to Retzlaff, 2009 had been a good year for Stada despite “difficult framework conditions in particular in the German domestic market and high burdens from currency effects”. The firm's strong international business – accounting for approximately 66% of sales – had been an important factor, he said.

Commenting on external growth, Stada's board said it was “currently hesitant” to increase the group's net debt to finance external growth. However, the board did not rule out taking advantage of “special opportunities”.

Responding to a question about central and eastern Europe, Retzlaff said Stada had no footprint in Croatia and only a minimal presence in Poland. However, he added, the German group did not plan to spend more than €80 million on any individual transaction this year.

Meanwhile, Retzlaff revealed Stada was examining opportunities to expand in the Middle East and North Africa (MENA) region. Noting that Egypt alone offered a US\$1.6 billion (€1.2 billion) pharmaceuticals market, Retzlaff highlighted that the MENA region was largely a “Teva-free zone”.

Annual Results

Double-digit OTC rise fails to lift Podravka in Croatia

Croatia's Podravka said double-digit sales growth for its domestic OTC brands last year had not been enough to offset a sales drop for prescription-only drugs. Its Pharmaceuticals division reported sales down by 2% to CrK474 million (€65.2 million).

The 17% rise in OTC sales during the year had been driven by the Lupocet and Neofen brands, the firm said, and dietary supplement sales had grown by 2%. Domestic growth had been aided by a lift in sales through the company's Deltis Pharma pharmacy chain, the company added.

Overall, OTC drugs accounted for about a tenth – around CrK75 million – of total Pharmaceuticals sales, which grew by 3% to CrK753 million. Pharmaceuticals represented about a fifth of Podravka's business, which is mostly in food and beverages.

Outside of Croatia, Pharmaceuticals' sales had increased by 14% to CrK279 million, the company noted, primarily due to 34% growth in Bosnia and Herzegovina, driven by its pharmaceutical wholesaler and manufacturer Farmavita.

The double-digit improvement in Bosnia and Herzegovina helped push Pharmaceuticals' turnover in its south-east Europe region – which mostly includes former Yugoslavia – to CrK196 million, or 26% of the division's total (see Figure 1).

In the company's eastern Europe region,

which includes the Baltic States, Romania, Russia, the Ukraine and other countries, sales stood at CrK60.2 million. Meanwhile, in the central Europe region – covering Czech Republic, Hungary, Poland and Slovakia – turnover reached CrK22.6 million.

The higher share of sales generated by the lower margin Farmavita and Deltis distribution operations had led to a 510 basis-point drop in the Pharmaceuticals division's gross margin to 52.7%, Podravka noted. Earnings before interest and tax (EBIT) fell by 15% to CrK93.4 million, as the EBIT margin declined by 260 basis points to 12.4%.

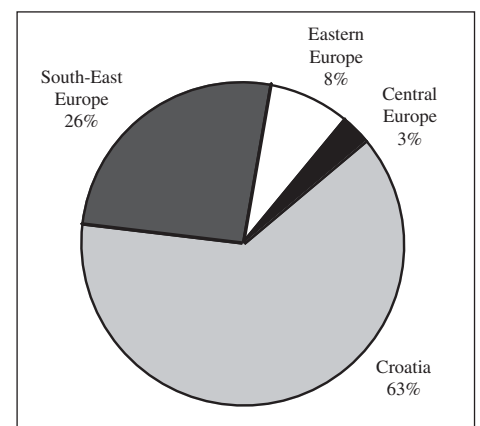


Figure 1: Sales at Podravka's Pharmaceuticals division in 2009 – CrK753 million – broken down by region (Source – Podravka)

Second-Quarter Results

Walgreens grows in tough period

Walgreens, the largest drugstore chain in the US, said its sales had grown by 3.1% to US\$17.0 billion (€12.7 billion) in the three months ended 28 February 2010, despite the “sluggish economy”. Operating profit grew by 5.4% to US\$1.09 billion.

Greg Wasson, chief executive officer of Walgreens, said that the company had maintained its focus on its key strategies during the quarter and had generated “significant cash flow” in the face of a hostile economic environment and a cold and flu season that had ended earlier than anticipated.

Turning to the six-month figures, Wasson pointed out that the early cold and flu season had helped the company's first-quarter results,

but hurt its second-quarter performance. Overall, the company had been pleased with sales growing by 6.1% to US\$33.4 billion for the six months ended 28 February 2010.

In February, Walgreens agreed to acquire Duane Reade and its 258-strong New York-based drugstore chain for US\$1.08 billion in cash (OTC bulletin, 17 March 2010, page 9). The deal was approved by the US Federal Trade Commission on 30 March, and was completed on 9 April.

As of 28 February 2010, Walgreens was operating 7,680 locations – 7,180 of which were drugstores – in 50 US states, the District of Columbia, Guam and Puerto Rico.

Annual Results

Blunt talking boosts sales at Dr Wolff

Germany's Dr Wolff Group claims its "unconventionally direct description" of vaginal dryness helped to break taboos and increase sales of its gynaecological range by 22% to €14 million last year.

Including the group's other pharmaceutical products and its cosmetics range, Dr Wolff grew its turnover by 12% to €166 million in 2009.

This performance, the German firm noted, represented an acceleration over the 9% rise to €148 million achieved in 2008 (*OTC bulletin*, 17 March 2009, page 9).

Dr Wolff said introducing the hormone-free Vagisan Feuchtcreme vaginal lubricant – which has a pH value of 4.5 and is classified as a medical device – had been a major driver of the higher gynaecological sales. The brand also includes an intimate wash lotion and lactic acid pessaries (*OTC bulletin*, 28 August 2008, page 22).

In 2010, the German firm intends to continue its forthright advertising campaign for Vagisan "with creative ideas". "Many millions

Product type	Annual sales (€ millions)	Change (%)	Proportion of total (%)
Cosmetics	112	+13	67
Linola	36	+7	22
Gynaecology	14	+22	8
Others	3	–	2
Pharma	53	+9	32
Total Dr Wolff	166	+12	100

Figure 1: Breakdown by product type of Dr Wolff Group's sales in 2009 (Source – Dr Wolff)

of women suffer unnecessarily from this problem," the firm insisted.

Sales of the linoleic acid-based Linola dry skin brand increased by 7% to €36 million (see Figure 1). With more than three million packs sold last year, Dr Wolff claimed Linola had captured second position within its market.

Launching the Linola Gesicht face cream with the advertising claim "Wenn die Haut austrocknet und die Feuchtigkeitscreme nicht aus-

reicht...." – or "If your skin dries out and your moisturiser isn't enough...." – had been a significant success, the German firm asserted.

Continued research into linoleic acid would produce more innovative products for dry skin over the next few years, Dr Wolff promised. In 2009, the group invested more than 10% of its annual turnover into research and development.

Among the group's current research projects are anti-inflammatory peptides for intestinal infections and active ingredients to combat hair loss caused by chemotherapy. Dr Wolff has also licensed-in a patented ingredient to reduce itching and tackle inflammation that is moving toward proof-of-concept trials.

Including €3 million in turnover from other products – such as the dimethicone-based Eto-Pril head-lice treatment – total sales by the Dr August Wolff pharma business improved by 9% to €53 million last year.

The Dr Kurt Wolff cosmetics unit performed even more strongly with turnover ahead by 13% to €112 million, or two-thirds of the German group's total sales.

The Alpecin and Alcina hair and skincare brands each showed 5% sales growth to €47 million and €34 million respectively, while turnover from the Plantur39 range for hormone-related hair loss climbed by 13% to €25 million. Another €6 million of cosmetics sales came from the recently-launched BioRepair oral-care brand.

Annual Results

Veropharm gets OTC sales boost

Veropharm's OTC drugs easily outperformed the Russian group as a whole in 2009. OTC sales rose by 36%, which compared with a 2% improvement overall.

OTC turnover increased to RUB527 million (€13.5 million), accounting for 12% of Veropharm's total sales, which edged up to RUB4.40 billion (see Figure 1).

The company's top five best-selling OTC drugs – Motilak, Poludan Nasal, Slabilen, Vitasharm/Vitatress and Xilen – generated 99% of its OTC sales.

Prescription drugs dominated Veropharm's sales, accounting for 69% of the total, while Adhesive Bandages contributed 17% and Traditional drugs the remaining 2%.

Meanwhile, Veropharm's future as part of

Russia's Pharmacy Chain 36.6 remains unclear.

A spokesperson for Pharmacy Chain 36.6 would not comment on whether the Russian pharmacy group was still considering selling its stake in Veropharm. In February of last year, Pharmacy Chain 36.6 said it was evaluating offers for its 50.1% stake in Veropharm as it struggled with cash-flow problems (*OTC bulletin*, 27 February 2009, page 7).

The company sold almost five million Veropharm shares – the equivalent to a 49.9% stake – in 2006 at US\$28.00 (€21.04) per share, valuing the manufacturer at US\$280 million (*OTC bulletin*, 31 May 2006, page 2).

Veropharm generates around 16% of Pharmacy Chain 36.6's turnover.

Product type	Annual sales (RUB millions)	Change (%)	Proportion of total (%)
Prescription	3,013	+7	69
Adhesive bandages	765	±0	17
OTC	527	+36	12
Traditional drugs	90	-73	2
Total Veropharm	4,395	+2	100

Figure 1: Breakdown of Veropharm's sales in 2009 by product type (Source – Veropharm)

IN BRIEF

■ **ALLIANCE PHARMA's sales grew by 44%** to £31.2 million (€34.7 million) in 2009. Operating profits rose by 77% to £11.3 million before exceptional items. The UK-based speciality pharmaceutical company, said 2009 had been a "landmark" year, with "major increases in turnover, profitability and cash generation".

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THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

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Annual Results

Plethico pushes up sales by a quarter

India's Plethico Pharmaceuticals saw sales rise by 26.4% to Rs12.5 billion (€210 million) in 2009.

The nutritional products company said it had benefited from higher sales by its US-based subsidiary Natrol and in pharmacies in the Commonwealth of Independent States (CIS). Plethico also has an operation in the United Arab Emirates (UAE).

Earnings before interest and tax (EBIT) rose by 14.3% to Rs2.24 billion in 2009.

Plethico's brands include the Travisil and Mountain Herbz herbal healthcare products; Coach's Formula sports nutrition products; and Effertabs and Therasil OTC pharmaceuticals. Natrol's lines include MRI, Prolab, Laci Le Beau, Promensil, Trinovin, and Nu Hair.

Meanwhile, Plethico's board of directors has agreed to raise the amount the company can seek through share placement offers from US\$40 million (€30 million) to US\$100 million. The new limit will be proposed at an extraordinary general meeting of Plethico's shareholders on 19 April.

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IN BRIEF

■ **ALAPIS** said its sales had increased by 8.5% to **€1.23 billion in 2009**. The Greek company's Human Health division, which includes OTC products, pushed sales up by 5% to €876 million. In February, Alapis paid €50,000 for OTC and cosmetics firm Gerolyntos Inc, which reported turnover of US\$1.85 million (€1.38 million) in 2009.

■ **GLAXOSMITHKLINE** declined to comment on media reports that it was considering taking a stake in South Korean pharmaceutical group **Dong-A Pharmaceutical**. A spokesperson for GlaxoSmithKline told *OTC bulletin* the company did not comment on market speculation. Dong-A offers a range of prescription and OTC drugs, as well as energy drinks, consumer products, active pharmaceutical ingredients and biologicals.

■ **SINCLAIR PHARMA** reported a 32% decline in sales to £11.0 million (€12.0 million) in the six months ended 31 December 2009. The UK-based speciality pharmaceutical company's **operating loss widened** to £3.9 million from £0.9 million a year earlier.

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Government Cost-Cutting Measures

BAH tells German minister to rethink rebate proposal

Non-prescription medicines should not be included in plans to increase from 6% to 16% Germany's mandatory rebate on medicines without reference prices, according to the country's medicines manufacturers' association, the BAH.

In a letter to health minister Philipp Rösler, the BAH's chairman Hans-Georg Hoffmann argues that prescriptions for non-prescription medicines have not been responsible for a rise in the drugs bill of the statutory health insurance funds. Manufacturers of non-prescription medicines should not, therefore, have to pay back an additional 10% to the statutory funds as a mandatory rebate, he maintains.

According to official data, rebate contracts for off-patent drugs cut the funds' spending on products in Germany's reference-price system in 2009, but spending on medicines not covered by reference prices grew by 8.9%.

Noting the government had laid the blame for higher costs on "cost-intensive special products", Hoffmann said this description clearly did not apply to the "highly-competitive" non-prescription sector.

Between January 2008 and February 2010, he observed, prices for non-prescription medicines reimbursed by the statutory funds had risen by just 2.8%. This, Hoffmann pointed out, was less than half of the average 6.2% price increase for medicines not covered by reference prices.

"A higher mandatory rebate for non-prescription medicines would be disproportionate," Hoffmann maintained, stressing that the industry had already been hit by the exclusion from reimbursement of most non-prescription medicines in 2004.

The government's plan to increase the mandatory rebate for drugs without reference prices from 1 August is part of a series of short-term cost-cutting measures recently unveiled in an action plan for the pharmaceutical sector.

Four-page action plan unveiled

The four-page action plan from Germany's ruling coalition of Christian Democrats (CDU), Christian Socialists (CSU) and Free Democrats (FDP) is designed to tackle last year's 5.3%, or €1.5 billion, increase in the drugs bill of the statutory funds to more than €32 billion. It is also intended to bring about more structural reforms to the sector.

The coalition's plans include strengthening cost-benefit assessments for new drugs, and encouraging funds to negotiate directly on prices for medicines that are considered to have additional therapeutic value. Furthermore, patented 'me-too' drugs that are not considered to deliver added value are to be brought into the reference-price system.

In addition to these structural changes to the patent-protected market, the coalition intends to control the rising drugs bill by implementing a price freeze until 2014, raising the mandatory rebate for drugs without reference prices from

	Sales in 2009 (€ billions)	Change 2008/2009 (%)	Proportion of market (%)
Sales of prescription-only medicines	32.31	+1.9	81
Prescription-generated sales of non-prescription medicines and unlicensed healthcare products in pharmacy outlets	1.37	-2.5	3
Self-medication or OTC sales of non-prescription medicines and unlicensed healthcare products in pharmacy outlets	4.85	-0.9	12
Self-medication or OTC sales of non-prescription medicines and unlicensed healthcare products in non-pharmacy retail outlets	0.94	+3.4	2
Self-medication or OTC sales of non-prescription medicines and unlicensed healthcare products through mail-order pharmacies	0.61	+31.6	1
Medicines and unlicensed healthcare products	40.08	+1.7	100

Figure 1: Breakdown of the German market for medicines and unlicensed healthcare products in 2009 at retail selling prices (Source – IMS Health)

6% to 16%, and amending wholesalers' margins through a combination of fixed and price-based payments.

However, the coalition insists that its plans for the reference-price system will not produce an uncontrolled downward spiral in prices. It promises to take into account during annual reference-price revisions the effects of an existing provision that allows companies to qualify their products for exemption from patient co-payments by pricing their drugs at a 30% discount to the relevant reference price.

"Rebate contracts will be further developed," the action plan states, adding that the jurisdiction of civil courts over procurement and cartel law will be established. It also heralds "flanking regulations" that will ensure vibrant competition in the market and prevent an oligopoly of leading players developing in the medium term.

In a new move, the coalition also intends to open the door for patients to receive a different medicine to the one covered by their fund's rebate contract, provided the patient pays for the difference in cost. The action plan also proposes a general rationalisation of measures in the medicines sector, but is scant on details.

Pick-up points will be banned

Distribution channels merit just three lines in the action plan. However, the coalition has committed to ban 'pick-up points', which are kiosks within drugstores at which consumers can collect prescription-only and pharmacy-only medicines ordered through a mail-order pharmacy. This move, the plan says, will "strengthen the comprehensive and safe provision of medicines to the public through pharmacies".

Reacting to the action plan, the BAH said Rösler had reneged on his promises by introducing "short-term cost-cutting interventions", rather than focusing on structural improvements to the market.

The industry association "regretted" the coalition's determination to stick with rebate contracts for generic drugs, and described the plan to allow patients to pay extra to receive specific medicines not covered by such contracts as "positive, but not enough".

Meanwhile, the association of the German pharmaceutical industry, the BPI, saw the action plan as offering "light and shade" by combining "good ideas with false measures, as well as real improvement with a lack of courage".

In the patented sector, the price moratorium and the increased mandatory discount were "improper measures", the BPI felt, while the coalition had failed to provide a clear definition of what 'benefit' meant in the context of risk-benefit assessments.

And while the plans for the off-patent market

offered some improvements – not least by giving patients more freedom to choose specific products – the coalition had "lacked the necessary courage to do away with rebate contracts".

As Figure 1 shows, the costs to the funds of prescriptions for non-prescription medicines and unlicensed healthcare products declined last year. Measured at retail selling prices, prescription-generated sales of these products fell by 2.5% to €1.37 billion, according to data from market researcher IMS Health.

Statutory health insurance funds accounted for around two-fifths of those prescriptions by value, with the other three-fifths coming from private insurance funds.

Self-medication sales of non-prescription medicines and unlicensed healthcare products through German pharmacies fared little better, slipping down by 0.9% to €4.85 billion.

This shortfall was largely offset by a 3.4% rise to €939 million in sales of general-sale medicines and unlicensed healthcare products through non-pharmacy outlets such as drugstores and supermarkets.

Drugstores accounted for just over half of that €939 million total following a 2.5% sales rise to €494 million. Turnover through super-

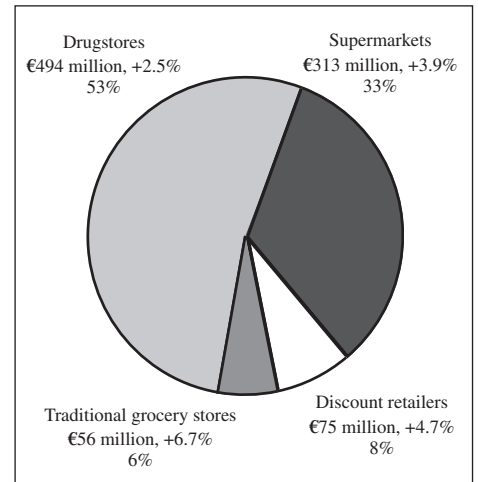


Figure 2: Breakdown by type of retail outlet of self-medication or OTC sales of non-prescription medicines and unlicensed healthcare products through non-pharmacy outlets in Germany in 2009. Total sales through these outlets rose by 3.4% to €939 million (Source – IMS Health)

markets climbed by 3.9% to €313 million, while traditional grocery stores also fared well with a 6.7% increase to €56.3 million (see Figure 2). Discount retailers made up the other 8% of non-pharmacy turnover with sales 4.7% higher at €75.3 million.

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CONSUMER *viewpoint*

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

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

Of the five countries covered by the Ipsos MORI survey, the UK has the highest proportion of people who say that they have suffered from indigestion during the past year at 16.1%, followed by Italy at 13.8%, Spain at 7.4%, Germany at 6.7% and France at 6.3% (see Figure 1).

Men are more likely than women to say that they have suffered from the condition in France, Italy and the UK, but the reverse is the case in Germany and Spain (see Figure 2).

As can be seen from Figure 3, OTC remedies are the most popular treatment option for indigestion in all five countries.

Germany has the highest proportion of sufferers who have treated their indigestion with an OTC product at 61.1% (see Figure 4).

OTC treaters are more likely to be women than men in France, but there is little to choose between the sexes in the other four countries (see Figure 5).

France and the UK have the highest proportion of people who have treated indigestion with a prescription remedy at 25.1% (see Figure 6), while Spain has the highest proportion of herbal treaters at 30.2% (see Figure 7).

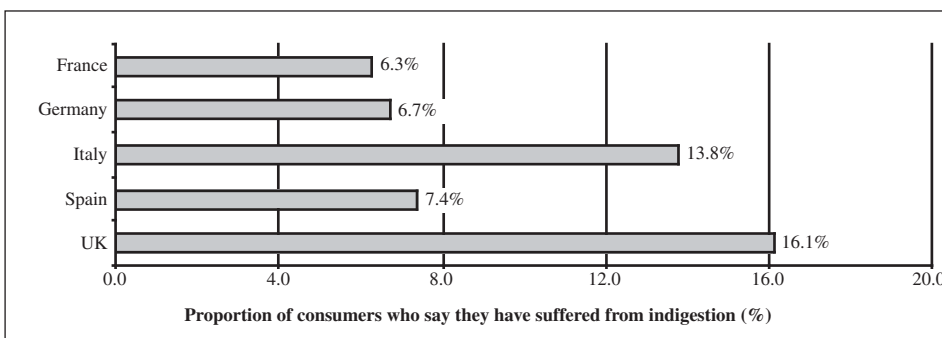


Figure 1: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from indigestion within the past year (Source – OTC bulletin 2010/Ipsos MORI)

	Proportion of sufferers (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	52.8	41.2	52.9	44.7	53.7	110	85	108	94	110
Female	47.2	58.8	47.1	55.3	46.3	90	114	92	106	90
18-24	21.4	1.3	9.1	11.6	7.2	186	15	100	97	58
25-34	19.7	2.2	19.5	23.7	12.0	104	16	111	114	72
35-44	27.6	24.8	20.4	22.4	21.5	143	123	103	118	109
45-54	18.1	14.2	17.9	11.8	21.9	118	79	109	73	129
55-64	6.0	19.8	17.9	9.3	16.7	36	138	121	74	114
65+	7.2	37.7	15.1	21.2	20.7	40	151	81	109	107

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

Ipsos MORI and the ailments survey

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

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

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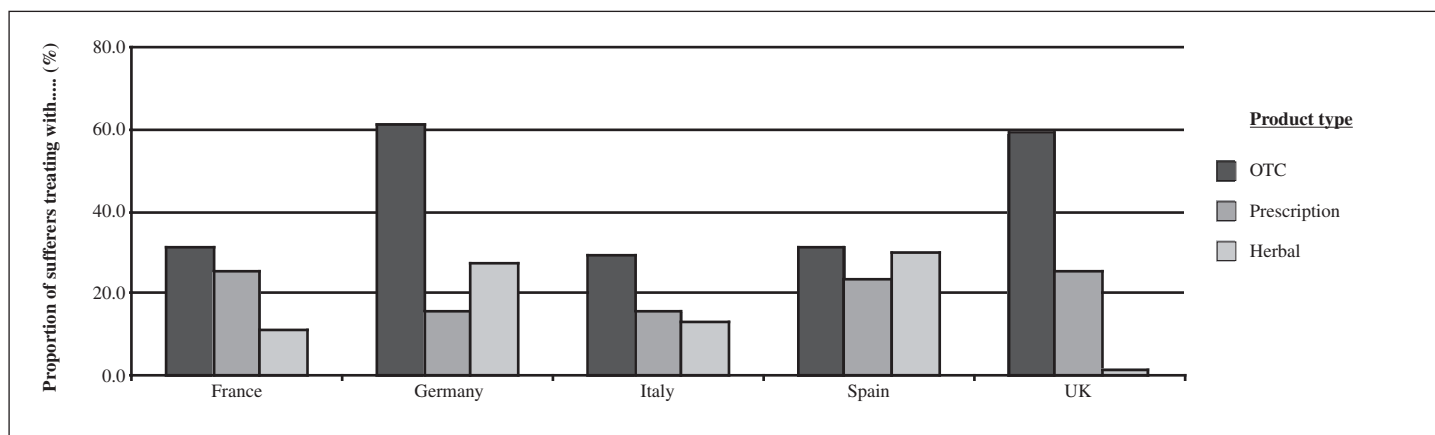


Figure 3: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from indigestion who have treated the condition with an OTC, prescription or herbal remedy (Source – OTC bulletin 2010/Ipsos MORI)

indigestion

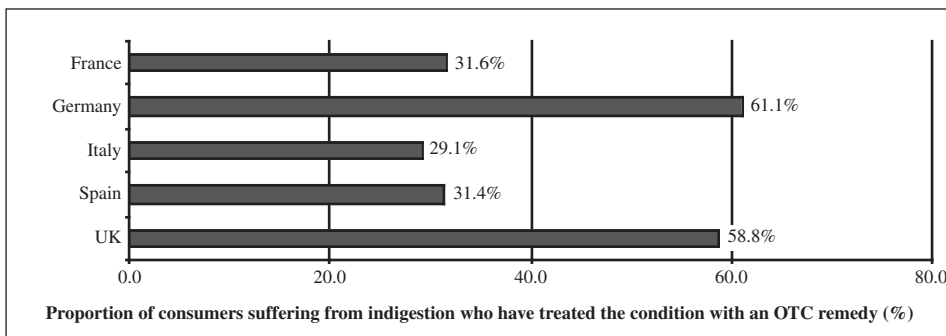


Figure 4: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from indigestion who have treated the condition with an OTC remedy (Source – OTC bulletin 2010/Ipsos MORI)

	Proportion of sufferers treating with OTC (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	35.8	46.7	46.9	49.0	47.4	75	96	96	103	98
Female	64.2	53.3	53.1	51.0	52.6	123	103	104	97	102
18-24	20.5	–	2.8	3.1	3.8	178	–	31	26	30
25-34	4.5	–	20.3	29.1	13.0	24	–	115	141	78
35-44	38.8	27.1	18.3	26.5	19.6	201	135	92	139	99
45-54	18.7	12.9	22.2	–	24.4	121	72	135	–	144
55-64	7.7	20.2	24.8	16.1	18.9	46	140	168	128	129
65+	9.8	39.8	11.5	25.2	20.4	55	159	62	129	105

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

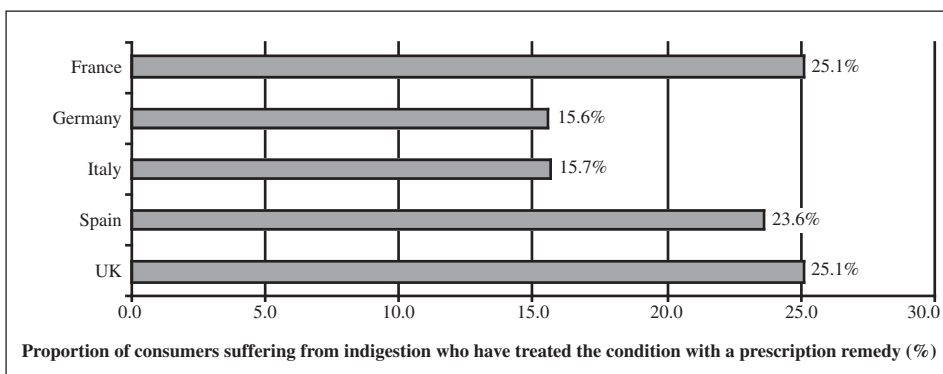


Figure 6: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from indigestion who have treated the condition with a prescription remedy (Source – OTC bulletin 2010/Ipsos MORI)

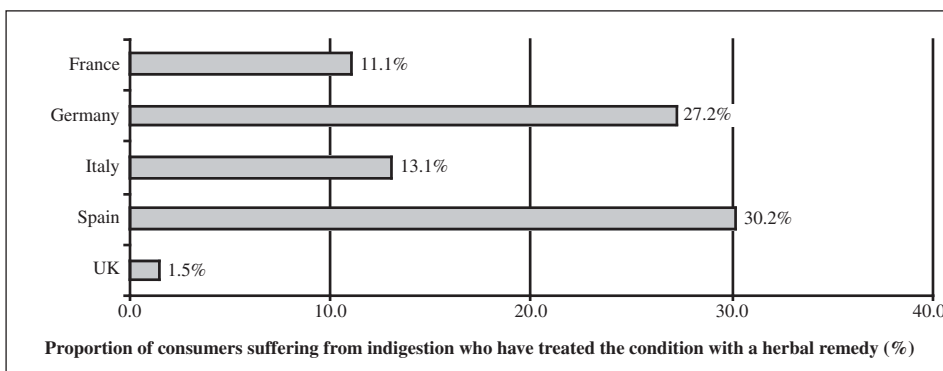


Figure 7: Proportion of consumers in France, Germany, Italy, Spain and the UK who say they have suffered from indigestion who have treated the condition with a herbal remedy (Source – OTC bulletin 2010/Ipsos MORI)

Switches

10% ibuprofen gel may go GSL in UK

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

Diomed Developments is seeking to switch 10% w/w ibuprofen gel from pharmacy to general-sales list (P-to-GSL) status. GSL classification already applies to topical 5% ibuprofen formulations.

The new GSL medicine would be sold under Dendron’s Ibuleve brand as Speed Relief Max Strength Gel.

The MHRA’s consultation document ARM 68 points out that Ibuleve Speed Relief Max Strength Gel would be indicated for the “fast local relief of rheumatic pain, muscular aches, sprains, strains and sports injuries”. The product would be supplied in a 40g tube containing 4g ibuprofen.

ARM 68 notes that topical 5% ibuprofen formulations have been available as GSL medicines for more than 10 years, and “no significant safety issues have emerged”. The Ibuleve range already includes a topical 5% ibuprofen formulation called Speed Relief Gel.

Addressing concerns about doubling the maximum strength available GSL, ARM 68 stresses that the effects of potential overdose are “minimal”. It notes that Dendron’s existing pharmacy-only medicine containing 10% ibuprofen – Ibuleve Maximum Strength Gel – has been available for almost eight years with “no reports of significant adverse effects”.

“To minimise the risk,” states ARM 68, “the patient will be alerted to the increased strength by the product name and the ‘new’ flash, and the dose volume will be clearly highlighted on the product packaging and the patient information leaflet.”

IN BRIEF

■ VALEANT Pharmaceuticals International plans to raise **US\$400 million** (€300 million) by offering senior unsecured notes due in 2020. The cash will be used in part to fund its acquisition of an unnamed Brazilian generics and OTC company. The US-based firm announced in March that it would pay US\$28.0 million for the unnamed firm and a further US\$28.0 million for a manufacturing plant in Brazil (*OTC bulletin*, 31 March 2010, page 3).

Counterfeiting

Chinese man arrested in the US for counterfeit Alli

A Chinese national has been arrested for trafficking a counterfeit and potentially-harmful version of GlaxoSmithKline Consumer Healthcare's non-prescription weight-loss medicine Alli (60mg orlistat) and other illegal dietary supplement products by federal authorities in the US.

Following an investigation partly carried out by the Food and Drug Administration (FDA), Sengyang Zhou, 30, was charged for importing the illegal drugs into the US from China and selling them over the internet.

His accomplice – a 60 year-old naturalised American born in China called Qingming Hu – was arrested for aiding the scheme and operating a branch in Texas.

Zhou – also known as Tom – was charged

in Hawaii after admitting he was the manufacturer of the counterfeit Alli at a meeting with undercover investigators who claimed to be interested in distributing the products. He appeared before a US magistrate judge in Honolulu on 23 March and, like Hu, faces prosecution in Colorado.

Commenting on the charges, FDA commissioner Margaret Hamburg said: "The FDA will work together with other government entities to aggressively target those individuals who put the public's health at risk by selling counterfeit drugs. International borders and the perceived anonymity of the internet will not deter the FDA from investigations of the law."

Counterfeits were sold as an Alli 120-count refill kit by email and websites including eBay.

After one of Zhou's customers developed heart-attack symptoms, FDA laboratory tests showed the product was a counterfeit version of Alli containing sibutramine rather than orlistat. They also linked the purchase to Zhou.

The FDA had previously warned the public of the dangers of sibutramine because it could cause high blood pressure, seizures, tachycardia, palpitations, heart attacks or strokes. "It should not be used in certain patient populations or without physician oversight," the FDA noted, adding that it could also interact in a harmful way with other medications (*OTC bulletin*, 10 February 2010, page 20).

The European Medicines Agency (EMA) recently recommended that market authorisations for sibutramine should be suspended in all markets of the European Union after it was associated with an increased risk of cardiovascular events (*OTC bulletin*, 10 February 2010, page 20).

Consumers began reporting suspected counterfeit Alli to GlaxoSmithKline in December 2009. The company urged consumers only to buy Alli from reputable retailers or from retailer's branded websites.

OTC

Regulatory Affairs

Many more herbals try traditional route in the UK

Almost double the number of traditional herbal medicine applications were received in the part-year to 23 March 2010 by the UK Medicines and Healthcare products Regulatory Agency (MHRA) than in the previous April 2008 to March 2009 period.

As Figure 1 shows, the agency received 53 applications under its traditional herbal registration (THR) scheme in the most recent period compared with 32 a year earlier. Approvals rose from 17 to 27.

The cumulative total now stands at 120 applications since the scheme was started in October 2005 in response to European Directive 2004/24/EC.

Of this number, three have been applications for products that already held product licences under the UK's previous rules. None of the three are included in the cumulative total of 56 registrations.

Although this meant that 64 applications were still outstanding last month, the MHRA

noted that none had yet been rejected.

Since October last year, the 56 registered products have been entitled to carry a certification mark. This indicates that they have been registered by the MHRA under its THR scheme, and therefore meet the required quality, safety and evidence of traditional-use standards set out in the directive.

Use of the certification mark is not compulsory. Companies can choose whether to include the THR certification mark on their registered products. However, the MHRA is recommending its use to help consumers identify those herbal medicines made to the standards set under the THR scheme.

Consumers are told the certification mark means that the MHRA has assessed the product to ensure that it is "acceptably safe" when used as intended. Moreover, it has been manufactured to the quality standards set by the agency, and is accompanied by reliable and accurate product information.

However, the MHRA goes on to stress that "the effectiveness of the product has not been assessed by the MHRA", adding that the authorised usage and dosage of the medicine is based on evidence of its traditional use.

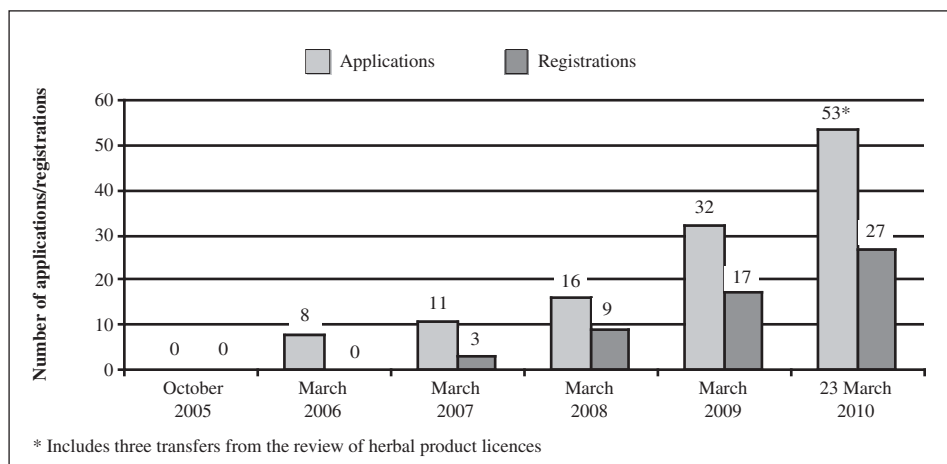


Figure 1: Applications and registrations under the UK's traditional herbal medicines registration scheme from its inception in October 2005. The numbers are for the periods between the dates shown (Source – MHRA)

OTC

Switches

Australia switches two proton-pump inhibitors

Australia will switch two more proton-pump inhibitors – lansoprazole and omeprazole – to non-prescription status with effect from 1 September 2010. They will join rivals pantoprazole and rabeprazole, which have already made the move.

However, Australia has once again turned down an application to allow non-prescription medicines based on pantoprazole to be advertised to consumers. It has also rejected similar applications for lansoprazole, omeprazole and rabeprazole.

The country's National Drugs and Poisons Schedule Committee (NDPSC) recently rejected the proposal to add 20mg pantoprazole to Appendix H, which would have allowed the medicine to be advertised to consumers. The decision was taken at its meeting on 16-17 February 2010, for which the record of reasons has just been released.

It is the third time that the NDPSC has said no to consumer advertising for 20mg pantoprazole tablets, which are marketed by Nycomed under the Somac Heartburn Relief brand as a Schedule 3, or pharmacist-only, non-prescription medicine.

When the product was first switched from prescription-only to non-prescription status, the NDPSC said it would not consider an Appendix H listing “until patterns of use of pantoprazole as a Schedule 3 medicine had been established”.

Faced with a second application last year, the committee said there was a “lack of Australian data on pantoprazole as an OTC medicine”, and it was “premature” to consider an Appendix H listing (*OTC bulletin*, 17 April 2009, page 8).

Concerns raised this time included potential interactions between proton-pump inhibitors and clopidogrel, as well as recent reports claiming an association between proton-pump inhibitors and increased incidence of fractures. The committee also discussed a suggestion that advertising for pantoprazole would “potentially impair the ability of pharmacists to adequately carry out their professional responsibilities”.

In Europe, non-prescription medicines containing pantoprazole have been advertised to consumers in several countries (*OTC bulletin*, 30 September 2009, page 30).

At its February meeting, the NDPSC agreed that oral medicines containing up to 15mg lansoprazole or up to 20mg omeprazole per dosage unit should be reclassified as Schedule 3 non-prescription medicines. They will be indicated for relief of heartburn and other symptoms of gastro-oesophageal reflux disease, and the packs will be restricted to a 14-day supply.

Also at its February meeting, the NDPSC ruled out a switch for oral famciclovir following a referral from New Zealand's Medicines Classification Committee. The NDPSC had already rejected such a reclassification twice before (*OTC bulletin*, 18 December 2009, page 9).

At the beginning of this year, New Zealand became the first country in the world to give non-prescription status to oral famciclovir for treating cold sores (*OTC bulletin*, 20 January 2010, page 10).

February 2010, page 18). The spot, which has an opening sequence reminiscent of the film *Reservoir Dogs*, sees Nuro eliminating five anti-heroes known as “The Headaches”. These take the form of dark creatures representing thumping, piercing, irritating, niggling and annoying headaches.

Nuro comes to the rescue, targeting them with Nurofen and turning “The Headaches” into fluffy creatures known as “The Reliefs”.

Reckitt Benckiser said the claim would also be used in a wider multimedia campaign encompassing online initiatives, in-store activity and public relations.

Regulatory Affairs

German court bans ginkgo biloba teas

Ginkgo biloba leaves are a medicine and cannot be used in an unlicensed tea, a German district court in Hamburg has decided.

Ruling on the basis of competition law, the Hamburg court found a tea containing 10% ginkgo biloba leaves contravened Germany's food law by including a banned additive. “A typically informed and knowledgeable consumer,” the court stated, “would hold ginkgo biloba leaves to be a medicine rather than a food.”

Dozens of products containing ginkgo biloba are classified as pharmacy-only medicines in Germany.

The court added that it was irrelevant to the situation in Germany whether different rules applied in other member states of the European Union. Consumer protection was an issue of national competency, it pointed out.

Court has also ruled on capsules

Last year, the same court banned a food supplement consisting of capsules containing 100mg ginkgo biloba extract (*OTC bulletin*, 30 November 2009, page 11).

OTC

Switches

Trimethoprim switch is stopped in the UK

■ Continued from front page

-creased bacterial resistance. The subject was covered in some detail in the MHRA's consultation document, which noted that the Committee on Safety of Medicines was seeking independent expert advice in parallel with the consultation. It was particularly keen to find out how P availability could affect the resistance rate and how resistance could be monitored in the self-medication environment.

Will continue to pursue switches

Announcing its withdrawal, Actavis said it would continue to pursue its “robust POM-to-P pipeline in other therapeutic areas”.

The company has already switched 500mg azithromycin tablets in the UK for treating chlamydia under the Clamelle brand.

The UK was the first country in the world to give non-prescription status to the oral antibiotic azithromycin (*OTC bulletin*, 29 August 2008, page 1).

OTC

Marketing Campaigns

Nurofen targets paracetamol

■ Continued from front page

“challenge consumers' purchasing decisions”. “Research has shown that 52% of consumers would use paracetamol to treat their headache pain,” it noted.

The claim is the sign-off message at the end of a new television commercial for Nurofen that made its debut in the UK on 12 April.

Created by the agency Mother, the 30-second commercial features the animated superhero Nuro, who was first seen in Nurofen advertising earlier this year (*OTC bulletin*, 10



SSL International has extended its Scholl footcare brand in the UK with a range of products formulated to “banish hard, stubborn skin on the feet”.

The trio of products includes the Scholl Hard Skin Softening Pen, which is described on the packaging as a “no-mess precision applicator”.

SSL said the pen had been designed for treating rough skin in small areas that were tough to tackle, such as toes and the underside of feet. It contains salicylic acid and fruit acids, and is claimed to produce a “visible effect in seven days”.

The second new addition – Scholl Hard Skin Softening Cream – is formulated for use on larger areas including the heels and balls of the feet. SSL said the cream contained salicylic acid to break down the hard skin cells, and lactic acid to soften and plump up the skin underneath, revealing visibly softer skin in seven days.

Both the pen and cream can be used with the new Scholl Instant Hard Skin Remover, which SSL described as a “revolutionary” device that scraped away the toughest of hard skin. The company said it used a “safe and effective” blade technology to remove hard skin without damaging healthy skin.

The Scholl Hard Skin Softening Pen is a 2ml unit with a recommended retail price of £6.99 (£7.95), the Scholl Hard Skin Softening Cream comes in a 75ml pack priced £5.99, and the Scholl Instant Hard Skin Remover sells for £9.99.

IN BRIEF

■ **ASA** – the UK’s Advertising Standards Authority – has upheld a complaint about a magazine advertisement for SMA Nutrition’s **SMA Follow-on Milk**, which featured the claim “For every stage, a formula”. The ASA said the advertisement implied that SMA products could be used for the entirety of a child’s development which included the period from birth. The advertisement was “irresponsible” because it indirectly promoted infant formula, concluded the ASA. Meanwhile, the ASA rejected a complaint about another claim in the advertisement, which stated that omega-3 and omega-6 were “critical in a child’s development”.

■ **SSL INTERNATIONAL** said three condoms just introduced in the UK were the “thinnest” ever produced by the **Durex brand**. The thinnest of the three is the polyurethane condom Durex Deluxe, while Durex Fetherlite Ultra is the brand’s “thinnest-ever latex condom”. Durex RealFeel is a non-latex condom that offers a “truly natural skin-on-skin feeling”.

Switches

Zegerid urges Americans to discover the difference

A man taking off his shirt and painting a series of images on his chest is the eye-catching advertising concept that Schering-Plough has chosen for the launch of Zegerid OTC in the US.

The television commercial, which is built around the slogan “Discover the Difference”, opens with the fully-clothed man telling viewers he has “big news for everybody with frequent heartburn”.

“Let me show you,” he says, removing his shirt and painting the first image on his chest. “There’s a new 24-hour heartburn formula that’s different,” he explains, painting a heart with flames coming out of the top. “It’s called Zegerid OTC,” he adds, whilst painting the brand logo.

“Only Zegerid OTC has both prescription-strength medicine and a special ingredient to allow its powerful medicine to be quickly absorbed,” continues the man, whilst painting a series of images including a hare to illustrate speed of action. “Zegerid OTC controls and suppresses acid all day and all night.”

The final painting is a light bulb to support the claim that “there’s a brilliant new idea in heartburn relief”. The commercial ends with a pack of Zegerid OTC and the message “New Zegerid OTC. Discover the Difference”.

Zegerid OTC has been launched in the US after the Food and Drug Administration (FDA) approved Schering-Plough’s application for a switch from prescription to OTC status (**OTC bulletin**, 18 December 2009, page 14). It combines 20mg of the proton-pump inhibitor omeprazole with 1,100mg sodium bicarbonate.

Frequent heartburn sufferers in the US now have three OTC medicines based on proton-pump inhibitors to choose from. Zegerid OTC competes with Novartis Consumer Health’s recently-launched lansoprazole-based Prevacid 24HR (**OTC bulletin**, 16 November 2009, page 1), and Procter & Gamble’s established omeprazole-based Prilosec OTC in the US market for frequent heartburn products. There are also many store-brand versions of Prilosec OTC.

Zegerid OTC’s omeprazole-based formulation puts it in direct competition with Procter & Gamble’s Prilosec OTC (20mg omeprazole). However, unlike its rival, Zegerid OTC is built on what Merck & Co – which acquired Schering-Plough during November (**OTC bulletin**, 16 November 2009, page 3) – described as a



“Discover the Difference” is the theme of Schering-Plough’s launch television commercial for Zegerid OTC in the US

“unique dual-ingredient formulation” featuring sodium bicarbonate to protect the omeprazole from stomach acids.

Like Prevacid 24HR, Zegerid OTC capsules will be available in their original prescription formulation, but Zegerid OTC will benefit from patent protection until 2016.

Prevacid 24HR (15mg lansoprazole) – which Novartis believes will be one of the “biggest prescription-to-OTC switches”, as well as a “top five OTC brand in the US” – is only protected by three years of marketing exclusivity ending in May 2012 (**OTC bulletin**, 31 July 2009, page 6), as its patent protection expired in October 2009.

Schering-Plough gained the exclusive rights to market Zegerid OTC in both the US and Canada through a licensing agreement with Santarus (**OTC bulletin**, 31 October 2006, page 1).

Santarus said the OTC heartburn market in the US was worth US\$1.7 billion (€1.25 billion) a year based on figures from Information Resources and company estimates.

Switches

UK authorises switch for heavy menstrual bleeding

Women suffering from heavy periods will soon be able to buy tranexamic acid tablets without a prescription in the UK.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has given the go-ahead for Meda Pharmaceuticals' 500mg tranexamic acid tablets to be switched from prescription-only to pharmacy (POM-to-P) status. Cyklo-f will be available through pharmacies for women aged 18 to 45 years with a history of regular heavy menstrual bleeding – menorrhagia – over several consecutive cycles.

A spokesperson for Meda told **OTC bulletin** that Cyklo-f would be launched into the OTC market in “early 2011”.

Meda currently markets 500mg tranexamic acid tablets as the prescription-only drug Cyklokapon, which is used by 40,000 women in the UK a year. The drug made its worldwide debut 40 years ago, and has been available without a prescription for menorrhagia in Sweden since 1997.

The MHRA started consulting on Meda's switch application more than three years ago (**OTC bulletin**, 27 February 2007, page 9).

It received 19 responses to the consultation, of which 13 were favourable. Those in favour of the switch believed women were able to self-

diagnose heavy menstrual bleeding, and felt pharmacy availability of tranexamic acid would provide greater convenience.

Unfavourable responses to the consultation questioned the haematological safety of tranexamic acid and raised the potential for misdiagnosis of other underlying conditions.

Concerns that pharmacy availability could mask an underlying condition, such as endometrial or cervical cancer, and delay diagnosis and treatment, were addressed in the MHRA's consultation document ARM 39. “The critical issue in both cases is that the bleeding is irregular,” said ARM 39, adding that “the importance of determining this factor to supplying Cyklo-f for self-medication will be strongly highlighted in the pharmacy protocol and Pharmacists' Training Pack”.

Commenting on the switch, June Raine, the MHRA's director of vigilance and risk management of medicines, said that “quick access to treatment will allow women to successfully take charge of this condition”. “Making Cyklo-f available through pharmacies without a prescription is an important step for women, helping improve their quality of life and provide them with the greater convenience of better access to medicines,” she added.

Launches

Catacrom eye drops are preservative-free

Preservative-free eye drops for relieving allergy symptoms have been launched in the UK by Moorfields Pharmaceuticals.

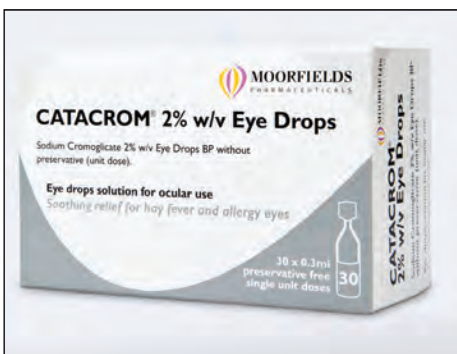
Called Catacrom, the 2% w/v sodium cromoglicate eye drops are supplied as single unit

doses that do not need any preservatives. Moorfields said the innovative presentation meant symptoms would not be exacerbated by preservatives, which were often used in multi-dose formats.

Pharmacy-press advertising explains that Catacrom is a “new presentation”, which provides “relief and treatment of seasonal and perennial allergic conjunctivitis” and “prevents allergic symptoms such as redness, watering, itching and puffiness”.

A pharmacy-only medicine, Catacrom comes in a pack of 30 single unit doses, and should be used four times a day. The National Health Service (NHS) trade price is £8.99 (€10.19).

A strapline on the predominantly-white packaging points out the product provides “Soothing relief for hayfever and allergy eyes”.



Catacrom 2% sodium cromoglicate eye drops come in single unit doses that do not require preservatives



A stopwatch symbolises rapid relief in the latest pharmacy-press advertising for Novartis Consumer Health's Lamisil athlete's foot brand in Germany. The stopwatch, which is held by the outline of a foot, appears beneath the headline “Nichts hilft schneller gegen Fußpilz”. This translates as “Nothing helps more quickly against athlete's foot”. The advertisement claims the terbinafine-based brand is Germany's leading athlete's foot treatment. Bullet-points highlight that the 1% terbinafine formulations treat athlete's foot in just one week. The fungicidal active ingredient remains within the skin for up to 13 days, they point out.



Altacor has repackaged its Clinitas Soothe dry eye relief drops in a purple and blue pack that is said by the company to be “easier to spot” in UK stores. Straplines on the packaging highlight that the 0.5ml daily-dose units are “resealable”, and that the product provides “quick, soothing, effective relief for dry, gritty, irritable eyes”. Consumers are also reminded that the product is “gentle and preservative free” and “suitable for contact lens wearers”. Based on 0.4% sodium hyaluronate, Clinitas Soothe comes in packs of 20 sterile, daily-dose vials that can be recapped for up to 12 hours. The recommended retail selling price is £6.49 (€7.30).

Launches

Boots offers Brez to British snorers

“Clinically-proven to significantly reduce snoring” is the promise to Britons for a new nasal breathing aid available exclusively from Boots.

The retailer said Airware’s Brez was a soft and pliable device that fitted inside the nostrils. It worked by supporting the tissues in the nose to aid unrestricted airflow in and out of the nas-



Brez is a new anti-snoring product available exclusively in the UK from retailer Boots

al passageway, explained Boots, adding that the product reduced snoring by more than 50% in clinical trials.

Boots is backing the launch with public relations activity targeting the consumer press.

Journalists were given the chance to win a voucher worth £500 (€565) by entering a “spot the snorer” competition. They had to pick the human snorer from three sound clips of snoring creatures.

Boots is also working with Chris Idzikowski, sleep expert at the Edinburgh Sleep Clinic, for the launch.

Brez comes in three sizes and has a recommended retail selling price of £12.99 for a 14-day supply.

Straplines on the packaging highlight that the product is “a premium nasal breathing aid” that is “clinically proven to significantly reduce snoring”. They also point out that Brez does not contain drugs, latex or adhesives.

Brez is already available in the US.

Legal Actions

US court rules Perrigo was fair to compare with brand

Inviting consumers on product packaging to compare store-brands with established brands was both fair and legal, according to a jury in a New York district court.

In a case brought by Rexall Sundown against Perrigo over the former’s Osteo Bi-Flex brand, the New York jury found unanimously that Perrigo’s statement was not false and misleading, and was therefore not illegal.

Joseph Papa, Perrigo’s chairman and chief executive officer, commented: “[Our] statement helps consumers identify the store-brand they want, and helps them save as they choose the

affordable, store-brand option.” The verdict was an “important victory” for store-brands, US retailers and consumers, he added.

The jury found unanimously in favour of Perrigo’s statement on both wholesalers’ and retailers’ store-brand packaging for its joint-care products with glucosamine and chondroitin.

A false-advertising counterclaim by Perrigo against NBTY subsidiary Rexall Sundown was also decided in the store-brand specialist’s favour. Used by Rexall Sundown from 2006 to 2008, the statement was found to be false and misleading by the jury.

OTC

People

Scheske leaves GlaxoSmithKline

Continued from front page

medicine] Alli, which surpassed ambitious expectations.”

Walmsley has been recruited from cosmetics company L’Oréal as worldwide-president-designate to succeed Clarke, 61, within the next two years (OTC bulletin, 31 March 2010, page 1). In the meantime, she will serve as European president in place of Scheske.

An internal announcement of Scheske’s decision highlights that his most recent success was the “phenomenal” pan-European launch of Alli in 29 countries in 2009. “This was the first-ever pan-European switch,” notes the announcement, “and under Manfred’s leadership Alli became the third-largest OTC brand in Eur-

ope, receiving numerous awards from the industry, and achieving sales in excess of £100 million (€115 million) in its first year.”

President of the firm’s European Consumer Healthcare unit since 2004, Scheske had grown the business from sales of £1.3 billion to just under £2.0 billion. He was “widely acknowledged as an inspirational leader”, the company commented.

Previously, Scheske had spent six years leading the North American business, building a market-leading position in smoking cessation and playing a key role in acquiring Block Drug and its Sensodyne brand.

OTC bulletin understands that Scheske is currently seeking a new position.

OTC

A larger heat pack for people suffering from severe back pain is the latest addition to Kobayashi Healthcare’s Cura-Heat brand in the UK.

Kobayashi said new Cura-Heat Back Pain Max Size was twice as large as the original Cura-Heat Back Pain product. “It delivers warmth over a larger area making it more suitable for those who may suffer from severe back pain,” noted the company.

According to Kobayashi, the heat pack was “thin and discreet” and had been developed for customers who suffered from severe pain but did not want products that were bulky or cumbersome to apply.

A box of two heat packs has a recommended retail selling price of £4.49 (€5.05). A strapline on the packaging points out that the product provides relief for 12 hours.

Kobayashi said it would back the Cura-Heat range with an “extensive” television advertising campaign running from the end of 2010 into 2011.



OTC

MAY

6 May

■ **Healthcare Products and Food Supplements**

Bonn, Germany

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

Contact: BAH, Ueberstrasse 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.

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

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

Contact: Management Forum, 98-100 Maybury Road, Woking,

Surrey GU21 5JL, UK.

Tel: +44 1483 730071.

Fax: +44 1483 730008.

E-mail: registrations@management-forum.co.uk.

Website: www.management-forum.co.uk.

18-20 May

■ **Vitafoods**

Geneva, Switzerland

A three-day exhibition and conference covering nutraceuticals, cosmeceuticals and functional foods.

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.

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; Etienne de Larouillière, vice-president and head of global business unit OTC at Nycomed; and Dirk Van De Put, president and chief executive officer, global OTC, at Novartis Consumer Health.

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

Contact: AESGP, 7 Avenue de Tervuren, 1040 Brussels, Belgium.

Tel: +32 2 735 51 30. Fax: +32 2 735 52 22. E-mail: c.andreason@aesgp.be.

Website: www.aesgp.be.

30-31 May

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

Dubai, United Arab Emirates

Bahrain, Kuwait 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.

scription 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.

22-23 June

■ **Pharmaceutical Regulatory Affairs in Canada**

London, UK

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

Contact: Management Forum, 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 pre-

CRN offers supplement webinars

The US Council for Responsible Nutrition (CRN) and Virgo Publishing are running a trio of webinars in 2010.

The first of these – entitled 'Dietary supplement safety: understanding the role of adverse event reports in product recalls' – will take place on 6 May at 14.00 hours (Eastern Daylight Time).

The CRN said the two-hour webinar would provide a basic understanding of the role of a corporate post-market safety surveillance system that includes adverse event reporting to meet mandatory requirements of the US Food and Drug Administration (FDA). A session on post-market surveillance presented by Rick Kingston, president of SafetyCall International, will be followed by a presentation on standardised terminology led by Patrick Revelle, director of MedDRA MSSO. Bob Moore of the FDA's Center for Food Safety and Applied Nutrition will share the agency's perspective.

The other two webinars are scheduled for 3 August and 4 November. Topics and speakers have not yet been announced.

Visit www.naturalproductsinsider.com to find out more about the three webinars.

OTC

JULY

14 July

■ **Marketing Authorisation in Japan**

Frankfurt, Germany

Gaining marketing authorisations for generics and new chemical entities in Japan will be one of the subjects discussed at this one-day conference.

Contact: Forum Institut für Management, Postfach 10 50 60, 69040 Heidelberg, Germany.

Tel: +49 6221 500 680.

Fax: +49 6221 500 555.

E-mail: h.wolf-klein@forum-institut.de.

Website: www.forum-institut.com.

Pricing and distribution stay on French agenda

Pricing and distribution are very much on the OTC agenda in France, with industry seeking more self-selection displays in pharmacies and supermarket chain Leclerc continuing to challenge the pharmacy monopoly. David Wallace looks at the trends.

Waging war against French pharmacists over the pricing and distribution of OTC medicines is becoming a habit for Leclerc. A court of appeal has just allowed the supermarket giant to resume an advertising campaign arguing that France's pharmacy monopoly on the sale of non-prescription medicines should be removed. Leclerc insists that its parapharmacies – which do not have the legal status of a pharmacy but are managed by pharmacists and sell food supplements and other health and beauty products – should be allowed to sell a selection of medicines to stimulate price competition.

Unsurprisingly, the campaign – which echoes a similar Leclerc publicity initiative during 2008 (*OTC bulletin*, 29 April 2008, page 18) – has provoked a strong reaction from pharmacists. A court of first instance initially judged Leclerc's message to be damaging to the profession and ordered the television commercial – which is based around a sick woman in bed dreaming of OTC medicines at “Leclerc prices” – to be suspended. It also told the retailer to take down the campaign website.

However, that decision has now been successfully appealed, and the campaign is once again tilting at France's distribution rules.

Leclerc says it only wants to establish gen-

uine competition, claiming that the prices of some non-reimbursable, non-prescription medicines can vary by as much as three times between different pharmacies. The supermarket argues that allowing new distributors to sell self-medication products would result in prices being more competitive. Furthermore, it insists the majority of French consumers care about pricing, but are prevented from drawing comparisons due to a lack of information and poor communication where prices are concerned.

However, a recent survey of French consumers found that less than a quarter would be happy to see medicines made available in supermarkets. According to the survey – which was conducted by UPMC and GERMS with the support of the French OTC industry association, AFIPA – over three-quarters, 77%, opposed the sale of medicines in supermarkets (see Figure 1).

Furthermore, only one in 20 of those surveyed said that they would be prepared to buy medicines via the internet if this were possible (see Figure 2).

The survey did find that pricing was important to French consumers. Nearly half of those surveyed said pricing was important or very important when choosing a medicine. However, few were aware of the actual retail sell-

	Value sales in 2009 (€ billions)	Change (%)	Volume sales in 2009 (units millions)	Change (%)
<i>Self-medication sales of non-reimbursable, non-prescription medicines</i>	1.6	+0.2	285.1	-2.1
<i>Self-medication sales of reimbursable, non-prescription medicines</i>	0.3	+2.2	139.7	+3.0
Total self-medication sales of non-prescription medicines	1.9	+0.6	424.8	-0.5
Prescription-generated sales of non-prescription medicines	3.6	–	–	–
Total non-prescription medicines market	5.5	+1.1	–	–

Figure 3: Breakdown of France's non-prescription medicines market in 2009. Value sales are at retail selling prices (Source – IMS Consumer Health/AFIPA)

Product category	Value sales (€ millions)	Change (%)	Proportion of total (%)	Volume sales (units millions)	Change (%)	Proportion of total (%)
Respiratory tract	471.3	-0.7	29.5	92.9	-0.3	32.6
Gastrointestinal medicines	235.7	+6.1	14.8	41.0	-4.2	14.4
Analgesics	189.8	+2.5	11.9	43.7	+1.3	15.3
Skin treatments	141.8	+0.2	8.9	24.9	+0.2	8.7
Circulatory products	123.0	+1.9	7.7	17.4	-6.5	6.1
Mood modifiers	76.8	-2.0	4.8	16.4	-3.6	5.8
Vitamins, minerals and supplements	76.2	+6.0	4.8	12.1	+0.1	4.2
Nicotine-replacement therapies	73.6	-1.5	4.6	4.0	-3.5	1.4
Oral-care products	35.7	-6.6	2.2	5.9	-8.8	2.1
Eyecare products	35.4	-4.2	2.2	6.4	-5.4	2.2
Top 10	1,459.2	+1.0	91.3	264.6	-1.6	92.8
Others	138.2	-7.4	8.7	20.5	-7.5	7.2
Self-medication sales of non-reimbursable, non-prescription medicines	1,597.4	+0.2	100.0	285.1	-2.1	100.0

Figure 4: Breakdown of France's 'strict' OTC market – self-medication sales of non-reimbursable, non-prescription medicines – in 2009. Value sales are at retail selling prices (Source – IMS Consumer Health/AFIPA)

ing prices of well-known OTC products.

Carried out between December 2009 and February 2010, the survey marks 18 months since the 'free-access' initiative was implemented in pharmacies by the French government on 1 July 2008 (*OTC bulletin*, 31 July 2008, page 17). For the first time, self-selection displays of certain non-prescription medicines were permitted within pharmacies, and the prices of these medicines had to be clearly indicated. The government's objectives were to promote self-medication, to make the OTC medicines sector more competitive, and to increase the involvement of consumers.

Following some new additions earlier this year, the list of free-access medicines now comprises 334 products, including 28 homoeopathic medicines and 22 herbal medicines. Among the categories covered by the list are antacids, anti-diarrhoeals, nicotine-replacement therapies, pain relievers, skin treatments, sore-throat products and tonics.

Nearly half of all pharmacies in France have now introduced self-selection displays, according to the survey, which found that the free-access initiative was "slowly but surely" making progress.

However, although the survey found that the free-access initiative was better known and better perceived than a year ago, there had been little change in buying habits since its launch. Around 59% of consumers surveyed said they had never bought a free-access medicine, 10% said that they had done so on only one occasion, and 31% said they had bought free-access medicines more than once. These figures were broadly in line with the findings of a similar survey a year ago.

Slow to gain a hold

AFIPA observed that the free-access initiative had been slow to gain a hold, and had produced only a limited impact on the OTC industry as a whole.

According to market data just released by IMS Consumer Health and AFIPA, total sales of all products in French pharmacies grew by 0.7% in both volume and value terms in 2009, with unit sales of 3.5 billion equating to value sales of €35 billion. Sales of medicines were up by 0.5% to €30 billion, while sales of unlicensed products grew by 2.5% to €5 billion.

IMS drew attention to the fact that the pharmacy market had done better in 2009 than in 2008, when value sales had slipped back slightly by 0.02% and volume sales had fallen by 3.5%. "The pharmacy market was one of the few industrial sectors in France to have performed better in 2009 than 2008," said IMS.

Within the €30 billion medicines sector, the vast majority of sales, 81.7%, came from pre-

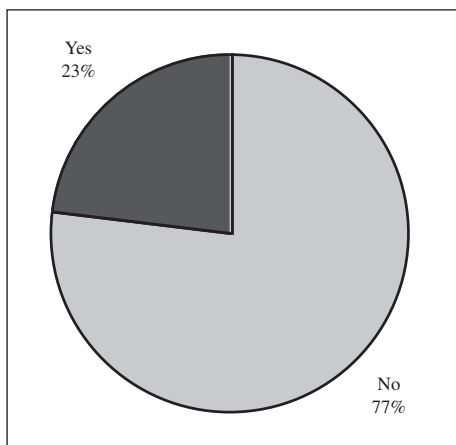


Figure 1: Response of French consumers when they were asked between December 2009 and February 2010: "Would you be happy if medicines were sold in supermarkets?"
(Source – UPMC/GERMS/AFIPA)

scription-only medicines. The remaining 18.3% came from non-prescription medicines.

As can be seen from Figure 3, total sales of non-prescription medicines increased by 1.1% to €5.5 billion in 2009. Two-thirds of this – €3.6 billion – was generated by prescriptions.

France's self-medication sector – encompassing self-medication sales of both reimbursable and non-reimbursable non-prescription medicines – recorded growth of 0.6% to €1.9 billion in 2009, which was slightly better than the 0.5% for medicines overall. However, volume sales were down by 0.5% to 425 million units.

Self-medication sales of reimbursable, non-prescription medicines did particularly well, moving ahead by 2.2% in value terms to €0.3 billion and by 3.0% in volume terms to 140 million units.

IMS said there had been a "positive market dynamic" in 2009, driven by dermatology products and winter remedies such as analgesics and cough/cold products. Paracetamol-containing medicines – both branded and generic – remained important, added IMS, and syrups did well in the respiratory-tract category.

IMS highlighted the arrival of generics producers in certain product categories, notably vitamins and minerals, eyecare and oral care. The effects of the financial crisis had been keenly felt, noted IMS, with more than two in five consumers admitting to buying fewer medicines and opting for cheaper products.

Looking at the so-called 'strict' OTC market – self-medication sales of non-reimbursable, non-prescription medicines – trends were not so good. Value sales only edged up by 0.2% to €1.59 billion in 2009, and volume sales decreased by 2.1% to 285 million units.

This compared with value growth of 4.0% in 2008, following the delisting from reimbursement of vein tonics on 1 January 2008 (*OTC bulletin*, 14 February 2006, page 9). Exclud-

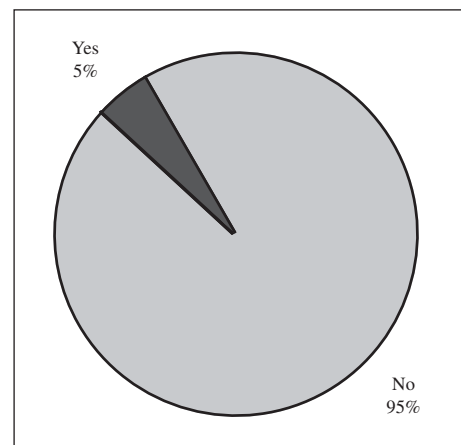


Figure 2: Response of French consumers when they were asked between December 2009 and February 2010: "If it was possible, would you buy your medicines via the internet?"
(Source – UPMC/GERMS/AFIPA)

ing vein tonics, self-medication sales of non-reimbursable, non-prescription medicines were flat in 2008, according to IMS.

IMS pointed out that the strict OTC market had benefited last year from increased demand for winter remedies – particularly Boiron's Oscilloccinum – in the wake of concerns about flu. In the analgesics category, oral 400mg ibuprofen formulations had done well.

Generics increasing in importance

The strict OTC market had been lifted by the performance of well-established brands, IMS stated, as well as the arrival of important new products like GlaxoSmithKline's weight-loss medicine Alli (orlistat) and Nycomed's Pantozol Control (pantoprazole). However, the market researcher noted that generic OTC medicines accounted for one out of every 10 packs sold in some product categories.

Respiratory-tract products was the largest category within the strict OTC market, accounting for almost a third of total sales in both value and volume terms. Value sales dropped by 0.7% to €471 million, while volume sales fell by 0.3% to 92.9 million units in 2009 (see Figure 4).

Looking at innovation, IMS said there had been 76 product launches in the strict OTC market during 2009. These generated sales of €41.7 million, representing 2.6% of the strict OTC market. As can be seen from Figure 5 on page 20, GlaxoSmithKline's Alli alone accounted for 58% of this €41.7 million.

Nycomed's Pantozol Control was another significant entry, but came too late to have a meaningful impact on sales.

In volume terms, Boehringer Ingelheim's new addition to its Lysopaine brand led the way. The newcomer generated more than a fifth of the combined volume sales of the 76 new products, despite only having been introduced in September.

Average retail prices of medicines in the total self-medication market were little changed in 2009. The overall increase was just 1.0%, as the average price of non-reimbursable, non-prescription medicines moved ahead by 2.3%, while the average price of reimbursable, non-prescription medicines declined by 0.8% (see Figure 6).

IMS pointed out that the 2.3% rise for strict OTC products was largely due to the launch of GlaxoSmithKline's Alli. Excluding Alli, the increase would have been just 1.1%.

Boiron was the number one company in the strict OTC market in 2009, up from third place in 2008 (see Figure 7). But Sanofi-Aventis was the top player in terms of total self-medication sales (see Figure 8). GlaxoSmithKline climbed from tenth to seventh place in both tables, thanks to the launch of Alli.

Developments in the pipeline

Commenting on prospects for 2010, IMS said the year had got off to a "gentle" start, but there were developments in the pipeline.

For example, France's health minister Roselyne Bachelot announced last October that the government would reduce the reimbursement rate of a number of medicines – including some non-prescription products – from 35% to 15%. More details should be released in May.

An interesting development for pharmacists will be France's new HPST law on "hôpital, patients, santé et territoires" or "hospitals, patients, health and territories". The law positions pharmacists as the first point of contact for people with a health problem, and provides for the creation of a regional healthcare agency to organise all healthcare professionals at a local level. This is likely to result in new duties for pharmacists, as they play a more involved role in national public-information campaigns and healthcare education.

	Average retail prices of medicines in 2009 (€ per pack)	Change (%)
Non-reimbursable, non-prescription medicines	5.60	+2.3
Reimbursable, non-prescription medicines	2.50	-0.8
Total self-medication market	4.58	+1.0

Figure 6: Average retail prices in French self-medication market in 2009 (Source – IMS Consumer Health/AFIPA)

Rank 2009	Rank 2008	Company	Proportion of sales (%)
1	3	Boiron	8
2	1	McNeil	7
3	2	Sanofi-Aventis	7
4	4	Pierre Fabre	6
5	5	UPSA	6
6	6	Bayer	6
7	10	GlaxoSmithKline	5
8	7	Merck KGaA	4
9	8	Cooper	4
10	9	Reckitt Benckiser	4
–	–	Others (208)	43

Figure 7: Top 10 companies ranked by self-medication sales of non-reimbursable, non-prescription medicines by value at retail selling prices in France in 2009 (Source – IMS Consumer Health/AFIPA)

Rank 2009	Rank 2008	Company	Proportion of sales (%)
1	1	Sanofi-Aventis	11
2	2	UPSA	7
3	3	McNeil	7
4	5	Boiron	6
5	4	Pierre Fabre	6
6	6	Bayer	5
7	10	GlaxoSmithKline	4
8	8	Reckitt Benckiser	4
9	7	Cooper	4
10	9	Merck KGaA	3
–	–	Others (231)	43

Figure 8: Top 10 companies ranked by self-medication sales of non-reimbursable and reimbursable, non-prescription medicines by value at retail selling prices in France in 2009 (Source – IMS Consumer Health/AFIPA)

Despite Leclerc's efforts, France's existing distribution system for non-prescription medicines looks set to remain in place for the foreseeable future. The pharmacy monopoly on the sale of non-prescription medicines seems unlikely to be relaxed. Meanwhile, last year's ruling by the European Court of Justice (ECJ) means France can keep its ban on pharmacy chains (*OTC bulletin*, 29 May 2009, page 1).

However, Andy Tisman, consulting principal at IMS Consumer Health, points out that symbol groups, like Alliance Boots' Alphega Pharmacy, are playing an increasingly important role in France. "Alphega behaves in some respects like a pharmacy chain," says Tisman.

Launched in 2001, Alphega Pharmacy claims to support more than 2,700 independent pharmacy members in six countries – the Czech Republic, France, Italy, Russia, Spain and the UK. Members have access to pharmacy-management resources, increased buying and negotiating power, and exclusive retail brands.

IMS also noted that free-access had been slow to establish itself. The recent survey highlighted that a number of problems needed to be resolved. Consumers still felt poorly informed about free access, according to the survey, and better signing and management of free-access zones in pharmacies was needed.

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Product	Month of launch	Value sales (€ millions)	Proportion of sales value (%)	Volume sales (units millions)	Proportion of sales volume (%)
Alli gelules 60mg 84	April	19.3	46.3	0.36	9.1
Alli gelules 60mg 42	April	5.0	11.9	0.13	3.4
Lysopaine nf cpr a suc ss 36	September	4.3	10.3	0.85	21.7
Mucomyst sac. Pdr 200mg 15 3.5g	February	2.4	5.8	0.70	17.8
Nurofenflash cpr pellicu 400mg 12	September	1.5	3.7	0.38	9.8
Dulcolax cp gastrores 5mg 30	September	1.5	3.6	0.29	7.4
Nicorette Inhal cart 10mg 42	April	1.3	3.1	0.04	1.1
Oligosol cu amp cuivre 28 2ml	April	0.6	1.5	0.09	2.4
Rhinallergy cpr a sucer 40	May	0.6	1.4	0.12	3.2
Advilcaps caps molles 400mg 14	September	0.5	1.3	0.12	3.1
All new non-reimbursable, non-prescription medicines	–	41.7	100.0	3.91	100.0

Figure 5: Top 10 'strict' OTC launches – non-reimbursable, non-prescription medicines – ranked by self-medication sales in value terms at retail selling prices in France in 2009 (Source – IMS Consumer Health/AFIPA)

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Manufacturers

Beiersdorf revamps its executive board

Beiersdorf is revamping its executive board into three functional and three regional areas of responsibility with effect from 1 May.

The Germany company said the new structure would help it focus on core competencies in growth categories, address regional consumer wishes, and flexibly align with markets.

Commenting on the functional responsibilities, Beiersdorf noted **Bernhard Düttmann** would remain in charge of finance and would take on human resources, while **Pieter Nota** would continue to oversee marketing and innovation. **Peter Kleinschmidt**, who is in charge of human resources and sustainability, will leave the company after 25 years.

In terms of regions, **Markus Pinger** will take responsibility for the Americas, and will continue to be in charge of the global supply chain. **James Wei** will head up the Asia region, and a new board member will be named for the Europe region.

Thomas Quaas will remain chairman of the executive board.

According to Quaas, the “changed market situation resulting from the global economic crisis” meant there was a “new reality”. He said the next few years would be shaped by uneven growth in global markets, changed trade structures, increasing consumer interest in low prices with an excellent price to performance ratio, and intensified competition from private-label manufacturers.

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European Commission

Testori Coggi is new chief for Health and Consumers

The European Commission has promoted **Paola Testori Coggi** to director-general of its directorate-general for Health and Consumers (SANCO).

Health and Consumers, which is headed by commissioner John Dalli, now has responsibility for pharmaceuticals and the European Medicines Agency (EMA), which had previously come under Enterprise and Industry (*OTC bulletin*, 18 December 2009, page 1). It also covers food legislation.

An Italian national, Testori Coggi has been deputy director-general of Health and Consumers since August 2007. Before that, she was director for safety of the food chain, where she was responsible for the White Paper on food safety and the legislative action programme.



Paola Testori Coggi

She joined the European Commission in 1983.

Testori Coggi takes over from **Robert Madelin**, who has been appointed director-general for Information Society and Media.

OIC

Wholesalers

Lang to take over at Germany's Sanacorp

The supervisory board at German wholesaler Sanacorp has voted unanimously to appoint **Herbert Lang** as its executive chairman with effect from 1 July.

He will take over from **Manfred Renner**, who is retiring from the post after 27 years with the group.

Lang joined Sanacorp in 1997, and for the past seven years has served on the board as director of sales and marketing.

Meanwhile, **Christoph Mauz** has been re-elected to the board of the pharmacist-controlled group. A pharmacist, Mauz has served on Sanacorp's board since 1994.

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Retailers

Turk quits UK NPA after two years in the top job

John Turk has quit the UK's National Pharmacy Association (NPA) just two years after joining the trade body as chief executive.

The NPA said in a statement that Turk had resigned to "pursue other projects". It did not comment on plans to replace him.

Turk took up the top job at the NPA in April 2008. He replaced Alison White, who had stepped down as chief executive after only a few months in the position (*OTC bulletin*, 31 March 2008, page 22).

Prior to White's appointment, John D'Arcy had been chief executive for a decade, leaving the pharmacy association on 1 May 2007 to take up the position of commercial director at Rowlands Pharmacy.

Turk joined the NPA from health and social care provider Care UK, where he created and directed the 400-employee Children's Services



John Turk

division. After starting his commercial career at GlaxoSmithKline, Turk gained 18 years of experience in senior management, including a spell as managing director of medical device and healthcare company Gambro.

Regulatory Agencies

Bamford bolsters two MHRA panels

Elizabeth Bamford has joined two independent advisory panels to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

Bamford – who was director of regulatory, medical and consumer affairs at GlaxoSmithKline Consumer Healthcare until the end of last year – will serve four-year terms on the Independent Review Panel for Advertising (IRPA) and the Independent Review Panel for Borderline Products (IRPBP).

In addition, **David Kettle** – interim medical affairs manager at Norgine Pharmaceuticals – will be a member of the IRPA and IRPBP for the next two years.

Bamford and Kettle, who are both registered pharmacists, will work with the MHRA to advise UK health ministers on relevant issues. They are among 13 members appointed to the two panels.

Meanwhile, **Jidong Wu** has been reappointed to the Herbal Medicines Advisory Committee (HMAC). Wu is a traditional Chinese medicine practitioner and a senior lecturer in traditional Chinese medicine at Middlesex University, and will serve a four-year term.

HMAC is an independent body that works with the MHRA to advise health ministers on traditional herbal medicines. The committee has 18 members.

Furthermore, six new members will join the Advisory Board on the Registration of Homeopathic Products (ABRHP). **Gillian Eccleston, Andrew Farrow, David Needleman, Gary Smyth, Dominic Williams** and **Alan Worsley** will all serve four-year terms.

The ABRHP, which works closely with the MHRA to advise health ministers on the regulation of homoeopathic products, now has 17 members.

IN BRIEF

■ **CLAYTON, DUBILIER & RICE** – the private-equity investment company with bases in the UK and the US – has appointed **Alan Lafley** as a special partner. Lafley retired as chairman of Procter & Gamble on 25 February 2010 after 32 years with the company. Up until July 2009, Lafley was also president and chief executive officer of Procter & Gamble (*OTC bulletin*, 19 June 2009, page 23).

■ **THE CARLYLE GROUP** has announced that **Robert Essner** – former chairman and chief executive officer of Wyeth – has joined the global private-equity investment group as senior adviser to its Global Healthcare Group. Essner retired from Wyeth in June 2008 after approaching 20 years with the US-based pharmaceutical company (*OTC bulletin*, 15 May 2008, page 22).

■ **OMEGA PHARMA** plans to appoint two new independent directors to its board at the Annual General Meeting on 3 May. **Chris Van Doorslaer**, the chief executive officer of Cartamundi, and **Karel Van Eetvelt**, managing director of Unizo, will serve on the board of the Belgian OTC firm for four years. **Jean-Louis Duplat** will step down at the meeting,

as he legally cannot serve another term as an independent director after holding the position for the past three terms. Omega will also propose the reappointment of chairman **Lucas Laureys** to the board.

■ **PRESTIGE BRANDS HOLDINGS** has promoted **Eric Klee** to general counsel and secretary. Klee was previously the US-based company's associate general counsel. He replaces **Charles Jolly**, who had been general counsel since 2005.

■ **PERRIGO** has recruited **Carlos Paz** to be senior director in charge of its formulation research and development department in Allegan in the US. Paz joins the store-brand specialist from Impax Laboratories, where he was director of process development and pilot plant operations. Paz has also worked for Andrx Pharmaceuticals, Watson Pharmaceuticals and Schering-Plough. Meanwhile, **Donna Seibert** has joined Perrigo as a principal scientist in PMI analytical research and development. Perrigo said Seibert, who has previously held positions at Mylan and Pfizer, would provide support for new consumer healthcare product development projects.

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IN BRIEF

■ **TRIS PHARMA** – the US-based drug delivery specialist – has named **Peter Ciano** as vice-president of corporate development. Ciano had been working for Tris as a business development consultant for around 18 months. In his new role, Ciano will manage the company's commercial activities for its brand side of the business, including business development, licensing, identifying growth opportunities, and executing deals.

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