16 December 2010

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THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

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Reckitt Benckiser set to buy India's Paras for INR32.6bn

Reckitt Benckiser is set to boost its consumer healthcare business by acquiring India's Paras Pharmaceuticals for INR32.6 billion (€546 million).

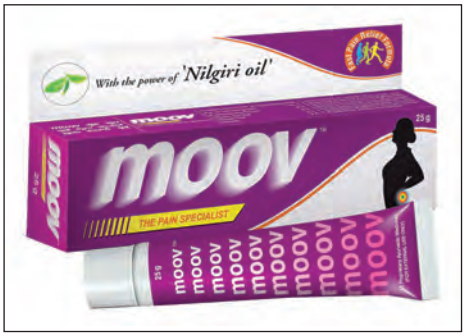
The premium price tag represents more than eight-times Paras' sales of INR4.0 billion in the year to March 2010, and nearly 30-times the company's operating earnings before interest, tax, depreciation and amortisation (EBITDA) of INR1.1 billion.

The deal comes soon after Reckitt Benckiser expanded its consumer healthcare business with the purchase of SSL International and its Durex and Scholl brands for £2.54 billion (€3.02 billion) (**OTC *bulletin***, 30 July 2010, page 1).

Commenting on the Paras deal, Bart Becht, Reckitt Benckiser's chief executive officer, said the growth potential of the business, the creation of a material healthcare business in India's large and growing healthcare market, and the global synergies available made Paras an "exciting addition" to the company's portfolio.

Reckitt Benckiser pointed out that acquiring privately-held Paras would give it a portfolio of Indian OTC brands with leading market positions, including India's number two topical analgesic pain ointment Moov and the number two cold and flu remedy D'Cold.

Paras also marketed Krack, India's leading medicated skin treatment for cracked heels, Reckitt Benckiser pointed out, along with the Itch Guard and Ring Guard antifungal creams.



Buying Paras will give Reckitt Benckiser a portfolio of OTC brands in India including Moov topical analgesics

Paras' personal-care business, meanwhile, was led by the Set Wet brand of hair gels and deodorants for men, the company said.

The deal will also give Reckitt Benckiser a new state-of-the-art and Good Manufacturing Practice compliant manufacturing plant in Northern India, which employs around 700 people.

Becht said the Paras deal was another step forward in Reckitt Benckiser's consumer healthcare growth strategy. "We believe the Paras business has extremely good growth potential when supported by Reckitt Benckiser's investment and innovation strength," he added.

Reckitt Benckiser's Health & Personal Care division is the company's largest, with sales of £1.67 billion in the first nine months of 2010 (**OTC *bulletin***, 16 November 2010, page 4). It represented 27% of Reckitt Benckiser's total sales for the period of £6.18 billion.

Kindler makes abrupt departure from Pfizer

Jeffrey Kindler has stepped down as chairman and chief executive officer of Pfizer, and retired from the company with immediate effect.

In the wake of Kindler's abrupt departure, the US-based pharmaceutical firm has named Ian Read, 57, head of its global biopharm-

■ *Continued on page 8*

GSK adds muscle with Maxinutrition

GlaxoSmithKline Consumer Healthcare is poised to expand its Nutritional Healthcare business by acquiring Maxinutrition from Darwin Private Equity for approximately £162 million (€192 million) including the repayment of outstanding debt.

Described as "Europe's number one sports

■ *Continued on page 7*

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Distribution Agreements

Sinclair signs Decapinol partner in US

Sinclair Pharma has signed up Sunstar Americas to relaunch its Decapinol mouthwash in the US. Sunstar will market Decapinol as an OTC product under its GUM brand name.

Under the terms of the agreement, said Sinclair, Sunstar had also taken an option to license Decapinol in Japan once the product had been registered, as well as further options covering several other countries where the product was not currently marketed.

The deal was struck shortly after Sinclair announced that it had teamed up with biopharmaceutical firm Invida to launch its dermatology and wound care products across 11 markets in the Asia-Pacific region, and had acquired the rights to the Kelo-cote wound care brand in the UK and Germany.

Sunstar – which already markets Sinclair's Aloclair mouth-ulcer gel and mouth rinse in the Americas region under the GUM Canker-X and GUM Rincinol brand names – would return Decapinol to the US market during 2011, Sinclair pointed out, and would market the product through pharmacies and other US retailers to appeal to the "health-conscious consumer".

Previously, Decapinol had been available in the US under the Impede brand name. However, in November of last year Sinclair said it had mutually agreed to terminate its US distribution deal with the Johnson & Johnson subsidiary Orapharma, so that the product could be repositioned for the OTC market (**OTC *bulletin***, 30 November 2009, page 2).

Sinclair claimed its "ecological" approach to oral hygiene was in marked contrast to the standard antiseptic mouthwashes that currently dominated the US$750 million (€566 million) mouthwash market in the US.

In light of this, the company was aiming to use consumer education to help grow the brand, in much the same way that food manufacturers had grown the market for probiotic yoghurts by educating consumers about gastro micro flora maintenance, according to Sinclair's commercial chief scientific officer Simon Youlton.

Adding Sinclair's delmopinol-based alternative to antiseptic mouthwashes to Sunstar's existing PerioBalance probiotic lozenge, Youlton pointed out, gave Sunstar the platform to move consumers towards a "healthier, natural approach to daily oral care".

A "slow initial build-up in sales" was anticipated, Sinclair noted, as the marketing message was developed and rolled out.

Meanwhile, Sinclair has named Invida as its exclusive distribution partner for its dermatology and wound care portfolios in Australia, China, Hong Kong, Indonesia, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

Chris Spooner, Sinclair's chief executive officer, said the deal was a "landmark" for the company. It validated the company's "strong conviction", he added, that there was a "terrific opportunity" to take Sinclair's product portfolio into "leading emerging markets".

In the medium term, the two companies were targeting "high volumes and strong profitability", Sinclair said, "requiring substantial marketing investment to build the brands".

Sinclair's Decapinol mouthwash will be sold by Sunstar under its GUM brand name in the US

Invida would market the brands to general practitioners, dermatologists and paediatricians, Sinclair noted, as well as through pharmacies, drugstores and other retail outlets.

The "early emphasis on marketing investment" demonstrated Sinclair's focus on "sustainable value creation", Spooner noted, adding that the deal structure would serve as a blueprint for future partnerships in the region.

Sinclair's dermatology portfolio covers acne, atopic dermatitis, fungal infections and family dermatology, and includes the company's flagship Atopiclair dermatitis brand. The company's wound care offering includes the Flammazine and XClair brands.

Regulatory approvals permitting, launches would begin in the summer of 2011, the company said, noting that it could take up to two years for the products to be introduced across all 11 markets.

On top of the deals in the US and Asia-Pacific, Sinclair has also expanded its wound care portfolio and direct sales presence by acquiring Cranage Healthcare in the UK for an initial payment of £0.40 million (€0.47 million).

The deal includes the distribution rights to the Kelo-cote wound care brand in the UK, which, although sold mainly on prescription, is also available via Cranage's online store.

In addition, the company has acquired the distribution rights to Kelo-cote in Germany from Advanced Bio-Technologies for an initial sum of €0.84 million. Sinclair already holds the distribution rights to Kelo-cote in France, Italy and Spain.

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Third-Quarter Results

36.6 resurrects its expansion strategy

Pharmacy Chain 36.6 will resurrect its expansion plans in 2011, following a period of store closures and restructuring, according to chief executive officer Artyom Bektemirov.

The Russian retailer had completed its programme of shutting under-performing stores, restructuring its finances and rebuilding relations with suppliers, Bektemirov said, and now had the requisite resources to resume the gradual expansion of its pharmacy chain.

As of 30 September 2010, Pharmacy Chain 36.6 was operating 997 stores across Russia (see Figure 1). This was down from 1,026 stores a year earlier.

Three stores had been opened organically during the third quarter, the company stated, five stores had been closed, 14 had been rebranded, and one had been reformatted.

The reduction in store numbers, Bektemirov pointed out, had been the primary reason behind the 3.3% decrease in Pharmacy Chain 36.6's third-quarter Retail sales to RUB3.41 billion (€83.2 million) (see Figure 2).

He added that the Retail business had been lifted by a "gradual recovery" in the consumer sector, as well as the expansion of its private-label range and its decision to cut the prices of its most popular products by an average of 20% in its Moscow stores (**OTC *bulletin***, 16 April 2010, page 2).

Average spend in stores increased

The size of the average spend in its stores had increased by 8.3% to RUB248 in the third quarter, Pharmacy Chain 36.6 noted, adding that in the Moscow region the average spend had risen by 6.7% to RUB350.

Sales of private-label products had grown by 10.5% to RUB300 million during the quarter, Pharmacy Chain 36.6 said, accounting for around a tenth of the company's Retail sales.

Parapharmaceuticals made up the bulk of the company's 932-strong private-label range, Pharmacy Chain 36.6 pointed out, with OTC drugs, and vitamins, minerals and supplements making up the remainder.

Region	Number of pharmacies	Share of sales (%)
Moscow Central	344	49.7
South Urals	179	13.0
South	168	12.0
Volga	147	11.7
North Urals	83	6.3
Siberia	52	4.3
North West	24	3.0
Total	**997**	**100.0**

Figure 1: Number of pharmacies operated by Pharmacy Chain 36.6 as of 30 September 2010, broken down by region of Russia (Source – Pharmacy Chain 36.6)

Business	Third-quarter sales (RUB millions)	Change 2009/2010 (%)	Proportion of sales (%)
Retail	3,413	-3.3	70
Veropharm	1,261	+37.8	26
Other	204	+18.7	4
Elimination	-10	–	–
Pharmacy Chain 36.6	**4,868**	**+6.3**	**100.0**

Figure 2: Breakdown of Pharmacy Chain 36.6's sales in the third quarter of 2010 (Source – Pharmacy Chain 36.6)

Retail sales accounted for 70% of Pharmacy Chain 36.6's total group sales in the third quarter, which ended up by 6.3% to RUB4.87 billion. The company's Veropharm manufacturing business generated a further 26% of the sales total, with the remainder coming from other businesses. Veropharm's sales jumped by 37.8% to RUB1.26 billion in the period.

Meanwhile, Pharmacy Chain 36.6 also confirmed its sales and earnings for the opening six months of 2010. Total group sales had slipped back by 14.9% to RUB9.75 billion, the company noted, while earnings before interest, tax, depreciation and amortisation (EBITDA) edged forward by 3.6% to RUB854 million.

OTC

IN BRIEF

■ **JOHNSON & JOHNSON** has launched a €24.75 per share offer for the 82% stake it does not own in Dutch vaccines company Crucell. The deal, which values Crucell at around €1.8 billion, has received the backing of Crucell's management and supervisory boards. Shareholders will vote on the offer at an extraordinary general meeting on 8 February 2011.

■ **GEDEON RICHTER** has agreed to invest RMB18 million (€2.0 million) in setting up a joint venture in China with its local marketing partner Rxmidas Pharmaceuticals. The companies will each hold a 50% share in **Gedeon Richter Rxmidas Joint Venture Co**, which the Hungarian company said would initially be used to register and launch its range of female healthcare products in the Chinese market.

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Annual Results

Tough market curbs sales at Merz

Merz Pharma Group said that an "aggressive marketplace" had led to a decline in turnover at its Consumer Care business – including the Tetesept portfolio of OTC products – in the year ended 30 June 2010.

The privately-held German firm reported Consumer Care sales down by 6.0% to €103 million in the 12 months. The result marks the second successive decline in Consumer Care's annual sales, following the 4.0% decrease during the previous year (**OTC *bulletin***, 30 November 2009, page 8).

Merz' Consumer Care business includes the Merz Spezial health and beauty brand, as well as the core Tetesept range of licensed and unlicensed healthcare products.

Consumer Care's sales accounted for 15% of Merz' turnover in the 12 months, which improved by 14.2% to €674 million. The bulk of Merz' group sales came from its Pharmaceuticals business, which posted sales up by 19.4% to €552 million from its portfolio of prescription products and non-prescription dermatology brands.

Acquired BioForm Medical

Earlier in the year, Merz advanced its strategy of becoming a "leading player in aesthetic medicine – a fast-growing, multibillion dollar global market" – by acquiring the medical aesthetics company BioForm Medical for US$253 million (€191 million) (**OTC *bulletin***, 26 February 2010, page 3).

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Business Strategy

Beiersdorf sets Vietnam targets

Beiersdorf – owner of the Nivea and Eucerin skincare brands – has established an independent affiliate business in Vietnam, as the company seeks to more than double its turnover in the country by 2015.

Beiersdorf Vietnam – which is based in Ho Chi Minh City – would not only enable the firm to meet the "strong and consistently rising demand" for skincare products in Vietnam, the German firm said, but would also act as a platform for expansion in South-East Asia.

Growing faster than the market

James Wei, the member of Beiersdorf's executive board in charge of Asian operations, insisted that the company's goal in Vietnam of "continuing to grow significantly faster than the market" would now be easier to reach.

"We can now adapt Nivea products even more closely to the specific needs of Vietnamese consumers," he added, "and react faster to local market trends."

"Nivea already holds leading positions in numerous product categories, and is the undisputed market leader for body care, deodorants and men's care products," Wei claimed, adding: "These market positions are a solid basis for future growth."

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Distribution Agreements

Navamedic secures rights to NYDA in three markets

Navamedic's Vitaflo Scandinavia sales and marketing business has gained the exclusive rights to distribute Pohl-Boskamp's NYDA non-prescription head-lice remedy in Denmark, Norway and Sweden.

Olof Milveden, Navamedic's chief executive officer, said the company was seeing a growth in demand for head-lice remedies. Milveden noted that the market for such products across all three countries was worth SEK18 million (€2.0 million) annually.

Described by the Norwegian company as a "unique" head-lice remedy, NYDA works by suffocating both the lice and eggs. If the product was used correctly, Navamedic pointed out, then it would get rid of all of the lice with just one treatment.

NYDA was a mild product suitable for children aged two years and older, added Navamedic, noting the product was a medical device.

Navamedic said the deal represented another step in the company's growth strategy, which had already seen it sign exclusive distribution agreements to sell the Norwegian firm Smartfish's medical nutrition products in Denmark, Finland and Sweden, and market the South African company Aspen Healthcare's generic products in the Benelux countries and Norway.

Pohl-Boskamp's NYDA head-lice remedy works by suffocating both the lice and the eggs

Navamedic's Vitaflo Scandinavia business reported sales down by 1.7% to NKr13.7 million (€1.7 million) in the third quarter of 2010 (**OTC *bulletin***, 30 November 2010, page 9). The business has a portfolio of over 40 brands in 10 product categories, including the Glucomed glucosamine brand, which it distributes in Denmark, Finland, Norway and Sweden.

OTC

Mergers & Acquisitions

GNC quiet on takeover speculation

General Nutrition Centers (GNC) is refusing to comment on speculation that China's Bright Food is poised to acquire the US-based nutritional supplements retailer.

Rumours are circulating as GNC prepares for an initial public offering (IPO), which could raise up to US$350 million (€265 million) (**OTC *bulletin***, 15 October 2010, page 2).

Various media outlets have reported that Bright Food is set to bid between US$2.0 billion and US$3.0 billion for GNC, and that the deal could be agreed before the end of 2010. A number of reports have also claimed that private-equity firm Blackstone could join forces with Bright Food for the bid.

Earlier in the year, GNC signed a memorandum of understanding to form a strategic partnership with Bright Food in China (**OTC *bulletin***, 26 February 2010, page 9). At the time, GNC said the joint venture – called GNC China – would be formed and would launch products by mid 2010.

The tie-up with GNC marked Bright Food's formal entry into the nutritional products arena, adding a new sector to its established operations in fresh and processed foodstuffs.

GNC was acquired by private-equity firm Apollo management for US$750 million seven years ago (**OTC *bulletin***, 31 October 2003, page 3). GNC postponed a planned IPO in 2006 (**OTC *bulletin***, 17 November 2006, page 1).

The company generated group turnover of US$1.71 billion in 2009, with an operating profit of US$181 million.

At the end of the year, the company had more than 6,900 outlets – over 5,400 of which were in the US – and had franchise operations across a further 47 countries (**OTC *bulletin***, 31 March 2010, page 7).

OTC

Business Strategy

PepTcell changes its name to SEEK

SEEK is the new name of UK-based drug-discovery firm PepTcell, which has a portfolio of prescription and consumer health products in development.

Explaining the change, SEEK's chief executive officer Gregory Stoloff said the company's new identity better reflected its efforts "to seek a cure" in a number of major disease areas.

SEEK recently appointed Manfred Scheske – the former European president of GlaxoSmithKline Consumer Healthcare – as chief executive officer of its Consumer Health unit (**OTC *bulletin***, 15 October 2010, page 1).

Scheske has full responsibility for SEEK's consumer health product portfolio, which includes what the company describes as a "first-in-class" cough suppressant.

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Nine-Month Results

Grindeks sees jump in sales

Latvia's Grindeks has reported a 21.7% increase in sales to LVL46.9 million (€66.1 million) in the opening nine months of 2010.

The majority of the firm's sales – LVL44.5 million – had been generated through exports to 51 countries worldwide, Grindeks said.

The company offers a portfolio of prescription medicines, generics, active pharmaceutical ingredients and OTC brands.

Looking ahead, Janis Romanovskis, Grindeks' chairman, said the company would continue to introduce new products, enter into new markets, increase production capacity, and invest in future development.

Meanwhile, Grindeks said that East Capital Asset Management had acquired a 10.18% stake in the company.

East Capital Asset Management has bought into Grindeks just over a month after the Russian pharmaceutical company Pharmstandard disposed of the 11.38% stake it had acquired controversially earlier this year (**OTC *bulletin***, 30 April 2010, page 7).

Explaining the reasons why Pharmstandard had sold its stake in Grindeks, a spokesperson told **OTC *bulletin*** that the company had not received any offers to increase its stake, and had decided to accept a good offer.

Pharmstandard – which markets Grindeks' prescription-only cardiovascular medicine Mildronate in Russia – acquired the stake from the president of Latvia's employers' confederation, the LEC, prompting Grindeks to resign from the organisation.

Grindeks accused the confederation's president Vitalijs Gavrilovs of "essentially breaching business ethics" by selling the stake to Pharmstandard.

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IN BRIEF

■ **PERRIGO** has launched a generic version of UCB Pharma's prescription-only medicine **Xyzal** in the US. The US-based store-brand specialist's generic levocetirizine tablets are protected by 180 days of generic market exclusivity, after its partner Synthon successfully challenged a Xyzal patent. Perrigo acquired exclusive US sales and distribution rights to the generic version of the switch candidate in 2008 (**OTC *bulletin***, 29 September 2008, page 2).

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Second-Quarter Results

Mag-Ox buy fails to offset OTC sales drop at Hi-Tech

Acquiring the Mag-Ox brand of magnesium supplements earlier this year did not prevent turnover at Hi-Tech Pharmacal's Health Care Products division slipping back in the company's second quarter ended 31 October 2010.

The US-based firm said turnover at its Health Care Products division had dropped by 7% to US$3.4 million (€2.6 million) during the three months, as lower sales of its existing diabetic product portfolio offset the addition of Mag-Ox, which the company acquired from Blaine Company in March (**OTC *bulletin***, 17 March 2010, page 3).

The acquisition gave Hi-Tech the rights to the Mag-Ox, Maginex, Uro-Mag and Corban brands, which generated net sales of US$3.4 million during 2009.

At the time of the deal, David Seltzer, Hi-Tech's president and chief executive officer, said Mag-Ox was a good strategic fit with the existing line of OTC brands for diabetics offered by the Health Care Products division.

Mag-Ox joined Hi-Tech's existing OTC brands for diabetics including Diabetic Tussin for coughs and colds, Diabeti Derm skincare creams, Diabeti Sweet sugar substitutes, the Multi-betic multimineral/multivitamin supplement for diabetics, and Zostrix cream for relief of diabetic foot pain.

Still seeking acquisitions

Despite the recent acquisition of Mag-Ox, Seltzer said the company was still looking to expand its OTC portfolio with "near and long-term acquisition and licensing opportunities".

The Health Care Products division accounted for 7.6% of Hi-Tech's total sales, which grew by 10% to US$44.9 million for the quarter.

Sales by the dominant Generics division, which increased by 13% to US$36.8 million, accounted for 82.0% of the firm's turnover. ECR Pharmaceuticals generated a further 10.5%.

Hi-Tech's total pre-tax profits jumped up by 34.6% to US$15.2 million.

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Nine-Month Results

Self-medication up at Slovenia's Krka

Slovenia's Krka said sales of its self-medication products had grown by 31% to €75.4 million in the opening nine months of 2010.

During the period, the company had expanded a number of its brands in various markets, Krka noted. In Estonia, Latvia and Slovenia, a pastille and spray had been added to its Septolete Plus sore-throat remedies, the company pointed out, while in Russia, the Pikovit vitamin line had been expanded with the Pikovit Omega 3 and Pikovit Prebiotik products.

Meanwhile, chewable tablet versions of Duovit Elegance and Duovit Sila had been added to the Duovit vitamin and supplement brand in Russia and Ukraine, Krka pointed out, while Orsoslim weight-management capsules had been approved in Kazakhstan and Ukraine.

Self-medication products generated 10.4% of Krka's total sales in the nine months, which grew by 5% to €727 million. Sales outside of Slovenia were responsible for 89% of the company's total turnover.

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Annual Results

Amerifit pushes up Martek's turnover

Acquiring Amerifit Brands in February of this year helped lift Martek Biosciences' sales by 32% to US$435 million (€329 million) in the year ended 31 October 2010.

The US-based nutritional ingredients firm said Amerifit – which it bought from private-equity firm Charterhouse Group for US$200 million (**OTC *bulletin***, 10 February 2010, page 3) – had contributed sales of US$61.4 million from the acquisition date of 12 February until the end of the period.

Martek gained a number of natural-wellness brands in the US by acquiring Amerifit, including the probiotic supplement Culturelle and the menopause-relief supplement Estroven.

The majority of Martek's sales came from its nutritional ingredient's business, which reported turnover up by 14% to US$372 million. Non-nutritional products generated a further US$1.45 million.

Martek's operating profit dropped by a fifth to US$50.8 million in the 12-month period.

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Business Strategy

Beiersdorf to cut offering as it focuses on skincare

Beiersdorf – owner of the Nivea and Eucerin skincare brands – is streamlining its product portfolio and realigning its regional structures.

A "comprehensive package of measures and investments" had been drawn up, the German company pointed out, to help implement its new "Focus on Skin Care. Closer to Markets" consumer business strategy.

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

Although the product portfolio would be trimmed, substantial investments in the company's skin and body care brands were planned, Beiersdorf stressed, with a large number of new products scheduled.

Implementing these changes would lead to additional costs of approximately €270 million up to 2012, Beiersdorf said, noting that roughly €120 million of this amount would probably be booked in 2010. The costs also include write-downs of intangible assets relating to the firm's Chinese business.

As a result of these additional costs, the company's earnings before interest and tax (EBIT) margin was expected to be approximately 9% in 2010, Beiersdorf stated, while sales growth should be 2% to 3%.

Meanwhile, Beiersdorf has appointed Ümit Subasi as its new executive board member for emerging markets.

As of 1 March 2011, Subasi would be responsible for Africa, India, Latin America, the Middle East and Turkey, as well as Russia and the Commonwealth of Independent States.

Subasi will join Beiersdorf from SC Johnson, where he was responsible for the central, northern and eastern European regions.

OTC

People

Merck KGaA gets new pharma chief

Merck KGaA said Stefan Oschmann would become the new head of its Pharmaceuticals business sector on 1 January 2011, after Elmar Schnee had decided to leave the German company for "personal reasons" at the end of this year.

Oschmann, 53, will join the German firm's executive board and become a general partner in the company with overall responsibility for both the Merck Serono and Consumer Health Care divisions.

Merck noted that Oschmann would take full control of the Merck Serono business, while Peter Shotter would remain in charge of the Consumer Health Care business and would report to Oschmann.

Oschmann joins Merck KGaA from US-based Merck & Co, where he has served as president of emerging markets since 2009.

In a separate move, Merck said Kai Beckmann had been appointed to the new position of head of human resources. He would join the executive board and become a general partner on 1 April 2011, the company noted.

OTC

People

Avicenna appoints Coles to board

Avicenna has announced the appointment of **David Coles** to its board as a non-executive director with effect from 1 January 2011.

The UK-based virtual pharmacy chain said Coles brought "immense knowledge" of the pharmaceutical sector to the position. He is a former managing director of Unichem and a former chairman of the British Association of Pharmaceutical Wholesalers (BAPW).

In a separate development, Avicenna has promoted **Dipesh Vaja** from pharmacy business manager to national sales manager. He joined the company in 2008.

OTC

Mergers & Acquisitions

GSK adds muscle with Maxinutrition

■ *Continued from front page*

nutrition company by market share", Maxinutrition generated sales of around £36 million in the year ended April 2010, and achieved a compound annual growth rate (CAGR) of approximately 21% over the past three years.

Acquiring the UK-based company adds the Maximuscle, Maxifuel and Maxitone sports nutrition brands to GlaxoSmithKline's existing Nutritional Healthcare business, which is dominated by the Horlicks, Lucozade and Ribena drinks lines.

John Clarke, worldwide president of GlaxoSmithKline Consumer Healthcare, said the deal would give the company a "strong presence in the fast-developing protein-based sports nutrition market" with brands that appealed across a "broad spectrum of consumers from elite athletes to sports participants and those seeking additional nutritional supplementation".

The acquisition demonstrated GlaxoSmithKline's strategy of expanding its Consumer Healthcare business through appropriate bolt-on purchases which met the company's strict financial criteria, he added.

"GlaxoSmithKline will invest behind Maxinutrition's science-proven products to extend the growth of Maxinutrition within its UK and European footprint," Clarke pointed out, "and expand it to the global marketplace where GlaxoSmithKline has existing infrastructure and capabilities."

Peter Boddy, chief executive officer of Maxinutrition, said that as a "fast-growing, focused sports nutrition business with excellent growth prospects and a strong management team", the company was a "perfect fit" for GlaxoSmithKline and its ambition to grow its Nutritional Healthcare business.

GlaxoSmithKline's strong commercial and research and development capability, Boddy added, coupled with its investment in expanding its global nutrition healthcare franchise in new markets and territories, offered "tremendous new opportunities" to develop the Maxinutrition brands and deliver impressive growth going forward.

GlaxoSmithKline's Nutritional Healthcare business generated turnover of £851 million in 2009, of which £791 million came from the Horlicks, Lucozade and Ribena brands. The business represented 18% of Consumer Healthcare's total turnover of £4.65 billion (**OTC *bulletin***, 26 February 2010, page 6).

OTC

Product Recalls

McNeil recalls Rolaids in Canada and the US

McNeil Consumer Healthcare has recalled a number of its Rolaids products in Canada and the US, and has halted production following consumer reports of foreign materials in the gastrointestinal remedies.

The news follows a series of product recalls and suspension of production at the Johnson & Johnson subsidiary's Fort Washington manufacturing facility in the US. As a result, US sales by Johnson & Johnson's OTC & Nutritionals business are expected to decline by US$600 million (€454 million) in 2010 (**OTC *bulletin***, 29 October 2010, page 4).

The latest recall includes all lots of Rolaids Extra Strength Softchews, Rolaids Extra Strength plus Gas Softchews and Rolaids Multi-Symptom plus Anti-Gas Softchews distributed in the US. It also applies to all lots of Rolaids Ultra Strength SoftChews and Rolaids Ultra Strength SoftChews plus Gas Relief sold in Canada.

McNeil said it had initiated the recall following some consumer reports of foreign materials in the product, including metal and wood particles. The company stressed that while the risk of "serious adverse health consequences" was remote, consumers were advised to stop using the recalled products.

An investigation had determined that the materials had been potentially introduced into the product during the manufacturing process at a third-party manufacturer, McNeil said.

While the investigation was ongoing, the company noted, production of all three products had been suspended and would not be restarted until the required corrective actions had been implemented.

This latest recall comes less than a month after McNeil recalled a number of OTC medicines in the US, including products sold under the Benadryl, Motrin, Rolaids and Tylenol brands (**OTC *bulletin***, 30 November 2010, page 12).

Meanwhile, Johnson & Johnson-Merck Consumer Pharmaceuticals – the OTC joint venture between Johnson & Johnson and Merck & Co – has issued a wholesale and retail level recall of 12 Mylanta gastrointestinal liquid remedies and one AlternaGEL antacid liquid product. The recall affecting the US and Puerto Rico is due to a labelling problem.

The recall had been initiated, the company said, after an internal review had revealed that information about the presence of alcohol from flavouring agents had not been noted on the packaging.

It was unlikely that the use of these products would cause either alcohol absorption or alcohol sensitivity-related adverse events, Johnson & Johnson-Merck Consumer Pharmaceuticals stressed, adding the recall had not been undertaken on the basis of adverse events.

OTC

Manufacturers

Kindler makes abrupt departure from Pfizer

■ *Continued from front page*

-aceutical operations, as president, chief executive officer and director. A new non-executive chairman would be appointed before the end of December, Pfizer said.

Kindler's departure comes a little over a year after Pfizer completed the US$68 billion (€52 billion) acquisition of its smaller rival Wyeth (**OTC *bulletin***, 30 October 2009, page 3). The buy broadened Pfizer's portfolio, and returned the company to the consumer healthcare market just under three years after selling its own global OTC business to Johnson & Johnson (**OTC *bulletin***, 25 January 2007, page 6).

Explaining his departure after nine years at Pfizer, including four and a half as chief executive officer, Kindler said that he felt it was time to "recharge my batteries, spend some rare time with my family, and prepare for the next challenge in my career".

Ian Read

"Our team can proudly boast of some transformational accomplishments," Kindler added. "However, the combination of meeting the requirements of our many stakeholders around the world and the 24/7 nature of my responsibilities, has made this period extremely demanding on me personally."

Commenting on Read's appointment, Pfizer's lead independent director Constance Horner said that over the past four years Read had "redefined" the company's go-to-market approach with the creation of global business units and had brought to product development a focus and commitment to advance only medicines that have clear value to our customers.

Read joined Pfizer in 1978, and was appointed president of the company's international pharmaceuticals group with responsibility for Latin America and Canada in 1996. In 2001, Pfizer made Read its corporate vice-president with responsibility for Europe and Canada, and subsequently added the Africa/Middle East and Latin America regions to his leadership responsibilities. He was promoted to head of Pfizer's global biopharmaceutical operations in 2006.

OTC

Stiefel Laboratories has announced the winner of its MaxClarity Fresh Face Challenge in the US.

She is Cindy Reed (pictured above), whose story about her new-found confidence since tackling acne with MaxClarity was "a clear favourite". Reed has won a shopping and pampering trip for two to Los Angeles or New York.

To take part in the challenge, acne sufferers had to use MaxClarity for up to 30 days and submit their self-defined "moment of clarity" – together with before and after photographs of their skin – to the company's website www.freshfacechallenge.com. A panel of judges selected the finalists, then visitors to the website voted for their favourite.

Launched earlier this year, MaxClarity is claimed to be "the first non-prescription foam-based acne treatment system with VersaFoam technology".

The MaxClarity Foam Acne Medication range comprises a deep cleanser, an advanced acne treatment and a rejuvenating toner. The products contain either benzoyl peroxide or salicylic acid, which Stiefel said "penetrate the skin quickly and fight acne at the source before it becomes a pimple".

Stiefel said the range provided consumers with "an acne solution that is easy-to-use, effective and backed by science from dermatology experts".

OTC

Regulatory Affairs

UK's MHRA offers OTC 'slots' in 2011

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) says it has slots available in 2011 in all therapeutic areas, including biologicals and OTC medicines, to act as reference member state (RMS) for decentralised licensing applications in the European Union.

Companies which have completed dossiers ready for submission, or can submit earlier than originally anticipated, are invited to contact MR-DCprocedures@mhra.gsi.gov.uk.

OTC

Switches

MHRA consults on a Nicorette change

Nicorette 15mg Inhalator could soon go on general sale in the UK, if the latest switch proposal from the Medicines and Healthcare products Regulatory Agency (MHRA) is given the go-ahead.

Consultation document ARM 69 states that McNeil Products is seeking to switch the Nicorette 15mg Inhalator from pharmacy to general-sales list (P-to-GSL) status. GSL status already applies to the Nicorette 10mg Inhalator.

ARM 69 argues that the GSL version of Nicorette 15mg Inhalator will provide "no additional safety risk or issues" because it delivers the same dose of nicotine per puff as the 10mg cartridge.

The benefit of a cartridge containing 15mg of nicotine is that it can be used for twice as long as the 10mg version, notes ARM 69, adding that this would "reduce the number of cartridges needed during a quit attempt and thereby aid patient compliance".

The Nicorette 15mg Inhalator will be indicated for "smokers wishing to quit or reduce prior to quitting", says ARM 69, adding it will "assist smokers who are unwilling or unable to smoke", and provide "a safer alternative to smoking for smokers and those around them".

If the switch is approved, Nicorette 15mg Inhalator will be available in packs of four, 20 and 36 cartridges.

■ Comments on ARM 69 should be sent by 11 January 2011 to Clare Hedges, Reclassification Unit, Room 3-O, 151 Buckingham Palace Road, London SW1W 9SZ, UK (E-mail: reclassification@mhra.gsi.gov.uk).

OTC

Retailers

Three pharmacy bodies speak with single voice

Three pharmacy associations in the UK have teamed up to establish a community pharmacy organisation with "a stronger, unified voice" for its members.

Set up by the Association of Independent Multiple Pharmacies (AIMp), the Company Chemists' Association (CCA) and the National Pharmacy Association (NPA), Pharmacy Voice will begin operating in the New Year.

The group had been established, said the three bodies, to simplify and strengthen the way they represented their members.

Noting the National Health Service (NHS) was entering "a period of rapid change", they said "community pharmacy must fulfil its potential and play an expanded role as a healthcare provider of choice in the new NHS".

This would be achieved by "offering unrivalled accessibility, value and quality for patients and driving forward both the medicines optimisation and public health agendas", the trio added.

Pharmacy Voice will be led by chairman Ian Facer and chief executive Rob Darracott. Facer is also chairman of the NPA, while Darracott serves as chief executive of the CCA.

Facer and Darracott were unanimously appointed by the Pharmacy Voice board, which consists of two nominees each from the AIMp, the CCA and the NPA.

The three organisations highlighted that they would continue to provide their members with a full range of other support services, such as insurance, training, and information.

OTC

CONSUMER *viewpoint*

Erectile dysfunction 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.

French men are more likely to say they have suffered from erectile dysfunction during the past year than their counterparts in Germany, Italy, Spain or the UK, according to our **Consumer** ***viewpoint*** European survey.

Of the five countries covered by the Ipsos MORI survey, France has the highest proportion of men who say they have suffered from erectile dysfunction during the past year at 1.6%, followed by Italy and the UK at 0.8%, Germany at 0.7% and Spain at 0.4% (see Figure 1).

Sufferers are more likely to be aged over 65 years in all five countries (see Figure 2).

The low incidence of erectile dysfunction in the survey countries means the following results should be treated with caution.

As can be seen from Figure 3, prescription products are the most popular treatment option in the survey countries.

The UK has the highest proportion of men who have treated the condition with an OTC remedy or a prescription product (see Figures 4 and 5). Germany has the highest proportion of herbal treaters (see Figure 6).

OTC

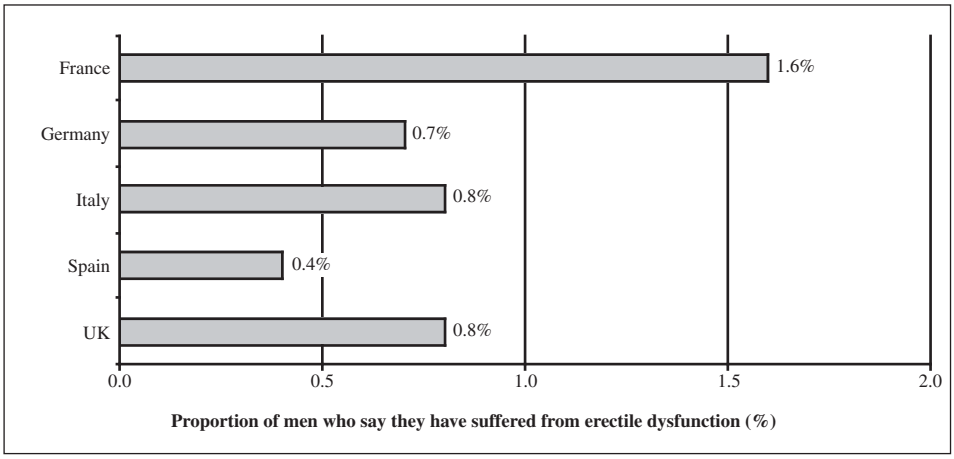


Figure 1: Proportion of men in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction within the past year (Source – OTC *bulletin* 2010/Ipsos MORI)

	Proportion of sufferers (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	100.0	100.0	100.0	100.0	100.0	–	–	–	–	–
Female	–	–	–	–	–	–	–	–	–	–
18-24	–	–	–	–	5.4	–	–	–	–	43
25-34	11.0	–	–	–	–	58	–	–	–	–
35-44	8.6	17.6	25.7	–	–	45	88	**130**	–	–
45-54	21.1	13.2	–	–	20.5	**137**	73	–	–	**121**
55-64	15.1	6.8	18.3	21.4	–	89	47	**124**	**170**	–
65+	44.2	62.4	56.0	78.6	74.1	**247**	**250**	**301**	**403**	**382**

Figure 2: Consumers in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction 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 erectile dysfunction, 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)

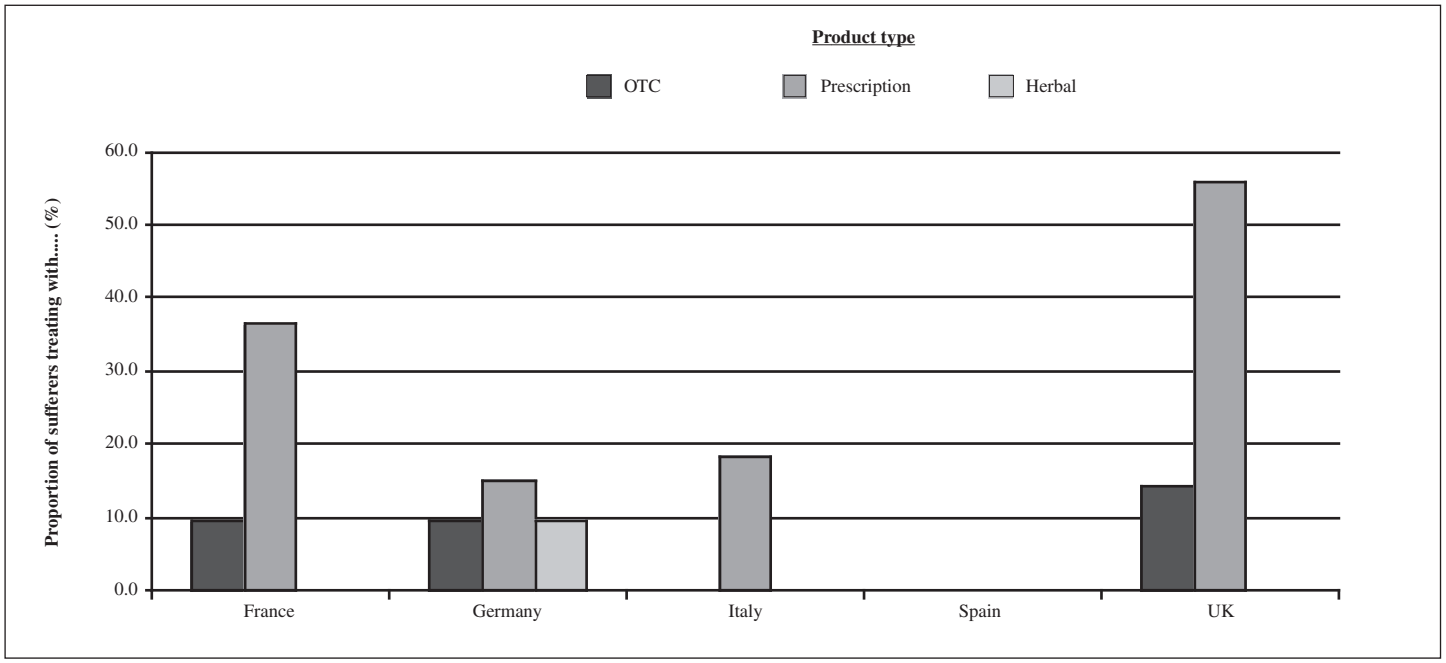


Figure 3: Proportion of men in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction who have treated the condition with an OTC, prescription or herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

..... erectile dysfunction

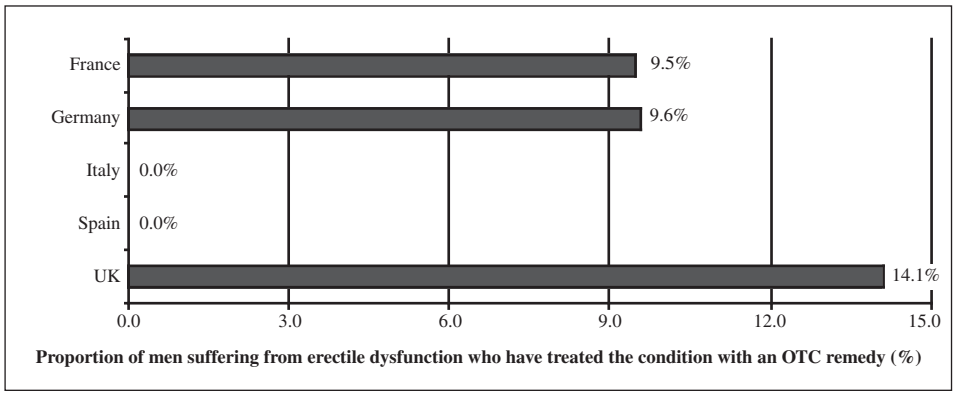


Figure 4: Proportion of men in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction who have treated the condition with an OTC remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

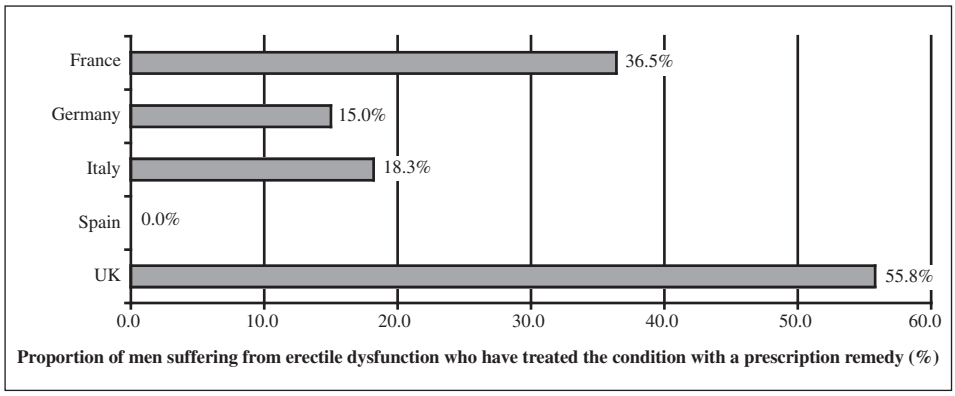


Figure 5: Proportion of men in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction who have treated the condition with a prescription remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

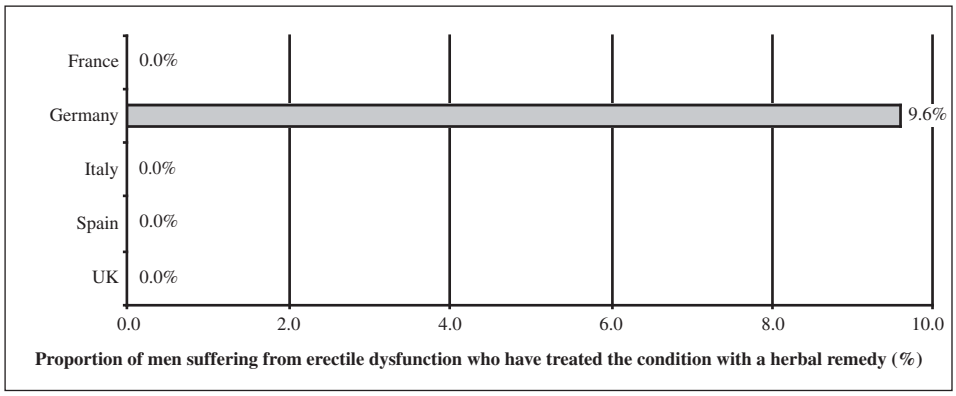


Figure 6: Proportion of men in France, Germany, Italy, Spain and the UK who say they have suffered from erectile dysfunction who have treated the condition with a herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

Ipsos MORI and the ailments survey

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

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

Advertising Complaints

ASA gives Lyclear the all-clear in UK

Claims made in Omega Pharma's television advertising for its Lyclear head-lice treatment have been given the okay by the UK's Advertising Standards Authority (ASA).

Rival Thornton & Ross lodged three complaints with the ASA about the commercial for Omega Pharma's Lyclear Spray.

Firstly, Thornton & Ross maintained that Omega Pharma's claim that Lyclear was "an unbeatable treatment for head lice" was misleading and could not be substantiated.

Noting that "unbeatable" was a top parity rather than a superiority claim, the ASA said it referred to the 100% effectiveness rate of the treatment only, and not the time or ease of use. As no treatment could exceed 100%, ruled the ASA, the advertisement was not misleading.

Secondly, Thornton & Ross challenged the claim that "Lyclear is guaranteed to remove 100% of head lice and eggs". Pointing out that egg removal was only possible with the use of a comb, Thornton & Ross said the commercial implied that a comb was not necessary.

However, the ASA rejected this challenge. The focus of the advertisement was the properties of the treatment, commented the ASA, adding that it understood that most viewers would be aware that a comb was needed.

The final complaint lodged by Thornton & Ross was that the commercial was misleading because it did not distinguish between the advertised spray and other less effective products in the Lyclear range.

Rejecting this complaint, the ASA noted that the advertisement focused on the spray only and not the portfolio of products.

OTC

IN BRIEF

■ **ASA** – the UK Advertising Standards Authority – has upheld three complaints about a press insert for **Revitalise's** joint pain tablets and cream. The ASA pointed out the company had made "breakthrough" claims – including that the products could reverse the effects of arthritis, eliminate pain and had no known side-effects – that could not be substantiated and were therefore misleading. Describing the insert as "irresponsible", the ASA added that it could discourage people from seeking essential treatment for a serious medical condition. The ASA ruled that the insert must not appear again in its current form.

OTC

"A new and delicious way to help Americans reach their recommended daily calcium and vitamin D intake," is how Pfizer Consumer Healthcare describes Caltrate Soft Chews.

Pfizer highlighted that new US health guidelines recommended that consumers increased their daily intake of vitamin D. The company said Caltrate Soft Chews, which come in a choice of chocolate truffle or vanilla crème flavours, were "a great-tasting and convenient way" to help them reach these goals.

Furthermore, pointed out Pfizer, each chew provided "20% more essential calcium than McNeil Nutritional's Viactiv" chews, and contained just 15 calories.

Pfizer is backing Caltrate Soft Chews with a television commercial featuring the sign-off message "We put the yum in calcium", as well as print and online activity aimed at women.

Two of the soft chews provide 1,200mg calcium and 800 IU vitamin D.

A pack of 60 chews has a recommended retail selling price of US$8.00-US$9.00 (€6.00-€7.00).

Pfizer acquired the Caltrate range of calcium supplements when it bought Wyeth for US$68 billion last year (OTC *bulletin*, 30 October 2009, page 3).

OTC

Regulatory Affairs

Clarityn's fast acting claim is stopped in UK by MHRA

MSD Consumer Care has agreed to stop using the "fast acting" claim for its Clarityn Allergy Tablets in the UK, after a complaint was made to the Medicines and Healthcare products Regulatory Agency (MHRA).

The company recently used the claim on its packaging and other marketing materials for Clarityn Allergy Tablets.

Rival firm McNeil Products complained to the MHRA because it believed the claim "Fast acting hay fever relief" used in point-of-sale material for the 10mg loratadine tablets was not supported by adequate evidence.

The MHRA upheld the complaint, pointing out that there was inadequate evidence to show that symptomatic relief could be achieved within around 30 minutes after taking the tablets.

According to the MHRA, claims for fast action for a hayfever product need to be supported by "evidence demonstrating that the average consumer would experience meaningful relief from their symptoms within a period of around 30 minutes after taking the product".

The MHRA noted that it had taken action to ensure the claims were removed from the packaging and advertising of other medicines containing loratadine.

McNeil's competing products Benadryl Allergy Relief and Benadryl Plus, which both contain the active ingredient acrivastine, are claimed to start working in 15 minutes.

Meanwhile, the MHRA has upheld a complaint against the consumer goods company Multibrands.

The firm had stated on a website that its Panodyne products, which are claimed to relieve pain, were "tested and certified by MHRA". However, the products were not authorised, said the MHRA, adding it did not test or certify individual products.

Multibrands has agreed to withdraw the website until the products have been authorised.

OTC

Marketing Campaigns

Durex plays with bewitching chemistry

Reckitt Benckiser is backing the Durex Play lubricants and massage products it has just acquired with a European advertising campaign that "explores the bewitching chemistry between lovers".

Created by the agency McCann Manchester, the campaign includes two television commercials, which made their debut in the UK at the end of November and will be rolled out to other countries in Europe over the next six months. The UK campaign, which is running for four weeks, also includes in-store, online and social media activity.

The commercials, which focus on Durex Play lubricants and Durex Play Massage 2 in 1 gels, are running terrestrially on Channel 4 and Five, as well as on satellite channels.

The commercial for Durex Play lubricants highlights the sexual chemistry between two lovers. A scantily clad woman is seen stroking different parts of a man's body with the lubricant. Her touch produces a tingling sensation on his skin, followed by drawings of flames and tigers.

"Discover new and exciting sensations with a magical range of Play lubes from Durex," states a sexy female voiceover.

Meanwhile, television advertising for Durex Play Massage 2 in 1 products features a passionate couple undressing and massaging each other with gel, leaving trails of "magic" over each other's bodies.

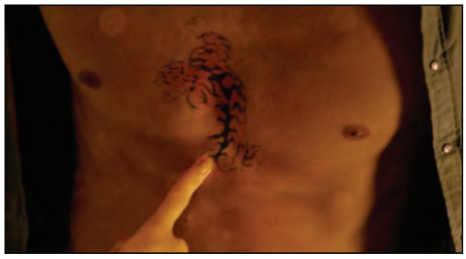
A female voiceover advises consumers to "get in the mood with the new Durex 2 in 1 Massage range".

Both commercials carry the sign-off message "Love sex. Durex". The company has just introduced this as the first-ever brand signature for Durex, marking a "strategic shift away from safe sex to more magical sex" (**OTC *bulletin***, 30 November 2010, page 15).

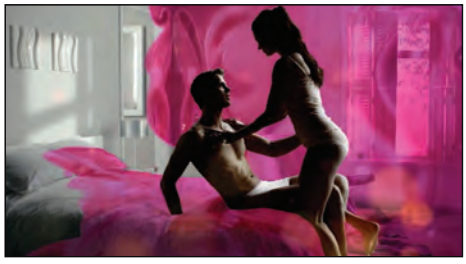
Commenting on the campaign for Durex Play, brand manager Katy Oliver, said "the magic of sexual connection is what makes this Durex campaign so special". "It is all too easy to get into the same routine, but sex should be magical," she explained.

Reckitt Benckiser gained the Durex 'powerbrand' after purchasing SSL International in a deal worth £2.54 billion (€2.97 billion) (**OTC *bulletin***, 30 July 2010, page 1).

OTC



A tiger is one of the images that appear on a man's skin in Reckitt Benckiser's new television commercial for Durex Play lubricants



A passionate couple are the stars of television advertising for Durex Play Massage 2 in 1 gels

"Love sex. Durex" is the sign-off message for both television commercials

Marketing Campaigns

Happy and healthy kids star in PediaCare spots

Prestige Brands Holdings is backing its recently-acquired PediaCare children's cough and cold remedies in the US with a new national television advertising campaign.

Tim Connors, chief marketing officer of Prestige, pointed out that the commercials were on air just two weeks after the company had acquired PediaCare. "It is our plan to reach consumers now, at the beginning of the cough/cold season, when parents are most in need of remedies for their children's ailments," he said, adding that Prestige was "fully committed to support and invest in PediaCare as a key brand".

Prestige explained that the two new commercials – created by the agency VIA Group – "repositioned the brand for continued long-term growth" by "celebrating the joys of healthy and happy children".

The campaign had a "cinéma vérité style", continued Prestige, adding that it captured "parent-child moments in a way that is reminiscent of a home movie shot by a mom or dad".

The first commercial supports PediaCare Infants Fever Reducer Pain Reliever, which was launched in September and contains the active ingredient acetaminophen.

A dietary supplement containing honey is the latest addition to Prestige's Little Remedies range for children in the US

Based around a giggling baby who has just recovered from a fever, the commercial features the on-screen text "Goodbye: Fever" followed by the word "Hello" accompanied by a yellow smiley logo. A voiceover points out new PediaCare infant drops with acetaminophen is "recommended by paediatricians to reduce fever".

Meanwhile, the second commercial focuses on PediaCare Children's Fever Reducer Pain Reliever Plus Multi Symptom Cold.

Images of a young girl dancing to music are accompanied by the on-screen message "Yesterday: Scratchy throat, fever.....Today: Dancing queen". A voiceover states that PediaCare is "relied on by moms and paediatricians to help kids feel better".

Prestige acquired PediaCare when it purchased Blacksmith Brands Holdings for US$190 million (€122 million) (**OTC *bulletin***, 29 September 2010, page 1).

The launch of PediaCare Infants Fever Reducer Pain Reliever came soon after Johnson & Johnson's McNeil Consumer Healthcare subsidiary recalled more than 40 OTC medicines for infants and children manufactured at its Fort Washington facility in the US. The recall included liquid Tylenol products containing acetaminophen, known as paracetamol in many markets (**OTC *bulletin***, 14 May 2010, page 1).

Johnson & Johnson has since resumed shipping limited quantities of the acetaminophen-based Children's Tylenol Grape Splash liquid (**OTC *bulletin***, 15 October 2010, page 4).

In a separate development, Prestige Brands has extended its Little Remedies range in the US with a dietary supplement that is claimed to naturally soothe infants' coughs with honey.

The company said that Little Colds Honey Elixir "brings the benefits of natural honey" to children aged one to four years – the group most often advised against taking medicated products for a cough or sore throat.

A giggling baby and a dancing girl are the stars of Prestige's first television campaign in the US for its recently-acquired PediaCare brand

The newcomer offered a "pleasant, sweet taste that makes taking the elixir easier for kids who don't like the taste of most medications", Prestige commented.

Furthermore, added the company, the product did not contain any alcohol, saccharin, dyes and gluten.

New addition "soothes cough naturally"

A packaging strapline highlights that the newcomer is "Non-medicated". Meanwhile, bullet-points state that it is "Safe for toddlers 12 months & older", "Soothes cough naturally" and "Calms fiery throats".

Infants aged one to four years should take a teaspoon every two to four hours. The supplement is also suitable for children aged over four years, who should take two teaspoons every two to four hours.

The recommended retail selling price for a 120ml pack is US$6.99.

OTC

Homoeopathic Medicines

Study by Sophien supports Katimun

German company Sophien-Arzneimittel said it had achieved "clear success" with what it claims is the country's first scientifically-conducted observational study of a homoeopathic medicine. The study involved 64 consumers who had bought Sophien's Katimun homoeopathic cold remedy in 14 pharmacies spread throughout Germany.

Of this group of consumers, 11% reported feeling better on the first day after taking Katimun, and nearly half – 47% – said there had been an improvement two or three days after taking the product.

A further third of the group of consumers felt better more than three days after taking the licensed medicine, which contains extracts of boneset, bryony, jessamine, monkshood and sorrel.

OTC

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DEALS TO DRIVE YOUR BUSINESS

Long-lasting relief from dry, burning and painful eyes is the on-pack claim for Bausch & Lomb's Artelac Rebalance eye drops in Germany.

The company explained that the artificial tears used "an innovative two-polymer combination" of hyaluronic acid and PEG 8000 to rebalance moisture levels in the eye. While 0.15% hyaluronic acid is said to offer rapid distribution across the eye's surface with hydrophilic properties, PEG 8000 increases how the acid remains on the cornea.

Bausch & Lomb noted that Artelac Rebalance's moisturising effect was boosted by electrolytes including calcium, magnesium and potassium – as well as vitamins such as vitamin B12 – that were naturally found in tears.

According to the company, the artificial tears used the "innovative preservative" Oxyd, which broke down into the constituents of tears – water, oxygen and salts – upon coming into contact with the eye.

Bausch & Lomb said the 10ml bottle of eye drops was portable and easy to use. It has a recommended retail price of €13.99.

The company is promoting the medical device through advertising in the trade press and inserting laminated information cards in pharmacists' magazines.

Furthermore, Bausch & Lomb is running promotions with certain online pharmacies, whereby customers who order Artelac Rebalance receive a free branded lip balm.

OTC

IN BRIEF

■ **ASA** – the UK's Advertising Standards Authority – has upheld a complaint about a press advertisement for **NeoCell's beauty supplement** containing collagen. Rival company Vitabiotics challenged whether the headline "The world's best selling natural beauty supplement" was misleading. The ASA noted that consumers might not realise the claim referred to collagen supplements only. Vitabiotics also questioned whether claims that the product led to "the reduction of fine lines and wrinkles" and "repaired nails" could be substantiated. The authority concluded that NeoCell could not support these claims, which were therefore misleading. The ASA ruled the advertisement must not appear again in its current form.

OTC

Launches

Flucalyptol offers France 'free access' pholcodine

A 'free-access' version of Zambon's Biocalyptol cough syrup has been launched in France under the brand name Flucalyptol.

The eucalyptus-flavoured medicine for dry and irritating coughs contains 1.31mg/ml of the cough suppressant pholcodine. The non-reimbursable, non-prescription medicine comes in a 200ml bottle.

France's 'free-access' initiative, allowing self-selection displays of certain non-prescription medicines in pharmacies, was launched in 2008 (**OTC *bulletin***, 31 July 2008, page 17).

Flucalyptol Toux Sèche is suitable for adults and children above six years of age. The medicine comes with a measuring cup that allows cough sufferers to prepare the correct dose.

The adult dose is 15ml up to four times a day. Children between 12 and 15 years of age can take 5ml up to six times a day, while children younger than 12 years of age can take 2.5ml up to six times a day. The maximum treatment period is five days.

Other 'free access' cough syrups containing pholcodine include Cooper's Clarix Sirop, Laboratoires Genévrier's Codotussyl Toux Sèche, Laboratoires Urgo's Toux Sèche Humex and Sanofi-Aventis' Rhinathiol Toux Sèche.

Zambon's Flucalyptol is a non-reimbursable medicine

Zambon's Biocalyptol is a reimbursable, non-prescription medicine.

OTC

Relaunches

GlaxoSmithKline rethinks Contac in UK

GlaxoSmithKline Consumer Healthcare has replaced its Contac 12 Hour Relief decongestant medicine with Contac Dual Relief in the UK.

According to the company, Contac 12 Hour Relief – a pharmacy-only (P) medicine containing 120mg pseudoephedrine hydrochloride per prolonged-release capsule – had been discontinued because of "export restrictions in the country of manufacture".

New Contac Dual Relief tablets contain paracetamol as well as pseudoephedrine

GlaxoSmithKline said the new non-drowsy formulation would provide "additional benefits to consumers due to its dual-action formula".

Contac Dual Relief comprises tablets containing 30mg pseudoephedrine hydrochloride and 500mg paracetamol. Packaging highlights that the P medicine is a "New formula with paracetamol" that "Clears nasal and sinus congestion" and "Relieves headache and pain".

The newcomer is suitable for adults and children aged over 12 years, who should take two tablets up to three times a day.

A pack of 18 tablets has a recommended retail selling price of £3.89 (€4.59).

Restrictions have been imposed on medicines containing pseudoephedrine in a number of countries because of the potential for misuse in the illegal manufacture of methylamphetamine or 'crystal meth'.

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Nicotine gum that helps to keep teeth white while doubling the chances of quitting smoking is the latest addition to McNeil Consumer Healthcare's Nicorette portfolio of smoking-cessation aids in Germany.

Nicorette Kaugummi Whitemint comes in a choice of 2mg and 4mg nicotine strengths, and is said by McNeil to have an "irresistible fresh mint flavour".

The newcomer joins the existing Mint, Freshmint and Spicemint flavours, as well as the Classic and Freshfruit variants.

Launch trade-press advertising for Whitemint stresses that the flavour is "neu vom Marktführer", or "new from the market leader". The gum is said to "maintain the natural whiteness of teeth".

Thirty-piece packs of the pharmacy-only medicine have recommended retail selling prices of €9.93 for the 2mg strength and €11.00 for the 4mg version.

Larger packs containing 105 pieces are also available.

OTC

Line Extensions

Anadin gets a boost in UK with effervescent ibuprofen

Pfizer Consumer Healthcare has extended its Anadin pain relievers in the UK with effervescent ibuprofen tablets that are claimed to work "four times faster than standard ibuprofen".

The company is positioning Anadin LiquiFast Effervescent tablets, which each contain 200mg ibuprofen, as "a perfect painkilling solution" for people who have trouble swallowing capsules or tablets. The newcomer can relieve back, muscle, period and dental pain.

Describing the effervescent tablets as "powerful" and "cleverly designed", Pfizer said they "dissolve quickly and easily in water", and "work fast to relieve your pain and let you get on with your life".

"Aside from easing pain," Pfizer continued, the tablets "also help relieve inflammation by blocking prostaglandin production in the tissues of the body".

A general-sales list (GSL) medicine, Anadin LiquiFast Effervescent is grapefruit flavoured. It has a recommended retail selling price of £3.49 (€4.19) for a pack of 10 tablets.

The tablets are suitable for adults and children aged over 12 years. Users should take one or two tablets dissolved in a glass of water every four to six hours, and take no more than six in a 24-hour period.

Effervescent tablets containing 200mg ibuprofen are the latest addition to Pfizer Consumer Healthcare's Anadin range of pain relievers in the UK

Pfizer is currently backing the Anadin brand with television, print and radio advertising based on the theme "Wherever your pain your answer is Anadin" (**OTC *bulletin***, 16 November 2010, page 17).

The company has also recently repackaged the range, revamped its website at www.anadin.co.uk and launched an iPhone application.

Pfizer acquired Anadin when it purchased Wyeth for US$68 billion last year (**OTC *bulletin***, 30 October 2009, page 3).

OTC

Marketing Campaigns

Pepto-Bismol puts a stop to American under-indulgence

Procter & Gamble is backing its Pepto-Bismol stomach remedy in the US with a television and digital marketing campaign focusing on "holiday party under-indulgence".

The company explained that the humorous campaign "aims to increase awareness about this common buzz kill at all holiday parties". It added that it had teamed up with actor Ken Jeong – who recently starred in the movies *Knocked Up* and *The Hangover* – to fulfil this "very important initiative".

"Under-indulgent tummies are as dead as a condemned disco club," commented Jeong. "Enjoying your holiday parties includes enjoying various meats and treats. Normal indulging is fine and if you occasionally overdo it, Pepto has you covered."

Created by the agency Publicis, the campaign includes a 15-second television commercial, which will run throughout December on channels including ABC, CBS, FOX and NBC.

A man and woman holding virtually empty plates at a Christmas party are interrupted by Jeong, who bursts in between them and knocks the plates out of their hands. "Pathetic. Call this a holiday party? We need a help," he says, pointing out "these people are under-indulgers" who are "not enjoying the holidays".

The party begins to liven up as Jeong explains that "together, we can end under-indulgence". "And if you over-do it, Pepto-Bismol's got you covered," he adds, grabbing a bottle of Pepto-Bismol.

The commercial ends with the sign-off message "Eat, drink & be covered".

The company is also backing Pepto-Bismol with a 30-second online video based around the same theme. It is available on Facebook at www.facebook.com/peptobismol and on YouTube at http://www.youtube.com/peptobismol.

In addition, Procter & Gamble is running a public relations campaign offering "search and rescue tactics to liberate under-indulgers".

Procter & Gamble's humorous television commercial for Pepto-Bismol in the US stars Ken Jeong

OTC

An extra strong lotion that kills 100% of head lice within just 15 minutes of a single application is the latest addition to Cooper's Pouxit range of head lice treatments in France.

Pharmacy-press advertising for Pouxit XF – which stands for "extra fort" or "extra strong" – calls the product the "ultimate weapon" against head lice. It points out Pouxit XF contains the additive Penetrol, which makes the eggs of head lice absorb the product more effectively than other Pouxit treatments.

Clinical tests indicate that just one shampoo with Pouxit XF kills all head lice within 15 minutes, Cooper claims, after which the product can be rinsed out of the hair. Other Pouxit products must be applied for an hour, and then reapplied seven days later to kill young head lice that had not been affected by the first application.

The odourless, colourless and insecticide-free product – which is available in a 100ml bottle of 4% dimeticone lotion – can be used on children from the age of six months and is suitable for pregnant women and asthmatics.

OTC

Marketing Campaigns

Coughing animals promote Buttercup's benefits in UK

Coughing animals highlight that Buttercup Syrup contains "only natural active ingredients" in Omega Pharma's new television advertising campaign for the medicine in the UK.

Devised by the agency VCCP, the £0.25 million (€0.30 million) plus campaign is built on the sign-off message "It's soothing, by nature".

The humorous campaign comprises a 30-second commercial together with a 10-second cut-down version, both of which are running until 23 January on channels including ITV1, ITV2, Fiver and Sky. It is voiced by comedians Jon Culshaw and Kevin Bishop.

Filmed in the style of a nature programme, the commercial features different animals – including a stag and a bird – that cannot stop coughing. After a pair of grebes joke about the animals, the stag takes action by instructing the others to "take Buttercup".

A mouse then appears and advises consumers that "For an effective cough medicine with only natural active ingredients, choose Buttercup Syrup". "It's soothing, by nature," states the mouse, as packs of the medicine appear in the landscape shot.

The commercial ends with the bird flying up into the air and squawking excitedly: "I'm feeling better now."

Commenting on the approach taken in the campaign, Omega Pharma said the focus on soothing – rather than fighting – coughs clearly differentiated the Buttercup brand from its competitors. "The intention of this campaign is to stand out by communicating a different and unique reason to purchase, and to engage consumers with humour and a refreshingly different tone of voice," the company added.

"It's soothing, by nature" is the theme of Omega Pharma's new television advertising for Buttercup Syrup in the UK

OTC

Launches

J&J refreshes Aveeno eczema range in US

Johnson & Johnson has replaced its Aveeno Eczema Care products in the US with a trio of "clinically shown" moisturisers aimed at adults and babies.

The company said the "breakthrough formulas", which contained natural colloidal oatmeal and oat essence, supported healthy development of delicate skin and helped relieve irritation due to mild to moderate eczema.

The three products – Aveeno Baby Eczema Therapy Moisturizing Cream, Aveeno Baby Cleansing Therapy Moisturizing Wash and Aveeno Eczema Therapy Moisturizing Cream for adults – did not contain parabens, steroids or propylglycol, added Johnson & Johnson.

Johnson & Johnson highlighted a clinical study in which the baby wash and cream had improved multiple symptoms of eczema in over 90% of babies who had been treated with the products daily.

Packaging for the products carries the National Eczema Association's Seal of Acceptance.

A trio of moisturisers for adults and babies suffering from eczema has been added to Johnson & Johnson's Aveeno portfolio in the US

Johnson & Johnson said it had teamed up with the National Eczema Association to "educate and empower" eczema sufferers about the condition for the winter. The campaign includes online videos – entitled 'Introducing Aveeno Eczema Therapy', 'Revolutionary Ingredient' and 'Soothing Skin Testimonial" – which are available on the Facebook social-networking site.

The firm is also running consumer-press advertising and public relations activity.

The cream for adults is supplied in a 7.3 oz tube with a recommended retail selling price of US$8.20 (€6.19). Supplied in a 5.0 oz tube, the cream for babies retails at US$5.99, while an 8.0 fl.oz bottle of the wash for babies has a price of US$4.99.

The discontinued Aveeno Eczema Care range offered a body wash and cream suitable for both adults and babies (**OTC *bulletin***, 25 January 2008, page 13).

OTC

JANUARY

20 January

■ **Herbal Products After April 2011**

London, UK

A one-day seminar organised by the British Herbal Medicine Association (BHMA) and the Royal Pharmaceutical Society (RPS). It will focus on the end of the transitional period for the European Union's traditional herbal medicinal products directive, and will explore the borderline between medicines, foods, cosmetics and medical devices.

***Contact**: Royal Pharmaceutical Society (RPS).*
Tel: +44 20 7572 2737.
Fax: +44 20 7735 7629.
E-mail: support@rpharms.com.
Website: www.rpharms.com.

26 January

■ **Homoeopathic Medicines**

Bonn, Germany

Speakers from Germany's federal institute for drugs and medical devices, BfArM, will be at this one-day conference run by Germany's medicines manufacturers' association, the BAH. It will be conducted in German.

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

26 January

■ **Marketing Authorisation in Turkey**

Frankfurt, Germany

Classification and pharmacovigilance in Turkey are on the agenda for this one-day conference.

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

27-28 January

■ **Latest Developments in Pharmacovigilance**

London, UK

A two-day event focusing on developments in Europe and the US.

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

FEBRUARY

3 February

■ **Basics of Regulatory Affairs**

London, UK

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

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

8 February

■ **Introduction to Medicines Law**

Bonn, Germany

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

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

10 February

■ **The Pharma Summit 2011**

London, UK

This event will look at 'Reinventing pharma for a new generation'.

***Contact**: Economist Conferences.*
Tel: +44 20 7576 8116.
Fax: +44 20 7576 8472.
E-mail: weurope_customerservice@economist.com.
Website: www.economistconferences.com.

17-18 February

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

London, UK

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

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

22-23 February

■ **Variations Regulation**

Bonn, Germany

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

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

1-2 February

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

Brussels, Belgium

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

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

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

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

24 February

■ **Hot Topics in Advertising**

A one-day event run by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

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

28 February-1 March

■ **EuroPLX 45**

Lisbon, Portugal

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

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

MARCH

10-12 March

■ **CHPA Annual Executive Conference**

Aventura, Florida, US

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

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

22-23 March

■ **Regulatory Affairs in India and China**

Frankfurt, Germany

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

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

28-30 March

■ **DIA Annual EuroMeeting**

Geneva, Switzerland

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

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

JUNE

8-10 June

■ **47th AESGP Annual Meeting**

Rome, Italy

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

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

2010 turns out to be an eventful year

Product recalls, mergers and acquisitions, people on the move, traditional herbal medicinal products and food claims have all been hot topics in 2010. Deborah Wilkes reports.

Companies dominated the headlines in 2010, with both good and bad stories unfolding during the year. Johnson & Johnson's McNeil Consumer Healthcare subsidiary had a truly terrible time, following a series of product recalls and suspension of production at its Fort Washington manufacturing facility in the US. By contrast, Reckitt Benckiser finally acquired SSL International after years of speculation, and has just agreed to buy India's Paras Pharmaceuticals (see front cover). Meanwhile, Sanofi-Aventis continued to grow its OTC business with acquisitions in Canada, China, Poland and the US.

People on the move

People on the move in the OTC industry also hit the headlines on a regular basis. One of the biggest stories came in September, when Johnson & Johnson announced that Colleen Goggins would step down as worldwide chairman of its troubled Consumer division at the beginning of March 2011 (**OTC *bulletin***, 29 September 2010, page 25).

Goggins will leave Johnson & Johnson just over a year after the company received a Warning Letter from the US Food and Drug Administration (FDA) about McNeil Consumer Healthcare's plant in Las Piedras, Puerto Rico (**OTC *bulletin***, 10 February 2010, page 22). A few months after receiving the Warning Letter, McNeil also announced that it had suspended production at its Fort Washington facility after voluntarily recalling over 40 OTC medicines for infants and children made at the plant (**OTC *bulletin***, 14 May 2010, page 1).

> ***By 13 December 2010, 194 traditional herbal medicines had been registered using Europe's simplified procedure***

The recalls sparked an investigation by the Committee on Oversight and Government Reform within the US House of Representatives. Goggins told the committee hearing that the recall was a "disappointment" and that McNeil's quality and process issues had been "unacceptable" (**OTC *bulletin***, 11 June 2010, page 11). She also apologised to parents for the "concern and inconvenience caused".

As **OTC *bulletin*** went to press, Johnson & Johnson had just announced more product recalls affecting its Rolaids brand in Canada and the US (see page 8).

As a result of its troubles, Johnson & Johnson expects that US sales at its OTC & Nutritionals business will decline by US$600 million (€457 million) during 2010 .

Meanwhile, at the beginning of 2010, Sanofi-Aventis recruited Hans Regenauer – previously worldwide head of Boehringer Ingelheim's Consumer Health Care division – to develop its OTC business. Regenauer took on the newly-created post of vice-president, Consumer Health Care, Europe, and global development (**OTC *bulletin***, 20 January 2010, page 22).

News of Regenauer's appointment followed hard on the heels of the announcement that Sanofi-Aventis intended to enter the US OTC market by acquiring Chattem for around US$1.9 billion (**OTC *bulletin***, 20 January 2010, page 1). Since then, Sanofi-Aventis has boosted its OTC business by acquiring Poland's Nepentes for PLN420 million (€105 million) and Canada's Canderm for an undisclosed sum. Last month, it unveiled plans to strengthen its presence in the Chinese OTC market by acquiring BMP Sunstone and its portfolio of cough/cold and women's health brands for around US$520 million (**OTC *bulletin***, 16 November 2010, page 1).

Merck & Co signalled its ambitions for its recently-acquired Consumer Care business in February by recruiting Bridgette Heller to lead the operation. Previously president of Johnson & Johnson's global Baby business unit, Heller has a brief to grow the Consumer Care business in non-US markets (**OTC *bulletin***, 26 February 2010, page 1).

The following month, GlaxoSmithKline announced that it had recruited the next worldwide head of its Consumer Healthcare division from cosmetics company L'Oreal. Emma Walmsley – formerly leader of L'Oreal's Consumer Products business in China – joined GlaxoSmithKline on 1 May as European president and worldwide president designate of the worldwide Consumer Healthcare division (**OTC *bulletin***, 31 March 2010, page 1).

And in April, it emerged that Dirk Van de Put was leaving Novartis just eight months after becoming worldwide head of the company's OTC business unit (**OTC *bulletin***, 30 April 2010, page 23).

Although companies and people grabbed the lion's share of the headlines in 2010, regulatory issues also had their fair share of coverage.

Herbal medicines were recently back in the news when Members of the European Parliament (MEPs) probed John Dalli, European Commissioner for health and consumer policy, about the European Union's simplified procedure for registering traditional herbal medicinal products (**OTC *bulletin***, 30 November 2010, page 12).

Two MEPs pointed out that no Chinese or Indian Ayurvedic medicinal products had so far been registered using the simplified procedure. They wanted to know whether the Commission planned to amend Directive 2004/24/EC to make it more applicable to non-European herbal cultures before the transition period ended in April of next year.

Products that were already on the market when the directive entered into force have to comply with its requirements by 30 April 2011.

Noting the simplified procedure was handled by member states, Dalli said the Commission did not have information on the products licensed by the member states. As a result, he added, it did not know whether there had been applications and registrations for Chinese or Indian products.

Does not reduce access

However, Dalli insisted that the European Union's simplified procedure for registering traditional herbal medicinal products did not reduce access to Chinese or Indian products. Neither did it reduce access to products of companies with reduced financial capacity, he said.

Dalli stressed that the simplified procedure facilitated the possibility to place specific traditional medicinal products on the European market, and did not introduce new requirements more burdensome than the ones following from the marketing authorisation procedures.

"On the contrary," Dalli maintained, "the aim of these rules is to safeguard public health and at the same time facilitate the free circulation of traditional herbal medicinal products within the European market."

Dalli was adamant that if a traditional herbal medicinal product was not registered or authorised as such by 1 May 2011, then the product could not be placed on the European market.

According to figures compiled by the Association of the European Self-Medication Industry, the AESGP, the number of registrations in Europe is growing relatively fast but is still low.

The AESGP told **OTC *bulletin*** that 194 products had been registered using the simplified procedure by 13 December 2010. This is up from 162 at the end of April 2010 (**OTC *bulletin***, 30 June 2010, page 23), and 66 a year earlier (**OTC *bulletin***, 19 June 2009, page 19).

The UK leads the way in terms of the number of traditional herbal medicinal products registered by 13 December 2010. The UK had registered 73 products, almost double the number achieved by second-placed Austria with 40.

Of the 194 traditional herbal medicinal products registered, 129 contain only one plant and 65 contain combinations of plants.

Some companies are taking their products to market via alternative routes, such as authorisation as a well-established herbal medicine or a food supplement. Dalli noted that herbal products may be placed on the market as foods, provided that they do not fulfil the definition of medicinal products.

Companies are also tapping into the existing pool of registrations. Schwabe Pharma UK, for example, said in October that it could supply other firms with a 'piggy-back' variation to its registrations for Thisilyn Milk Thistle and Thisilyn Maximum Strength Milk Thistle in the UK. "Some companies have already contacted us and are in a position to launch their own versions of our milk thistle traditional herbal medicines before the April 2011 deadline," commented the company (**OTC *bulletin***, 15 October 2010, page 15).

Schwabe Pharma UK highlighted that it already had 18 registrations for traditional herbal medicines, and planned to obtain more.

A portfolio of registrations for traditional herbal medicines is also available from Diapharm. The German pharmaceutical services provider recently announced that it had registered Europe's first traditional herbal medicinal product to be combined with minerals (**OTC *bulletin***, 15 October 2010, page 8).

The traditional herbal medicine containing 40mg hawthorn extract together with potassium and magnesium salts has just been registered by Germany's federal institute for drugs and medical devices, BfArM. It is indicated for supporting cardiovascular function and protecting against climatic stress.

Diapharm said it planned to register the traditional herbal medicine in other European countries, including Austria and the UK.

Slow progress with herbal products was behind the European Medicines Agency's (EMA's) announcement in June of an action plan to increase significantly the "quality and number" of Community herbal monographs and list entries produced by its Committee on Herbal Medicinal Products (HMPC).

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

Since directive 2004/24/EC came into force six years ago, only seven entries have been added to the Community list (**OTC *bulletin***, 31 May 2010, page 15). The HMPC proposes entries to the Commission, which then adds them to the Community list.

Meanwhile, only around 70 monographs have been finalised (**OTC *bulletin***, 15 October 2010, page 9).

Full application of the directive would require between 200 and 300 herbal monographs, the HMPC has said in the past.

The low number of herbal monographs – together with the unwillingness of some countries to act upon them – is causing problems for industry. **OTC *bulletin*** understands that gaining access to market for new herbal medicines, including traditional herbal medicinal products, is a key concern for industry.

The OTC industry will have a chance to air its views on both food claims and traditional herbal medicinal products in February

Another hot topic during 2010 was food claims. The European Commission recently decided to change the process for adopting general health claims for foods (**OTC *bulletin***, 15 October 2010, page 1).

The move came after industry and some member states complained about the Commission's progressive approach whereby claims were set to be adopted in a number of batches. They pointed out that this approach could lead to market distortions between companies whose claims had been rejected and companies whose claims had not yet been assessed.

Botanicals were treated differently

Furthermore, concerns had been expressed that botanical ingredients were treated differently under the food claims regulation than they were under the legislation for traditional herbal medicinal products.

The Commission announced in October that the community list of permitted general health claims for foods would now be established in two steps. The list for all substances other than botanicals would be adopted in a single step, it explained, with claims for botanicals considered once the first step had been completed.

The Commission noted that the European Food Safety Authority (EFSA) was expected to finalise opinions on all claims other than botanicals by the end of June 2011. The Commission would then "immediately" follow up with the necessary legislative measures.

The community list of permitted general health claims for foods – covered by Article 13.1 of regulation 1924/2006 – should have been completed by 31 January 2010. However, it became clear some time ago that the deadline would not be met (**OTC *bulletin***, 30 October 2009, page 18).

The first batch of permitted general health claims was finally put forward for adoption recently. But the European Union's Standing Committee on the Food Chain and Animal Health (SCFCAH) did not adopt the claims (**OTC *bulletin***, 30 July 2010, page 13).

Adoption was necessary for these general health claims to be included in a community register, as described by Article 20 of the regulation. Claims rejected by EFSA would have featured in a negative list in the community register and would have had to have been withdrawn from the market.

The first batch was based on the scientific opinions published by EFSA last October. EFSA only gave the go-ahead to a third of the first group of 500-plus general health claims assessed (**OTC *bulletin***, 16 October 2009, page 11).

EFSA published a second group of opinions earlier this year (**OTC *bulletin***, 17 March 2010, page 11). Only a handful of the 416 submissions in the second group were given the okay.

When the third group of opinions was published in October, most of the 808 submissions had been rejected (**OTC *bulletin***, 29 October 2010, page 9).

EFSA has now said no to 80% of the 1,745 general-function health claims assessed to date. So far, the authority has assessed just over a third of the 4,637 health claims compiled by European Union member states and the European Commission.

The OTC industry will have a chance to air its views on both food claims and traditional herbal medicinal products at a meeting organised by the AESGP in Brussels on 1-2 February. Speakers will include Basil Mathioudakis and Paola Testori-Coggi of the European Commission, and EFSA's Albert Flynn (see page 19).

Ending on a positive note, 2010 saw the arrival of Boehringer Ingelheim's Flomax Relief in the self-medication arena. The UK was the first country in the world to make 0.4mg tamsulosin hydrochloride a non-prescription medicine for treating benign prostatic hyperplasia (BPH), or an enlarged prostate (**OTC *bulletin***, 31 March 2010, page 13).

OTC

Manufacturers

Wines moving to Seven Seas

Omega Pharma's **Andy Wines** is moving to Seven Seas as marketing director at the beginning of 2011.

Wines has been Omega's marketing director for the UK and Ireland since November 2009. Together with the team at Omega, he has revamped the consumer marketing campaigns for a number of brands including Jungle Formula and Wartner (**OTC *bulletin***, 11 June 2010, page 8).

He pointed out that his eight years at Roche Consumer Health would be valuable when dealing with the Seven Seas portfolio of food supplements. Wines held the positions of marketing director, global head of category marketing and group brand manager at Roche Consumer Health, which is now part of Bayer HealthCare, and worked on the company's Berocca and Sanatogen food supplements.

Wines has also had global marketing posts at Johnson & Johnson and Reckitt Benckiser.

Andy Wines

OTC

IN BRIEF

■ **TBWA\PALING WALTERS** said its chairman and chief executive officer, **Mike Paling**, had received the Judge's Award for Outstanding Contribution to Pharmaceutical Marketing at the UK's Pharmaceutical Marketing Excellence Awards (PMEAs). At the end of this year, Paling will hand over the running of the health communications agency – which he founded 30 years ago and is now part of the TBWA\London Group – to managing director **Andy Hayley**. Paling will continue to advise and support the UK-based agency in a non-executive chairman's role.

OTC

Manufacturers/Retailers

NBTY names Nagel as its new chief executive

NBTY has appointed **Jeffrey Nagel** as its new chief executive officer. Nagel succeeds **Scott Rudolph**, who will continue as chairman of the US-based nutritional supplements manufacturer and retailer.

The news of Nagel's appointment comes shortly after NBTY was acquired by the private-equity company The Carlyle Group in a deal worth US$3.8 billion (€2.8 billion) (**OTC *bulletin***, 15 October 2010, page 2).

Commenting on the appointment, Rudolph said that Nagel would be able to "take NBTY to the next level of growth and performance and further establish its position as a global market leader".

Jeffrey Nagel

Joins from General Electric

Nagel joins NBTY from General Electric Company (GE), where he most recently served as vice-president and general manager of GE Oil & Gas Global Services. His previous positions at the company included president and chief executive officer of GE Inspection Technologies, general manager of business development at GE Aircraft Engines, and president of GE Home Electric Products. Nagel joined GE in 1997 as a manager in business development at GE Lighting.

Prior to joining GE, Nagel worked at Energy Biosystems, Cannon Associates, Reid & Hostage, and Strategic Planning Associates (now Mercer Management).

OTC

Manufacturers

Prestige recruits new finance chief

Prestige Brands Holdings has recruited **Ron Lombardi** as the replacement for its retiring chief financial officer **Pete Anderson**.

The US-based company said that Lombardi brought extensive financial management experience to his new role. Most recently, he served as chief financial officer for Waterbury International Holdings, a private equity-owned firm.

Commenting on the appointment, Matthew Mannelly, president and chief executive officer of Prestige, described Lombardi as a "results-orientated financial professional". "His extensive background in business development, acquisitions and divestitures, and debt and equity structuring will serve Prestige well as we move into our next phase of growth following our recent acquisition of Blacksmith Brands," he said.

Prestige acquired Blacksmith Brands Holdings and its portfolio of OTC brands for US$190 million (€122 million) (**OTC *bulletin***, 29 September 2010, page 1).

Mannelly noted that Anderson had made "many significant contributions to Prestige" during his 10 years with the company.

OTC

Retailers

China Nepstar changes finance head

China Nepstar said its chief financial officer, **William Weili Dai**, had left the drugstore chain due to "personal reasons".

Zixin Shao – vice-president and financial controller of the company – has been promoted to chief financial officer. He joined in 2003.

Previously, Shao worked as a director, vice general manager and chief financial officer in China Resources Supermarket (Suzhou) Co.

OTC

Manufacturers

Merck raises Frazier to chief executive officer

Merck & Co has promoted **Kenneth Frazier** to chief executive officer with effect from 1 January 2011. He will also remain president of the US-based pharmaceutical company.

Frazier will replace **Richard Clark**, who will continue in his role as chairman. Clark has been chief executive officer since 2005.

Merck said Frazier's appointment was the result of a "long-term thoughtful succession-planning process".

Frazier has spent 18 years with Merck in a number of senior posts, including general counsel from 1999-2007. He was appointed executive vice-president and president of Global Human Health in 2007, before becoming president of Merck earlier this year (**OTC *bulletin***, 14 May 2010, page 27).

Merck pointed out that he had played a key role in the firm's US$41 billion (€32 billion) acquisition of Schering-Plough (**OTC *bulletin***, 17 March 2009, page 1).

The company also noted that Frazier had improved the effectiveness of its three largest worldwide divisions responsible for pharmaceutical and vaccine sales and marketing, research and development, and manufacturing and supply.

Kenneth Frazier

Merck said that in his new position Frazier would "take the helm and guide the continued implementation of our long-term strategy".

The company's strategy includes expanding the reach of its Consumer Care business in Europe and emerging markets (**OTC *bulletin***, 18 August 2010, page 1).

OTC

Retailers

Walmart sues CVS over Mullany

Walmart has taken legal action against CVS Caremark over its appointment of **Hank Mullany** as president of the CVS/pharmacy retail operations in the US.

Mullany, 52 – former executive vice-president and president of Walmart North – has been temporarily suspended from joining CVS after Walmart filed a lawsuit in the Court of Chancery in Delaware claiming that he is in breach of a contract forbidding him from working for a competitor for two years. Mullany worked at Walmart until 5 November.

Allegations are "without merit"

CVS insisted that the allegations in the lawsuit were "without merit".

If Mullany is granted permission to join CVS following a preliminary hearing on 15 December, he will bring nearly 30 years of retail experience to the US pharmacy chain.

Noting that Mullany had "a strong background in operations, finance and strategic planning", CVS pointed out that he had been responsible for the operation of 1,300 stores across 19 states in his role at Walmart.

Earlier in his career, Mullany held a number of senior management roles, including as president of Genuardi's Family Markets.

Larry Merlo, president and chief operating officer of CVS Caremark, said Mullany understood the many demands and challenges of the retail business. "His expertise, along with his demonstrated ability to execute strategies and produce outstanding results, make him the right candidate to drive continued growth in our retail business and further our industry leadership for many years to come," he added.

Mullany is set to succeed Merlo, who will replace **Tom Ryan** as chief executive officer at CVS' meeting of shareholders in May 2011 (**OTC *bulletin***, 31 May 2010, page 31).

OTC

Retailers

D'Arcy heads Numark after Mottram departs

Tony Mottram has stepped down as the managing director of Numark less than 18 months after taking up the post. The UK-based virtual pharmacy chain said Mottram had left to "pursue other business interests".

He has been replaced by **John D'Arcy**, commercial director of sister company Rowlands Pharmacy. D'Arcy had been managing director of Numark on an interim basis prior to Mottram's promotion from the post of commercial director in June 2009 (**OTC *bulletin***, 15 May 2009, page 22).

D'Arcy was interim managing director for more than a year following the death of Simon Colebeck in 2007 (**OTC *bulletin***, 25 January 2008, page 21).

Commenting on his appointment, D'Arcy said he had rejoined Numark at a "challenging time for community pharmacy, particularly the independent sector". "Numark has a key role in equipping its members with the tools needed not just to rise to the challenges ahead," he added, "but also to maximise the opportunities."

Paul Smith, chairman of Numark, said that D'Arcy would provide "clarity and leadership for Numark, its membership and staff".

John D'Arcy

Tony Mottram

OTC

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