11 June 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

J&J accused of covering up a "phantom" product recall

Johnson & Johnson initially tried to cover up the potential US recall of its Motrin analgesic two years ago, it has been revealed. The US company's McNeil OTC subsidiary claimed at the time that its contractor had been asked to perform "statistical sampling".

This news came as the Food and Drug Administration (FDA) announced yet another McNeil-related recall, this time of a McNeil-made children's OTC brand – Blacksmith Brands' PediaCare – and said it was considering further action, including criminal charges, against McNeil in the light of recent recalls.

Referring to the "phantom recall" of Motrin, the chairman of the Congressional committee investigating Johnson & Johnson's recent recall of more than 40 children's medicines (**OTC *bulletin***, 14 May 2010, page 1), said that it warranted further investigation. "It raises the question of whether Johnson & Johnson placed a higher priority on preserving the reputation of its Motrin brand than it did on consumer protection," said representative Ed Towns in a letter to the firm's chief executive officer William Weldon.

Addressing a hearing of the House of Representatives' Committee on Oversight and Government Reform, Towns said the FDA had given his committee a document that showed Johnson & Johnson's McNeil OTC subsidiary had known there was a potential problem with one of its Motrin products in 2008. Rather than issue a public recall, however, Johnson & Johnson allegedly sent contractors out to stores to buy the product back and told the stores "not to mention" a recall.

"It was not until the FDA caught Johnson & Johnson in the midst of the phantom recall that the company announced a proper recall of the flawed Motrin," Towns observed, adding that the incident "raises serious questions about the integrity of this company".

According to a document provided to the committee by the FDA, the CSCS Motrin Pur-

■ *Continued on page 11*

FDA sends Warning Letter to Perrigo

The Food and Drug Administration (FDA) in the US has sent Perrigo a Warning Letter about its manufacturing plant in Allegan, Michigan, which makes some of the company's store-brand ibuprofen.

An inspection of the plant between 17 November 2009 and 14 January 2010 had uncovered "significant violations" of current Good Manufacturing Practice (cGMP) regulations for finished pharmaceuticals, said the regulatory agency. These had rendered the drug products adulterated within the meaning of the Federal Food, Drug and Cosmetic Act, it said.

The Warning Letter was issued after the agency said that Perrigo's 1 February 2010 response to the inspection findings lacked "sufficient corrective actions".

■ *Continued on page 10*

OTC *bulletin*

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

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Business Strategy

Bayer enters talks with US haircare firm

Bayer's German subsidiary Bayer Vital is in early discussions with US-based company Divine Skin over possible collaborations in the hair-regrowth and haircare categories.

However, Divine Skin – which markets a range of OTC hair-regrowth products and dandruff shampoos – noted that it could offer "no assurances" that a formal relationship between the two companies would be established.

Any possible tie-up with Divine Skin could expand Bayer Vital's position in the hair-regrowth category, where it offers Priorin shampoo and oral capsules as OTC products.

Priorin has been on the market in Germany for over 40 years and was picked up by Bayer when the company acquired Roche Consumer Health at the end of 2004 (**OTC *bulletin***, 28 January 2005, page 27). The brand is available in Austria, Belgium, Germany, Greece, the Netherlands, Switzerland and Turkey.

Divine Skin's flagship brand, DS Laboratories, markets a range of topical hair-regrowth products, which competes in the US with McNeil's minoxidil-based Rogaine brand.

Two topical products with 5% minoxidil – Spectral.DNC and Spectral.DNC-L – are part of Divine Skin's range, as is the minoxidil-free Spectral.RS topical hair-regrowth product.

Spectral.DNC and Spectral.DNC-L combine minoxidil, which has been clinically proven, with additional compounds. Divine Skin pointed out that these had also been proven in clinical trials to extend the hairline.

Divine Skin also markets shampoos under the Dandrene and Revita names and a hydrating shampoo and conditioner sold under the Nia brand, as well as a range of skincare and personal care products.

Daniel Khesin, Divine Skin's chief executive officer, said the company had established itself as a "leader in several topical therapies, especially hair regrowth", with a business model built on "aggressive innovation".

Divine Skin pointed out that the company's products were distributed in more than 20 countries worldwide through wholesalers, specialty retailers, online stores, spas, salons and medical establishments.

Divine Skin's hair-regrowth range includes the minoxidil-based Spectral.DNC product

OTC

Business Strategy/First-Half Results

Phytopharm eyes Hoodia opportunities

Phytopharm is talking to "major branded companies" about the development of its *Hoodia gordonii* extract, which is claimed to be a novel appetite suppressant.

The UK-based firm said it had been evaluating opportunities and had held talks with major companies with the aim of moving its Hoodia programme forward and eventually developing consumer products containing the extract.

Phytopharm added, however, that it was too early to say whether any commercial opportunities would emerge.

In 2008, Phytopharm and consumer products giant Unilever agreed mutually to terminate a deal to develop and commercialise the *Hoodia gordonii* extract (**OTC *bulletin***, 28 November 2008, page 4), which Phytopharm has exclusively licensed from the South African Council for Scientific and Industrial Research (CSIR).

At the time, Phytopharm said data from a clinical study using Hoodia extract in a drink-based product had "led Unilever to conclude that [the extract] was unsuitable to be taken forward by Unilever". However, Unilever said the traditional ingredient had not met its safety or efficacy standards.

Unilever had spent around €20 million over four years on developing Hoodia through the licensing and joint-development agreement, which had potentially been worth £21 million (€25 million) to Phytopharm.

As part of the termination agreement, the two firms are evaluating data arising from one of the development studies, with the final report expected in the third quarter of 2010.

Meanwhile, Phytopharm reported an operating loss of £2.16 million for the six months ended 31 March 2010. Revenue of £0.11 million for the period came from Unilever reimbursing Phytopharm's expenses, the sale of certain raw materials from inventory, and sales of the company's Phytopica animal health product to Intervet/Schering-Plough.

More than £24 million was raised by Phytopharm last December to finance the development of its product pipeline, including its key Parkinson's disease treatment Cogane.

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First-Half Results

Price rises lift OTC sales at Adcock

South Africa's Adcock Ingram said its OTC sales had increased by 7.2% during the six months ended 31 March 2010, as the company increased prices despite a shift by consumers towards cheaper brands and generics due to the tough economic climate.

OTC turnover had increased to R635 million (€67.5 million) reflecting an 8% price increase, Adcock Ingram said (see Figure 1). However, the firm claimed it had been evident in both the pharmacy and 'fast-moving consumer goods' (FMCG) distribution channels that consumers had continued to feel under financial pressure.

In the pharmacy channel, where Adcock generated 71.8% – R456 million – of its OTC sales over the six months, the company said it had seen higher sales of "economy brands" as both consumers and healthcare funders opted for "lower-priced products" in what it described as a "trade-off between efficacy and price".

Meanwhile, in the FMCG channel – which accounted for the remaining 28.2%, or R179 million, of OTC sales for the period – Adcock reported a decline in volume sales of its analgesics, and cough drops and lozenges.

However, on a brighter note, sales through the FMCG channel of the company's vitamins, tonics and food supplement brands had more than doubled, Adcock Ingram pointed out, driven by the acquisitions last year of the Tender Loving Care and Unique Formulations businesses (**OTC *bulletin***, 17 April 2009, page 7; **OTC *bulletin***, 30 November 2009, page 1). A move by consumers towards preventive products had also boosted sales in this category, the company added.

Operating profit at the OTC business grew by 9.8% to R208 million, pushing up the operating margin by 0.8 percentage points to 32.8%.

Noting that it had grown its share of South Africa's OTC market over the six months, Adcock Ingram said the company remained positive about its prospects in the sector.

Business	First-half sales (R millions)	Change (%)	Operating profit (R millions)	Change (%)
Prescription	749	+6.9	204	+0.5
Hospital	645	+6.7	123	+11.6
OTC	635	+7.2	208	+9.8
Total	**2,028**	**+6.9**	**535**	**+6.4**

Figure 1: Adcock Ingram's sales and operating profit in the six months ended 31 March 2010, broken down by business (Source – Adcock Ingram)

Successfully integrating Tender Loving Care and Unique Formulations would boost the OTC business, the firm added, while further price increases in the March-to-May period would lift OTC margins.

Investment in the company's OTC brands would continue, Adcock Ingram stated, with "major campaigns" planned for the second half of the company's year to September 2010.

OTC categories produce mixed results

The OTC business' key product categories in the FMCG channel had produced a mixed performance in volume terms during the six-month period, Adcock Ingram pointed out.

Quoting data from market researcher AC Nielsen, the company said volume sales of its analgesics brands as well as its cough drops and lozenges had fallen. The declines had been less severe, however, than those of their respective categories in the South African FMCG market as a whole (see Figure 2).

Meanwhile, volume growth of the OTC business' digestive/stomach/urinary remedies and its vitamins/minerals/supplements/tonics brands had easily outstripped that of their respective categories' volume rises, the firm pointed out.

In value terms, only two of the OTC business' four key categories in the FMCG channel had performed better than the market, Adcock Ingram said.

Cough drops and lozenges posted sales up by 5.8% in a category which had declined by 8.6% overall, while the firm's vitamins/minerals/supplements/tonics portfolio had more than doubled its sales, eclipsing the total category growth of 19.8%.

By contrast, analgesics recorded sales down by 2.1%, compared with total category growth of 0.5%, while the 1.4% sales gain made by the company's digestive/stomach/urinary remedies segment was slower than the total category advance of 3.4%.

Adcock's OTC business accounted for 31% of Adcock Ingram's total turnover for the six months, which increased by 6.9% to R2.02 billion. The dominant Prescription business generated a further 37%, while the Hospitals unit was responsible for the remaining 32%. Adcock's operating profit grew by 6.4% to R535 million.

OTC

Category	Volume sales growth (%)		Value sales growth (%)	
	Total category	Adcock Ingram	Total category	Adcock Ingram
Analgesics	-12.3	-10.0	+0.5	-2.1
Cough drops & lozenges	-14.5	-3.0	-8.6	+5.8
Digestive/stomach/ urinary remedies	-4.5	+3.0	+3.4	+1.4
Vitamins/minerals/ supplements/tonics*	+20.6	+118.0	+19.8	+129.8

* Including Tender Loving Care and Unique Formulations

Figure 2: Adcock Ingram's volume and value sales growth in key product categories in South Africa's 'fast-moving consumer goods' channel for the six months ended March 2010 (Source – AC Nielsen/Adcock Ingram)

IN BRIEF

■ **DAIICHI SANKYO** said sales of its **OTC products in Japan had declined** by 7.4% to ¥43.7 billion (€394 million) in the year ended 31 March 2010. The Japanese firm blamed the drop on lower sales of 'category 1 medicines' – OTC medicines such as switch products, deemed to hold the highest degree of adverse-event risk – including its Gaster 10 brand.

■ **TAKEDA** said a decline in sales of its **Benza cold remedy and Nicorette smoking-cessation products** had led to a 9.5% fall in turnover at its Consumer Healthcare business to ¥58.2 billion (€530 million) in the year ended 31 March 2010. The Japanese company's total sales fell by 4.7% to ¥1.47 trillion.

■ **NAVAMEDIC** said sales through its Vitaflo Scandinavia sales and distribution business had **increased by 7.5% to NKr13.1 million (€1.61 million)** in the first quarter of 2010. Vitaflo Scandinavia distributes the Glucomed glucosamine brand in Denmark, Finland, Norway and Sweden.

OTC

First-Quarter Results

A&D overcomes tough conditions

A&D Pharma reported a "very strong set of top-line results" in the first quarter of 2010, despite an operating environment that remained challenging, according to chief executive officer Robert Popescu.

Sales at A&D Pharma – the Dutch holding company which operates the Sensiblu pharmacy chain and Mediplus wholesaling businesses in Romania – increased by 33% to €150 million over the three months.

The 227-strong Sensiblu pharmacy chain reported turnover up by 32% to €57.6 million, as A&D Pharma focused on improving profitability at existing stores.

Mediplus said wholesaling revenue – including intra-company sales – had improved by 56% to €121 million in the face of what A&D Pharma described as "difficult macroeconomic conditions".

Although turnover at the company's sales and marketing business dropped by a fifth to €10.9 million – due to reclassifying some products to the wholesale business – A&D Pharma said the business remained at the centre of its expansion plans, thanks to the sales and marketing business' "flexibility and ability to develop strategic partnerships".

Several new partnerships had already been agreed this year, the firm revealed, including a deal with Bristol-Myers Squibb's European OTC business, UPSA, whose products were now promoted more prominently within Sensiblu pharmacies.

Focus on higher-margin portfolio

The sales and marketing unit would continue to focus on developing a higher-margin product portfolio, A&D Pharma stated, containing "speciality and primary-care medicines, OTC products, cosmetics, dermo-cosmetics and medical devices".

At the beginning of this year, A&D Pharma struck a deal to acquire several pharmaceutical firms across five countries in central and eastern Europe for €23.2 million (**OTC *bulletin***, 20 January 2010, page 5).

The company agreed to acquire Bulgaria's Arishop Pharma AD and its local subsidiary, as well as the Romanian-based Ozone Laboratories' businesses in the Czech Republic, Hungary, Poland and Slovakia. A&D Pharma said the companies would add around 12% to the group's annual turnover.

OTC

Mergers & Acquisitions

Sigma opens accounts to South Africa's Aspen

Australia's Sigma Pharmaceuticals will not solicit any further takeover bids for the next four weeks, as South Africa's Aspen Pharmacare undertakes due diligence ahead of a possible A$1.49 billion (€1.02 billion) acquisition of the company.

Sigma said it would provide Aspen with due diligence information under the terms of a confidentiality agreement. It had also agreed "not to solicit rival bids for another whole business transaction for Sigma, or to enter into contracts in relation to asset sales" for four weeks from 31 May 2010.

However, the troubled Australian firm noted that it would continue with its previously-announced asset-sale programme.

Sigma's board of directors continued to advise the firm's shareholders to take no action over Aspen's "non-binding, indicative and conditional proposal". Made at the end of May, this was for all of the company's issued share capital at a price of A$0.60 per share (**OTC *bulletin***, 31 May 2010, page 1). The deal would also see Aspen assume Sigma's debts of A$785 million, taking its value to A$1.49 billion.

The board warned that the due-diligence process Aspen was undertaking "may or may not result in a formal proposal or a recommendation by the board".

Aspen's takeover bid came after Sigma – which has interests in OTC products, generic pharmaceuticals, pharmacy retailing and drug wholesaling – reported a net loss of A$389 million for the year ended 31 January 2010.

Sigma reported the net loss after cutting its goodwill valuations by A$424 million. Sales rose by 4.5% to A$3.22 billion (**OTC *bulletin***, 16 April 2010, page 2).

In the wake of the results announcement, Sigma's chief executive officer Elmo de Alwis and chief financial officer Mark Smith stepped down. Smith has already left the firm, while de Alwis – who has spent 33 years at Sigma – will remain in place until a replacement is found.

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

OTC

Distribution Agreements/Trading Update

Decapinol gains distribution in France

Sinclair Pharma's Decapinol gingivitis products will soon be available for the first time in France after the UK-based speciality pharmaceutical company signed up Laboratoires Expanscience as a distributor.

The agreement gives Expanscience the right to distribute the mouthwash, toothpaste, gel and spray based on delmopinol under a brand name to be decided.

Expanscience would target French dentists and pharmacists throughout the country as well as in overseas départments and territories, Sinclair pointed out, adding that it anticipated product launches would begin in 2011.

Meanwhile, negotiations with a new US distributor for Decapinol were at an "advanced stage", with the company confident of signing an agreement before the end of 2010.

In November of last year, Sinclair announced it was seeking a US distributor that could reposition Decapinol mouth rinse for the OTC market, after mutually terminating its deal with the Johnson & Johnson subsidiary Orapharma (**OTC *bulletin***, 30 November 2009, page 2).

Chris Spooner, chief executive officer of Sinclair, said further Decapinol distribution deals could be expected during the rest of 2010.

Looking ahead, Spooner – who was made chief executive officer late last year (**OTC *bulletin***, 30 October 2009, page 26) – said the company anticipated reporting like-for-like underlying sales growth of 7% for the final six months of its financial year ending 30 June 2010. This compared with a decline in sales of 1% over the opening six months.

A strong recovery in the Italian market and a new strategy in France had driven the improved performance, Spooner said.

Annualised costs had also been reduced by £1.5 million, Spooner noted, thanks to a restructuring programme.

OTC

First-Quarter Results

Hypermarcas doubles sales

Brazil's leading OTC company, Hypermarcas, said that acquiring the Neo Química OTC and generics business at the end of last year had helped to more than double its Pharma sales during the first quarter of 2010 to BRL318 million (€134 million).

Neo Química had contributed BRL105 million in sales to the company's Pharma division, which comprises the Dorsay Monange OTC business and the company's prescription unit. Excluding the acquisition, Pharma's turnover increased by 35%.

Purchased in a cash and share deal worth BRL1.29 billion in December of last year (**OTC *bulletin***, 18 December 2009, page 3), Neo Química not only expanded Hypermarcas' Dorsay Monange OTC business, it also took the company into the Brazilian generics market for the first time.

The Pharma division accounted for 48.5% of Hypermarcas' total first-quarter sales, which increased by 70.7% to BRL657 million. The

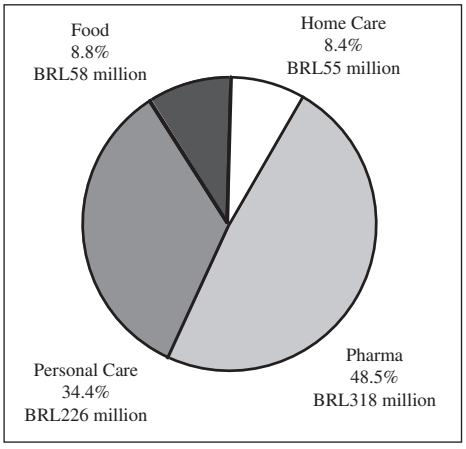


Figure 1: Hypermarcas' sales in the first quarter of 2010 – BRL657 million – broken down by business (Source – Hypermarcas)

Personal Care business generated a further 34.4%, Food another 8.8% and Home Care the remaining 8.4% (see Figure 1).

Total group earnings before interest, tax, depreciation and amortisation (EBITDA) increased by 75.1% to BRL179 million.

Founded in 2002, Hypermarcas' business strategy is built on an aggressive acquisitions policy, which has seen the company make numerous purchases across all of its business areas over the past seven years. In 2009, the company made five acquisitions totalling around BRL2.0 billion.

OTC

First-Quarter Results

Weak cold season hits sales at ProPhase Labs

Sales at ProPhase Labs – formerly Quigley Corporation – halved in the first quarter of 2010 to US$2.0 million (€1.6 million) due to a lower incidence of colds and reduced confectionery and contract manufacturing turnover.

However, Ted Karkus, chairman and chief executive officer of ProPhase, said that overall he had been pleased with the company's performance over the 2009/2010 cold season.

"Concerns over swine flu in the third quarter of 2009 started our cold season early," Karkus noted, adding that the incidence of swine flu "then ended abruptly".

The sales weakness caused by the swift end to swine flu demand had been compounded by a lower incidence of respiratory illness than in the same period of 2009, Karkus added, which had meant sales of cold products had peaked in the fourth quarter of 2010 and dropped off during the first quarter of this year.

Despite the decline in turnover, ProPhase – which owns the Cold-EEZE and Kids-EEZE cold remedies – managed to cut its net loss in half from US$2.2 million over the first three months of 2009 to US$1.1 million this time.

The reduction was thanks to a US$2.2 million cut in sales, marketing and administration costs, ProPhase noted, and spending US$0.16 million less on research and development.

Looking ahead, Karkus said the end of the 2009/2010 cold season marked the "beginning of a wonderful new phase" at the company, which had changed its name from Quigley to ProPhase Labs at the end of May (**OTC *bulletin***, 14 May 2010, page 9).

The name change came after a year during which the company's founder Guy Quigley was ousted by Karkus (**OTC *bulletin***, 31 July 2009, page 31).

For the upcoming season, the company had "dramatically" upgraded product packaging, Karkus pointed out, significantly improved the taste of existing Cold-EEZE flavours and had also developed a new mint frost fresh flavour.

Kids-EEZE non-liquid medicines would also be reintroduced, Karkus revealed, with improved packaging, pricing and taste.

Advertising campaigns and "go-to-market" strategies had been overhauled, Karkus added, while senior management had met with key retail customers with the aim of greatly improving distribution of the company's products.

OTC

First-Quarter Results

Alkaloid drives up OTC sales by 7.9%

Alkaloid's OTC sales increased by 7.9% to €4.48 million in the first quarter of 2010.

The OTC business generated 23.5% of sales by the Macedonian company's dominant Pharmaceuticals division, which reported turnover down by 0.6% to €19.0 million. Antibiotics, central nervous system products and cardiovascular ranges mainly made up the remainder of the division's sales.

Alkaloid's OTC portfolio includes the Bil-ol, Caffetin, Diprol and Primulin brands, as well as various herbal drops.

Group sales – including the Chemical, Cosmetics and Botanicals divisions as well as Pharmaceuticals – improved by 2.4% to €22.9 million. Operating profit had advanced by 5.0% to €3.18 million, the company said.

OTC

First-Quarter Results

Grindeks reports decline in turnover

Latvia's Grindeks has reported sales down by 4.9% to LVL13.5 million (€19.1 million) in the first quarter of 2010. The company offers a portfolio of prescription medicines, generics, active pharmaceutical ingredients and OTC brands.

The majority of the firm's sales – LVL12.6 million – had been generated through exports to 39 countries worldwide, Grindeks said.

Following the close of the quarter, Grindeks resigned from Latvia's employers' confederation, the LEC, in protest at the body's president selling an 11.3% stake in the company to Russian pharmaceutical firm Pharmstandard (**OTC *bulletin***, 30 April 2010, page 7).

The company accused the LEC's president of "essentially breaching business ethics".

OTC

Business Opportunities

Oxford Nutrascience offers two new chews to industry

Oxford Nutrascience has two new chewy confectionery products available for licensing to brand owners worldwide. One is a cranberry supplement, and the other is a children's product containing prebiotic fibre, omega-3 and vitamins A, C, D and E.

Nigel Theobald, chief executive officer of Oxford Nutrascience, said the firm could offer exclusive licensing deals to brand owners.

Theobald added that the formulations of the 6g twist-wrap chews could be "tweaked" to meet the needs of brand owners. The cranberry supplement currently contained 250mg cranberry extract, he said, but this could be increased to 500mg. Similarly, the children's product incorporated 50mg omega-3, but this could be raised to 200mg.

According to Theobald, the company's proprietary fortified chewy confectionery system was a good format for unpleasant-to-take products, such as large calcium tablets or children's supplements. "The use of soluble fibres enables functional ingredients, such as vitamins and minerals, to be added without compromising taste, texture or stability," he said, adding that products were "high in fibre yet reduced in sugar and fat".

Brand owners can request samples of the products by contacting Theobald via e-mail (n.theobald@nutrascience.co.uk).

Oxford Nutrascience said many ingredients, such as omega-3, had poor taste profiles and food supplements containing them were often rejected by consumers. However, the company added that functional foods fortified with these ingredients often tended to have too low a dose to be effective.

Traditional confectionery chews were made soft, it noted, by balancing the use of crystallising sugars (sucrose) with reducing sugars (glucose syrup). Adding minerals to traditional confectionery chews could lead to a gritty texture, the company maintained.

The taste benefits of using traditional confectionery chews could also be outweighed by the high sugar content, the company said, but reducing the sugar and fat content of a traditional confectionery chew could compromise both its taste and texture.

Oxford Nutrascience said its system used a blend of prebiotic soluble fibres to reduce the sugars and fat traditionally used to make chews, and to provide favourable organoleptic properties. There was "no loss in taste profile" from the reduced sugar, it insisted.

As well as seeking brand owners to license the products, Oxford Nutrascience said the two chews would be launched under the company's own brand names during the second half of this year. The cranberry supplement will be part of the Ellactiva range, which is sold in the UK and the Middle East.

Oxford Nutrascience recently signed an exclusive manufacturing agreement with confectionery specialist Lamy Lutti. "The partnership with Lamy Lutti provides a scaleable production facility and allows the company to expand its chew development capability," said Oxford Nutrascience, noting that further chews should be brought to market in 2011.

Oxford Nutrascience has developed a cranberry supplement (pictured above) and a children's product containing omega-3 (below) using its fortified chewy confectionery technology

It is still early days for Oxford Nutrascience, which through the Ellactiva brand had sales of £54,293 (€65,000) in the year ended 31 December 2009. The company's operating loss increased from £120,038 in 2008 to £240,518 in 2009.

Oxford Nutrascience has just raised £1.1 million before expenses through an initial public offering (IPO) on London's Alternative Investment Market (AIM) (**OTC *bulletin***, 26 February 2010, page 8).

The company has also just filed two international patent applications covering more than 130 countries. One involves the chewable oral delivery system of the company's Chewitab technology, while the other covers its gels, syrups and suspension systems. Oxford Nutrascience said both applications claimed priority from the delivery system patent application filed by the company in April 2009.

OTC

Distribution Agreements

BioGaia to take first step into China

BioGaia is set to take its first step into the Chinese market, after signing Asia United (China) Medical to distribute its probiotic drops.

Under the terms of the exclusive deal, Asia United will sell the drops – containing the Swedish firm's *Lactobacillus reuteri* probiotic – under the BioGaia brand name in mainland China. BioGaia said the drops were expected to be introduced at the end of 2011.

Peter Rothschild, president of BioGaia, said the deal represented an "important first step" into China. He added that Asia United was an ideal partner to help the company establish its probiotic drops in the "very large and growing" Chinese market.

Primarily a distributor of oral cholera vaccines and growth hormones, Asia United is a member of the Unilab Group, described by BioGaia as a "privately-held regional pharmaceutical and healthcare company with a leading position in south-east Asia". Unilab had strong brands in Indonesia, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam, the company added.

An important consideration had been Asia United's marketing and distribution experience with pharmaceutical products requiring refrigeration, BioGaia noted.

The deal with Asia United is BioGaia's second major agreement in Asia so far this year. In February, the company expanded its presence in Japan by signing a distribution agreement for the majority of its BioGaia-branded probiotic products with wholesaler Nippon Access (**OTC *bulletin***, 17 March 2010, page 7).

BioGaia's probiotic drops will also be available in Indonesia from 2011 since the company struck a distribution deal with Interbat in April (**OTC *bulletin***, 30 April 2010, page 9).

OTC

Business Strategy

Omega aims to double its UK business

Belgium's Omega Pharma is seeking to double the size of its UK business over the next four years through a combination of organic growth, acquisitions and licensing deals.

UK managing director Nigel Bathurst said the former Chefaro operation – which owns the Buttercup, Jungle Formula, Lyclear, TCP and Wartner brands – had been a "sleeping giant" in the UK OTC market. "But we have made a fresh start across the entire operation," he pointed out, adding that the company was "working to unlock the potential of its existing brands through an approach rooted in consumer insight".

Since becoming managing director a year ago, Bathurst has moved the business to London and recruited a team with OTC expertise.

Marketing director Andy Wines has a strong record in the OTC industry, including global marketing positions with Johnson & Johnson, Reckitt Benckiser, and Roche Consumer Health. Similarly, sales director Kay Patton has worked on the Nicorette and Benecol brands.

Bathurst said Omega Pharma had reviewed its roster of agencies, and taken a long hard look at how it did business with its retail customers. "The coming months will see the company's profile grow as star brands are relaunched with a dynamism rarely seen in consumer health," Bathurst promised.

At the start of this year, Omega Pharma appointed VCCP – the advertising agency behind the memorable "meerkat" campaign for comparethemarket.com – to reinvigorate its OTC brands. The company is also working with the media buyer AW Media, and the public relations firm Virgo Health.

The first fruits of the partnership with VCCP will be seen on 17 June, when a new television commercial for the Jungle Formula range of insect repellants makes its debut.

Wines said the "jungle boogie" creative took a "fun and engaging" approach that broke away from the norms of the OTC market. Featuring a soundtrack from Kool & The Gang, the commercial was based around holidaymakers reacting to the instantly-recognisable sound of an approaching mosquito, he explained.

Wines said Omega Pharma was investing £1.0 million (€1.2 million) in the Jungle Formula campaign, which was the first significant consumer advertising for the brand in years.

Wartner would be the next to benefit, said Wines, with a digital, outdoor and trade-press advertising campaign commencing at the end of June. The theme of the campaign would be "happy fingers and toes", he said.

Wines stressed that Omega Pharma would do "whatever is right to drive growth of its brands". Brands would be backed by impactful consumer communications, he added, and some would also benefit from strong pharmacy communications.

"Jungle boogie" is the theme of Omega Pharma's new television advertising for its Jungle Formula insect repellents in the UK

According to Bathurst, Omega Pharma was ranked around number 10 in the UK OTC market with a share of around 1.5%. He stressed this was "not good enough".

As well as stepping up marketing activity, Omega Pharma intends to drive growth in the UK by extending its brands with product innovations. Bathurst noted that these could be drawn from Omega Pharma's subsidiaries in other countries, the company's innovation centre in Belgium, or the local new product development facility in the UK.

Bathurst added that the company was keen to make acquisitions and agree licensing deals. He declined to comment in detail but said the company was looking for deals that complemented its existing business.

In the longer term, Bathurst said that the UK business would be boosted by tapping into Omega Pharma's portfolio of established brands in other countries.

It is still early days for the new team, but releasing its first-quarter results earlier this year Omega Pharma noted that the UK business had been boosted by "strong growth" for the first time in two years (**OTC *bulletin***, 30 April 2010, page 5).

The team behind the new strategy at Omega Pharma in the UK comprises marketing director Andy Wines (pictured left), managing director Nigel Bathurst (centre) and sales director Kay Patton (right)

OTC

IN BRIEF

■ **MHRA** – the UK's Medicines and Healthcare products Regulatory Agency – said a new area on its website was dedicated to the Regulation of Medicines Review Panel, which dealt with **disputes over regulation** of medicines.

■ **FDA** – the US Food and Drug Administration – is working with the website **Drugs.com** to expand access to the agency's consumer health information. "Drugs.com seeks to provide patients with information to better manage their own healthcare and to assist in the reduction of medication errors," said the FDA, adding the site attracted more than 12 million unique visitors each month. A joint resource on Drugs.com will provide consumers with FDA Consumer Update articles, videos, and slideshows. Consumers will also have access to FDA health information on Drugs.com's mobile phone platform.

■ **FDA** – the US Food and Drug Administration – has warned Americans not to purchase or use a product called **Arrow Brand** Medicated Oil and Embrocation. The regulatory agency said that the product, which contained methyl salicylate and camphor, was potentially toxic. Preliminary testing on samples indicated that it contained diethylene glycol, an ingredient used in antifreeze, added the FDA.

OTC

Distribution

ECJ at odds with Commission on pharmacy

Rules for establishing pharmacies that are based on population density and location constitute a restriction on the freedom of establishment, the European Court of Justice (ECJ) has ruled. However, it also found that such measures, which are frowned upon by the European Commission, could be justified under certain circumstances and were therefore compatible with European Union law.

The Commission has called for such pharmacy-establishment rules to be abolished, and is still pursuing an infringement proceeding against Spain.

In a judgement delivered on 1 June 2010, the ECJ named four conditions under which pharmacy-establishment rules could be justified: the measures must apply in a non-discriminatory manner; they must be justified by overriding reasons relating to the general interest; they must be appropriate for attaining the objective pursued; and they must not go beyond what is necessary for attaining that objective.

Noting that pharmacy-establishment rules contributed to an even distribution of pharmacies, John Chave, secretary-general of the pharmacy body, the Pharmaceutical Group of the European Union (PGEU), commented: "More than half European Union states have establishment rules for pharmacy, some based on rules almost exactly the same as Spain's. If the Court had declared them illegal, it would have brought about a significant change in how these states manage their health systems."

A matter for member states

Chave noted, however, that while the ECJ had not questioned the validity of the rules, it had qualified its judgement by saying that such pharmacy-establishment rules needed to be flexible enough to meet local needs. He also added: "This judgement will be welcomed by those who believe that health-service planning should be a matter for member states."

In Spain, national legislation makes the setting up of a new pharmacy conditional upon prior administrative authorisation. That legislation is implemented by the Autonomous Communities, which set specific criteria for the licensing of new pharmacies.

Two pharmacists in Spain – José Manuel Blanco Pérez and Maria del Pilar Chao Gómez – had challenged the Autonomous Community in Asturias, Spain, over the local pharmacy-licensing system. Uncertain whether the Asturian decree was compatible with the European Union principle of freedom of establishment, the local court had referred the matter to the ECJ.

The two pharmacists were objecting to a system in Asturias that allows only one pharmacy per 2,800 inhabitants and insists pharmacies must be at least 250 metres apart. Subsequent pharmacies may be opened once the population threshold has been exceeded, but for the fraction above 2,000 inhabitants. Selection criteria, with licences awarded to pharmacists on the basis of their professional and teaching experience, are also part of the local rules.

The ECJ found firstly that the rules relating to population density and minimum distance between pharmacies applied without discrimination on grounds of nationality, thus meeting the first of the Court's four conditions.

National legislation was justified, the ECJ continued, as its objective – namely that the provision of medicines to the public was reliable and of good quality – constituted an overriding reason relating to the general interest.

Nevertheless, the ECJ had reservations about whether a uniform application of the 2,800 inhabitants and 250 metres rules would be successful in ensuring adequate access everywhere. If the inhabitants rule were to be uniformly applied in rural areas, it said, certain inhabitants would find themselves beyond reasonable reach of a pharmacy. Conversely, in areas of high population density, the 250 metres rule could give rise to pharmacies serving an area containing more than 2,800 inhabitants.

However, the Asturian decree implemented national legislation, the Court observed, and this provided for adjustments to the basic formulae. "The Court finds that it is for the referring court to determine whether the competent authorities make use of the power conferred by national legislation," the ECJ said.

On the matter of selection criteria, however, the ECJ pointed out that preferring local candidates was discriminatory, and was therefore precluded by freedom of establishment.

OTC

Regulatory Affairs

Alli labelling to include liver injury warning in US

GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine in the US will carry a warning about rare reports of severe liver injury, after the Food and Drug Administration (FDA) completed a safety review of the product's active ingredient, orlistat.

The company said the updated Alli label advised users to: "Stop use and ask a doctor if you develop itching, yellow eyes or skin, dark urine or loss of appetite. There have been rare reports of liver injury in people taking orlistat."

Labelling on Xenical – Roche's prescription drug containing orlistat – has also been changed to reflect the new safety information.

The FDA said the label revisions had been agreed after it had completed the safety review of orlistat – covering both the 120mg prescription strength used in Xenical and Alli's 60mg non-prescription strength – that had been announced in August of last year (**OTC *bulletin***, 31 August 2009, page 1).

The agency noted that one US report concerning severe liver injury with Alli and 12 foreign reports with Xenical had been identified by the review.

However, the FDA acknowledged that it had been unable to establish a cause and effect relationship between severe liver injury and orlistat for a number of reasons. Only 13 cases had been reported between April 1999 and August 2009 out of an estimated 40 million people worldwide who had used Xenical or Alli. Furthermore, some patients in the reported cases had used other drugs or had other conditions that may have contributed to the development of severe liver injury, the FDA said, and severe liver injury could occur in people not taking drugs and without a distinct cause.

Although there was no confirmed link, the FDA said it had added the information about reported cases of severe liver injury to the labels of Alli and Xenical to educate the public about the signs and symptoms of liver injury and the need to see a physician promptly should they occur.

Commenting on the new safety information, Howard Marsh, chief medical officer for GlaxoSmithKline Consumer Healthcare, said the company was committed to ensuring that consumers and physicians understood the safety profile of orlistat and Alli.

In the wake of the FDA's "early communication about an ongoing safety review" into orlistat last August, GlaxoSmithKline launched a major communication campaign in the US to stress publicly the safety and efficacy of Alli (**OTC *bulletin***, 30 September 2009, page 14).

OTC

Regulatory Affairs

FDA sends Warning Letter to Perrigo

■ *Continued from front page*

The FDA said it expected Perrigo's corporate management to carry out a "comprehensive evaluation of manufacturing operations to ensure compliance with cGMP".

Perrigo had 15 working days from receipt of the Warning Letter to notify the FDA of the steps it had taken to correct violations or to state the reason for delay and the time within which it would complete the corrections. The company said it had now submitted a written response.

The FDA stressed in the Warning Letter that failure to correct the violations promptly "may result in legal action without further notice including – without limitation – seizure and injunction". Furthermore, the FDA may withhold approval of pending drug applications listing the facility, added the FDA, and other federal agencies could take the Warning Letter into account when considering the award of contracts.

In its Warning Letter, the FDA said the inspection had found that Perrigo had not rejected drug products that "failed to meet established standards or specifications and any other relevant quality control criteria".

It cited Perrigo's failure to reject a lot of 200mg ibuprofen tablets that had been contaminated with metal shavings due to an equipment failure as an example. Although Perrigo had segregated a portion of the lot that had been affected, the Warning Letter explained, the company had released and shipped a subportion of that segregated lot, resulting in the recall of the entire lot.

Furthermore, the store-brand specialist had failed to "thoroughly investigate the failure of a batch – or any of its components – to meet its specifications, whether or not the batch had already been distributed", the Warning Letter noted, and had failed to "extend investigations to other batches of the same drug products that may have been associated with the failure".

One example of this had been the company's decision not to investigate thoroughly possible foreign tablet-contamination in its filling equipment, the FDA said.

After finding a brown, round ibuprofen tablet in a lot of brown, oval ibuprofen tablets, Perrigo did not inspect the lot of orange, round ibuprofen tablets that was packaged in between the two lots, and therefore could not provide any assurance that this lot had not also been contaminated, the agency pointed out.

Further violations included the failure of Perrigo's quality control unit to follow written standard operating procedures, the FDA said. This had led to recalls of batches of regular, cherry-flavoured and mint-flavoured Milk of Magnesia due to mislabelling.

The Warning Letter pointed out that the FDA's investigators had documented Perrigo's failure to follow standard operating procedures during the past three FDA inspections, as well as in other inspections since 1998.

Although Perrigo had acknowledged the procedural errors and recalls in its 1 February 2010 response to the findings, the company had not provided the "corrective actions" it planned to take to prevent recurrences in the future, the FDA said.

Meanwhile, the Warning Letter pointed out, Perrigo had also failed "to inspect adequately the packaging and labelling facilities immediately before use to assure that all drug products had been removed from previous operations".

Specifically, on 10 December 2008 and 13 February 2009 film-packaging employees had observed foreign tablets, the FDA said, after Perrigo had failed to remove all ibuprofen tablets from a prior lot before starting the packaging and labelling of ibuprofen caplets.

The FDA Warning Letter pointed out that Perrigo had had an ongoing programme since 2005 to address mix-ups. However, the company had continued to receive complaints, the agency said, and the deviations had continued, despite past assurances that previous enhancements would control these problems.

As a result, the FDA said it had "concerns" about the failure of Perrigo, including its quality control unit, to act "proactively" to ensure compliance with standard operating procedures and cGMP regulations.

OTC

Regulatory Affairs

Bill seeks full enforcement of DSHEA supplements law

More than 15 years after the US passed landmark dietary supplement legislation, a bill has been introduced into the Senate that seeks to ensure the legislation is fully implemented and enforced.

Tabled by senators Tom Harkin and Orrin Hatch, bill S3414 refers to the Dietary Supplement Health and Education Act (DSHEA) of 1994 that covers new dietary ingredients, scientific substantiation of claims, good manufacturing practice (GMP) requirements and penalties for mislabelled or adulterated dietary supplements. "While the Food and Drug Administration (FDA) has taken some important steps to implement and enforce DSHEA," the two senators say in their bill, "the agency has not fully implemented and enforced it."

The move has been welcomed by the Council for Responsible Nutrition (CRN) and the Natural Products Association (NPA). "Many of the challenges our industry continues to face," the CRN said, "can be attributed to the lack of enforcement of the basic tenets of DSHEA."

Noting that the FDA had estimated in 2002 that it would need between US$24 million (€20 million) and US$65 million per year fully to implement DSHEA, the bill also highlights the FDA's need for adequate resources. Additional funds of just US$14 million were made available for the job in the year to September 2009, the senators note.

The FDA should increase its efforts to implement DSHEA "more fully and effectively", the bill says, by conducting inspections of all facilities where supplements are made to ensure compliance with GMP regulations for supplements. The agency should also ensure claims are "truthful, non-misleading and substantiated", and give the "highest regulatory priority" to "clear violations of the law" concerning intentional adulteration and spiking of products.

All dietary supplement manufacturers, packers and distributors should be required to participate in an annual registration process, and the FDA should develop consumer education initiatives.

Noting that the FDA had raised objections to more than 70% of all new dietary ingredient notifications submitted to the agency, the bill wants prompt guidance from the FDA that clarifies "when a dietary supplement ingredient is a new dietary ingredient, the evidence needed to document the safety of new dietary ingredients, and appropriate methods of establishing the identity of a new dietary ingredient".

Moreover, the bill wants the FDA to liaise more closely with the Drug Enforcement Administration over anabolic steroids, or analogues of anabolic steroids, that the agency suspects may be in a dietary supplement as a result of rejecting a new dietary ingredient notification.

The bill authorises US$30 million to be spent in the year to September 2011 "and such sums as may be necessary" for the subsequent years to September 2014 to carry out its provisions. In the current year, it wants US$20 million to be found for its purposes.

The Office of Dietary Supplements within the National Institutes of Health should get US$40 million this year for "expanded research and development of consumer information on dietary supplements", and sums as needed until September 2014.

One of the first jobs given to the FDA is to estimate the annual costs of fully implementing and enforcing DSHEA over the next five years. The agency is also tasked with producing comprehensive annual reports from January 2011 on how it is spending the money and fulfilling the bill's requirements.

OTC

Regulatory Affairs

J&J accused of covering up a "phantom" product recall

■ *Continued from front page*

-chase Project involved buying all of the Motrin IB Caplet 8 count vial products available in stores. "You should simply act like a regular customer while making these purchases," the contractor's agents were told. "THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!" it adds (emphasis as in the original).

Nearly 100,000 packs of the Motrin product had been distributed in August 2008, the FDA document says, but a dissolution problem was identified a few months later in November. The contractor had been asked to perform "statistical sampling" of retailers, according to the company, to determine if a recall was necessary, but the FDA learned of its actions.

In July 2009, McNeil initiated a recall after having been contacted by the FDA about the third-party contractor's activities. Although the dissolution problem had been identified in November 2008, the agency emphasises, the recall was not started until the following July.

Towns said at the committee hearing that he would be seeking a change in the law to give the FDA mandatory recall authority, as well as the power to order a halt in drug production. "The FDA shouldn't have to persuade a company to recall suspect products," he said. "I intend to introduce legislation to give FDA that authority."

In a statement following the hearing, Towns added that he had "serious questions" about McNeil's Fort Washington, Pennsylvania plant which had made the four PediaCare products recalled at the end of May.

These had been recalled as a precautionary step, Blacksmith Brands said, "because they were made at the McNeil plant that has been temporarily shut down".

Misrepresented size of recall

Towns noted that Johnson & Johnson had misrepresented the size of the most recent McNeil recall, putting it at six million bottles, making it the "largest recall of children's medicine in history". "But today we learned from the FDA that it was more than twenty-times that, namely 136 million bottles."

Colleen Goggins, worldwide chairman of Johnson & Johnson's Consumer Group, told the hearing the recall was a "disappointment". McNeil's quality and process issues were "unacceptable", she said, apologising to parents for the "concern and inconvenience caused".

The FDA's principal deputy commissioner, Joshua Sharfstein, said the FDA had expressed its "significant concern" that McNeil had shown "a pattern of conduct", including failure to report material information to the agency. It was also concerned about whether McNeil's corporate culture "was appropriately focused on product quality".

"FDA is considering additional enforcement actions against the company for its pattern of non-compliance which may include seizure, injunction or criminal penalties," commented Sharfstein.

OTC

CONSUMER *viewpoint*

Period pain 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.

Italian women are more likely to say that they have suffered from period pain in the past year than their counterparts in France, Germany, Spain or the UK, according to our **Consumer** ***viewpoint*** European survey.

Of the five countries covered by the Ipsos MORI survey, Italy has the highest proportion of women who say that they have suffered from period pain during the past year at 27.9%, followed by Spain at 20.2%, France at 15.4%, Germany at 10.5% and the UK at 6.5% (see Figure 1).

The vast majority of period-pain sufferers in all five survey countries are women under 45 years of age (see Figure 2).

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

Germany has the highest proportion of sufferers who have treated their period pain with an OTC product at 75.9% (see Figure 4). OTC treaters are most likely to be women under 45 years of age (see Figure 5).

Spain has the highest proportion of women who have treated the condition with a prescription remedy at 31.7% (see Figure 6), but only one in 10 sufferers in the UK say that they have used a prescription remedy.

Spain also has the highest proportion of herbal treaters at 11.1%, closely followed by Italy at 10.6% and the UK at 9.1% (see Figure 7).

OTC

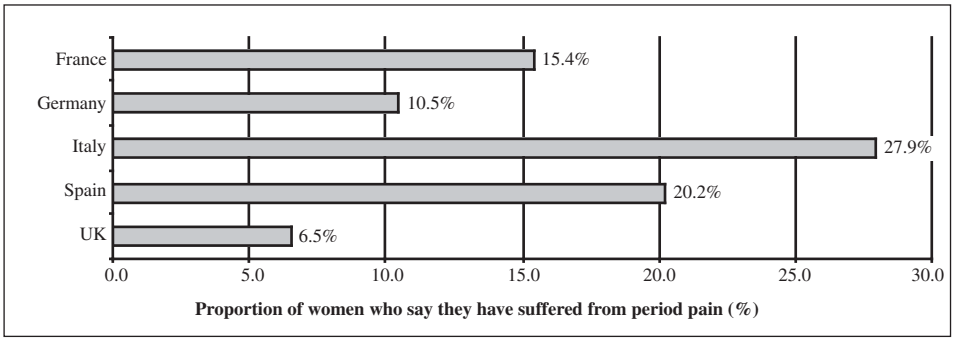


Figure 1: Proportion of women in France, Germany, Italy, Spain and the UK who say they have suffered from period pain within the past year (Source – OTC *bulletin* 2010/Ipsos MORI)

	Proportion of sufferers (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	–	–	–	–	–	–	–	–	–	–
Female	100.0	100.0	100.0	100.0	100.0	–	–	–	–	–
18-24	31.3	21.0	23.9	18.4	23.0	**272**	**236**	**263**	**153**	**184**
25-34	25.9	34.9	26.4	38.1	34.1	**136**	**257**	**150**	**184**	**204**
35-44	42.7	25.5	32.0	29.9	30.5	**221**	**127**	**162**	**157**	**155**
45-54	–	16.2	16.2	13.5	11.3	–	90	99	83	66
55-64	–	1.1	1.6	–	0.9	–	8	11	–	6
65+	–	1.3	–	–	0.3	–	5	–	–	2

Figure 2: Consumers in France, Germany, Italy, Spain and the UK who say they have suffered from period pain 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 period pain, and is the ratio of the proportion of total sufferers in a population group to the proportion of that group in the population as a whole (Source – OTC *bulletin* 2010/Ipsos MORI)

Ipsos MORI and the ailments survey

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

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

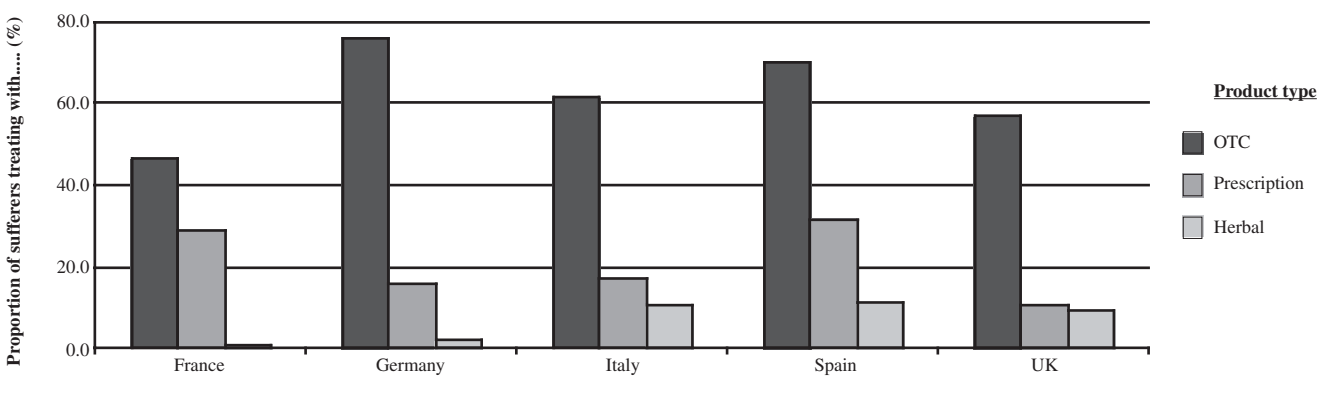


Figure 3: Proportion of women in France, Germany, Italy, Spain and the UK who say they have suffered from period pain who have treated the condition with an OTC, prescription or herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

period pain

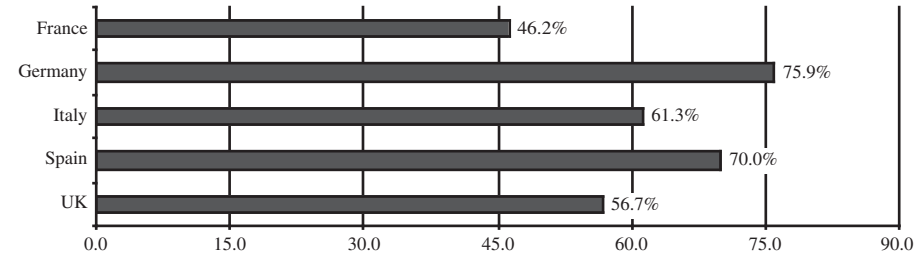


Figure 4: Proportion of women in France, Germany, Italy, Spain and the UK who say they have suffered from period pain who have treated the condition with an OTC remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

	Proportion of sufferers treating with OTC (%)					Index				
	Fra	Ger	Ita	Spa	UK	Fra	Ger	Ita	Spa	UK
Male	–	–	–	–	–	–	–	–	–	–
Female	100.0	100.0	100.0	100.0	100.0	–	–	–	–	–
18-24	22.7	27.0	15.0	26.3	28.1	**197**	**303**	**165**	**219**	**225**
25-34	33.1	20.5	47.5	37.2	22.9	**174**	**151**	**270**	**180**	**137**
35-44	28.0	33.6	31.3	31.7	49.0	**145**	**167**	**158**	**167**	**249**
45-54	16.3	19.0	6.3	4.8	–	**106**	**106**	38	30	–
55-64	–	–	–	–	–	–	–	–	–	–
65+	–	–	–	–	–	–	–	–	–	–

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

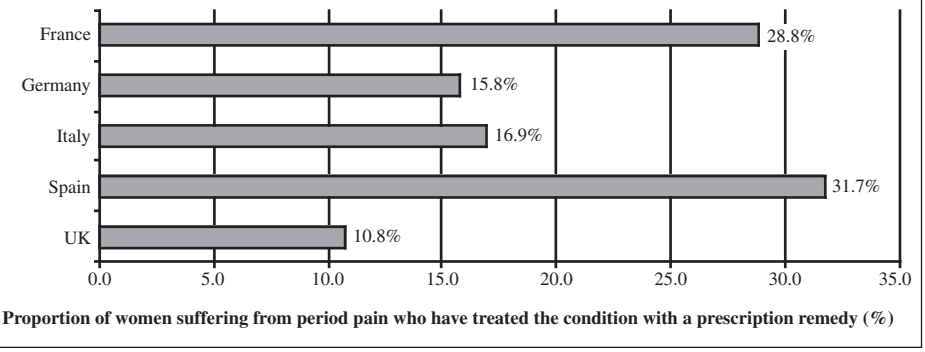


Figure 6: Proportion of women in France, Germany, Italy, Spain and the UK who say they have suffered from period pain who have treated the condition with a prescription remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

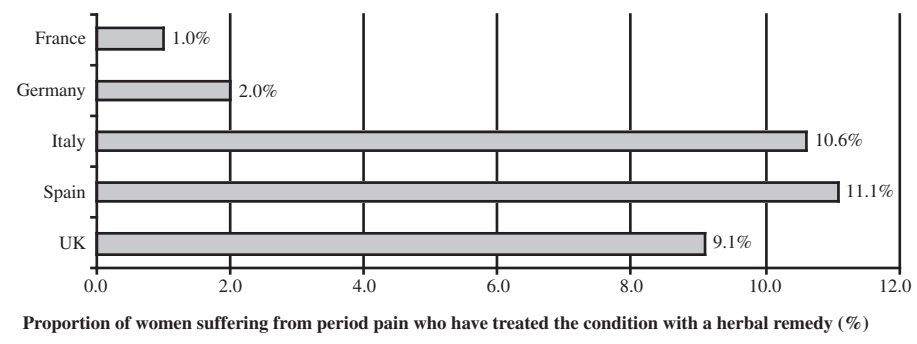


Figure 7: Proportion of women in France, Germany, Italy, Spain and the UK who say they have suffered from period pain who have treated the condition with a herbal remedy (Source – OTC *bulletin* 2010/Ipsos MORI)

Regulatory Affairs

Three more herbal monographs done

Three more Community herbal monographs have been finalised by Europe's Committee on Herbal Medicinal Products (HMPC).

Monographs for *Mate folium* (mate leaf), *Ribis nigri folium* (blackcurrant leaf), and the combination of *Valerianae radix* and *Lupuli flos* (valerian root and hop strobiles) were finalised at the HMPC's May 2010 meeting. They bring the total number of final Community herbal monographs to 63.

At its May meeting, the HMPC also adopted three draft Community herbal monographs, which were released for consultation until 15 August 2010. They are for *Leonuri cardiacae herba* (motherwort), *Tanaceti parthenii herba* (feverfew), and *Trigonellae foenugraeci semen* (fenugreek seed).

The HMPC also endorsed a recommendation by the Working Party on Community Monographs and Community List (MLWP) to stop the assessment work for *Terebinthinae laricina* (larix). Only one combination product and no single-ingredient products could be found on the European market, noted the committee, and no interested parties had reported a high priority level for the work.

Furthermore, the HMPC is calling for the submission of scientific data for *Arnicae flos* (arnica flower), *Hippocastani cortex* (horse chestnut bark), and *Visci albi herba* (mistletoe). Data should be submitted by 30 July 2010.

The HMPC is also keen to hear from interested parties about the priorities for establishing Community herbal monographs and Community list entries. The deadline is the end of July.

Seven entries have so far been added to the Community list of herbal substances, preparations and combinations for use in traditional herbal medicinal products (**OTC *bulletin***, 31 May 2010, page 15).

Meanwhile, the Association of the European Self-Medication Industry (AESGP) recently had a chance to discuss industry's experience of national implementation of European Union directive 2004/24/EC with the MLWP. The AESGP highlighted its concerns about fee levels for traditional-use registration in some countries, deviation from herbal monographs, and the substantial delays in some assessment procedures.

The MLWP asked for further information on industry's experience.

Marketing Campaigns

Nicabate shows Australians how smoking can age skin

GlaxoSmithKline Consumer Healthcare is backing its Nicabate nicotine-replacement therapies in Australia with digitally-enhanced images showing how smoking cigarettes can damage women's skin.

The public relations campaign was launched ahead of World No Tobacco Day 2010 on 31 May, which had a theme of gender and tobacco with an emphasis on marketing to women. Former smoker and Australian model Chloe Maxwell is fronting the campaign, which features eight images of her at the ages of 34, 47, 61 and 72 years as a smoker and a non-smoker.

GlaxoSmithKline said that recent research had discovered that 80% of Australian smokers did not believe cigarettes had damaged their skin. The company pointed out, however, that its research suggested "smokers of more than 20 cigarettes a day are three-times more likely to wrinkle prematurely than non-smokers, and the effect is more pronounced in women than in men".

GlaxoSmithKline Consumer Healthcare is supporting its Nicabate nicotine-replacement therapies in Australia with an online programme called QuitPartner

The research also found that women were less likely to have tried to quit than men. Only 13% of smokers had not tried to quit, 17% of whom were women and 9% men.

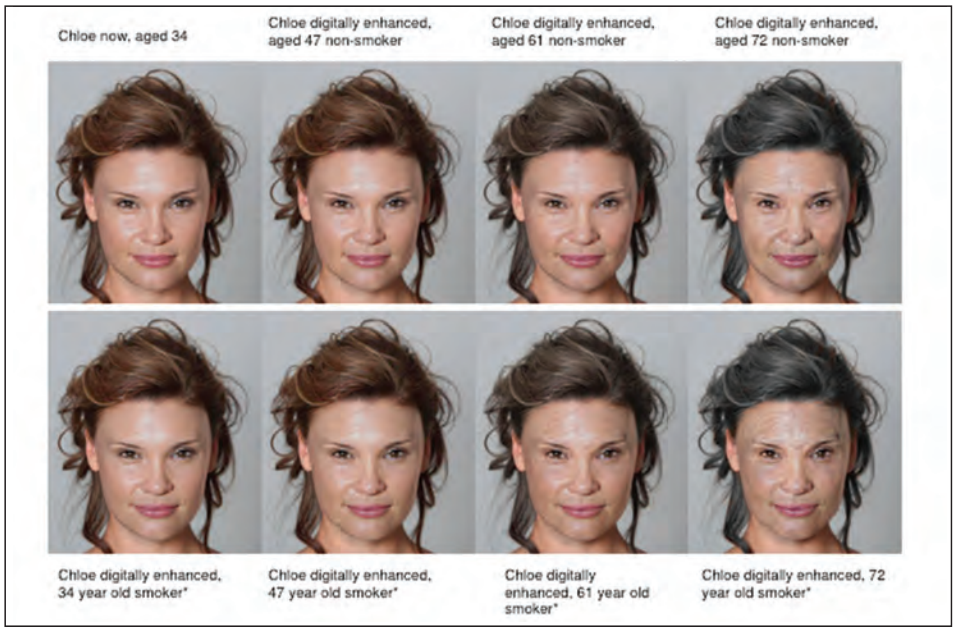
Also to coincide with World No Tobacco Day 2010, GlaxoSmithKline has launched an online behavioural support programme called QuitPartner in Australia.

The company said the programme, which was available at www.quitpartner.com.au, was "designed to work hand-in-hand with Nicabate products to help smokers deal with not only their physical attachment but also their emotional and habitual attachment to cigarettes".

Once smokers have registered online, they can track their daily quit progress, receive a personalised quit programme, record where they were tempted to smoke and receive tips. In addition, online games are available if smokers need an immediate distraction to take their mind of cravings.

The Nicabate brand in Australia includes gum, lozenges and patches.

OTC



The impact of smoking cigarettes on a woman's skin is illustrated by digitally-enhanced images in GlaxoSmithKline Consumer Healthcare's public relations campaign for Nicabate in Australia

Inova Pharmaceuticals has added a eucalyptus and menthol-flavoured lozenge to its Duro-Tuss range of cough medicines in Australia.

Noting that the newcomer was free of sugar, alcohol, lactose and gluten, Inova pointed out that it was a "full-strength cough medicine in a convenient, portable dose form for those on the go".

Each Duro-Tuss Chesty Cough lozenge contains 8mg of the mucolytic bromhexine hydrochloride to "clear chest congestion" and 1.33mg of the antibacterial cetylpyridinium chloride to "relieve a sore throat". A strapline on the packaging highlights that Duro-Tuss Chesty Cough "Clears congestion and relieves a sore throat associated with chesty cough".

Last year, Inova launched a lemon-flavoured Duro-Tuss Chesty Cough lozenge, which contains the same active ingredients as the latest addition. The company said it was backing the two products with a "campaign to help pharmacy staff make appropriate recommendations to consumers".

Both products are suitable for adults and children aged six years of age and older, and come in packs of 24 lozenges.

OTC

Marketing Campaigns

Herbalife has deal with FC Barcelona

Herbalife is sponsoring Spanish football club Barcelona in a "multimillion dollar" deal.

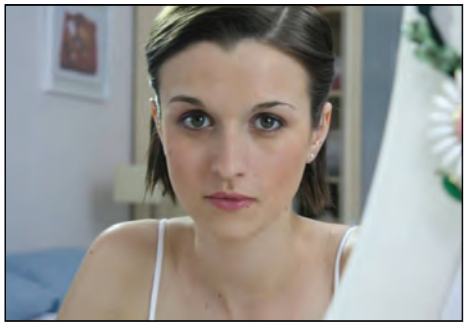
The US-based direct-selling specialist has also agreed a three-year personal sponsorship deal with team player Lionel Messi, who will be involved in its global promotional activities.

The agreement with Barcelona to be its Official Nutrition Sponsor covers global association rights, publicity assets, and a presence at the team's pre-season friendly games and international tours over the next three years. In addition, Herbalife will provide nutrition programmes to the club's first team.

Michael Johnson, chairman and chief executive officer of Herbalife, said Barcelona was one of the greatest clubs in the world with extraordinary athletes who "illustrate our philosophy of living a healthy, active life".

Herbalife recently announced that it had become the official nutrition adviser to Brazilian football team Santos, which lists Pele amongst its former players. The company already sponsors Inter Milan in Italy, Valencia in Spain, Schalke 04 in Germany, LA Galaxy in the US, and Pumas in Mexico.

OTC



"Sudocrem's small babies become big babies, but we will always need soothing," is the opening line of Forest Laboratories latest television commercial for Sudocrem Skin Care Cream in the UK.

The company said babies had been "relegated to a subsidiary role" for the first time in the history of the nappy-rash brand, because the product was aimed at a "new audience of beauty-conscious but cash-strapped women aged 16-34 years".

The commercial builds on Sudocrem's heritage as a nappy-rash brand by using a brief shot of a baby at the beginning, but then quickly shifts to a young woman looking in a mirror.

She sees a blemish on her face, and starts applying the cream. Next, she is seen rubbing the cream into other parts of her body, including her elbows and knees, and a sunburnt shoulder.

"There, sorted," states the voiceover, as the young woman grins. "Try new Sudocrem Skin Care Cream, I am never without it," adds the voiceover, as the woman grabs her jacket and leaves her house.

The commercial draws attention to the fact that Sudocrem Skin Care Cream comes in a "handbag-friendly" 30g tube.

It ends with a shot of a tube of Sudocrem Skin Care Cream accompanied by the website address sudocremtube.com and the message "available at most Boots and Boots.com".

The 20-second commercial and two 10-second spots have just been aired on Channel 4, Five and satellite channels. Forest Laboratories said they were likely to be repeated later this year.

The company launched Sudocrem Skin Care Cream last year.

OTC

Launches

FDA gives final approval to Perrigo's generic Monistat

The Food and Drug Administration (FDA) has given final approval in the US to Perrigo's generic version of Johnson & Johnson's Monistat-1 Combination Pack for treating vaginal thrush.

Perrigo said that it expected to begin shipping store-brand versions of the OTC medicine "immediately".

The store-brand specialist pointed out that the FDA approval included 180 days of generic exclusivity, as the company had been the first to file an Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification. The resulting patent-infringement litigation filed by Johnson & Johnson was dismissed in 2008 (**OTC *bulletin***, 29 September 2008, page 11).

According to Perrigo, Monistat-1 had annual retail sales of around US$90 million (€75 million. The vaginal cream and suppository based on the active ingredient miconazole nitrate are indicated for treating vaginal yeast infections and relieving associated external itching and irritation.

Perrigo's chairman and chief executive officer Joseph Papa said the launch was "another example of Perrigo's commitment to innovation by challenging brand patents and bringing new products to market". "These innovations help save OTC healthcare consumers more than an estimated US$1 billion annually," he added.

A spokesperson for Perrigo said the company would support the product with marketing and promotional activity.

Perrigo said it would start shipping store-brand versions of Johnson & Johnson's Monistat-1 Combination Pack immediately in the US

OTC

Marketing Campaigns

Zantac 75 offers "Beat the Burn" game

"Beat the Burn" is the name of an online game that GlaxoSmithKline Consumer Healthcare is using to promote its Zantac 75 heartburn and indigestion remedy in the UK.

The company claimed the "viral" game – which is part of a £1.0 million plus (€1.2 million plus) press, online and public relations campaign – was "a breakthrough in healthcare promotion". It would put a "completely new spin" on the "De-fuse your food" theme of the established consumer advertising for Zantac 75 insisted GlaxoSmithKline (**OTC *bulletin***, 16 October 2009, page 17).

"Players are asked to undertake a choice of tasks, and as they select various foods to keep their energy levels up a time bomb shows the effect on their digestion," explained GlaxoSmithKline, adding that "Zantac 75 can then be used to put out the fuse".

A "viral" game is a key element of GlaxoSmithKline Consumer Healthcare's latest support for its Zantac 75 brand in the UK

In addition, the company is targeting pharmacy assistants with a similar game, giving them the chance to win a coffee maker. This "delivers education and tests their knowledge of the category", noted GlaxoSmithKline.

Devised by the agencies Spink and Tamba, the games are available on the brand website at www.zantac.co.uk. GlaxoSmithKline said players would be recruited through a "massive" e-mail campaign, as well as press advertising and public relations activity.

Meanwhile, the consumer-press campaign for Zantac 75 – created by the agency t7F – is targeting both men and women with advertisements in women's titles and urban commuter magazines until the end of June. A series of four advertisements includes a new barbeque-based execution in which a lighted fuse is attached to a dish of food that "may cause heartburn and indigestion". All feature the established strapline "De-fuse your food".

GlaxoSmithKline, which is working in partnership with Ceuta Healthcare, is also supporting Zantac 75 with a Pharmasite poster campaign and point-of-sale material.

OTC

Flomax stays put at top of the rankings

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

Boehringer Ingelheim's humorous launch campaign for Flomax Relief is once again the best performer in our **Pharmacy *viewpoint*** survey by a clear margin.

For the second month running, the pharmacy-only medicine fought off tough competition to maintain its place at the top of the rankings in all four sections of the May survey (see Figures 1, 2, 3 and 4).

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

Boehringer Ingelheim is backing the launch of Flomax Relief with a package including pharmacy training, pharmacy-press advertising, public relations activity and consumer advertising. The company is investing more than £5.0 million (€6.0 million) in the consumer campaign, which uses an animated blue letter 'P' to represent annoying pee problems (**OTC *bulletin***, 31 March 2010, page 13).

When IMS Consumer Health questioned UK pharmacists between 26 April and 19 May 2010 using its Intr@PharmQ service, one in five of them said Flomax Relief was backed by the best current trade-press advertising for an OTC medicine or dietary supplement (see Figure 1). Trade-press advertising for Flomax Relief urges pharmacy staff to "Help men take control of their annoying pee problems", and shows a product pack flattening the letter 'P'.

Reckitt Benckiser's Nurofen range of pain relievers followed in second place, attracting 7.8% of the best trade-press advertising vote.

Boehringer Ingelheim's Flomax Relief sits at the top of the rankings in all four sections of our Pharmacy *viewpoint* survey for the second month in a row

"A painkiller feared by headaches" is the message to pharmacists in trade-press advertising for Nurofen, which features the "Nuro" superhero from the new consumer campaign for the brand (**OTC *bulletin***, 10 February 2010, page 18). Advertising also includes the claim "Nurofen 200mg tablets (ibuprofen) provide faster and longer relief from headaches than standard paracetamol tablets".

Meanwhile, Boehringer Ingelheim's launch trade-press advertising for Buscopan Cramps entered the rankings in third place with 5.6% of the vote.

Boehringer Ingelheim recently extended its Buscopan brand with Buscopan Cramps, which it claimed was the UK's "first specialist treatment for abdominal pain and cramps". It contains the same active ingredient – 10mg hyoscine butylbromide – as Buscopan IBS Relief for irritable bowel syndrome (**OTC *bulletin***, 31 March 2010, page 15).

In the television section of **Pharmacy *view-***

BEST CURRENT REPRESENTATIVE DETAILING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	17.8
2	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	6.7
3=	Nurofen	Reckitt Benckiser	Oral/topical analgesic	4.4
	Gaviscon	Reckitt Benckiser	Indigestion remedy	4.4
	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	4.4
	Solpadeine	GlaxoSmithKline	Oral analgesic	4.4
7=	Alli	GlaxoSmithKline	Weight-loss medicine	3.3
	Lemsip	Reckitt Benckiser	Cough/cold remedy	3.3

Base: 90 pharmacists who named a brand of OTC medicine or food supplement

Figure 4: Unprompted response of UK pharmacists between 26 April and 19 May 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best representative detailing?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

Intr@PharmQ and Pharmacy *viewpoint*

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

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

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

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

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

Second place in the trade-press section was taken by Reckitt Benckiser's Nurofen

Trade-press advertising for Boehringer Ingelheim's Buscopan Cramps entered the rankings in third place

point, Flomax Relief led the way with 27.8% of the best-advertising vote (see Figure 2). The commercial is aimed at older men through the straightforward message "Take control of your annoying pee problems". The letter 'P' is seen distracting one man from his game of golf, irritating a second trapped in a traffic jam, and keeping a third awake at night.

Reckitt Benckiser's Gaviscon indigestion remedy was in second place with 6.7% of the best television advertising vote, just ahead of the same company's Nurofen brand with 5.6%.

For the best pharmacy-support package, one in four pharmacists voted for Boehringer Ingelheim's Flomax Relief. GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine was in second spot with 6.7% of the vote (see Figure 3).

And in the best current representative detailing section, Flomax Relief led the way with 17.8% of the vote (see Figure 4).

Of the hayfever remedies, GlaxoSmithKline Consumer Healthcare's Piri Team – comprising the Piriton and Piriteze brands – was the best performer, putting in an appearance in the television, pharmacy-support package and representative detailing rankings. The company is backing the Piri Team this hayfever season with a £2.4 million television-advertising campaign, as well as point-of-sale material and category-management initiatives in stores (**OTC *bulletin***, 31 March 2010, page 18).

PHARMACY *viewpoint*

BEST CURRENT TRADE-PRESS ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	20.0
2	Nurofen	Reckitt Benckiser	Oral/topical analgesic	7.8
3	Buscopan	Boehringer Ingelheim	Irritable bowel syndrome	5.6
4=	Alli	GlaxoSmithKline	Weight-loss medicine	4.4
	Nicorette	McNeil Products	Smoking-cessation aid	4.4
	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	4.4
	Vitabiotics	Vitabiotics	Food supplement	4.4
8	Lanacane	Combe International	Skincare	3.3

Base: 90 pharmacists who named a brand of OTC medicine or food supplement

Figure 1: Unprompted response of UK pharmacists between 26 April and 19 May 2010 when they were asked the question: "In your opinion, what is the best current trade-press advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT TELEVISION ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	27.8
2	Gaviscon	Reckitt Benckiser	Indigestion remedy	6.7
3	Nurofen	Reckitt Benckiser	Oral/topical analgesic	5.6
4=	Alli	GlaxoSmithKline	Weight-loss medicine	4.4
	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	4.4
6=	Adios	Dendron	Slimming aid	3.3
	Berocca	Bayer	Vitamin supplement	3.3
	Nicorette	McNeil Products	Smoking-cessation aid	3.3

Base: 90 pharmacists who named a brand of OTC medicine or food supplement

Figure 2: Unprompted response of UK pharmacists between 26 April and 19 May 2010 when they were asked the question: "In your opinion, what is the best current television consumer advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT PHARMACY-SUPPORT PACKAGE

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	24.4
2	Alli	GlaxoSmithKline	Weight-loss medicine	6.7
3=	Gaviscon	Reckitt Benckiser	Indigestion remedy	5.6
	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	5.6
5	Nurofen	Reckitt Benckiser	Oral/topical analgesic	4.4
6=	Benadryl	McNeil Products	Allergy remedy	3.3
	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	3.3
	Solpadeine	GlaxoSmithKline	Oral analgesic	3.3

Base: 90 pharmacists who named a brand of OTC medicine or food supplement

Figure 3: Unprompted response of UK pharmacists between 26 April and 19 May 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best pharmacy-support package (consumer/trade advertising, bonus deals, profit margin, training, etc)?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

Blackmores has extended its natural health portfolio in Australia with a trio of products that relieve the symptoms of colds and flu and/or support the body's immune system.

Blackmores Cold & Flu Day/Night comprises two separate herbal combinations that are claimed to relieve symptoms and help the body fight colds and flu. The day capsules contain echinacea, eucalyptus, holy basil and willow bark, while the night capsules have a similar formulation but with hops instead of echinacea.

A pack of 24 capsules – sufficient for six days – has a recommended retail selling price of A$16.95 (€11.75).

The company said the second new addition – Blackmores Immunodefence – contained lactoferrin, which "helps to boost the activity of certain immune cells", and vitamin D and zinc, which "may help to support healthy immune resistance". A one-month supply of 60 capsules retails at A$39.95.

Meanwhile, Blackmores Kids Immunities is claimed to "support growing children's immune systems". Free of artificial sweeteners, colours and flavours, the product is suitable for children aged 2-12 years and contains vitamins A, C, D and E, together with zinc. A one-month pack of 60 tablets costs A$14.95.

Blackmores is backing the launches with a "high impact" consumer campaign throughout the Australian winter.

Current trade-press advertising (pictured above) advises retailers "When winter strikes, be ready with Blackmores".

OTC

IN BRIEF

■ **COMBE INTERNATIONAL** is supporting its **Vagisil** brand with television advertising "in all areas" of the UK from 31 May. The four-week burst is part of a £1.0 million (€1.2 million) spend on television advertising for the brand this year. Meanwhile, current pharmacy-press advertising highlights that "Nobody understands intimate feminine care better than Vagisil". The Vagisil range comprises Medicated Feminine Wipes, Feminine Wash, Compact Deodorant Mist, Feminine Powder and Medicated Crème.

OTC

Distribution Agreements

Power Health acquires rights to Sanatogen protein powder

Power Health has acquired the worldwide distribution rights to Sanatogen High Protein Powder from Bayer Consumer Care.

The food supplement would initially be sold in Canada, Malta, Mauritius, Sierra Leone, the UK, and the US, said Power Health.

The company noted that Bayer – which acquired the Sanatogen brand when it purchased Roche Consumer Health in 2005 (**OTC *bulletin,*** 28 January 2005, page 27) – would continue to hold the trademark for Sanatogen High Protein Powder.

Commenting on the position in the UK, a spokesperson for Power Health told **OTC *bulletin*** that Sanatogen High Protein Powder had been discontinued briefly because it was unprofitable. However, the product was now available from www.powerhealth.co.uk and Boots stores, she added, after Power Health had taken a fresh approach to the product including sourcing new suppliers.

The spokesperson said the food supplement should soon be available from more retailers. "Our salesforce is pursuing more retail outlets and talking to pharmaceutical wholesalers – it's just early days," she remarked.

Describing Sanatogen High Protein Powder as an "excellent source of high-quality protein", Power Health said that it was "easy to prepare", and could be "easily absorbed by the body". "It can be added to hot or cold drinks, or simply sprinkled onto meals such as soups, stews, breakfast cereals or desserts," commented the company.

Power Health is offering Sanatogen High Protein Powder in a number of countries including Canada, the UK and the US

Suitable for all ages, Sanatogen High Protein Powder is supplied in a 275g pack with a recommended retail price of £8.99 (€10.50) in the UK.

Bayer's Sanatogen range also includes Sanatogen Gold, Sanatogen Kids, Sanatogen New Mother, and Sanatogen Vital 50+.

OTC

Kobayashi Healthcare has relaunched its Fever Kool 'n' Soothe cooling gel sheets in the UK with new packaging featuring Disney characters.

The company said the actual cooling gel sheets – which are for use by children aged one year and over with fever and a high temperature – would also carry images of Mickey Mouse, Donald Duck and Goofy.

Kobayashi said the move would "help younger children feel more comfortable about wearing the cooling gel sheets". "Parents too will be attracted to use the cooling gel sheets for their children, since Disney is one of the world's most universally loved and recognised brands," added the company.

The revamp followed "strong sales growth" for the Kool 'n' Soothe brand – which also includes Migraine Kool 'n' Soothe for adults – in 2009, said Kobayashi, noting it had doubled its marketing spend on the brand in 2010 compared to last year.

Kobayashi added that it was backing the Kool 'n' Soothe brand with a burst of television advertising in July. The campaign will feature a testimonial-style commercial for Migraine Kool 'n' Soothe, with Fever Kool 'n' Soothe highlighted in a tag at the end of the commercial.

Fever Kool 'n' Soothe comes in packs of four or eight sheets with recommended retail selling prices of £2.59 (€3.05) and £4.59 respectively.

OTC

JULY

7-8 July

■ **Marketing Authorisation in the Middle East**

Frankfurt, Germany

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

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

8-9 July

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

London, UK

This two-day meeting will cover recent and expected regulatory developments and pharmacovigilance requirements.

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

14 July

■ **Marketing Authorisation in Japan**

Frankfurt, Germany

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

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

AUGUST

4 August

■ **Basics of Regulatory Affairs**

London, UK

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

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

26-28 August

■ **Natural Products Expo Asia 2010**

Wan Chai, Hong Kong

A three-day exhibition and conference focusing on natural health ingredients and finished products, including dietary supplements.

***Contact**: Angel Ng, Marketing and Conference, Penton Media Asia. Tel: +852 3104 0660. Fax: +852 2857 6144. E-mail: ang@penton.com. Website: www.naturalproducts asia.com.*

30-31 August

■ **All About Regulatory Affairs in Europe**

Heidelberg, Germany

Speakers at this two-day conference conducted in German will include Peter Bachmann of Germany's federal institute for drugs and medical devices, BfArM.

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

SEPTEMBER

8 September

■ **OTC Approval and Marketing Strategies**

Bonn, Germany

This one-day conference in German will look at OTC products in Europe including food supplements, devices and cosmetics.

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

27 September

■ **The Borderline Between Medicines and Foods**

London, UK

This one-day seminar will focus on the borderline between medicines and foods.

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

5-8 November

■ **8th WSMI Asia-Pacific Regional Conference**

Chinese Taipei

'The changing landscape of Self-Medication' is the theme of the 8th World Self-Medication Industry (WSMI) Asia-Pacific Regional Conference to be held in Chinese Taipei.

The four-day meeting will review the global and regional regulatory trends and developments in self-medication, with a focus on switching, new indications and market opportunities.

***Contact**: 2010 WSMI Secretariat. Tel: +886 2 8226 1010. E-mail: 2010wsmi.tw@gmail.com. Website: www.2010wsmi-taiwan.org.*

29 September-2 October

■ **CRN's Annual Symposium for the Dietary Supplements Industry**

Austin, Texas, US

This four-day event is organised by the US Council for Responsible Nutrition (CRN).

***Contact**: Jill Ferguson, PlanNet. Tel: +1 703 778 9000. Fax: +1 703 778 9001. E-mail: CRN2010@YourMeeting.com. Website: www.crnusa.org.*

OCTOBER

4-5 October

■ **Herbal Medicines: Quality Data for Approval and Registration**

Bonn, Germany

Speakers at this two-day meeting conducted in German will include Friederike Stolte from Germany's federal institute for drugs and medical devices, BfArM.

***Contact**: Elsa Eckert, Conference Manager, Forum Institut für Management. Tel: +49 6221 500 650. Fax: +49 6221 500 555. E-mail: e.eckert@forum-institut.de. Website: www.forum-institut.com.*

4-6 October

■ **The 7th TOPRA Annual Symposium**

London, UK

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

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

7-10 October

■ **Expopharm 2010**

Munich, Germany

International pharmaceutical trade fair and conference.

***Contact**: Gabriele Stadler, Project Manager, Werbe- und Vertriebsgesellschaft Deutscher Apotheker. Tel: +49 6196 928 411. Fax: +49 6196 928 404. E-mail: g.stadler@wuv.aponet.de. Website: www.expopharm.de.*

25-26 October

■ **Nutraceuticals and Functional Foods**

London, UK

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

***Contact**: Samantha Graves, SMi Group. Tel: +44 20 7827 6052. Fax: +44 20 7827 6001. E-mail: sgraves@smi-group.co.uk. Website: www.smi-online.co.uk.*

26-27 October

■ **AESGP Conference**

Antwerp, Belgium

'How can non-prescription medicines best contribute towards public health?' is the theme of this two-day event organised by the Association of the European Self-Medication Industry, the AESGP.

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

NOVEMBER

8-9 November

■ **EuroPLX 44**

Barcelona, Spain

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

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German firms expect consolidation

More mergers and acquisitions are expected in Germany's OTC industry as pharmacy groupings increase their influence, according to a new study from Sempora Consulting. Aidan Fry reports.

German pharma companies are unanimous in believing that the growing influence of pharmacy franchises and mail-order pharmacies will lead to more OTC mergers and takeovers, according to a major new study conducted by management consultancy Sempora Consulting.

When Sempora asked 48 executives from the OTC, prescription and diagnostic industries how likely it was that there would be "further market consolidation among OTC producers due to the growing market influence of pharmacy co-operatives and mail-order pharmacies", 54% or 26 thought it was probable, while 46% or 22 believed such a development was very probable. None of the executives felt that industry consolidation was unlikely.

Germany's current ban on third-party ownership of pharmacies – which effectively prohibits major pharmacy chains – was the leading issue identified by the executives when Sempora asked them to identify the key topics that would face industry in future.

Mail-order pharmacies, falling prices for OTC products, key-account management and the borderline between pharmacy-only and general-sale status were also high up the list of the issues industry expected to be tackling in future.

Industry professionals said they were at present occupied primarily with OTC pricing issues, pharmacy exclusivity, mail-order trade and pharmacy franchises.

Furthermore, just over half of the executives identified prescription-to-OTC switches as among the strategic issues with which their firm was grappling. A similar proportion said their company had reduced the size of its sales-force in favour of key-account management.

To compile its German pharmacy market study – the seventh such survey that the management consultancy has carried out – Sempora also questioned 133 pharmacists and 298 consumers. The research was conducted in March and April this year.

Revealing their expectations for OTC prices in community pharmacies, the 48 industry executives were divided in their forecasts. Almost two-fifths felt prices would fall, while nearly half foresaw stable prices. A minority – 13% – expected OTC prices to rise (see Figure 1).

A third of the executives thought OTC prices offered by mail-order pharmacies would fall, but a quarter believed prices would rise. As Figure 2 shows, 42% expected no major change.

The 133 pharmacists surveyed were less optimistic. Nearly three-fifths of them anticipated OTC price declines for community pharmacies, with just 7% predicting higher retail prices. One out of 10 believed prices offered by mail-order pharmacies would increase, but this was far fewer than the 38% that believed mail-order OTC retailers would cut their prices. Just over half of pharmacists expected mail-order retailers to keep their OTC prices constant.

Four-fifths of the pharmacists surveyed said they regularly ran special OTC offers, while one out of three claimed to have permanently reduced their prices for non-prescription products.

This relatively high level of discounting perhaps explains a steep reduction in the number of pharmacists who said their plans for the future included cutting OTC prices. Whereas just over three-quarters of pharmacists who responded to Sempora's survey in 2009 were preparing for OTC discounting, this year just a quarter said price cuts were in their plans.

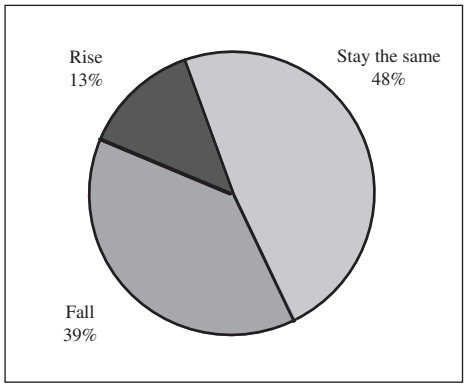

Figure 1: Proportion of a panel of 48 executives from pharmaceutical manufacturers in Germany who think prices for OTC products in community pharmacies will rise, stay the same, or fall (Source – Sempora)

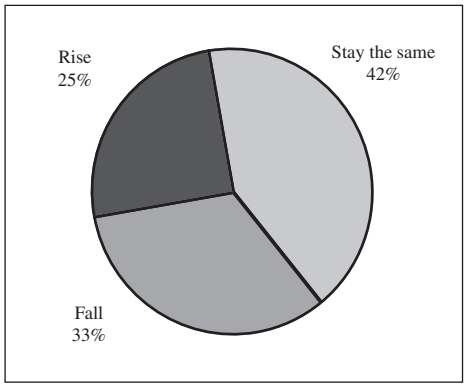

Figure 2: Proportion of a panel of 48 executives from pharmaceutical manufacturers in Germany who think prices for OTC products sold by mail-order pharmacies will rise, stay the same, or fall (Source – Sempora)

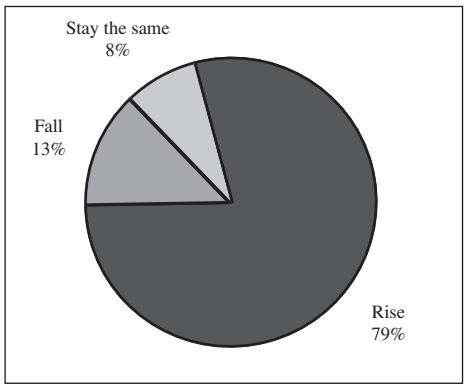

Figure 3: Proportion of a panel of 48 executives from pharmaceutical manufacturers in Germany who think the importance of own-label healthcare products will rise, stay the same, or fall (Source – Sempora)

Another reason for pharmacists' reticence to cut OTC prices could be that their customers are showing little interest in seeking the best deals.

Only 37% of the 298 German consumers questioned by Sempora said they were increasingly asking about offers on non-prescription medicines, while 27% did research about prices online before buying from their local pharmacy. Only one in every 20 consumers said they tried to negotiate a discount with their pharmacist.

Sempora noted that consumers tended to overestimate retail prices for OTC medicines, often to a considerable degree. For example, the German public on average thought that a 30-tablet pack of 500mg paracetamol from Ratiopharm cost €6.53, three-times the actual recommended retail price of €2.20.

This over-inflated impression of OTC prices must have been a key factor behind 81% of German consumers maintaining that medicines prices were too high. Nearly half of those surveyed believed that pharmacists were to a large part responsible for preventing a lasting reduction in the cost of self-medication.

German consumers, the study suggests, are open to the idea of buying healthcare products from retailers other than pharmacies. Fewer than half of them believe general-sale medicines from pharmacies are of 'higher value' than those available from drugstores or supermarkets.

The vast majority of the industry executives felt it was likely that supermarkets and drugstores would increasingly sell pharmacy-exclusive products. But any move in that direction would be a major gamble for suppliers.

Sempora's research found that many community pharmacists in Germany were ready

to replicate the infamous example of the boycott of Lichtwer's whole portfolio after the herbals specialist decided in 1998 to sell its Kwai garlic medicine through general-sale outlets. Within a year, Lichtwer was forced to backtrack with its reputation and balance sheet in tatters (**OTC *bulletin***, 14 October 1999, page 1).

Asked how they would react if a manufacturer supplied a formerly pharmacy-exclusive product to drugstores and supermarkets, a third of pharmacists said they would stop stocking the product. Three-fifths of pharmacists said they would remove the product from display, but would continue to stock it.

Sempora noted that 17% of pharmacists appeared to have no problem with such a general-sale move, as they would keep recommending the product in question. In last year's survey, not one pharmacist had been prepared to advise customers to use such a brand (**OTC *bulletin***, 30 November 2009, page 12).

Nearly a third of German pharmacists said they would refuse to recommend products from any company that produced own-label ranges for pharmacy franchise groups. And two-fifths would not recommend brands from firms that were clearly supporting such franchise groups.

Nevertheless, three-quarters of industry executives believed it was probable or very probable that manufacturers would increasingly produce own-label products for retailers. Similarly, four-fifths of the executives expected the overall importance of own labels to increase (see Figure 3), although only 55% of pharmacists agreed.

Accordingly, four-fifths of industry representatives thought the number of brands per category or indication would decrease, and a similar proportion anticipated pharmacy franchises in time stocking only the top two brands in a category or indication, plus an own-label version.

What was less clear was whether the industry executives had clearly thought through what the consequences could be of such stocking decisions by pharmacy franchises. Nearly half of the executives believed the variety of non-prescription medicines available would rise in future.

This belief does not seem to tally with the widespread expectation among both pharmaceutical executives and pharmacists that pharmacy franchises or co-operatives will become more prevalent over the next few years.

More than three-quarters of the independent pharmacists surveyed already belonged to a franchise or similar grouping. More than half of the group members said they got support with OTC pricing strategies, while 74% received own-label support.

Meanwhile, two-thirds of the industry executives questioned said their firm already worked closely with such groups. Half of the executives believed working with these groups could help their company influence which products individual pharmacies recommended.

Last year's ruling by the European Court of Justice (ECJ) that European Union member states could ban third parties from owning and operating pharmacies (**OTC *bulletin***, 29 May 2009, page 1) means there is no immediate prospect of fully-fledged pharmacy chains taking hold in Germany. Indeed, Germany's recently-elected coalition government has shown no signs of wanting to liberalise the country's pharmacy market.

Nevertheless, almost three out of five industry executives – and two out of five pharmacists – expected Germany to drop its ban on third-party ownership of pharmacies within the next five years.

Should the ban on chains fall, then Celesio appears well-placed to capitalise. The DocMorris brand that the German pharmacy and wholesale group acquired three years ago (**OTC *bulletin***, 30 April 2007, page 1) was adjudged by the industry representatives to have the strongest brand identity of any pharmacy franchise.

And when Sempora prompted consumers with a list of pharmacy groups or brands, 73% recognised DocMorris, ahead of the Linda franchise operated by the German pharmacists' marketing association, the MVDA, on 53%. No other group scored over 20%.

DocMorris largely made its name as a mail-order pharmacy supplying medicines to German customers from a base in the Netherlands. When prompted, 69% of German consumers identified DocMorris as a mail-order pharmacy. Its closest rival on 19% was Sanicare, which the industry executives named as the most effective mail-order player in Germany.

The executives were unanimous in forecasting that mail-order retailers would form an increasingly important channel for OTC firms.

Noting that mail-order pharmacies had a market share of around 9% to 10% of Germany's non-prescription market in 2009, Sempora asked the industry representatives what share they would have in 2013. Nearly two out of five executives thought it would be between 10% and 12%, while half of them pointed to the 12% to 15% band. Another 13% thought mail-order pharmacies would account for more than 15% of the OTC market within the next three years (see Figure 4).

By contrast, a quarter of pharmacists did not expect mail-order retailers to capture any additional share of the OTC medicines market. However, nearly one in five thought mail-order pharmacies would hold more than 15% of the market by 2013.

The vast majority – 88% – of the executives questioned said their firms were already collaborating with mail-order pharmacies. Their partnerships comprised mainly of advertising in the retailers' catalogues or on their websites, as well as including flyers in mail-order packages sent to customers.

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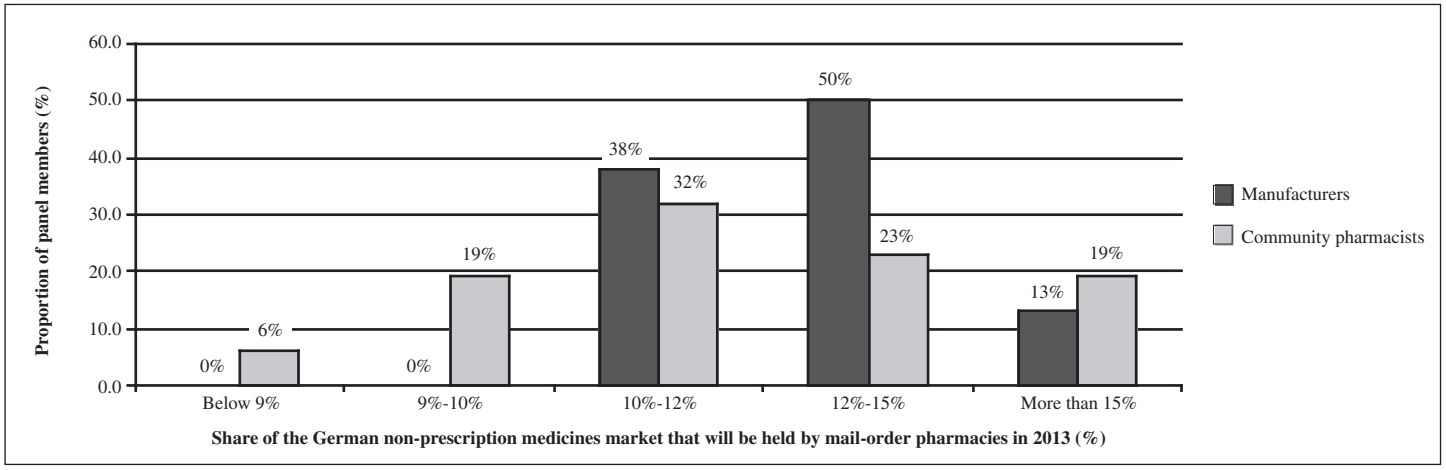

Figure 4: Estimates by a panel of 48 executives from pharmaceutical manufacturers and 133 community pharmacists in Germany of the share of the country's non-prescription medicines market that will be held by mail-order pharmacies in 2013 (Source – Sempora)

Obituary

Tylenol launch man Robert McNeil dies

Robert Lincoln McNeil Jnr, the man who launched Tylenol in 1955 before selling his family's business to Johnson & Johnson a few years later, has died at the age of 94.

The third generation of his family to work at the firm founded by his grandfather in 1879, McNeil introduced the first version of one of the world's biggest-selling OTC products as a liquid children's analgesic called Tylenol Elixir. Its marketing campaign included a cartoon fire engine and the slogan "For little hotheads".

A qualified pharmacist, McNeil is credited with coming up with the active ingredient's US generic name of acetaminophen, that is known as paracetamol in other parts of the world.

Although it had been known for more than 50 years, little work had been done to evaluate the drug's efficacy and develop it for commercial use. Moreover, aspirin was already established as a relatively low-cost painkiller.

McNeil launched Tylenol as a prescription drug in 1955 and became chairman of the company a year later.

It was not until a year after Johnson & Johnson bought the company in 1959 that Tylenol became an OTC product.

McNeil continued as chairman after the takeover until 1964.

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Manufacturers

Beiersdorf recruits Feld to lead European region

Beiersdorf has named **Peter Feld** as executive board member with responsibility for Europe.

He takes over from **Thomas Quaas**, chairman of the executive board, who had been performing the role on an interim basis since a new board structure was unveiled earlier this year (**OTC *bulletin***, 16 April 2010, page 22).

Most recently at Johnson & Johnson as management board chairman of the US firm's German subsidiary, Feld's areas of responsibility were the consumer and OTC business segments. He had also been an area managing director covering Austria, the Benelux countries, Germany and Switzerland. This had followed similar responsibilities for Procter & Gamble.

Meanwhile, **Pieter Nota** – chief marketing and innovation officer, and the executive board member responsible for marketing, sales and research and development – is leaving Beiersdorf at the end of the month to take up a "top management position at a large brand-name company" in his native Netherlands.

As a result, Nota's functions on Beiersdorf's executive board will be combined with responsibilities for the supply chain, currently discharged by existing executive board member **Markus Pinger**. Pinger will take over the newly-created brands and supply chain function on 1 July in a role that would, for the first time, bring together all product-related areas and direct them from a single source, the company commented.

Peter Feld

Pinger's successor as executive board member with responsibility for the Americas, a role he had recently assumed, would be named at a later date, the company noted.

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IN BRIEF

■ **PRESTIGE BRANDS HOLDINGS** has appointed **Charles Hinkaty** to its board of directors. In almost four decades working in consumer products, Hinkaty was most recently president and chief executive officer of Del Laboratories, where he spent 23 years. He has also worked for Bristol-Myers Squibb in marketing, acquisitions, licensing, strategic planning and business development, and is a past chairman of the US Consumer Healthcare Products Association (CHPA).

■ **PODRAVKA** re-elected **Miroslav Vitkovic** as president of its management board at a meeting held on 31 May. **Krunoslav Besvir**, **Lidija Kljajic**, **Marin Pucar** and **Miroslav Repic** form the rest of the Croatian company's management board. Meanwhile, **Branko Vuljak** is stepping down as deputy board member to return to the firm's supervisory board.

■ **BAUSCH & LOMB** has appointed **Hideyuki Ashikaga** as president, Japan. He joins the US-based eyecare specialist from Nippon Becton Dickinson, where he was president of the Japanese subsidiary.

■ **RELIV INTERNATIONAL** has elected **John Klimek** from the US-based hedge-fund management company HFR Asset Management to its board of directors.

■ **TGA** – Australia's Therapeutic Goods Administration – is recruiting members for its new Advisory Committee on Non-prescription Medicines (ACNM) that will provide advice and make recommendations to the TGA and the Minister for Health and Ageing. Formed in January 2010, the ACNM effectively replaces the Medicines Evaluation Committee. **Experts** on consumer issues as well as community pharmacy, microbiology, pharmacology, pharmaceutical chemistry and other related areas are sought by the TGA for a three-year term of office from 1 January 2011 until 31 December 2013. Successful candidates will attend five, one-day meetings per year in Canberra. Interested parties should send an e-mail to otc.medicines@tga.gov.au.

■ **MHRA** – the UK's Medicines and Healthcare products Regulatory Agency – has announced the appointment of two new members to the **Committee on the Safety of Devices** (CSD). **Adrian Harris** has been named an expert member for accident and emergency medicine, while **Timothy Wilton** has been appointed as an expert member of orthopaedics.

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Retailers

China Nepstar appoints acting chief executive

China Nepstar has promoted its chief operating officer **Jason Xinghua Wu** as its acting chief executive officer with immediate effect. He succeeds **Ian Wade**, whose resignation from the drugstore chain was effective from 2 June, the day it was announced.

Wade had spent just 18 months with China Nepstar, having been appointed co-chief executive officer in January 2009. He only took full control of the business in August of last year, following the resignation of co-chief executive officer Jiannong Qian.

Commenting on Wu's appointment, Simin Zhang, chairman of China Nepstar, said Wu had been an important member of the company's operational team for two years. He had a deep knowledge of the Chinese retail market and of the China Nepstar business, pointed out Zhang.

Wu joined China Nepstar in July 2008. He served as vice general manager of the drugstore chain's Guangzhou branch and regional general manager of the company's North China region before being appointed vice-president of operations in March 2009. Three months later, he was made chief operating officer.

Meanwhile, China Nepstar said its sales had grown by 12.1% to CNY567 million (€69.0 million) in the first quarter of 2010. Higher operating costs, however, meant China Nepstar reported an operating loss of CNY4.16 million for the period.

Same store-sales – covering stores opened before 31 December 2008 – increased by 6.9%. The company was operating 2,559 stores on 31 March 2010, having added 104 new outlets and closed 24 during the quarter.

Sales of OTC drugs had represented 36.7% of China Nepstar's turnover during the quarter, the company noted, with prescription drugs contributing another 24.8%. Nutritional supplements generated a further 17.9%, traditional Chinese herbal products 3.7% and other products the remaining 16.9%.

The retailer noted that its private-label portfolio included 1,559 products as of 31 March 2010. Sales of private-label products represented approximately 26.6% of sales in the first quarter, it added.

Working on new type of store

During the quarter, China Nepstar said, it had entered into strategic collaborations with "certain world-leading fast-moving consumer goods companies" to design a new type of health and beauty concept store.

Aimed at attracting a broader customer base, the concept stores would use half of their display space for health and beauty products, China Nepstar said, while the remainder would be devoted to the core-product offering of an existing China Nepstar outlet. No information was given about when or where the new concept stores would open.

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