16 November 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

COMPANY NEWS 3

Alliance Boots eyes Chinese expansion 3
Regulatory problems hit Mucinex launch 4
Reckitt plans future of Durex and Scholl 5
Merck overcomes Latin American drop 6
Sanofi-Aventis works on consumer acquisitions 7
Energy drinks boost OTC sales at Taisho 8
Prilosec OTC holds back growth at P&G 9
Perrigo sees longevity in store-brands 10
Pfizer benefits from Wyeth's OTC brands 12
Key brands boost Bayer Consumer Care 13
Merck eyes global future for Consumer Care division 15

GENERAL NEWS 16

Benefits of self-care will be highlighted in the UK 16

MARKETING NEWS 17

Beiersdorf takes Nivea to travellers worldwide 17
Award rewards non-pharmacy performance 19
McNeil refreshes Sudafed with new names in the UK 20
Prilosec OTC teams up with NFL players in US 21
Actavis offers pharmacists "potent" First Resort in UK 22

FEATURES 24

Regulators grapple with non-prescription supply 24
A look at Europe's regulatory issues
PepTcell pursues OTC partners 26

REGULARS

Events – Our regular listing 23
People – Reckitt tasks Sydow with growing Durex and Scholl 27

Sanofi expands in China with BMP Sunstone deal

Sanofi-Aventis is set to strengthen its presence in the Chinese OTC market by acquiring BMP Sunstone and its portfolio of OTC cough/cold and women's health brands for around US$520 million (€375 million).

The price tag represents around 3.5-times BMP Sunstone's 2009 sales of US$147 million and 62-times its operating profit of US$8.4 million. The company is based in the US and operates through subsidiaries in China.

Almost 60% of BMP Sunstone's sales were generated by its OTC brands, Sanofi-Aventis said, which included China's leading paediatric cough and cold product Hao Wa Wa (GoodBaby) and the women's hygiene brand Kang Fu Te (Confort).

The company also markets a portfolio of third-party products – primarily focused on paediatrics and women's health – in China under exclusive multi-year licenses and provides pharmaceutical distribution services through subsidiaries in Beijing and Shanghai.

Sanofi-Aventis said the US$10.00 per share deal had been unanimously approved by BMP Sunstone's board of directors and had received the backing of shareholders representing 23% of the company's stock.

Combining BMP Sunstone with its existing Chinese joint venture business, Hangzhou Sanofi Minsheng Consumer Healthcare, would turn Sanofi-Aventis into a "leading consumer healthcare company in China", the French firm said, with a strong position in China's two largest OTC categories of cough and cold and vitamin and mineral supplements, each of which is worth around US$2.5 billion annually.

Sanofi-Aventis entered the Chinese OTC

■ *Continued on page 15*

Meda acquires three OTC brands

Meda has grown its OTC business for the third time in just over two months by acquiring three OTC brands from Dutch firm Norgine for SEK540 million (€57.6 million).

Through the acquisition, the Swedish company has gained Norgine's Pyralvex for relieving the pain caused by mouth ulcers, Spasmonal for treating irritable bowel syndrome and Waxsol ear drops.

Meda is paying almost three times the combined annual sales of the brands, which are approximately SEK190 million. The majority of the brands' sales are generated in Europe, the company said, adding that Pyralvex was the biggest-selling of the three, with annual turnover of around SEK90 million.

Commenting on the deal, Anders Lönner, Meda's chief executive officer, said the acquisition further strengthened the firm's presence in the growing OTC segment.

The acquisition is Meda's third in the OTC arena in recent months. In September, the company announced it would be entering the US OTC market after acquiring the speciality pharmaceutical company Alaven for US$350 million (€257 million) (**OTC *bulletin***, 10 September 2010, page 1).

Acquiring Alaven provided Meda with a "strategic OTC platform in the US", the company said, through which it could commercialise "strategic pipeline opportunities".

Meda followed the Alaven deal by acquiring BioPhausia's portfolio of Nordic OTC brands for SEK190 million at the end of September (**OTC *bulletin***, 29 September 2010, page 1).

Meda's OTC offering has grown steadily over the past few years, and now accounts for more than SEK2.0 billion of Meda's total sales, which the company expects to reach SEK11.4 billion in 2010.

The majority of the company's OTC sales are generated by its Betadine antiseptic brand, which had sales of SEK614 million in the opening nine months of 2010.

Business Strategy/Trading Update

Alliance Boots eyes Chinese expansion

Alliance Boots says it intends to become a leading player in the Chinese market and has identified ways to increase its presence.

A spokesperson for Alliance Boots told **OTC *bulletin*** that the pan-European wholesaler and retailer was looking at "several opportunities" and one might be "seized in the near future".

No "significant" deals would be signed during executive chairman Stefano Pessina's two-day trip to China, said the spokesperson, but Alliance Boots planned to develop its presence in China and become a leading player in the fast-growing market.

Pessina recently joined British Prime Minister David Cameron and a group of UK business leaders on a trade mission to China.

Currently, Alliance Boots' only presence in China is the 50:50 wholesaling joint venture with the Guangzhou Pharmaceutical Company, which was formed in January 2008 (**OTC *bulletin***, 15 February 2008, page 2).

Meanwhile, Alliance Boots reported total sales by its wholesaling, retailing and contract manufacturing businesses up by 6.0% to £8.95 billion (€10.4 billion) in the six months ended 30 September 2010 (see Figure 1).

Sales 2% ahead at Health & Beauty

The company's Health & Beauty retail division posted turnover up by 2.0% – 1.8% on a constant currency basis – to £3.64 billion. Like-for-like sales edged up by 0.3%.

Health & Beauty's Boots UK retail operation reported sales up by 1.8% on a like-for-like basis. The business had continued to grow market share in its core health and beauty product categories, Alliance Boots said, thanks to its "strong product offering combined with excellent customer service".

The company noted that its partnership with supermarket chain Waitrose had been extended during the period. A total of 12 Boots stores now sell a combined Boots and Waitrose lunchtime food offering, and a further seven incorporate a larger range of lunchtime and convenience foods. In addition, Waitrose is selling Boots health and beauty products in 12 of its shops.

Sales by Alliance Boots' international retail operation increased by 8.2% – 6.7% at constant exchange rates – compared to the same period a year earlier, Alliance Boots noted, but the fragile state of the economy in Ireland and civil unrest in Thailand had hampered trading.

Turnover at the Pharmaceutical Wholesale division had grown by 7.7% to £5.91 billion over the period, Alliance Boots said, or 8.7% on a constant currency basis.

The company has recently expanded its wholesaling business by becoming the majority shareholder in Turkish wholesaler Hedef Alliance Holding (**OTC *bulletin***, 13 August 2010, page 3), and by snapping up a further 51.65% stake in Germany's Andreae-Noris Zahn (Anzag) from German wholesalers Celesio, Phoenix and Sanacorp (**OTC *bulletin***, 29 October 2010, page 1).

Division*	First-half sales (£ millions)	Change 2009/2010 (%)	CER**
Pharmaceutical Wholesale	5,914	+7.7	+8.7
Health & Beauty	3,637	+2.0	+1.8
Contract Manufacturing	120	-3.2	–
Intra-group	-724	–	–
Total Alliance Boots	**8,947**	**+6.0**	**+6.6**

* Continuing operations ** CER is constant exchange rates

Figure 1: Alliance Boots' sales in the six months ended 30 September 2010 (Source – Alliance Boots)

OTC *bulletin*

16 November 2010 Number 352

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

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

Subscriptions
Annual subscriptions to **OTC *bulletin*** in Europe are £595.00 for single copies and £345.00 for additional copies to the same address, including delivery. Subscriptions to addresses outside Europe are subject to an additional charge of £30.00 to cover postage. Subscription enquiries in Korea should be directed to Pharma Koreana Ltd, 14th Floor, KTB Network Building, 826-14 Yeoksam-dong, Kangnam-gu, Seoul 135-080, Korea (Tel: +82 2 554 9591; Fax: +82 2 563 8289; E-mail: pkinfo@pharmakoreana.com).

Advertising
Advertising rates and data are available on request from the address above or at www.otc-bulletin.com.

About OTC *bulletin*
OTC *bulletin* is published 20 times a year by OTC Publications Limited: twice monthly in February, March, April, May, June, September, October and November; and monthly in December, January, July and August. A subscription to **OTC *bulletin*** includes the weekly electronic newsflash, ***news*@OTC*bulletin***, which is published around 45 times a year. **OTC *bulletin*** is printed by the Warwick Printing Company Limited, Caswell Road, Leamington Spa CV31 1QD, UK.

Company registered in England No 2765878. Registered Office: 54 Creynolds Lane, Solihull, West Midlands B90 4ER, UK.

ISSN 1350–1097 **www.OTC-bulletin.com**

Mergers & Acquisitions/Third-Quarter Results

Valeant grabs Australian skin brands

Valeant Pharmaceuticals International is set to acquire several pharmacy skincare brands in Australia, including Hamilton's Suncare and Hamilton's Skin Therapy, for an undisclosed sum.

Michael Pearson, Valeant's chief executive officer, said that the brands – which generated annual sales of around A$10 million (€7.3 million) – expanded the company's presence in Australia's pharmacy OTC market and fitted nicely with its existing suncare portfolio.

Meanwhile, Valeant has reported its first set of quarterly results since its creation through the merger of US-based Valeant Pharmaceuticals and Canada's Biovail (**OTC *bulletin***, 30 June 2010, page 3).

The enlarged business did not give combined sales figures for the third quarter of 2010, but reported turnover of legacy Biovail products down by 2% to US$208 million (€151 million). Sales of legacy Valeant products were reported to have increased by 18% to US$259 million in the period.

Nine-Month Results

Regulatory problems hit Mucinex launch

Reckitt Benckiser's Mucinex cough and cold medicines will not be launched in Europe before 2013.

Explaining that regulatory problems had delayed authorisation in Europe, Reckitt Benckiser's chief executive officer Bart Becht said the medicines containing extended-release guaifenesin would now be introduced in 2013 at the earliest. "You will see Mucinex in a number of markets outside Europe before you see it in Europe," he commented.

Becht pointed out, however, that the roll-out of Mucinex in non-US markets was now underway. The brand had been launched in Malaysia and Singapore "very recently", he said, and would be introduced in "one more market in the next six months".

Reckitt Benckiser gained the Mucinex brand when it acquired Adams Respiratory Therapeutics during 2008 (**OTC *bulletin***, 17 December 2007, page 1).

Meanwhile, turnover at Reckitt Benckiser's Health & Personal Care division rose by 10% – 7% at constant exchange rates – to £1.67 billion (€1.90 billion) in the first nine months of 2010 (see Figure 1).

The division's performance had continued to improve, Becht said, following a poor cold and flu season that had hit sales at the start of the year (**OTC *bulletin***, 14 May 2010, page 5).

Growth had primarily been driven by Dettol in the Personal Care category and Gaviscon in Health Care, Becht noted. These gains had offset "softer" sales of Mucinex and Strepsils earlier in the year.

Dettol's personal-wash range had delivered excellent growth in developing markets and Europe, Reckitt Benckiser said, while Personal Care's sales had also been lifted by the performance of the Lysol No-Touch Hand Soap system in North America.

Health & Personal Care accounted for 27% of Reckitt Benckiser's total sales for the nine months, which increased by 9% – 6% at constant exchange rates – to £6.18 billion. Operating profit rose by 19% – 16% at constant exchange rates – to £1.53 billion.

Business	Nine-month sales (£ millions)	Change 2009/2010 (%) £	CER*
Health & Personal Care	*1,667*	*+10*	*+7*
Fabric Care	*1,206*	*±0*	*-1*
Surface Care	*1,039*	*+8*	*+4*
Home Care	*842*	*+11*	*+7*
Dishwashing	*651*	*+4*	*+3*
Other Household	*49*	*+17*	*+18*
Household and Health & Personal Care	5,454	+7	+4
Pharmaceuticals	505	+28	+27
Food	217	+12	+11
Total Reckitt Benckiser	**6,176**	**+9**	**+6**

* CER is constant exchange rates

Figure 1: Reckitt Benckiser's sales in the first nine months of 2010 by business (Source – Reckitt Benckiser)

Mergers & Acquisitions

Reckitt to divest SSL's Anbesol

Reckitt Benckiser's £2.54 billion (€2.99 billion) acquisition of SSL International has been given the go-ahead by the European Commission, after the company agreed to sell two of SSL's mouth-pain-relief products in the UK and Ireland.

The European Commission noted Reckitt Benckiser had satisfied its competition concerns by offering to "divest SSL's brands for adult and infant mouth-pain-relief products in the UK and SSL's brand for mouth-pain-relief in Ireland".

SSL International's Anbesol range competes directly with Reckitt Benckiser's Bonjela brand

Following the European Commission ruling and approval from SSL's shareholders, Reckitt Benckiser took control of SSL on 29 October.

The brands were not disclosed by Reckitt Benckiser, but SSL's Anbesol mouth-pain-relief products compete directly with Reckitt Benckiser's Bonjela range in the UK and Ireland.

Both the Anbesol and Bonjela lines include adult versions for relieving the pain caused by mouth ulcers and denture irritation, as well as infant products to ease the pain of teething.

In early October, Reckitt Benckiser said that it would sell "two relatively minor local SSL brands" to gain European Commission approval (**OTC *bulletin***, 15 October 2010, page 3).

The news came two months after Reckitt Benckiser announced that it was acquiring SSL in a deal that would add the Durex and Scholl brands to its global health and personal care portfolio (**OTC *bulletin***, 30 July 2010, page 1).

The UK-based company said the purchase would increase its annual sales of health and personal care products by more than a third to about £2.8 billion. Reckitt Benckiser has established a Sexual Wellbeing and Footcare category to manage Durex and Scholl.

Anbesol is part of SSL's portfolio of locally-marketed OTC brands – including Earex ear drops, Full Marks head-lice treatments, Meltus cough medicines, Mister Baby baby products, and the Syndol and Cuprofen pain relievers – which reported sales down by 14.1% to £65 million in the year ended 31 March 2010.

Future of smaller brands unclear

The future of SSL's local brands, such as Full Marks and Meltus, remains unclear in the wake of Reckitt Benckiser's takeover, which was driven primarily by the strength of SSL's core Durex and Scholl brands.

Bart Becht, Reckitt Benckiser's chief executive officer, said the "drag" on SSL's sales caused by its locally-marketed brands and "other" products was something that had to be dealt with, although he refused to say whether any of these brands would be divested (see page 5).

Business Strategy

Reckitt plans future of Durex and Scholl

Innovation, investment and stronger marketing will enable Reckitt Benckiser to get the best out of SSL International and its Durex and Scholl brands, according to the UK-based firm's chief executive officer Bart Becht.

Acquiring SSL for £2.54 billion (€2.99 billion) (**OTC *bulletin***, 30 July 2010, page 1) was both "strategically and financially attractive", Becht insisted, as it had given the company two global 'powerbrands' with potential for further growth.

Becht said the company's growth strategy for Durex and Scholl would focus on increasing investment in brand support and brand-building initiatives, as well as developing a "gradually improving pipeline". "We do not believe," insisted Becht, "that the bigger benefits will come from scale or distribution or white spots."

SSL's brands were already well distributed and well merchandised in most countries, and there were only a limited number of "white spots" to be found, Becht pointed out, citing China and Japan as examples.

Combining the operations of the two companies in China and Japan would provide a "material increase in scale", he noted, which Reckitt Benckiser hoped would make both businesses "substantially stronger and more successful in the future".

Reckitt Benckiser gained control of SSL on 29 October 2010 after securing the backing of over 85% of SSL's shareholders and agreeing to sell two of SSL's mouth-pain-relief brands to satisfy competition concerns raised by the European Commission (see page 4).

The deal followed years of speculation linking Reckitt Benckiser with a takeover of SSL.

Asked why Reckitt Benckiser felt the time was now right to acquire SSL, Becht explained that in the past only a small percentage of SSL's sales had been generated by Durex and Scholl, while Reckitt Benckiser had very little capability in the pharmacy channel, where the majority of SSL's brands were distributed.

Reckitt Benckiser aims to translate Scholl's strong brand recognition into sales growth

However, acquiring Boots Healthcare International in 2006 (**OTC *bulletin***, 17 October 2005, page 1) and Adams Respiratory Therapeutics in 2008 (**OTC *bulletin***, 17 December 2007, page 1) had made Reckitt Benckiser much more capable in the pharmacy channel, Becht pointed out, while SSL had acted to condense its portfolio and switch its focus to Durex and Scholl.

Looking ahead, Becht said that Reckitt Benckiser wanted to raise SSL's underlying growth rate – which stood at 1.8% at constant exchange rates in the year ended 31 March 2010 (**OTC *bulletin***, 31 May 2010, page 8) – to match its own average growth rate through a "step change" in how SSL's brands were handled.

Innovations in existing and new categories would need to be bigger, Becht insisted, while brand support in certain countries would also need to be boosted.

Key challenges going forward

There were some interesting projects in SSL's pipeline, Becht noted, but most were relatively small and this represented a key challenge going forward.

"We are sitting on two brands – Durex and Scholl – which have huge recognition in the marketplace, but are relatively small in size," Becht pointed out. The challenge, he explained, was translating that brand equity and brand recognition into brand sales.

"It comes down to stretching these brands," Becht continued, "and that requires innovative thinking, and means we need some big projects and not lots of little ones."

To help achieve these goals, Reckitt Benckiser has created a new Sexual Wellbeing and Footcare category containing both Durex and Scholl. The new category will be led by former SSL group marketing director Volker Sydow, who has been given responsibility for developing both brands (see page 27).

Lifting growth rates would also be reliant on dealing with the "drag" caused by SSL's local brands – including its portfolio of UK OTC brands – and its "other" products, Becht said, although he refused to say whether any of these brands would be divested.

SSL's locally-marketed brands – including Earex ear drops, Full Marks head-lice treatments, Meltus cough medicines, Mister Baby baby products, and Syndol and Cuprofen pain relievers – reported annual turnover down by 14.1% to £65 million in the year to 31 March 2010, while turnover generated by its "other" consumer products dropped by 26.9%.

Big innovation projects will help Durex reach its potential, according to Reckitt Benckiser

The remainder of the portfolio was "not so bad", Becht noted, describing sales growth by the Durex condom business as "so-so" and the performance of the Durex Play line as "pretty good". Scholl footcare was "ok-ish", he continued, while Scholl footwear was "very good" in sales terms.

Adding SSL's brands to its portfolio means that health and personal care products will represent a third – approximately £2.8 billion – of Reckitt Benckiser's annual group sales.

On a regional basis, the deal would primarily benefit the operations in China and Japan, Becht claimed, where both Reckitt Benckiser and SSL had only a limited presence.

In Japan, purchasing SSL would add the Scholl brand to Reckitt Benckiser's Airwick air fresheners, its Clearasil skincare range, Finish dish-washing brand, Muse anti-bacterial products and Veet depilatory line, Becht noted.

These six brands would give the company a "reasonable critical mass" in Japan, Becht said, but not a fully operational organisation. All these brands were at an "infant stage", he added, and the firm needed more scale before it could have its own "fully-fledged go-to-market operation" in Japan, something that would come as it launched more of its powerbrands in the market.

The two companies' existing Chinese businesses were even smaller, Becht said. Dettol was Reckitt Benckiser's main franchise, with Veet as a smaller arm of the business; while Durex served as SSL's key brand.

Highlighting the limited geographic presence of both companies in China, Becht pointed out that although Durex had a good market presence, the brand was only available in a couple of Chinese cities. Combining operations was a good step forward in China, Becht insisted, but was not the ultimate step.

OTC

Third-Quarter Results

Merck overcomes Latin American drop

Better sales in Europe, as well as across Asia, Africa and Australasia, helped Merck KGaA's Consumer Health Care business offset a double-digit decline in Latin America and drive turnover up by 1.7% to €125 million in the third quarter of 2010.

The devaluation of Venezuela's currency, Merck pointed out, had been behind the 34.6% drop in Latin American sales over the three months to €17 million.

However, an 8.3% rise in European sales to €91 million, combined with a 23.1% increase in turnover across Consumer Health Care's Asia, Africa, Australasia region to €16 million managed to offset the poor result in Latin America.

Merck noted that the stronger British pound and Indonesian rupiah had helped negate the impact of the Venezuelan currency devaluation.

Latin America represented just 14% of Consumer Health Care's total third-quarter sales (see Figure 1), down from 21% a year earlier. Europe accounted for 73% – up from 68% a year ago – while Asia, Africa and Australasia's contribution increased from 11% to 13%.

Commenting on Consumer Health Care's performance, Merck said that sales of its international strategic brands – Bion3, Femibion, Flexagil (also known as Seven Seas and Kytta), and Nasivin – together with sales of the Cebion, Diabion and Kidabion "regionally driven" brands, now accounted for €72.5 million, or 58%, of the division's total turnover.

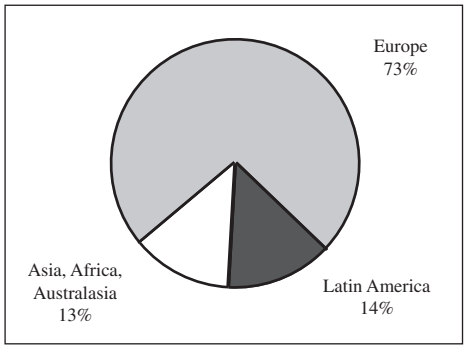

Figure 1: Sales by Merck KGaA's Consumer Health Care business in the third quarter of 2010 – €125 million – by region (Source – Merck KGaA)

Business	Third-quarter sales (€ millions)	Change (%)	Operating profit (€ millions)	Change (%)
Merck Serono	*1,394*	*+6*	*210*	*+70*
Consumer Health Care	*125*	*+2*	*16*	*-24*
Total Pharmaceuticals	1,518	+5	226	+56
Merck Millipore	574	–	10	–
Performance Materials	346	+23	152	+109
Corporate and others	–	–	-24	–
Total Merck	**2,438**	**+25**	**364**	**+64**

Figure 3: Merck KGaA's sales and operating profit in the third quarter of 2010 (Source – Merck KGaA)

High demand in Germany and Poland had led to a 40% jump in global sales of the Femibion vitamins and minerals supplement for pregnant women and nursing mothers, Merck pointed out, while the Bion3 probiotic multivitamin brand posted sales up by 13% thanks to greater demand in France and the UK.

Worldwide sales of the Nasivin nasal spray had increased by 24% in the quarter, driven by the brand's growing popularity in India and Poland, Merck noted. The company's key mobility brands, such as Flexagil, Kytta and Seven Seas, posted turnover up by 7.5%.

In contrast, sales of Cebion vitamin C products slumped by 30%, the company said, due primarily to the problems in Venezuela.

Women's and children's health was the only one of Merck's four OTC "health themes" – the others are everyday health protection; mobility; and cough and cold – to post a positive sales result in the third quarter, as Femibion's performance drove turnover up by 11% to €19 million (see Figure 2).

Everyday health protection remained the largest health theme, despite a 13% drop in sales to €40 million, caused by the double-digit decline in Cebion turnover.

Meanwhile, although the Nasivin brand had performed well, sales of cough and cold products declined by 6.6% to €25 million. Mobility sales fell by 6.4% to €19 million, despite the gains made by the category's strategic brands.

Consumer Health Care's operating income had dropped by 24% to €16 million during the quarter (see Figure 3), Merck said, due to the start of restructuring activities in China. This restructuring was expected to continue throughout the fourth quarter, the company noted.

Along with the restructuring in China, Merck blamed the profit fall on a rise in marketing and selling expenditure on its strategic brands, and higher research and development costs.

The decline in operating income meant Consumer Health Care recorded a return on sales of only 13.0% compared to 17.4% in the third quarter of 2009.

Consumer Health Care accounted for just 7% of Merck's Pharmaceuticals operating income for the quarter – which finished up by 56% to €226 million – and represented 8% of Pharmaceuticals sales, which improved by 5.3% to €1.52 billion.

The Merck Serono prescription drugs business reported sales up by 5.7% to €1.39 billion, representing 92% of the Pharmaceuticals division's turnover. Merck Serono's operating income jumped by 70% to €210 million.

Merck's total group sales increased by 25% to €2.44 billion. The majority of the rise – 16% – was due to acquiring the Millipore life-science company in July for €5.1 billion. Operating income finished up by 64% to €364 million.

OTC

Health theme	Third-quarter sales (€ millions)	Change 2009/2010 (%)	Proportion of total (%)
Everyday health protection	40	-13	32
Cough and cold	25	-7	20
Mobility	19	-6	15
Women's and children's health	19	+11	15
Others	22	+67	18
Consumer Health Care	**125**	**+2**	**100**

Figure 2: Sales by Merck KGaA's Consumer Health Care business in the third quarter of 2010, broken down by the company's health themes (Source – Merck KGaA)

IN BRIEF

■ **ORION** said sales at its Specialty Products business – including generic, prescription and self-care products – had risen **by 10% to €222 million** in the first nine months of 2010.

OTC

Third-Quarter Results

Sanofi works on consumer acquisitions

Sanofi-Aventis is working towards consumer healthcare acquisitions in Asia-Pacific and Latin America, according to its president of global operations Hanspeter Spek, and has identified some "very interesting opportunities".

Spek's comments came as the French firm reported an acquisition-driven 57.8% rise in third-quarter sales at its Consumer Health Care business to €576 million (see Figure 1). At constant exchange rates, sales grew by 45.8%.

Shortly after the results announcement, Spek proved as good as his word as Sanofi-Aventis revealed it was set to strengthen its presence in the Chinese OTC market by acquiring BMP Sunstone and its portfolio of OTC cough/cold and women's health brands for around US$520 million (€375 million) (see front page).

The price tag represents around 3.5-times BMP Sunstone's 2009 sales of US$147 million and 62-times its operating profit of US$8.4 million. The company is based in the US and operates through subsidiaries in China.

Acquiring BMP Sunstone is the latest demonstration of Sanofi-Aventis' aggressive acquisition strategy in the consumer healthcare arena, which led to the double-digit rise in third-quarter sales at its Consumer Health Care unit.

Over the past 20 months, Sanofi-Aventis has expanded its Consumer Health Care business by acquiring Gramon in Argentina, Kernpharm in the Netherlands, and Oenobiol in France (**OTC *bulletin***, 16 November 2009, page 1), as well as Zentiva in the Czech Republic and Nepentes in Poland (**OTC *bulletin***, 31 May 2010, page 1).

The biggest acquisition, however, came in the US, where Sanofi-Aventis entered the OTC market by paying US$1.9 billion for Chattem (**OTC *bulletin***, 20 January 2010, page 1).

Acquiring Chattem added €88 million to Consumer Health Care's sales in the third quarter, Sanofi-Aventis noted, as the US business achieved double-digit organic growth.

Emerging Markets remained Consumer Health Care's biggest region in terms of sales, with turnover growing by 41.0% at constant exchange rates to €277 million.

The growth had been led by Latin America, Poland and Russia, the company said, adding that acquiring Nepentes in September had further strengthened the business' presence in emerging markets.

Consumer Health Care's Rest of World sales grew even quicker than those in Emerging Markets, with turnover up by 47.2% at constant exchange rates to €63 million. In contrast, sales in Western Europe fell by 2% to €148 million.

Although acquisitions had contributed the majority of Consumer Health Care's third-quarter growth, Sanofi-Aventis noted the business had also benefited from strong organic growth over the three months. On a constant-structure and constant exchange rate basis, turnover had increased by 9.5%.

Consumer Health Care accounted for 8.7% of total sales by Sanofi-Aventis' Pharmaceuticals division, which increased by 3.8% to €6.60 billion (see Figure 2). At constant exchange rates, the division's sales slipped back by 3.5%.

Total group sales – including the Vaccines business as well as Pharmaceuticals – grew by 5.7% to €7.82 billion. At constant exchange rates, sales dropped by 1.7%.

OTC

Business	Third-quarter sales (€ millions)	Change (%) CER*	Proportion of sales (%)
Emerging Markets	277	+41.0	48
Western Europe	148	-2.0	26
US	88	–	15
Rest of World	63	+47.2	11
Total Consumer Health Care	**576**	**+45.8**	**100**

* CER is constant exchange rates

Figure 1: Breakdown of Sanofi-Aventis' Consumer Health Care sales in the third quarter of 2010 by region (Source – Sanofi-Aventis)

Business	Third-quarter sales (€ millions)	Change 2009/2010 (%) €	CER*
Diabetes brands	*1,097*	*-15.8*	*+6.7*
Other prescription brands	*3,022*	–	–
Other products	*1,510*	*+4.6*	*-1.2*
Consumer Health Care	*576*	*+57.8*	*+45.8*
Generics	*390*	*+29.1*	*+18.9*
Pharmaceuticals	6,595	+3.8	-3.5
Vaccines	1,226	+17.2	+8.9
Total Sanofi-Aventis	**7,821**	**+5.7**	**-1.7**

* CER is constant exchange rates

Figure 2: Sanofi-Aventis' sales in the third quarter of 2010 broken down by business (Source – Sanofi-Aventis)

Business Strategy

German chain targets 2,000 stores

German drugstore chain dm-drogerie markt plans to invest €68 million in its current financial year ending 30 September 2011 to set up 100 new outlets. This will take its total number of stores in Germany to 1,285.

"We believe there is potential for 2,000 dm stores in Germany," the chain's expansion head Markus Trojansky stated.

The drugstore group claims to be Germany's leading provider of healthcare products outside of the pharmacy channel.

In its financial year ended 30 September 2010, the German group increased its domestic turnover by 8.7% to €4.07 billion.

Sales in 10 other countries – largely in central and eastern Europe, including Croatia, Hungary, Romania, Serbia and Slovakia – rose by 8.8% to €1.57 billion, moving group turnover ahead by 8.7% to €5.65 billion.

In total, dm intends to invest €170 million in its current financial year to expand its European chain of 2,403 outlets. If the group hits its sales growth goal of around 7%, turnover should exceed €6.0 billion, including a sales increase of at least €200 million in Germany.

OTC

First-Half Results

Energy drinks boost OTC sales at Taisho

Taisho Pharmaceutical said robust sales of energy drinks helped drive up its OTC sales by 3.7% to ¥77.7 billion (€688 million) in the six months ended 30 September 2010, despite a "sluggish" Japanese OTC market.

Japan's largest OTC firm said the domestic market had been impacted by lower sales of cold-prevention products compared to a year earlier, when the category had spiked sharply due to an outbreak of swine flu (**OTC *bulletin***, 16 November 2009, page 11).

However, a hot summer period starting in July had benefited the company's core energy drink brands, Taisho said, which had helped push up OTC sales.

As a result of the firm's better OTC sales, turnover at Taisho's Self-Medication division increased by 4.6% to ¥85.4 billion in the six months (see Figure 1).

Operating income at the division had jumped by 30% to ¥20.9 billion, Taisho said, thanks to a dramatic reduction in advertising expenditure – which had peaked in the same period a year earlier due to the launch of new products, including RiUP X5 – and efforts to contain selling, general and administrative costs.

To drive further growth in the stagnant Japanese OTC market, the Self-Medication division was focused on increasing the "provision of information" for its category 1 drugs – OTC medicines deemed to hold the highest degree of risk – Taisho pointed out, as well as improving in-store promotional activities.

In May, the firm said it planned to broaden its range of category 1 drugs by switching more ingredients from prescription-only to OTC status, as well as "aggressively" developing new product categories (**OTC *bulletin***, 31 May 2010, page 6).

Taisho expects these efforts to push up sales at the Self-Medication division by 5.3% to ¥167 billion in the year ended 31 March 2011.

Sales of the company's core Lipovitan brand of energy and tonic drinks increased by 2.3% to ¥40.8 billion (see Figure 2), as the hot summer months lifted sales and offset a decline in the April-June period caused by "unseasonal weather in early spring" (**OTC *bulletin***, 13 August 2010, page 11).

The brand's leading Lipovitan D products had posted a solid performance, Taisho noted, while the low-calorie Lipovitan Fine and Lipovitan Half, as well as the Lipovitan FB product, had grown "steadily" over the six months.

Turnover by all of Taisho's tonic and nutrient drinks rose by 4.2% to ¥22.6 billion through food channels, but dropped by 0.3% to ¥20.6 billion through drug channels (see Figure 3).

Despite category 1 drugs generally struggling in the Japanese OTC market, the RiUP X5 minoxidil product for hair regrowth – launched in March last year (**OTC *bulletin***, 17 March 2009, page 17) – helped drive up sales of the RiUP brand by 16.4% to ¥7.4 billion.

Meanwhile, sales of the Pabron cold remedies brand dropped by 5.9% to ¥10.0 billion, due to the swine-flu driven rise in the same period last year.

Outside of Japan, Taisho said that its OTC assets in the Asia-Pacific region – excluding China and Japan – acquired from Bristol-Myers Squibb last year (**OTC *bulletin***, 30 September 2009, page 1) had contributed sales of ¥2.2 billion during the six-month period.

In the 'foods for specified health use' category, sales grew by 18.3% to ¥6.2 billion, thanks to a double-digit rise in sales of the Livita brand and the firm's portfolio of overseas drinks.

OTC

Business	First-half sales (¥ billions)	Change (%)	Forecast sales (¥ billions)	Change (%)
Livita brand	*1.7*	*+19.0*	*3.5*	*+12.9*
Overseas drinks	*3.3*	*+15.1*	*6.2*	*+8.8*
Others	*1.2*	*–*	*2.8*	*–*
Foods for specified health use	6.2	+18.3	12.5	+14.9
OTC products	77.7	+3.7	152.0	+4.8
Others	1.5	+3.7	2.7	-6.9
Total Self-Medication	**85.4**	**+4.6**	**167.2**	**+5.3**
Prescription operations	**47.6**	**-1.0**	**98.3**	**-1.3**
Total for Taisho	**133.0**	**+2.5**	**265.5**	**+2.7**

Figure 1: Taisho Pharmaceutical's sales in its first half ended 30 September 2010. Forecasted sales are for the year ending 31 March 2011 compared with actual sales in the previous 12 months (Source – Taisho Pharmaceutical)

Business	First-half sales (¥ billions)	Change (%)	Forecast sales (¥ billions)	Change (%)
Lipovitan D	*28.3*	*+0.7*	*50.0*	*+1.2*
Other Lipovitan	*12.5*	*+6.0*	*22.2*	*+3.7*
Total Lipovitan brand	*40.8*	*+2.3*	72.2	+2.0
Zena brand	1.5	-11.2	3.5	±0.0
Other drinks	0.9	–	–	–
Total tonics and nutrient drinks	**43.2**	**+2.0**	**–**	**–**
Cold remedies (Pabron brand)	**10.0**	**-5.9**	**25.5**	**+2.4**
Hair treatments (RiUP brand)	**7.4**	**+16.4**	**14.7**	**+15.7**
Analgesics (Naron brand)	**2.2**	**-1.9**	**4.6**	**+4.5**
Gastrointestinal treatments	**2.0**	**-3.3**	**4.3**	**±0.0**
Laxatives (Colac brand)	**1.9**	**-1.5**	**3.9**	**±0.0**
Cold remedies (Vicks brand)	**1.1**	**+1.6**	**3.1**	**+6.9**
Biofermin	**2.8**	**+1.1**	**5.2**	**-1.9**
Overseas OTC	**2.2**	**–**	**4.3**	**–**
Other OTC products	**4.9**	**–**	**10.7**	**–**
Total OTC products	**77.7**	**+3.7**	**152.0**	**+4.8**

Figure 2: Breakdown of Taisho Pharmaceutical's OTC sales in its first half ended 30 September 2010. Forecasted sales are for the year ending 31 March 2011 compared with actual sales in the previous 12 months (Source – Taisho Pharmaceutical)

	First-half sales (¥ billions)	Change (%)
Food channels	22.6	+4.2
Drug channels	20.6	-0.3
Total	**43.2**	**+2.0**

Figure 3: Breakdown by distribution channel of Taisho Pharmaceutical's sales of tonics and nutrient drinks in Japan in its first half ended 30 September 2010 (Source – Taisho Pharmaceutical)

First-Quarter Results

Prilosec OTC holds back growth at P&G

Volume sales growth at Procter & Gamble's Personal Health Care business in its first quarter ended 30 September 2010 was held back by Prilosec OTC's battle in the US with rival branded and store-brand heartburn medicines.

Personal Health Care's volume growth stalled in the low single digits in the three months, as the omeprazole-based Prilosec OTC reported volume sales down for a fourth consecutive quarter. This decline partially offset higher shipments of Vicks cold and flu products and PUR water filtration products across Africa, central and eastern Europe and the Middle East.

Prilosec OTC has been hit by the launch of two branded competitors over the past 12 months, as well as ongoing competition from store-brand equivalents.

The launch of Novartis Consumer Health's lansoprazole-based Prevacid 24HR a year ago – backed by a US$200 million (€142 million) consumer marketing campaign (**OTC *bulletin***, 16 November 2009, page 1) – led to a drop in Prilosec OTC's volume sales in the second and third quarters of the year ended 30 June 2010 (**OTC *bulletin***, 10 February 2010, page 9; **OTC *bulletin***, 14 May 2010, page 9).

This was compounded in the company's fourth quarter ended 30 June by the launch of Merck & Co's Zegerid OTC – which combines 20mg of omeprazole with 1,100mg of sodium bicarbonate – and a national television campaign in support of the newcomer, which urged consumers to "Discover the difference" (**OTC *bulletin***, 16 April 2010, page 14).

Merck & Co claims the product's "unique dual-ingredient formulation" protects the omeprazole from stomach acids and allows the medicine to be absorbed quickly.

Net first-quarter sales at Procter & Gamble's overall Health Care division – including its Feminine Care, Oral Care and Personal Health Care businesses – stood still at US$3.0 billion.

The static sales result was blamed on a negative 4% foreign exchange rate impact and a 2% decline in pricing, which wiped out a 6% volume sales gain.

The Feminine Care business had achieved mid-single-digit volume growth during the three months, Procter & Gamble pointed out, as a result of higher shipments of Naturella, thanks to the brand's launch in China, and the growth of the Always brand in Africa, central and eastern Europe and the Middle East.

Meanwhile, Oral Care posted a high-single-digit gain in volume sales as Procter & Gamble rolled out the Crest Pro-Health Clinical line in North America and expanded the Oral-B toothpaste range in Brazil, Belgium and the Netherlands. The category was also boosted by the success of the Crest Pro-Health line in various markets, the company noted.

Health Care's net earnings had dropped by 10% to US$495 million, Procter & Gamble stated, due to a lower operating margin caused by higher marketing spending.

The Health Care division accounted for around 15% of first-quarter group sales. Including beauty and grooming products, baby and family care brands, snack and pet care lines, and household products – as well as the firm's healthcare offering – these advanced by 2% to US$20.1 billion.

OTC

Second-Quarter Results

OTC sales decline at Prestige Brands

Sales at Prestige Brands' OTC Healthcare division fell by 1.7% to US$50.8 million (€35.7 million) in its second quarter ended 30 September 2010.

Prestige blamed the decline on lower sales of the Allergen Block and Chloraseptic brands, which had offset better sales of its Clear Eyes, Compound W and Little Remedies lines.

The drop in OTC turnover, combined with a 5.3% fall in sales at the Household division to US$27.5 million, resulted in the US-based company's total sales declining by 3.0% to US$78.3 million over the three months.

Meanwhile, the company announced that it had completed its US$190 million acquisition of Blacksmith Brands Holdings from Charlesbank Capital Partners (**OTC *bulletin***, 29 September 2010, page 1).

OTC

First-Quarter Results

Perrigo sees longevity in store-brands

Store-brand products remain strong in the US and now represent around 29% of dollar sales of OTC and nutritional products at retail prices, according to Perrigo's chairman and chief executive officer Joseph Papa.

The proportion of US retail sales taken by store-brand OTC and nutritional products had grown by 400 basis-points from 25% over the past two years, added Papa, noting a 4% rise in Perrigo's Consumer Healthcare sales to US$396 million (€285 million) in the three months ended 25 September 2010 (see Figure 1).

Business	First-quarter sales (US$ millions)	Change (%)	Operating income (US$ millions)	Change (%)
Consumer Healthcare	396	+4	71	-4
Nutritionals	123	+120	18	–
Prescription Pharmaceuticals	69	+47	18	–
Active Pharmaceutical Ingredients	37	+14	10	–
Other	16	+36	-6	–
Total Perrigo	**641**	**+21**	**112**	**+55**

Figure 1: Perrigo's sales and operating income in its first quarter ended 25 September 2010 (Source – Perrigo)

Asked whether he agreed with other consumer products companies that sales growth for store-brand products had started to flatten out as the US economy recovered, Papa said that on the contrary he felt growth was accelerating.

Quoting IRI data for the 52 weeks ended 26 September 2010, Papa said that in the major US OTC and supplements categories – analgesics; cough, cold, allergy and sinus; gastrointestinal; smoking cessation; and vitamins – store-brands had grown ahead of both their equivalent national brands and the categories as a whole.

"The overall OTC market was up just 1% versus last year, with national brands down by nearly 4%," Papa noted (see Figure 2), "but store-brands had gained 15% on the strength of new product launches, recalls of national brand products and market-share gains."

Papa said his views were further backed by the growing importance of store-brands to retailers. The large retailers had developed "significant programmes and promotions" to drive store brands, he claimed, and the company was not seeing any reduction in that activity.

The 4% gain made by Perrigo's own Consumer Healthcare division in its first quarter ended 25 September 2010 would have been even greater but for a loss of contract manufacturing sales due to problems at one of its manufacturing facilities and increased competition in the smoking-cessation category.

New products add US$17 million

New products contributed US$17 million of Consumer Healthcare's sales rise, to which was added a further US$18 million from existing products, primarily in the analgesics and cough/cold categories.

These increases were partially offset by a combined US$20 million loss in smoking-cessation and contract-manufacturing turnover.

Explaining the drop in contract manufacturing sales, Papa said the decline had been caused by the company's efforts to improve its production facility in Allegan, Michigan, which had been subject to a Warning Letter from the US Food and Drug Administration (FDA) (**OTC *bulletin***, 11 June 2010, page 1).

Correcting the violations highlighted in the Warning Letter had led to a US$25 million product back-log in the three months, Papa said, which had been carried through and shipped early in the company's second quarter.

These manufacturing problems had also been responsible for the 4% drop in Consumer Healthcare's operating income to US$71 million, Perrigo noted.

Meanwhile, Perrigo's newly-created Nutritionals division – which houses its recently acquired PBM infant formula business and its existing vitamin, mineral and supplement products, as well as oral electrolyte solutions – reported sales of US$123 million, up from US$56 million a year earlier. Operating income was US$18 million, which compared with a loss.

The sales growth had been driven by the acquisition of PBM in March (**OTC *bulletin***, 17 March 2010, page 3), Perrigo said, and partially offset by a year-on-year decline in sales of vitamins, minerals and supplements.

Looking ahead, Papa said the company was anticipating the switch of Sanofi-Aventis' allergy medicine Allegra (fexofenadine) from prescription-only to OTC status in the US sometime in "early 2011".

However, Papa cautioned that Perrigo's store-brand version of Allegra would most likely not appear until after the close of the company's current financial year in June 2011.

Perrigo acquired the exclusive rights to sell and market store-brand OTC Allegra from Teva Pharmaceutical Industries in July (**OTC *bulletin***, 30 July 2010, page 19).

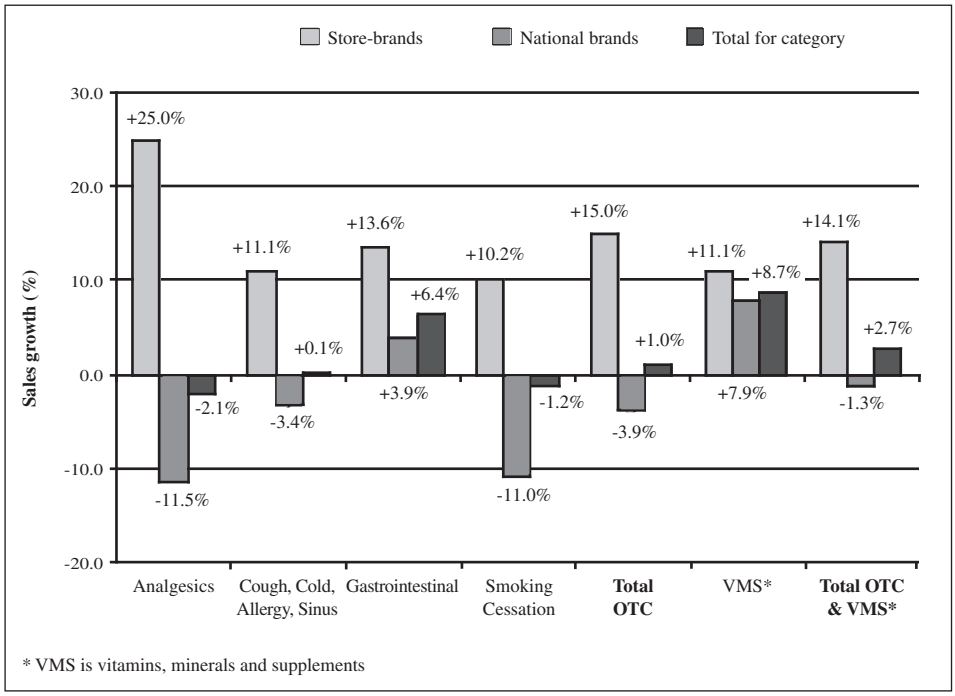

Figure 2: Retail sales growth of major categories in the US OTC medicines and vitamin, mineral and supplements markets in the 52 weeks ended 26 September 2010 (Source – Perrigo/IRI)

the real evidence that

GPs

are recommending OTC brands

81%

of GPs are asked by patients for recommendations of OTC pain relief medicines at least a few times a month, and 23% are asked on a daily basis*

75%

of GPs are asked by patients for recommendations of OTC cough/cold/sore throat medicines at least a few times a month, and 15% are asked on a daily basis*

To discuss how you can engage GPs (and/or hospital doctors) with your key messages, contact simon.grime@mess.doctors.org.uk, and quote OTC2 to get the full research document, free of charge.

Doctors.net.uk

for doctors, by doctors

* Source: MedeConnect Healthcare Insight, part of the Doctors.net.uk group, survey of 1,011 GPs, July 2010

Third-Quarter Results

Pfizer benefits from Wyeth's OTC brands

Pfizer said the Consumer Healthcare business it gained when it acquired Wyeth a year ago had contributed sales of US$673 million (€483 million) to the company's Diversified division in the third quarter of 2010.

The Consumer Healthcare business – which includes the Advil, Centrum and Robitussin brands – had posted international sales of US$299 million in the three months, Pfizer pointed out, while turnover in the US accounted for US$374 million.

Over the opening nine months of 2010, Consumer Healthcare generated worldwide sales of US$2.01 billion. The business reported US sales of US$1.02 billion and international turnover of US$998 million.

Consumer Healthcare accounted for 31.3% of the Diversified division's third-quarter sales, which more than doubled to US$2.15 billion (see Figure 1), thanks to the addition of Wyeth in October last year. Pfizer's existing brands contributed just four percentage points of the division's growth, with Wyeth accounting for the other 147 percentage points.

Business	Third-quarter sales (US$ millions)	Change 2009/2010 (%)	Proportion of sales (%)
Biopharmaceutical	13,945	+31	86.2
Animal Health	*860*	*+27*	*5.3*
Consumer Healthcare	*673*	*–*	*4.2*
Nutrition	*441*	*–*	*2.7*
Capsugel	*176*	*-1*	*1.1*
Diversified	2,150	+151	13.3
Other	76	-15	0.5
Pfizer	**16,171**	**+39**	**100.0**

Figure 1: Pfizer's sales in the third quarter of 2010 broken down by business (Source – Pfizer)

Animal Health generated 40.0% of the division's sales, while Nutrition was responsible for 20.5% and Capsugel the remaining 8.2%.

In early October, Pfizer announced that it was exploring strategic options, including divestment, for its Capsugel drug-delivery business (**OTC *bulletin***, 15 October 2010, page 1).

Asked if the Capsugel move signalled a change in Pfizer's attitude towards its Diversified businesses, Jeffrey Kindler, Pfizer's chairman and chief executive officer, said the company was "engaged in a continuous review" of the role of each of its businesses and not just the ones covered by the Diversified division.

The Capsugel decision had been the result of such a review, Kindler said, adding that every business had to demonstrate on an ongoing basis that it was creating shareholder value in "accordance with the strategic purpose of that business" and that it was creating "more value inside Pfizer than outside Pfizer".

Diversified businesses accounted for 13.3% of the firm's total third-quarter sales, which grew by 39% to US$16.2 billion. All the growth came from the Wyeth acquisition, with sales of Pfizer's legacy products dropping by 4%.

OTC

Third-Quarter Results

Herbalife's turnover improves by 14.7%

Herbalife said its net sales had grown by 14.7% to US$688 million (€491 million) in the third quarter of 2010, reflecting a double-digit rise in volume sales.

Michael Johnson, chairman and chief executive officer of the US-based direct-selling specialist, said the company had experienced volume sales growth across all regions, leading to a total rise in volume sales of 13.5%.

"Our distributors are driving momentum around the world," he commented, "by attracting and retaining long-term customers for our nutrition products."

The net sales growth was driven by the Asia Pacific and North America regions, where turnover increased by 40.5% to US$182 million and by 10.4% to US$156 million respectively.

Herbalife's operating income improved by 29.7% to US$101 million during the period.

Looking ahead, Herbalife said it expected a 16.5% to 17.0% net sales rise in 2010.

OTC

Regulatory Affairs

Qualiphar addresses FDA's concerns

Qualiphar said it had taken steps to resolve the manufacturing issues highlighted in a recent Warning Letter from the US Food and Drug Administration (FDA).

The Belgian company also drew attention to the fact that it had just received a satisfactory current Good Manufacturing Practice (cGMP) Inspection Report from the Belgian authorities. No critical observations were notified in the report dated 18 October 2010, said Qualiphar, which followed a four-day inspection during September of the company's manufacturing facility in Bornem, Belgium.

Bornem facility was inspected

The FDA sent the Warning Letter dated 30 September 2010 after its inspection of the Bornem facility in May had identified "significant violations" of cGMP regulations for finished pharmaceuticals. A response from Qualiphar dated 28 May 2010 had lacked "sufficient corrective actions", said the regulatory agency (**OTC *bulletin***, 29 October 2010, page 11).

Qualiphar told **OTC *bulletin*** that it had stopped manufacturing the product referred to in the Warning Letter some time ago.

The company added that the product had been made in "dedicated facilities", which had been completely separate to the main manufacturing plant. These facilities had now been totally dismantled, Qualiphar noted.

Stressing that it was "committed to addressing all concerns raised by the FDA", Qualiphar said it was supplying "all additional information, documentation and rationale behind the former manufacturing operations with regard to the Warning Letter product". This, it said, would provide the FDA with assurance that all products of Qualiphar "comply to all specifications that are critical to safety, efficacy and quality of the product".

Marc Van Diest, research and development manager of Qualiphar, said the Warning Letter had "no impact on any other products". "Sales of all existing products included in Qualiphar's product range and manufactured by Qualiphar may continue without restrictions," he added.

OTC

Third-Quarter Results

Key brands boost Bayer Consumer Care

Double-digit growth by five of Bayer's six key OTC brands helped drive up sales at the German firm's Consumer Care business by 13.3% in the third quarter of 2010. Adjusted for currency and portfolio effects, sales increased by 4.7%.

Consumer Care's turnover in the three months increased to €880 million (see Figure 1) as its Aspirin, Aleve, Bepanthen/Bepanthol, Canesten and One-A-Day brands all delivered double-digit gains.

Substantial sales growth in the US, Bayer pointed out, had led to the painkiller Aspirin posting global turnover up by 11.1% to €110 million and the Aleve analgesic reporting a 30.0% rise in sales to €78 million (see Figure 2). At constant exchange rates, Aspirin's and Aleve's gains were a more modest 3.4% and 18.2% respectively.

One-A-Day multivitamins had also been lifted by a strong US performance, Bayer noted, with worldwide sales rising by 33.3% – 20.3% on a constant-currency basis – to €48 million.

Meanwhile, the Canesten antifungal line posted sales up by 16.3% – 9.6% on a constant exchange rate basis – to €57 million, due primarily to launches in Canada and higher volumes in Italy. Bayer expanded its Canesten range in Canada earlier this year with the launch of CanesOral 150mg fluconazole oral tablets.

The Bepanthen/Bepanthol skincare brand also produced a double-digit rise, with sales growing by 15.9% – 14.3% at constant exchange rates – to €51 million, following positive developments in Brazil, France and Russia.

Of Consumer Care's six best-selling brands, only Supradyn failed to achieve a double-digit gain, with the multivitamin supplement's sales sticking at €37 million. At constant exchange rates, the brand's turnover declined by 4.9%.

The six brands accounted for 43.3% – €381 million – of Consumer Care's €880 million total for the third quarter.

Geographically, all regions had contributed to Consumer Care's performance, Bayer said, noting that North America in particular had enjoyed a good quarter.

Consumer Care generated 57.2% of sales at Bayer's Consumer Health division, which increased by 10.9% – 2.6% on a currency- and portfolio-adjusted basis – to €1.54 billion, with the business reporting growth across all regions.

Asia/Pacific made the biggest gain, with turnover growing by 19.3% as reported to €167 million (see Figure 3). However, at constant exchange rates, the rise was a more modest 3.6%. In the Latin America/Africa/Middle East region, sales improved by 15.1% – 5.1% at constant exchange rates – to €236 million.

Consumer Health's biggest region in terms of sales, Europe, reported the smallest advance in the quarter, with turnover moving forward by 5.7% – 3.5% on a constant exchange rate basis – to €576 million.

North America, meanwhile, posted sales of €560 million, up by 12.4% as reported. At constant exchange rates sales edged up by 1.1%.

Consumer Health's earnings before interest and tax (EBIT) fell by 4.2% to €300 million.

The Consumer Health division accounted for 36.0% of Bayer's total HealthCare turnover, which improved by 8.5% to €4.27 billion. Adjusted for currency and portfolio effects, the growth was 0.9%.

Meanwhile, Bayer said that as a result of a wider review of the Bayer brand, its pharmaceuticals business would no longer be known as Bayer Schering Pharma but simply as Bayer HealthCare.

Business	Third-quarter sales (€ millions)	Change 2009/2010 (%)	EBIT (€ millions)	Change 2009/2010 (%)
Pharmaceuticals	2,732	+7.2	412	+12.0
Consumer Care	*880*	*+13.3*	–	–
Medical Care	*375*	*+4.2*	–	–
Animal Health	*284*	*+13.1*	–	–
Consumer Health	1,539	+10.9	300	-4.2
Bayer HealthCare	**4,271**	**+8.5**	**712**	**+4.6**

Figure 1: Breakdown of Bayer HealthCare's sales and earnings before interest and tax (EBIT) in the third quarter of 2010 from continuing operations (Source – Bayer)

Brand (business unit)	Third-quarter sales (€ millions)	Change 2009/2010 (%) €	CER*
Contour (Medical Care)	147	-1.3	-6.5
Aspirin**	110	+11.1	+3.4
Advantage (Animal Health)	103	+17.0	+7.5
Aleve/naproxen	78	+30.0	+18.2
Canesten	57	+16.3	+9.6
Bepanthen/Bepanthol	51	+15.9	+14.3
One-A-Day	48	+33.3	+20.3
Baytril (Animal Health)	44	+18.9	+12.1
Supradyn	37	±0.0	-4.9
Breeze (Medical Care)	31	-8.8	+16.9
Top 10	**706**	**+11.5**	**+4.2**
Consumer Health	**1,539**	**+10.9**	**+2.9**

* CER is constant exchange rates
** Total Aspirin sales – including Aspirin Cardio, which is part of the Pharmaceuticals division – were €204 million

Figure 2: Sales of the top 10 best-selling brands in Bayer's Consumer Health division in the third quarter of 2010. Brands are part of the Consumer Care business unit unless stated (Source – Bayer)

Region	Third-quarter sales (€ millions)	Change 2009/2010 (%) €	CER*
Europe	576	+5.7	+3.5
North America	560	+12.4	+1.1
Latin America/Africa/Middle East	236	+15.1	+5.1
Asia/Pacific	167	+19.3	+3.6
Bayer Consumer Health	**1,539**	**+10.9**	**+2.9**

* CER is constant exchange rates

Figure 3: Breakdown of Bayer Consumer Health's sales in the third quarter of 2010 by region (Source – Bayer)

Mergers & Acquisitions

Sanofi-Aventis grows in China

■ *Continued from front page*

market a year ago, when it agreed to establish a joint venture with Minsheng Pharmaceuticals to produce vitamin and mineral supplements (**OTC *bulletin***, 30 October 2009, page 10).

Christopher Viehbacher, chief executive officer of Sanofi-Aventis, said the deal – which will be structured as a merger of BMP Sunstone and a wholly-owned subsidiary of Sanofi-Aventis – represented "another strategic move" that reinforced the firm's leadership position in China.

Acquiring BMP Sunstone would "not only leverage our consumer healthcare business in China", Viehbacher noted, but would also give the company "unique access to expanding distribution channels, which are expected to account for a third of the pharmaceutical market in China in the coming years".

Sanofi-Aventis said that BMP Sunstone had access to retailers, county hospitals and community clinics in Tier III and Tier IV markets. Tier III and Tier IV markets are classified as cities with a population of less than 500,000. There are approximately 200 Tier III county-level cities, the company pointed out, and 400 Tier IV towns, which are the capitals of the counties they are in.

China was now the world's second-largest consumer healthcare market after the US, Sanofi-Aventis claimed, with an estimated size of €12 billion in 2010 and a compound annual growth rate of 11% since 2005.

Plans for Chinese business

As well as growing its Chinese Consumer Health Care business via acquisitions, Sanofi-Aventis said it would drive organic growth by launching several legacy products – such as the Lactacyd feminine hygiene products and Essentiale vitamin and mineral supplements – and by introducing products that met consumer needs, such as food supplements, cardiovascular products and anti-ageing lines.

Sanofi-Aventis announced the BMP Sunstone deal just hours after reporting an acquisition-driven 45.8% rise in sales at its Consumer Health Care division during the third quarter of 2010 to €576 million (see page 7).

Hanspeter Spek, president of global operations at Sanofi-Aventis, said the company was working on more consumer healthcare acquisitions in the Asia-Pacific region and in Latin America.

OTC

Third-Quarter Results

Merck eyes global future for its Consumer Care unit

Merck & Co's Consumer Care division is an important part of the US company's future and is a business for which it has global ambitions, according to chief executive officer Richard Clark.

Asked about Merck & Co's strategic plans for the Consumer Care division, which was gained by acquiring Schering-Plough, Clark said the business contained "good brands" that would "last a long time" and were a "natural fit" with its core pharmaceuticals operations.

Schering-Plough had done a "tremendous job" of growing Consumer Care's brands in the US, Clark said, pointing out that Merck & Co now wanted to do the same thing globally.

"We're putting resources behind the growth of Consumer Care from a global standpoint," Clark insisted, "and so from a distribution and customer standpoint we are looking at growing it organically as we move forward."

Backing for Consumer Care

Clark has continually backed the Consumer Care division in the year since Merck & Co obtained the business by acquiring smaller rival Schering-Plough for US$41 billion (€29.3 billion) (**OTC *bulletin***, 17 March 2009, page 1) together with its portfolio of OTC brands.

In August, Clark said expanding the Consumer Care business in Europe and emerging markets represented an exciting opportunity for Merck & Co (**OTC *bulletin***, 13 August 2010, page 1), while in May, he said that the business had a "critical part" to play in the company's strategy going forward (**OTC *bulletin***, 14 May 2010, page 11).

Consumer Care reported sales in the US and Canada up by 3% to US$291 million in the third quarter of 2010 (see Figure 1). The growth reflected an 8% uplift in sales of the Claritin (loratadine) allergy brand to US$92 million, the firm said, along with "strong performances" from Coppertone suncare products and the Dr Scholl's footcare line.

This growth had been partially offset by the impact of generic versions of the MiraLAX laxative brand, Merck & Co noted. In October last year, store-brand specialist Perrigo and generics firm Mylan both received the go-ahead to launch their equivalents to the polyethylene glycol 3350-based product (**OTC *bulletin***, 16 October 2009, page 17).

The third-quarter sales rise, coupled with the 11% gain in the previous quarter, offset the 2% decline reported for the opening three months of 2010. This led to a 4% increase in Consumer Care's turnover to US$1.09 billion for the first nine months of the year.

Despite the combination of strong single-digit growth during the third quarter and a double-digit advance in the second quarter, Claritin's sales finished down by 2% to US$334 million, following a 26% fall in the first three months of the year.

International sales of Schering-Plough's consumer healthcare brands are now included in Merck & Co's Global Human Health division, which also includes its prescription, vaccines and biologics business units.

Consumer Care is one of the "five primary divisions" in the enlarged Merck & Co. The other four are Global Human Health, Animal Health, Merck Manufacturing and Merck Research Laboratories.

Consumer Care generated 3% of Merck & Co's total adjusted third-quarter sales, which declined by 4% to US$11.1 billion. For the first nine months of 2010, group turnover edged up by 0.4% to US$33.9 billion.

OTC

Business	Third-quarter sales (US$ millions)	Change 2009/2010 (%)	Proportion of total (%)
Human Health*	9,660	-4	87
Animal Health	687	+3	6
Claritin OTC	*92*	*+8*	*1*
Consumer Care**	291	+3	3
Other	487	+1	4
Merck & Co	**11,125**	**-4**	**100**

* Includes international Consumer Care sales outside of the US and Canada ** Sales in US and Canada only

Figure 1: Merck & Co's sales in the third quarter of 2010 broken down by business (Source – Merck & Co)

Government Initiatives

Benefits of self-care will be highlighted in the UK

Benefits of self-care will be highlighted in the UK during Self Care Week running from 15-21 November 2010.

The aim of Self Care Week 2010, said the Department of Health (DoH), was "to get people, especially those with a long-term condition, learning about how they could look after their own health better".

The DoH pointed out self-care meant "looking after yourself in a healthy way, whether it's brushing your teeth, taking medicine when you have a cold or doing some exercise".

A wide range of materials have been produced for the week, including a communication pack containing tips on how to support the campaign, statistics, and key messages. Posters and leaflets are also available.

The DoH promised there would be "lots of events and activities around the country to promote and explain the benefits of self-care".

"Learning to live well" is the theme of Self Care Week 2010 in the UK

People must be active partners

Self Care Week 2010 was launched earlier this month by Paul Burstow, minister of state for care services, at a Self Care Symposium organised jointly by the Royal College of General Practitioners (RCGP) and the Proprietary Association of Great Britain (PAGB). Commenting on the initiative, Burstow said: "I believe that if we want people to be active partners in all aspects of self-care, we need to ensure that they have access to information, education and support to help them do that with confidence."

At the symposium, the RCGP and the PAGB announced plans for an e-learning module to advise general practitioners on shared decision-making in consultations.

Nigel Sparrow, chair of the professional development board of the RCGP, said that "giving patients the information and support needed to make informed decisions about their own health and the healthcare they receive is vital to improving the public's general health". "Many general practitioners and nurses already do this," he added, "but I hope this module will provide clinicians with more opportunities to develop and enhance their consultation skills."

Gopa Mitra, the PAGB's director of health policy and public affairs, said the module was essential to end the culture of dependency in the National Health Service (NHS).

The e-learning module, which will be delivered through the RCGP's online learning environment, will be developed, piloted and delivered over the next 12 months.

OTC

Regulatory Affairs

HMA finalises its five-year strategy

Most of the comments made by Europe's OTC industry have been incorporated into the final version of the five-year strategy that has just been published by the Heads of Medicines Agencies (HMA).

The strategy document now acknowledged the different economic setting for the non-prescription sector, noted the Association of the European Self-Medication Industry, the AESGP, and had a dedicated section on improving the decentralised and mutual recognition authorisation procedures.

Put out for consultation in July (**OTC *bulletin***, 30 July 2010, page 12), the strategy highlights three areas in which the HMA "can make a real difference" in the coming years. These are in safeguarding public and animal health, supporting innovation, and further improving the operational efficiency of medicines authorisation by the decentralised and mutual-recognition procedures.

Speaking recently at a meeting in Antwerp organised by the AESGP, Kent Woods, chief executive of the UK's Medicines and Healthcare products Regulatory Agency (MHRA), said the strategy would be rolled out from 2011.

OTC

GlaxoSmithKline Consumer Healthcare's NiQuitin Minis smoking-cessation aid is now available in a cherry flavour as well as the original mint.

The company said the new 1.5mg nicotine lozenges would provide "an alternative fruity taste option for smokers attempting to quit".

Supplied in packs of 20 or 60 lozenges, the new addition has respective recommended retail selling prices of £4.99 (€5.70) and £13.99.

GlaxoSmithKline launched mint-flavoured NiQuitin Minis in the UK a year ago backed by the claim "Not big. But very clever" (OTC *bulletin*, 16 October 2009, page 15).

NiQuitin Minis are also available in a number of other countries including Australia, Belgium, France, Germany, the Netherlands, Poland and Sweden (OTC *bulletin*, 14 May 2010, page 6). Earlier this year, GlaxoSmithKline launched the product in the US as the Nicorette Mini Lozenge (OTC *bulletin*, 14 May 2010, page 21).

OTC

Trade Associations

Association set up in Asia-Pacific area

An OTC industry association for the Asia-Pacific region has been set up.

The chairperson of the Asia-Pacific Self-Medication Industry (APSMI) is Seiichi Sato, president of Japan's Sato Pharmaceutical Co.

Sato said several member associations of the World Self-Medication Industry (WSMI) wanted a regional body for Asia-Pacific.

OTC

Switches

Big ibuprofen pack

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

Consultation document ARM 71 says Thornton & Ross is seeking to switch a 100g pack of 5% w/w ibuprofen gel from pharmacy to general-sales list (P-to-GSL) status. GSL status already applies to 30g and 50g packs.

OTC

Business Strategy

Beiersdorf takes Nivea to travellers worldwide

Beiersdorf has unveiled a global travel retail strategy for its Nivea skincare brand, which will see more than 65 products plus exclusive travel sets available from aeroplanes, airports, border shops, cruise lines and ferries.

The German company, which is setting up the Beiersdorf Travel Retail Division to oversee the strategy, said the range would initially be available in Europe, the Middle East and Africa, followed by Asia, and then the Americas.

Travellers will be able to buy products from the Nivea Body, Nivea for Men, Nivea Lipcare and Nivea Visage ranges, as well as personal care products such as sunscreen, deodorant and shower gel. Recommended retail selling prices will range from €2.00-€49.00.

Successful in the Middle East

Beiersdorf noted that it had successfully expanded Nivea's travel retail presence in the Middle East over the past three years. "Much of this experience has played a role in our international strategy," the company added.

In Europe, Beiersdorf is working with Gebr Heinemann, which has retail outlets in 49 international airports. "Our first step will be to establish a presence inside German airports such as Frankfurt, Hamburg and Munich, as well as airports in Copenhagen, Istanbul and Vienna," said Beiersdorf.

Beiersdorf pointed out that around 70% of travellers made no purchases in travel retail shops inside airports because they were unable to find products that met their needs and budgets. "We will offer a very attractive range of Nivea products for both men and women, with the particular needs of two target groups – families and charter travellers – in mind," the company added.

Inken Menck, director of purchasing for perfumes and cosmetics at Gebr Heinemann, commented: "With this selection of Nivea products, we will be able to meet the demands of a previously under-served need and price segment, and we see great potential for attracting new buyers to our stores."

Beiersdorf said it would back Nivea in the travel retail channel with point-of-sale material. It added that the travel range would also benefit from multimedia advertising campaigns for the brand in many countries.

Nivea products are currently sold in more than 50 countries.

The Beiersdorf Travel Retail Division will have its headquarters in Switzerland, and will be led by Ilka Schütte.

Exclusive Nivea travel sets are among the products on offer from the new Beiersdorf Travel Retail Division

IN BRIEF

■ **SEVEN SEAS** is supporting its **Haliborange** food supplements in the UK with a public relations campaign based around research that found fewer than one in ten children ate enough fish to meet health guidelines. The firm said there was "strong evidence" linking omega-3 fatty acids, which are found in fish and fish oil supplements, with a significant boost to mental and physical health in babies and children. Seven Seas is also highlighting a separate scientific review, which found that omega-3 was needed for development of babies in the womb and infants' brain, eyes and immune systems.

People who have difficulty swallowing capsules and tablets are the target audience for the latest addition to Hexal's omeprazole-based medicine Omep in Germany.

Omep is now available not only as capsules but also as enteric-coated tablets, which can be either swallowed or dissolved in water before swallowing. Each tablet contains more than 1,000 'micro-pellets', which pass directly into the intestines before releasing the active ingredient, 20mg omeprazole.

Hexal, which is part of Novartis, noted that the one-a-day tablets could also be divided for ease of swallowing. They are free from gelatin, gluten and lactose.

The pharmacy-only medicine has recommended retail selling prices of €5.90 for seven tablets and €9.90 for a pack of 14.

A television advertising campaign for the brand is ongoing (OTC *bulletin*, 31 August 2009, page 21), while current trade-press advertising highlights the tablet newcomer.

"Wherever your pain your answer is Anadin" is Pfizer Consumer Healthcare's promise to consumers in press advertising for its Anadin brand in the UK.

Based around a computer game, the advertisement highlights that Anadin has "developed a whole range of different formulations to effectively tackle pain".

Joint-pain sufferers are advised to take Anadin Joint Pain, for example, while Anadin Extra is suggested for people with a headache.

Pfizer is also backing Anadin with radio advertising, an iPhone 'app' and a website at www.anadin.co.uk. Television advertising based around the computer game concept is scheduled to begin in December.

OTC bulletin

In association with ims | SymphonyIRIGroup

OTC Marketing Awards 2011

Recognising the achievements of the British OTC industry

Gala Dinner & Awards Presentation

Park Lane Hotel, Piccadilly, London
Thursday, 10th March 2011

Take Centre Stage at the Awards that Really Matter

Visit the Awards website at
www.otc-bulletin.com/awards
to find out more

Sponsored by

Euro RSCG Life UK
CCA Company Chemists' Association
Spink
pegasus
TENA
Source OTC
BOUNTY
Doctors.net.uk
MASH Health

OTC Marketing Awards 2011

Award rewards non-pharmacy performance

Has one of your OTC products put in a strong performance this year in UK non-pharmacy retail outlets? If it has, then make sure you put it forward for **OTC *bulletin***'s OTC Marketing Awards 2011.

Your product could win our new Award for Best OTC Performer Outside Pharmacy, which is sponsored by SymphonyIRI Group. The Award is aimed at OTC products wholly or partially selling outside the pharmacy environment in supermarkets, grocery stores, garage forecourts and other non-pharmacy outlets in the UK.

The Award is open to both new and existing OTC products. It is aimed at individual products or product lines sold under an umbrella brand rather than the umbrella brand itself. For further guidance contact Deborah Wilkes, Editor & Publisher of **OTC *bulletin***, by sending an e-mail to editor@OTC-bulletin.com.

The winner of the Award for Best OTC Performer Outside Pharmacy will be determined by a panel of non-pharmacy retailers put together by SymphonyIRI Group and **OTC *bulletin***. Judges will be looking for OTC products that have not only performed well but have contributed to overall category growth in non-pharmacy retail outlets.

For this Award, there is no entry fee and no supporting information is required. Applicants simply have to e-mail their proposals to Deborah Wilkes at editor@OTC-bulletin.com with OTC Marketing Awards 2011 as the subject.

The Award for Best OTC Performer Outside Pharmacy is open to all consumer healthcare companies operating in the UK or their agencies or associates. Entries are restricted to OTC products – general-sales list (GSL) medicines, unlicensed food supplements, herbal and homoeopathic remedies, medical devices and other selected unlicensed healthcare products – marketed in the UK.

You can also put forward proposals for six other Awards by e-mail to Deborah Wilkes:

- OTC Company of the Year
- OTC Brand of the Year
- OTC Launch of the Year
- OTC Brand Revitalisation of the Year
- Best OTC Pharmacy Support Package
- Best OTC Pharmacy Salesforce

There is no entry fee for these six Awards, and no supporting information is required. Winners are decided either by our Super Retail Panel or by independent market research.

Twelve other Awards do require an entry fee and supporting information. To obtain an Entry Information Pack for these Awards – covering advertising, product innovation, packaging design, public relations campaigns and pharmacy training – visit the Awards website at www.otc-bulletin.com/awards.

Meanwhile, retailers could win the Award for Best OTC Multiple Retailer of the Year.

The entry deadline for **OTC *bulletin*'s** OTC Marketing Awards 2011 is fast approaching. Friday, 3 December is less than three weeks away, so now is the time to make sure your best work is in the running to win one or more of the UK OTC industry's most prestigious Awards.

Winners will be announced at a Gala Dinner & Awards Presentation on Thursday, 10 March 2011 at London's Park Lane Hotel.

OTC *bulletin* is pleased to announce that the OTC Marketing Awards 2011 will be jointly co-hosted this year by IMS Consumer Health and SymphonyIRI Group.

Many thanks also go to our Award sponsors. These are Euro RSCG Life, the Company Chemists' Association, Spink, Pegasus, Tena, SourceOTC, Bounty & Bounty Health Network, Doctors.net.uk and Mash Health.

■ Find out how to enter, attend or sponsor the OTC Marketing Awards 2011 by contacting Jenna Lawrence or Val Davis at **OTC *bulletin*** (Tel: +44 1564 777550; Fax: +44 1564 777524; E-mail: jenna.lawrence@otc-bulletin.com or val.davis@otc-bulletin.com). Or visit the Awards website at www.otc-bulletin.com/awards.

OTC

The OTC Marketing Awards 2011:

OTC Company of the Year
Sponsored by IMS Consumer Health and SymphonyIRI Group

OTC Brand of the Year
Sponsored by Euro RSCG Life

OTC Launch of the Year
Sponsored by Tena

OTC Brand Revitalisation of the Year
Sponsored by Spink

Most Innovative New OTC Product

Best OTC Marketing Campaign on a Big Budget

Best OTC Marketing Campaign on a Small Budget
Sponsored by Bounty & Bounty Health Network

Best OTC Consumer Advertising on Television
Sponsored by Pegasus

Best OTC Consumer Advertising in the Press

Best OTC Consumer Advertising Out-of-Home

Best OTC Consumer Advertising on the Internet

Best OTC Public Relations Campaign for a Medicine

Best OTC Public Relations Campaign for a Non-Medicine

Best New OTC Packaging Design

Best OTC Trade & Professional Advertising
Sponsored by Doctors.net.uk

Best OTC Pharmacy Training
Sponsored by Mash Health

Best OTC Pharmacy Support Package
Sponsored by the Company Chemists' Association

Best OTC Pharmacy Salesforce
Sponsored by IMS Consumer Health

Best OTC Performer Outside Pharmacy
Sponsored by SymphonyIRI Group

Best OTC Multiple Retailer of the Year
*Sponsored by the Company Chemists' Association and **OTC bulletin***

AWARDS ENTRY DEADLINE

Friday, 3rd December 2010

Get your Entry Information Pack from the Awards website at www.otc-bulletin.com/awards

A cartoon explorer who finds relief from his haemorrhoids is the star of television advertising for Nycomed's Faktu lind herbal medicine in Germany.

The 25-second commercial opens with a line drawing of an explorer driving a jeep across a rough savannah landscape.

When he stops due to the pain of his haemorrhoids, a hand appears and draws a curved line of Faktu lind ointment. The explorer sits down in the curve, which turns out to be the trunk of an elephant. "Faktu lind. Wenn's juckt und brennt", or "Faktu lind. When it itches and burns", is the sign-off message.

Current trade-press advertising highlights the television support and cites an online survey of 52 brand users that found 85% were satisfied with the pharmacy-only medicine and 86% would buy it again.

Faktu lind ointment contains 6.25% witch-hazel distillate. It follows on from the Faktu Akut brand that Nycomed withdrew following the decision of Germany's federal institute for drugs and medical devices, BfArM, to ban bufexamac (OTC *bulletin*, 18 December 2009, page 13).

OTC

IN BRIEF

■ **MATRIXX INITIATIVES** is backing its **Zicam** brand in the US with a public relations campaign highlighting that pharmacists need to educate consumers about treating colds. The company said research had found that 93% of pharmacists believed early treatment of a cold could prevent a visit to the doctor. Furthermore, more than half of pharmacists recommended zinc – an active ingredient in Zicam – in the initial stages of a cold. However, a separate survey found that the majority of Americans were misinformed about the causes of colds and how to treat them, with almost three-quarters believing that there was not much they could do except mask the symptoms and wait it out. Only 12% took zinc-based products, while 41% tried chicken soup.

OTC

Relaunches/Marketing Campaigns

McNeil refreshes Sudafed with new names in the UK

McNeil Products has relaunched its Sudafed cough and cold medicines in the UK with new names and updated packaging.

The company has added Blocked Nose to the name of the majority of its general-sales list (GSL) medicines and Decongestant to some of its pharmacy-only (P) lines. A company spokesperson said the revamp would make the range more "consumer friendly".

The rebranded GSL range includes Sudafed Blocked Nose & Headache Capsules, Sudafed Blocked Nose & Sinus Capsules, Sudafed Blocked Nose Capsules, and Sudafed Blocked Nose Spray.

Meanwhile, the repositioned P medicines include Sudafed 12 Hour Decongestant Tablets, Sudafed Decongestant Liquid, Sudafed Decongestant Tablets, Sudafed Chesty Coughs with Decongestant, and Sudafed Dry Coughs with Decongestant.

McNeil has updated the packaging to include an illustration of airwaves that flow to and from the graphic of a face.

The company is backing Sudafed with an updated version of its established television commercial featuring a man on a tube train suffering from a cold. He takes Sudafed and is able to breathe clearly again.

McNeil Products has added the words Blocked Nose to the name of most of the general-sales list (GSL) medicines in its Sudafed range in the UK

The television campaign will run until the end of the year on satellite channels Dave, E4, Film4, Fiver, Gold, Living, More4, and Sky1.

In addition, McNeil is running three bursts of digital advertising on escalator panels at tube stations in London until January.

Sudafed is also sponsoring the Sky and Discovery Home & Health channels. The deal includes creatives broadcast daily, as well as an online banner that reads "Sponsored by Sudafed" on the Discovery Home & Health website.

OTC

Two vitamin supplements for teenagers have been added to Ernest Jackson's Bassetts Soft & Chewy brand in the UK.

Aimed at young women, Bassetts Soft & Chewy Healthy Balance is a multivitamin product with evening primrose oil and starflower oil. Straplines on the packaging point out that the "one-a-day" pastilles provide "skin health and hormone balance".

A month's supply of the "delicious orange & passion fruit flavour pastilles" has a recommended retail selling price of £6.99 (€7.99).

The second new addition – Bassetts Soft & Chewy Sport Health – is for teenagers who lead sporty and active lives. Supplied as "delicious citrus flavour pastilles", the newcomer is a multivitamin product with Coenzyme Q10.

A pack of 30, one-a-day pastilles retails at £4.99.

Both products carry the strapline "for young adults" on the packaging.

Ernest Jackson noted that the "easy-to-take" pastilles contained the recommended daily allowance of vitamins, as well as natural colours and flavours.

The Bassetts Soft & Chewy range also includes Active Health, Daily Energiser, Early Health, Everyday Health and Vitamin C variants.

OTC

Marketing Campaigns

Prilosec OTC teams up with NFL players in US

The "toughest offensive linemen" in the National Football League (NFL) highlight that Prilosec OTC is the "best protection available" for frequent heartburn in a new consumer campaign from Procter & Gamble in the US.

The Prilosec OTC Living Proof campaign, which runs until February, includes television and digital advertising as well as online videos.

Procter & Gamble said it had chosen New York Giants player David Diehl and Minnesota Vikings member Anthony Herrera to front the Prilosec OTC campaign, because they were "living proof that heartburn can happen to even the toughest people". These players would show that Prilosec OTC "blocked frequent heartburn for the toughest blockers in the NFL", the company added.

Noting that the players "can't afford to let anything undercut their fierce concentration", Procter & Gamble said their appearance in the campaign would "help people understand that frequent heartburn doesn't have to get in the way of their daily activities".

The 30-second television commercial – created by the advertising agency Publicis – shows the players taking part in a gruelling training regime. The sign-off message is "Heartburn gone, power on".

A voiceover explains that Prilosec OTC has travelled to the "front lines of the NFL training camp to put our 24-hour frequent heartburn protection to the test for two weeks".

Diehl and Herrera then tell viewers about the negative impact that heartburn has on their performance, despite people thinking that they are "indestructible". "Prilosec OTC is the one thing I can count on to block my heartburn," explains Diehl, while Herrera adds that "Prilosec OTC is protecting me".

The voiceover then urges consumers to take their own 14-day challenge through the Prilosec OTC website at www.prilosecotc.com.

The challenge involves consumers buying and taking a two-week supply of Prilosec OTC, filling out a log, and sending the receipt, product barcode and a form to Procter & Gamble to receive a US$10.00 (€7.20) coupon for their next pack.

Procter & Gamble is urging Americans to take a 14-day challenge for its Prilosec OTC frequent heartburn medicine

Visitors to the website can also view videos from Diehl and Herrera, who will share their stories about heartburn.

The campaign comes soon after Procter & Gamble reported that sales of the 20mg omeprazole tablets had declined in the three months ended 30 September 2010 because of increased competition. Sales were hit by the introduction of two branded competitors in the previous 12 months, as well as ongoing competition from store-brand equivalents (see page 9).

A year ago, Novartis Consumer Health introduced the lansoprazole-based Prevacid 24HR (**OTC *bulletin***, 16 November 2009, page 1).

Then earlier this year, Merck & Co introduced Zegerid OTC, a combination of 20mg omeprazole and 1,100mg sodium bicarbonate (**OTC *bulletin***, 16 April 2010, page 14).

"Heartburn gone, power on" is the theme of Procter & Gamble's new television commercial for Prilosec OTC in the US, which highlights that the medicine has blocked frequent heartburn for the toughest blockers in the National Football League (NFL)

IN BRIEF

■ **VERLA-PHARM** has added a raspberry flavour to its **Magnesium Verla Direkt** pharmacy-exclusive food supplement in Germany. The orodispersible granules – which provide 150mg magnesium per sachet – are already available in a citrus flavour. A pack of 30 sachets has a recommended retail price of €9.15.

■ **BRUNEL HEALTHCARE** said sales value for **Vertese** had increased by 58% in the UK health food trade during the first month after the relaunch of the brand earlier this year (**OTC *bulletin***, 10 February 2010, page 20).

Marketing Campaigns

Nelsons backs Bach with online course

Nelsons is backing its Bach Original Flower Remedies, including Bach Rescue Remedy, with an online course giving Britons an insight into the "system" of products.

The company said the course – available at www.bachintro.com – would advise consumers on how natural healthcare could help them, their families and their friends when they were feeling under pressure. The free course would enable consumers to "explore their emotions online", commented Nelsons.

"Users can progress through the course at their own pace, learning about a selection of remedies in detail and completing a number of fun, interactive quizzes and exercises," the company added. "We hope that those who take the course will be inspired to go on and learn more about the remedies."

The course covers Dr Bach's philosophy, the system of 38 Bach Original Flower Remedies, and the Bach Rescue Remedy. It explains that the products are made from natural flower essences, and tells people how to use them.

Reckitt Benckiser will extend its Scholl range of footcare products in France with a fungal nail treatment in February.

Pharmacy-press advertising (pictured above) states that the medical device – which was recently launched in the UK (OTC *bulletin*, 15 October 2010, page 14) – will be available exclusively in pharmacies and parapharmacies.

Pointing out that the newcomer can be ordered by pharmacists immediately, the advertising claims the product has "exceptional efficacy" and is precise and easy-to-use.

Straplines on the product packaging claim that the fungal nail treatment is "scientifically proven", "eliminates 99.9% of nail fungus", and "helps prevent the spread and recurrence" of fungus. The effect of the treatment is demonstrated by 'before' and 'after' photographs on the pack.

Reckitt Benckiser will support the launch with television advertising in the second quarter of 2011, as well as point-of-sale displays in pharmacies.

OTC

Launches

Actavis offers pharmacists "potent" First Resort in UK

"An advanced professional range for pharmacists" is how Actavis is positioning its new First Resort umbrella brand in the UK.

The generics and OTC company has initially launched two "potent" non-steroidal anti-inflammatory drugs (NSAIDs) under the First Resort brand. Further additions to the range of "expert first-choice solutions" are planned.

One newcomer is called Double Action Pain Relief and comprises oral 12.5mg diclofenac potassium tablets.

Actavis is positioning the pharmacy-only (P) medicine as "an advanced product that effectively targets backache, rheumatic pain, and muscular pain". The company notes that it is also effective for headache, dental pain, period pain, fever and symptoms of cold and flu.

Double Action Pain Relief competes with Novartis Consumer Health's Voltarol Pain-eze Tablets, which were the first diclofenac tablets to be sold without prescription in the UK (**OTC *bulletin***, 29 September 2008, page 10).

The Actavis product comes in packs of 18 tablets with a recommended retail selling price of £3.99 (€4.65).

The second product available under the First Resort brand is a P medicine called Period Pain Reliever and consists of oral gastro-resistant tablets containing 250mg naproxen.

Two oral non-steroidal anti-inflammatory drugs (NSAIDs) – diclofenac and naproxen – are Actavis' first offerings under its First Resort umbrella brand in the UK

Actavis noted that Period Pain Reliever was a "powerful NSAID that provides effective relief from period pain and cramps". A strapline on the packaging states that the tablets are "For period pain and cramps".

Period Pain Reliever competes with Bayer Healthcare's Feminax Ultra, which was launched in 2008 after oral formulations containing 250mg naproxen were switched from prescription-only to pharmacy status (**OTC *bulletin***, 31 March 2008, page 10).

Period Pain Reliever retails at £3.99 for a pack of nine tablets.

Actavis said launch marketing activity for the two First Resort products would focus on the trade. It added that there were no immediate plans for consumer advertising.

OTC

Launches

Herbalife debuts trio of products in US

"Energy for the heart" is Herbalife's on-pack promise for one of three new nutritional products in the US.

The US-based direct-selling specialist said the CoQ10 Plus dietary supplement was an "exclusive blend" of coenzyme Q10, vitamin D, and non-fish docosahexaenoic acid (DHA) from algae. The company noted the product worked in the body to convert fats and carbohydrates into energy for the heart, adding that it was also known to help regenerate essential antioxidants such as vitamin E.

A month's supply of the one-a-day CoQ10 Plus softgel capsules has a suggested retail selling price of US$39.95 (€28.95).

Meanwhile, Herbalife has extended its Formula 1 Healthy Meal Nutritional Shake Mix range "for healthy nutrition and weight management" with allergen-free and pumpkin spice-flavoured variants in the US.

The company said the allergen-free variant was a "perfect nutritional solution for those with common food allergies, as it is soy, dairy and gluten free". It noted that the product contained 20 vitamins and minerals; non genetically-modified protein from rice, pea and sesame sources; and more than two servings of fruit and vegetables.

The pumpkin spice variant is a limited edition for the festive season.

Both products provide 30 servings. The allergen-free variant has a suggested retail selling price of US$37.85, while the pumpkin spice version retails at US$34.40. Consumers should take up to two servings a day.

OTC

Vaseline Lip Therapy products are now available in the UK in sticks as well as the original tins.

Unilever has also extended the range with a cocoa butter variant, which will be available in both the stick and tin formats. It joins the existing aloe vera, original and rosy lip versions.

The launch will be backed by a £1.3 million (€1.5 million) marketing campaign.

Sticks have a recommended retail selling price of £1.99 for 4g, while the tins retail at £1.89 for 20g.

OTC

NOVEMBER

24 November

■ **Basics of Regulatory Affairs**

Brussels, Belgium

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.

25 November

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

Brussels, Belgium

Subtitled 'The key steps to a successful product launch', this one-day meeting will look at the regulatory challenges of marketing food supplements in Europe.

***Contact**: EAS.*
Tel: +32 2 218 1470.
Fax: +32 2 219 7342.
E-mail: workshop@eas.eu.
Website: www.eas.eu.

DECEMBER

2 December

■ **Marketing Authorisation in Latin America**

Düsseldorf, Germany

A one-day event looking at Argentina, Brazil, Chile, Colombia, Mexico and Peru.

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

6-7 December

■ **EMA/TOPRA Joint Review of the Year and Look to the Future**

London, UK

This two-day conference is organised by the European Medicines Agency (EMA) and 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.

7 December

■ **Labelling Food Supplements**

London, UK

Topics to be discussed at this two-day conference, organised by the UK's Health Food Manufacturers' Association (HFMA), will include the foods/medicines borderline, routes to market, definitions and compositional requirements.

***Contact**: Linda Phillips, Health Food Manufacturers' Association (HFMA).*
Tel: +44 20 8481 7100.
Fax: +44 20 8481 7101.
E-mail: hfma@hfma.co.uk.
Website: www.hfma.co.uk.

13-15 December

■ **Pharmacovigilance**

London, UK

A three-day course for those working on drug safety monitoring in Europe, Japan and the US.

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

1-2 February

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

Brussels, Belgium

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

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

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

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

JANUARY

26 January

■ **Marketing Authorisation in Turkey**

Frankfurt, Germany

Classification and pharmacovigilance in Turkey are on the agenda.

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

26 January

■ **Homoeopathic Medicines**

Bonn, Germany

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

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

27-28 January

■ **Latest Developments in Pharmacovigilance**

London, UK

This two-day event will focus on European developments.

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

FEBRUARY

10 February

■ **The Pharma Summit 2011**

London, UK

'Reinventing pharma for a new generation' is the theme of this one-day meeting.

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

17-18 February

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

London, UK

Countries to be covered at this two-day conference, include Bahrain, Israel, Syria and Yemen.

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

28 February-1 March

■ **EuroPLX 45**

Lisbon, Portugal

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

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

MARCH

10-12 March

■ **CHPA Annual Executive Conference**

Aventura, Florida, US

This three-day conference is the Annual Meeting of the US Consumer Healthcare Products Association (CHPA), and is only open to members.

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

22-23 March

■ **Regulatory Affairs in India & China**

Frankfurt, Germany

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

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

28-30 March

■ **DIA Annual EuroMeeting**

Geneva, Switzerland

A three-day conference organised by the Drug Information Association (DIA).

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

Regulators grapple with non-prescription supply

Initiatives in Belgium and Holland, experience with Europe's centralised authorisation procedure, and other regulatory developments at the European level were discussed at a recent meeting organised by the Association of the European Self-Medication Industry, the AESGP. Deborah Wilkes reports.

There was good news for companies operating in Belgium at a recent gathering of the European OTC industry in Antwerp. From next year, companies will have regular meetings with the Belgian Federal Agency for Medicines and Health Products. Xavier de Cuyper, the agency's chief executive officer, told the meeting organised by the Association of the European Self-Medication Industry, the AESGP, that the "platforms" would provide an opportunity to address issues affecting self-medication products.

The Belgian OTC manufacturers' association, BACHI, said there would be three or four platforms a year, with the first taking place in January 2011. The platforms would initially be attended by the agency and industry, but doctors, insurers, pharmacists and other relevant stakeholders might also take part at a later date.

Study progresses in the Netherlands

Next door in the Netherlands, meanwhile, the OTC industry is working with research and consultancy group Ecorys to work out the savings that could be achieved with greater self-medication and self-care by people suffering from minor ailments. The Dutch OTC industry association, Neprofarm, is hoping to capitalise on the new coalition government's stated intention of encouraging people to take greater responsibility for their own healthcare (**OTC *bulletin***, 29 October 2010, page 20).

> ***A preliminary quantitative analysis found that annual savings of aproximately €680 million could be achieved in the Netherlands***

Arthur ten Have, a partner at Ecorys, told the meeting that one preliminary quantitative analysis had found that annual savings of approximately €680 million could be achieved in the Netherlands. This represented an annual *per capita* saving of €41.00, he noted.

The analysis, explained ten Have, was based on methodology used by the AESGP in 2004 for a seven-country study. Entitled 'The economic and public health value of self-medication', the AESGP's study calculated the annual savings that could be achieved for public funds and national economies if just 5% of prescribed medicines were shifted to self-medication.

According to the AESGP's study, the annual savings across the seven countries would have been €11.5 billion and the average annual *per capita* saving would have been €35.78. The seven countries were Austria, France, Germany, Italy, Portugal, Spain and the UK (**OTC *bulletin***, 16 June 2004, page 22).

Ten Have said a second preliminary quantitative analysis by Ecorys had taken its lead from the Proprietary Association of Great Britain's (PAGB's) work on general practitioners and minor ailments carried out in 2008 (**OTC *bulletin***, 15 February 2008, page 13). A recent survey of general practitioners in the Netherlands found that they considered 29% of consultations to be unnecessary, he said, adding that the analysis suggested an annual *per capita* saving of €57.00.

The work was still at a "preliminary" stage, stressed ten Have. Neither of the quantitative analyses were "fully satisfactory", he added, noting that a better way of defining minor ailments was needed.

In addition to the quantitative work, Ecorys has carried out a preliminary qualitative analysis following meetings with general practitioners, pharmacists and druggists, and some interviews with health insurers.

Ten Have said that general practitioners had reported a heavy unnecessary workload, but were reluctant for patients to visit pharmacists or druggists – especially druggists – as an alternative. Both commercial and professional reasons had been cited by the general practitioners for this reluctance, he added.

General practitioners had acknowledged the importance of providing good information on medicines, continued ten Have, but they had also noted that patients seemed to become more insecure when they had access to more information. The issue of who should provide information had also been raised, he commented.

For druggists, a key concern was the quality of professional advice offered at the three types of retail outlet for non-prescription medicines in the Netherlands – drugstores, pharmacies and general-sale outlets. Maintaining that there was a low health literacy among consumers, druggists had mentioned the need for further safeguards to protect consumers, he said.

Moving on to health insurers, ten Have said they saw the potential for cost savings. However, they also appreciated that the current system meant their clients had easy access to general practitioners, he added.

The work by Ecorys had suggested a number of ways to reform the system in the long-term, according to ten Have, including 'assisted' self-medication, closer cooperation between pharmacies and drugstores, correct incentives for health insurers, and better inspection and enforcement by regulatory bodies.

Consumers need better health literacy

If self-medication and self-care were to play a greater role in healthcare, concluded ten Have, then the "self-reliance and health literacy" of consumers needed to be improved. Furthermore, the quality of advice had to be better, he said.

Noting that Ecorys was refining its methodology, ten Have said there was currently a political window of opportunity for self-medication to play a greater role in healthcare. The government was seeking to cut its expenditure by €18 billion over the next few years, he added.

At the European level, Eric Abadie – chairperson of the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) – offered advice to firms considering using the centralised procedure to authorise a non-prescription medicine.

According to Abadie, the sparsity of successful outcomes was not due to the regulatory framework but how it was interpreted by the CHMP. There was a need for more rapporteurs and peer reviewers with knowledge of non-prescription medicines, he accepted, and applicants should seek scientific advice for technical issues. Abadie also maintained that switching medicines from prescription to non-prescription status might require a "rethink" about the role of the pharmacist.

Abadie reminded the meeting that non-prescription medicines had two entry points to the centralised procedure. The first was automatic entry for switching centrally-authorised prescription medicines. The second was non-automatic entry for medicines that had not been authorised through the centralised procedure.

GlaxoSmithKline Consumer Healthcare's Alli – based on the active ingredient orlistat – is the only medicine to have gained non-prescription status using the first entry point (**OTC *bul-***

letin, 29 January 2009, page 1). Pfizer's application to switch Viagra (sildenafil citrate) was withdrawn from the procedure (**OTC *bulletin***, 28 November 2008, page 1).

The second entry point was used successfully by Nycomed to obtain non-prescription status for pantoprazole tablets. An application from Wyeth Consumer Healthcare – now part of Pfizer – to licence a new combination of existing non-prescription medicines was pulled out of the procedure (**OTC *bulletin***, 10 February 2010, page 1).

Abadie noted that there had been 13 requests for eligibility through the second entry point, of which only five had been accepted. Rejections often involved "old" products that were already available as non-prescription medicines in a number of member states, he noted.

He said the CHMP would probably have a positive view on eligibility for a "first in class" product that was not available as a non-prescription medicine in any member states or was only available in two or three member states. He stressed that experience in these two or three member states had to be "satisfactory".

However, "second in class" products – in the same pharmacological class as a previously-adopted non-prescription product – were less likely to be viewed positively, he said.

Abadie added that the CHMP might have a positive view about a product for which the legal status varied across Europe.

To date, there have been five applications to authorise a non-prescription medicine through the centralised procedure. Two of these have been successful, two have been withdrawn, and one is ongoing.

Abadie pointed out that the CHMP had been split over most of these applications, with two main issues causing concern. Firstly, he said, the impact of the CHMP's opinion on healthcare systems within each member state had been raised. Secondly, he added, the role of the regulator in assessing benefits and risks in the non-prescription setting had been a problem.

Discussing the first of these, Abadie said a positive CHMP opinion could cause concern for a member state that did not want the medicine to have non-prescription status. "I had this discussion when Alli received a positive opinion," he recalled. "I had a phone call from a good friend in one member state, saying the CHMP had made the wrong decision."

Conversely, added Abadie, a negative CHMP opinion could cause concern when a medicine already had non-prescription status in one or two member states.

Commenting on benefits and risks, Abadie said that question marks surrounding the non-prescription setting posed difficulties for regulators. "The more you have uncertainty, the more you are in trouble," he remarked. "For some colleagues, the non-prescription setting revealed a number of uncertainties that could have led to a negative opinion."

Offering advice to potential applicants, Abadie said they should give most prominence to "cumulative safety data from pre-existing non-prescription usage", including experience outside of the European Union. If the experience was within the European Union, he added, "pro-active participation of the member state with the experience is probably the way forward".

Potential applicants should also consider incorrect use of the product, he noted, and could identify co-morbidities. They could, for example, identify the proportion of people who were aware of the link between obesity and cardiovascular problems, he suggested, and mention this link on the product labelling.

Furthermore, the role of the doctor in the product's use should be examined. Abadie highlighted that the involvement of a doctor before or after a person purchased a non-prescription medicine could solve some of the problems in the non-prescription setting.

He also encouraged potential applicants to provide actual-use studies and surveys of patient-behaviour patterns. The latter should be linked to the disease rather than a specific medicine, he noted.

The CMDh is open to starting a dialogue with the self-medication industry to discuss how its concerns can be addressed

Moving on to the role of the pharmacist, Abadie maintained that this varied across the European Union. "The way pharmacists do their job is different in different member states," he said.

This issue was explained in more detail earlier this year by Patrick Le Courtois, head of the EMA's human medicines development and evaluation unit. It had been "a main issue for the small number of products that have been looked at by the CHMP", he said, adding that the role of the pharmacist had been "a breaking point" in one of the procedures (**OTC *bulletin***, 10 February 2010, page 25).

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

These reservations about pharmacists were challenged by John Chave, secretary-general of the Pharmaceutical Group of the European Union (PGEU). He told delegates attending the Antwerp meeting that pharmacists were well educated to ensure the safe use of non-prescription medicines.

The uncertainty of the non-prescription setting poses difficulties for regulators, according to Eric Abadie, chairperson of Europe's Committee for Medicinal Products for Human Use (CHMP)

Abadie also touched upon the fact that non-prescription medicines were available from non-pharmacy outlets in some European countries. He pointed out that the CHMP had the right to set criteria for non-prescription medicines, such as "supervised by pharmacists".

Europe's mutual-recognition and decentralised licensing procedures were also discussed at the Antwerp meeting. An AESGP study released earlier this year showed that companies using the two procedures for non-prescription medicines faced distant starting times and long review periods (**OTC *bulletin***, 26 February 2010, page 20).

Truus Janse-de Hoog – chairperson of the Coordination Group for Mutual Recognition and Decentralised Procedures, Human (CMDh) – claimed at the Antwerp meeting that the procedures had been successful with some substances, notably paracetamol, nicotine and xylometazoline. Nevertheless, she acknowledged that both procedures were "underutilised" by the self-medication sector.

Noting that the CMDh had addressed the specific needs of the innovative, generics and herbals sectors, she accepted that the CMDh needed to have "procedures that facilitate entry of OTC products to the market".

Potential for creating disharmony

Janse-de Hoog said there were a number of points for discussion with regard to non-prescription medicines. She highlighted the differences in legal classification of medicines, food supplements and borderline products from one member state to another, as well as the different procedures for switching medicines from prescription to non-prescription status. She also drew attention to the potential for creating disharmony with products that were already present in national markets.

"The CMDh is open to starting a dialogue with the self-medication industry to discuss how its concerns can be addressed," concluded Janse-de Hoog.

OTC

PepTcell pursues OTC partners

PepTcell is seeking global partners to develop and market a cough suppressant and a medicine to treat inflammatory flare. Deborah Wilkes asked Manfred Scheske, head of the drug-discovery company's Consumer Health division, about the two OTC prospects.

Manfred Scheske, chief executive officer of PepTcell's Consumer Health division, wants regulatory and marketing partners who will take a "strategic" rather than an "opportunisitic" approach to its OTC prospects

There has been "little innovation" for decades in the two biggest categories in the global OTC market, according to Manfred Scheske, chief executive officer of the Consumer Health division at PepTcell. Extended-release guaifenesin formulations have had a big impact in the cough and cold category in the US, observes Scheske, and the switch of oral naproxen from prescription-only to non-prescription status has been important in the pain-relief category in a number of countries. Other than that, he says, there has been very little innovation since ibuprofen was released from prescription control nearly 30 years ago.

The opportunity to bring substantial innovation to these two categories was what attracted Scheske to the drug-discovery company PepTcell. "There is more innovation in this relatively small company than in the OTC portfolios of most global players," he remarks.

The former European president of GlaxoSmithKline Consumer Healthcare (**OTC *bulletin***, 16 April 2010, page 1) has just joined the London-based firm, which has mid- to late-stage drugs in development, including vaccines, anti-inflammatories, and respiratory and cancer treatments. Announcing Scheske's appointment, PepTcell's chief executive officer Gregory Stoloff said consumer health was an important part of the company's business (**OTC *bulletin***, 15 October 2010, page 1).

Scheske's "superb industry knowledge and insight" would be invaluable, Stoloff stated, "for guiding our groundbreaking consumer assets to market".

Two prospects caught Scheske's eye. One is described as a "first-in-class" cough suppressant with clinically-proven efficacy and a good safety profile. The other is a small-molecule drug for inflammatory flare, which has a clinically-proven analgesic profile and is entering Phase III trials.

Scheske points out that both prospects have the potential to be non-prescription medicines, but he says regulatory agencies may initially keep them under prescription control. He adds, however, that the "surprising level of past exposure and safety data" should speed their transition into the non-prescription market. "We tick all the boxes for safety and efficacy with an indication that is suitable for OTC use," comments Scheske.

PepTcell is seeking regulatory and marketing partners for both prospects. Scheske says that the company would prefer to talk to global players with a presence in both the prescription and non-prescription sectors, but has not ruled out working with regional players. Partners must view the prospects as "strategic" rather than "opportunistic", stresses Scheske, adding that they must bring "passion" for the projects to the table.

According to Scheske, PepTcell's cough suppressant could be authorised in Europe and the US as soon as 2013, subject to gaining regulatory approval.

The product is already available in South Korea, where it was authorised as a prescription-only medicine in 2009. South Korea is the only country where PepTcell does not have the rights to the product, he states, adding that the company does have access to the Korean data including a Phase III clinical trial and a Post-Authorisation Safety Study (PASS).

Scheske notes that PepTcell will soon start another pivotal Phase III clinical trial for registration purposes in Europe.

The product is based on theobromine, which has previously been used in medicines for other indications, such as hypertension, but is a new active ingredient for suppressing coughs. Scheske points out that the Phase III clinical trial found that theobromine was equivalent to codeine as a cough suppressant, and did not have the negative effects of codeine.

A better risk/benefit profile

Discussing the risk/benefit profile, Scheske maintains that theobromine has advantages compared with existing cough suppressants, such as codeine and dextromethorphan, which are narcotics. Some teenagers and young adults in the US intentionally abuse large amounts of medicines containing dextromethorphan to get high. As a result, the non-prescription status of medicines containing dextromethorphan was recently reviewed by advisory committees to the US Food and Drug Administration (FDA), which voted against bringing the active ingredient under prescription control (**OTC *bulletin***, 29 September 2010, page 9).

Scheske believes that the potential to abuse existing cough medicines could even lead some regulatory agencies to fast-track the authorisation of PepTcell's cough suppressant.

He also points out that there is a lot of safety data on theobromine, which is present in chocolate, tea leaves and other foods and beverages.

Moving onto the small-molecule drug for inflammatory flare, Scheske says this is at an earlier stage in the development process than the cough suppressant. He declines to name the active ingredient, but says the patented product is an "adjuvant for a well-established and widely-used analgesic". "Much of the safety data exists," he adds, "so we hope to move directly into Phase III clinical trials and subsequently proceed on a truncated regulatory pathway towards authorisation."

Scheske maintains that his experience with GlaxoSmithKline Consumer Healthcare's Alli will be extremely valuable at PepTcell. Last year, the weight-loss medicine containing orlistat became the first product to be switched from prescription-only to-non-prescription status throughout the European Union using the centralised authorisation procedure.

He adds that PepTcell is "uniquely positioned" to provide breakthrough products in the two largest consumer health categories, which have long needed the kind of innovation that PepTcell is promising.

■ For more details contact Manfred Scheske, chief executive officer of PepTcell's Consumer Health division, by e-mail at manfred.scheske@peptcell.com.

OTC

Manufacturers

Krebs succeeds Roberts at Merz

Andreas Krebs, 52, is the new chairman of the supervisory board at Merz, following the retirement of **Edward Roberts**, 76, after more than 12 years in the post.

The German company pointed out that Roberts had stepped down after reaching the age limit for the role.

In addition to being elected chairman at the company's meeting of the shareholders on 16 September, Krebs was appointed deputy chairman of the shareholders' board and company counsellor.

Krebs previously spent 19 years at Bayer. He has also headed Wyeth's business in Germany, and been an executive board member at Wyeth's US headquarters with responsibility for overseeing Africa, Canada, Europe and the near East.

Following Pfizer's takeover of Wyeth, Krebs supported the company's integration before setting himself up independently as managing partner of CologneInvest.

OTC

Regulatory Agencies

EMA searches for Lönngren successor

The management board of the European Medicines Agency (EMA) is looking for a new executive director to replace **Thomas Lönngren**, who will leave the agency at the end of this year following the expiry of his second five-year mandate.

The EMA said it had recruited **Andreas Pott** – the agency's current head of administration – to serve as acting executive director for an interim period of around six months with effect from 1 January 2011.

According to the EMA, Pott – who became head of administration in 2000 – was its longest-serving senior manager at the right grade. In addition, Pott had served a similar role to that of executive director 10 years ago, the regulatory agency added.

Lönngren became executive director of the EMA in October 2000 (**OTC *bulletin***, 31 October 2000, page 27). He began his first five-year term in January 2001, and was reappointed to the role in October 2005 (**OTC *bulletin***, 17 October 2005, page 23).

OTC

Manufacturers

Reckitt tasks Sydow with growing Durex and Scholl

Reckitt Benckiser has given **Volker Sydow** – formerly SSL International's group marketing director – the job of growing its recently-acquired Durex and Scholl powerbrands.

Sydow has been appointed global category director for the newly-created Sexual Wellbeing and Footcare category at Reckitt Benckiser. This houses the Durex condom and Scholl footcare brands, which the company gained through its £2.54 billion (€2.99 billion) acquisition of SSL (**OTC *bulletin***, 30 July 2010, page 1).

Reckitt Benckiser said Sydow would lead "global new product development" and "equity development" for Durex and Scholl, and would work with teams from key local markets for the brands, including the UK. He reports to Rakesh Kapoor, Reckitt Benckiser's executive vice-president of category development.

Sydow's appointment is part of Reckitt Benckiser's growth strategy for Durex and Scholl, which is based around innovation, investment and marketing (see page 5).

Sydow began his career in 1995 as a junior brand manager at Reckitt Benckiser in Germany. He moved to Henkel in 1999, where he was international brand manager and then group marketing manager. In 2002, he joined Molkerei Muller as international marketing director.

Since moving to SSL in 2005, Sydow's positions have included managing director for Germany, regional managing director for central Europe, and regional managing director for northern Europe. He was made group marketing director in April of this year, reporting to SSL International's chief executive officer **Garry Watts**.

Volker Sydow

Following Reckitt Benckiser's acquisition of SSL on 29 October, Watts and SSL's chief finance officer **Mark Moran** have left the company. In addition, **Ian Adamson**, the company's group commercial director, has stepped down as an executive director but will remain with the company until the end of December to assist with the transition.

SSL's non-executive directors – **Gerald Corbett**, **Peter Read**, **Richard Adam** and **Peter Johnson** – have also stepped down.

Reckitt Benckiser has appointed four new directors at SSL International: **William Mordan**, Reckitt Benckiser's vice-president and general counsel; **Manish Dawar**, its senior vice-president and group controller; **Martin Keeley**, its senior vice-president of corporate planning; and **Simon Edwards**.

OTC

IN BRIEF

■ **BAUSCH + LOMB** has recruited **Mariano García-Valiño** to take the newly-created role of corporate vice-president and president, Latin America. Most recently, García-Valiño was an operating partner at private-equity group Advent International, where he focused on healthcare investment opportunities in Latin America. He has also held positions at Pfizer, McKinsey & Company, and Eli Lilly.

■ **ORIOLA-KD** said **Vladimir Knyazev** – general director of its Pharmaceutical Wholesale business in Russia and a member of the Finnish firm's group management – had left the company. **Henry Fogels**, general director of Oriola-KD's Pharmaceutical Retail business in Russia, has taken on Knyazev's role until a replacement is found.

■ **IMS HEALTH** has appointed **Sebastian Lempfert** as head of its health insurance department in Germany. Lempfert, 42, spent 12 years at statutory health insurance funds and joins from Steria Mummert Consulting.

■ **THE NATURAL PRODUCTS ASSOCIATION** in the US has elected **Mark LeDoux**, chairman and chief executive officer at Natural Alternatives International, to its board.

OTC