

# OTC *bulletin*

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

## COMPANY NEWS

Voltaren OTC claims top spot in Germany	2
Pfizer grabs 40% stake in Brazilian company Teuto	3
Reddy's grows in Russia and CIS	3
Johnson & Johnson hit by 40% drop in US OTC sales	4
Reckitt Benckiser faces £10.2 million fine	5
Innovation holds key for GlaxoSmithKline in the US	6
Omega Pharma buoyed by French gain	7
Boiron's sales boosted by international performance	8

## GENERAL NEWS

EFSA rejects majority of claims in third batch	9
UK's MHRA steps up its OTC codeine restrictions	11

## MARKETING NEWS

Principle aims Vit Heroes at kids in western Europe	12
Boots Pharmaceuticals brand offers everyday health ranges	13
Dolormin campaign focuses on life's beautiful moments	14
Swiss company Mepha enters herbals market	15
Don't miss the deadline for our headline Awards	17
Benylin Mucus Cough gains two new variants in the UK	18

## FEATURES

### Review finds few faults with Dutch distribution

– The three-tier classification system for non-prescription medicines in the Netherlands has emerged relatively unscathed from a review commissioned by the government

## REGULARS

Events – Our regular listing	19
People – Day is to depart Reckitt but no successor in place	23

## Alliance Boots poised to obtain Germany's Anzag

**Alliance Boots is poised to make its first major acquisition in Germany after agreeing to pay around €143 million to obtain a further 51.65% stake in the country's third-largest pharmaceutical distributor, Andreae-Noris Zahn (Anzag), from German wholesalers Celesio, Phoenix and Sanacorp.**

The pan-European wholesaler and retailer – which has held a 29.99% stake in Anzag since 2004 – intends to launch a voluntary tender offer for the outstanding 18.36%. This will be at around the same price of €26.00 per share that it is paying to Celesio, Phoenix and Sanacorp.

Through its wholesaling activities and its 1,100-strong Vivesco virtual pharmacy chain, Anzag reported a pre-tax profit of €40 million on a turnover of €4.2 billion in the year ended 31 August 2010.

A spokesperson for Alliance Boots told *OTC bulletin* that one option would be to bring the Vivesco operation under its Europe-wide Alphega Pharmacy virtual pharmacy banner. Alliance Boots is also keen to introduce Boots-branded products in Germany.

However, the company's plans were at an

early stage, stressed the spokesperson, adding that discussions would be held with Anzag's management once the deal had been completed in three to five months.

Both the acquisition and tender offer – which together value Anzag at around €278 million – were subject to regulatory approvals, Alliance Boots pointed out.

Stefano Pessina, Alliance Boots' executive chairman, said that taking control of Anzag would allow the group "to reinforce our strategic ties with manufacturers throughout Europe".

Privately-owned Alliance Boots has more than 360 pharmaceutical wholesale distribution centres in 16 countries and owns a network of nearly 3,150 pharmacies.

Acquiring Anzag will make Alliance Boots – which currently has only a small presence in the German market – one of the three largest pharmaceutical wholesalers in Germany, along with Celesio and Phoenix.

Pessina commented that acquiring Anzag was "key" to the company's growth strategy and was a "further step with regards to its ex-

■ *Continued on page 8*

## Omega completes two deals in Europe

Omega Pharma has strengthened its presence in Sweden by acquiring the ACO brand of vitamin and nutritional supplements from Johnson & Johnson Consumer Nordic for €3.1 million in cash.

Furthermore, the Belgian company has completed a €69 million deal for French natural products company Laboratoire de la Mer. Omega announced at the end of September that it had entered into exclusive negotiations with TCR Capital, the majority shareholder in Laboratoire de la Mer's parent company CH-Pharma (*OTC bulletin*, 15 October 2010, page 3).

Acquiring the ACO brand of vitamins and nutritional supplements widened its OTC offering in Sweden, commented Omega, and gave

it better visibility in the recently-deregulated Swedish pharmacy market.

Marc Coucke, Omega's chief executive officer, said that although the deal would initially have only a "limited impact" on the company's sales, it was an important step in growing its presence in Scandinavia.

ACO's product portfolio was an "ideal catalyst" to strengthen Omega's position outside the dermatology category in Sweden, Coucke pointed out, and also had "significant potential" in terms of growing the company's sales in the region in the long term.

The deal reunites the ACO vitamin and supplements range with the ACO Hud pharmacy

■ *Continued on page 8*

Third-Quarter Results

# Voltaren OTC claims top spot in Germany

Novartis Consumer Health's Voltaren pain-relief brand overtook Aspirin as the leading self-medication name in the German market in the third quarter of 2010, according to Joseph Jimenez, Novartis' chief executive officer. He pointed out that IMS data for July had Voltaren as the "largest self-medication brand in Germany" with sales of around €165 million.

This was a "great milestone", Jimenez noted, adding that the brand had secured a 44% share of Germany's topical analgesics market.

Voltaren had been a "key business driver" at Novartis Consumer Health's OTC unit, which had outperformed the global OTC market in the third quarter, the Swiss firm pointed out.

In the US, the paracetamol-based Excedrin brand had made market share gains, Novartis said, as a result of "solid advertising and promotional campaigns".

Meanwhile, the Triaminic OTC children's cough and cold brand had also gained share in the US, the company noted, behind the launch of Triaminic Fever Reducer Pain Reliever in July (*OTC bulletin*, 30 July 2010, page 2).

In August, Novartis gave away about a quarter of a million bottles of Triaminic Fever Reducer Pain Reliever as it sought to take advantage of Johnson & Johnson's product recalls (*OTC bulletin*, 13 August 2010, page 19).

The launch came after Johnson & Johnson's McNeil Consumer Healthcare subsidiary recalled all lots of 44 OTC medicines for infants and children manufactured at its Fort Washington facility (*OTC bulletin*, 14 May 2010, page 1).

McNeil has now returned a limited quantity of one of its Children's Tylenol liquid products to the US market (*OTC bulletin*, 15 October 2010, page 4), but admitted that it would not have sources of supply for the remaining products before the end of the year (see page 4).

Novartis' sales were also aided by the OTC proton-pump inhibitor brand Prevacid 24HR,

Region	Third-quarter sales (US\$ millions)	Change 2009/2010 (%)	
		US\$	Local currencies
Europe	664	+1	+8
US	521	+13	+13
Asia/Africa/Australasia	263	+16	+9
Canada and Latin America	139	+7	+5
<b>Novartis Consumer Health*</b>	<b>1,587</b>	<b>+8</b>	<b>+9</b>

\* Continuing operations

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

which was launched just under a year ago (*OTC bulletin*, 16 November 2009, page 1).

Prevacid 24HR had achieved an average 20% share of the US proton-pump inhibitor category in the third quarter of 2010, Novartis said, and had established itself as a "strong competitive brand" in what was a "high-growth" market.

## Market share dipped

However, the lansoprazole-based brand's market share dipped in the third quarter, falling below the 25% it had held in the opening six months and dropping well short of the 30% share it had held in the first quarter. These followed the launch of Merck & Co's Zegerid OTC brand, which combines 20mg of omeprazole with 1,100mg sodium bicarbonate (*OTC bulletin*, 16 April 2010, page 14).

Novartis noted that the US proton-pump inhibitor category had grown by 35% to date in 2010, with Zegerid OTC joining Prevacid 24HR and Procter & Gamble's established omeprazole-based Prilosec OTC – and its store-brand equivalents – on the market.

During the quarter, Novartis expanded its gastrointestinal franchise by launching Pantoloc Control in three more European markets through its co-marketing agreement with the pantoprazole product's originator Nycomed (*OTC bulletin*, 10 February 2010, page 1).

Pantoloc Control was now available in all 14 European markets covered by the co-marketing agreement, Novartis pointed out.

Sales by Novartis Consumer Health increased by 8% – 9% in local currencies – to US\$1.59 billion (€1.14 billion) during the third quarter (see Figure 1), as its Animal Health and CIBA Vision businesses added to growth from the firm's OTC unit.

Asia/Africa/Australasia was the division's best performing region, with sales up by 16% – 9% in local currencies – to US\$263 million.

In Europe, "robust growth" had been achieved, the company pointed out, thanks to its performances in Germany and Italy, with sales increasing by 1% to US\$664 million. In local currencies, the rise was a more substantial 8%.

Strong performances across all three businesses, Novartis said, had lifted Consumer Health's turnover in the US by 13% to US\$521 million (see Figure 2). Canada and Latin America reported growth of 7% – 5% in local currencies – to US\$139 million.

Novartis also highlighted that in Consumer Health's top-six emerging markets, sales had grown by 12% – 9% in local currencies – to US\$123 million, thanks to "solid" single-digit growth in Brazil and double-digit gains in the remaining five markets.

OTC

Division	Third-quarter sales (US\$ millions)	Change 2009/2010 (%)		Operating income (US\$ millions)	Change 2009/2010 (%)	Operating margin (%)
		US\$	Local currencies			
Pharmaceuticals	7,565	+5	+6	1,844	-17	24.4
Sandoz	2,177	+18	+23	415	+33	19.1
Consumer Health*	1,587	+8	+9	386	+27	24.3
Vaccines and Diagnostics	632	+16	+21	68	+196	10.8
Alcon	617	–	–	101	–	16.4
Corporate	–	–	–	-227	–	–
<b>Novartis</b>	<b>12,578</b>	<b>+13</b>	<b>+16</b>	<b>2,587</b>	<b>-2</b>	<b>20.6</b>

\* Continuing operations

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

## Mergers &amp; Acquisitions

# Pfizer grabs 40% stake in Brazilian company Teuto

Pfizer has struck a deal to acquire a 40% stake in Brazilian generics and OTC firm Laboratório Teuto Brasileiro for BRL400 million (€169 million). The two firms will also enter into a series of commercial agreements.

Under the terms of the deal, Pfizer has an option to buy the remaining 60% in 2014, while Teuto's shareholders have an option to sell their shares to Pfizer beginning in 2015.

The US-based company said the deal gave it access to Teuto's portfolio of approximately

250 prescription and OTC products in more than 400 presentations, and the rights to register and commercialise Teuto's branded and unbranded generics products in various markets outside of Brazil.

Teuto's product portfolio covered a broad range of therapeutic areas, Pfizer noted, such as anti-infectives, cardiovascular, central nervous system, pain and inflammation, and respiratory.

Noting that branded and unbranded generics accounted for around 60% of the value of the Brazilian retail pharmaceutical market, Pfizer said the deal with Teuto provided access to "significant distribution networks in rural and suburban areas in Brazil" and demonstrated the company's "commitment to pursue focused investments in key emerging markets".

Teuto – which claims to be Brazil's third-largest generics firm – will gain access to select Pfizer products for distribution across its network and the right to commercialise them under Teuto's own brand in Brazil.

Pfizer will have two representatives on Teuto's board of directors.

Teuto's OTC portfolio includes: the Analgesin pain reliever containing acetylsalicylic acid; the Dimezin anti-flatulent with dimeticone; the Ibupril pain reliever with ibuprofen; and Poliseng with panax ginseng and multivitamins.

Meanwhile, Pfizer has also announced that it is set to acquire the US-based prescription pain-relief specialist King Pharmaceuticals for US\$3.6 billion (€2.6 billion) in cash. Pfizer said that the deal would strengthen its position in the fast-growing pain-relief market.

## Marketing Agreements

# Reddy's grows in Russia/CIS

Dr Reddy's Laboratories has expanded its product offering in Russia and the Commonwealth of Independent States (CIS) through two separate marketing agreements.

The company said it had gained the exclusive marketing rights to a portfolio of OTC and prescription products from fellow Indian firm Cipla in Russia and Ukraine.

Sales in Russia were already underway, Dr Reddy's noted, while it would begin sales in Ukraine in 2011.

In addition, the company had also secured the exclusive marketing rights to Vitabiotics' Jointace and Dietrim supplements in Russia and select CIS countries. UK-based Vitabiotics would supply the products on a long-term basis from its European facilities, Dr Reddy's noted.

Satish Reddy, Dr Reddy's managing director and chief operating officer, said the agreements gave the company a range of established OTC and prescription brands in Russia and the CIS that would immediately add to the company's turnover in the region.

## Long-term synergies

"We see long-term synergies," Reddy added, "as Dr Reddy's has a strong sales and marketing network and our partners have a basket of products already registered and distributed in these markets."

MV Ramana, Dr Reddy's head of Russia and CIS region, said the agreement with Cipla would enhance the company's presence in the OTC space and in the gastrointestinal, dermatology and oncology therapy areas in both Russia and Ukraine. Ramana noted that the deal also covered Cipla's range of respiratory products in Ukraine.

Meanwhile, Vitabiotics' Jointace brand of joint-care supplements would complement Dr Reddy's existing pain management portfolio and increase its presence in the nutraceutical market, Ramana pointed out, while the Dietrim product marked the company's entry into the weight-management arena in the region.

Dr Reddy's claims to be the largest Indian pharmaceutical company in Russia. Its sales in Russia and other CIS markets in the year ended 31 March 2010 rose by a fifth to Rs9.1 billion (€146 million).

In the six months to 30 September 2010, the company's turnover in the region stood at Rs5.3 billion.

## OTC bulletin

29 October 2010 Number 351

**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](http://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 newflash, *news@OTCbulletin*, 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.

No part of this publication may be copied, reproduced, stored in a retrieval system or transmitted in any form without prior permission from OTC Publications Ltd.

© OTC Publications Ltd. All rights reserved.

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

*OTC bulletin*® is registered as a trademark in the European Community.

ISSN 1350-1097

[www.OTC-bulletin.com](http://www.OTC-bulletin.com)

## IN BRIEF

■ **PERRIGO** looks set to **expand its presence in Asia** following the success of its PBM Products division's Insulac IQ infant formula brand in Vietnam. Perrigo said it was "very excited" about expanding into these markets with its offering of "high-quality, private-label and now branded nutritionals".

■ **STADA's** Serbian subsidiary **Hemofarm has expanded and refitted a production plant** for solid-dosage forms in Banja Luka, Bosnia and Herzegovina, more than doubling the plant's capacity to 30 million packs per year.

Third-Quarter Results

# J&J hit by 40% drop in US OTC sales

US sales by Johnson & Johnson's OTC & Nutritionals unit plummeted by US\$294 million (€213 million) in the third quarter, as the impact of multiple product recalls and suspending of production at McNeil Consumer Healthcare's Fort Washington manufacturing facility hit home.

More than 40% was wiped from US sales to leave them at US\$438 million, sending worldwide turnover at the OTC & Nutritionals business down by over a fifth to US\$1.11 billion. An operational decline of 19.4% was compounded by a 1.3% negative currency effect.

Although McNeil had returned one Children's Tylenol product to the market earlier this month (*OTC bulletin*, 15 October 2010, page 4), Dominic Caruso, Johnson & Johnson's chief financial officer, said that production of other items impacted by closing Fort Washington would not start until the first quarter of 2011 and "probably will not reach normal levels until mid-way through the year".

The Fort Washington facility itself would not reopen until late 2011, Caruso noted.

As a result, US sales by the firm's OTC & Nutritionals business are expected to decline by US\$600 million in 2010.

Meanwhile, international OTC & Nutrition-

als sales edged up by 0.8% during the quarter to US\$671 million (see Figure 1). The gain would have been even greater, but for a negative currency effect of 2.7%, which wiped out the majority of the 3.5% operational advance.

International OTC & Nutritionals sales had been boosted during the quarter by a positive performance from its smoking-cessation aids, Johnson & Johnson noted.

### Further product recalls

McNeil's recall woes continued following the close of the quarter, with the company announcing a voluntary recall of one lot of its 50-count bottles of Tylenol 8 Hour caplets, manufactured at its Las Piedras plant in Puerto Rico.

The recall was instigated due to an "uncharacteristic odour" caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole, which could result from the breakdown of a wood-treatment chemical used on wooden pallets that transport and store product packaging materials.

A similar problem led to the January recall of various OTC brands manufactured at the Las Piedras plant and also landed McNeil with a warning letter from the US Food and Drug Administration related to conditions at the facil-

ity (*OTC bulletin*, 10 February 2010, page 22).

Johnson & Johnson extended the recall in both June and July (*OTC bulletin*, 30 July 2010, page 4), but Louise Mehrotra, the company's vice-president of investor relations, pointed out that production levels at the Las Piedras plant had now returned to normal.

Four months after the Las Piedras recall, McNeil announced it had suspended production at its Fort Washington facility after voluntarily recalling all lots of 44 infant's and children's liquid products made at the plant and sold under the Benadryl, Motrin, Tylenol and Zyrtec names (*OTC bulletin*, 14 May 2010, page 1).

The move came after an FDA inspection found grime and contaminated ingredients at the facility, which the agency said could affect the "quality, purity or potency" of products manufactured at the plant.

McNeil's recall of products made at Fort Washington was the sixth significant recall implemented by the business between October 2009 and May 2010, and sparked an investigation by the US House of Representatives' Committee on Oversight and Government Reform (*OTC bulletin*, 11 June 2010, page 1).

Testifying to the congressional committee in September, William Weldon, Johnson & John-

Business	Third-quarter sales (US\$ millions)	Change 2009/2010 (%)	Operational change (%)	Currency effect (%)
<i>OTC &amp; Nutritionals – US</i>	438	-40.2	-40.2	–
<i>OTC &amp; Nutritionals – International</i>	671	+0.8	+3.5	-2.7
Total OTC & Nutritionals	1,109	-20.7	-19.4	-1.3
<i>Skin Care – US</i>	311	-15.9	-15.9	–
<i>Skin Care – International</i>	489	+3.6	+3.7	-0.1
Total Skin Care	800	-5.0	-4.9	-0.1
<i>Baby Care – US</i>	104	+2.0	+2.0	–
<i>Baby Care – International</i>	462	+4.5	+3.6	+0.9
Total Baby Care	566	+4.0	+3.3	+0.7
<i>Women's Health – US</i>	121	-14.8	-14.8	–
<i>Women's Health – International</i>	338	-6.1	-5.1	-1.0
Total Women's Health	459	-8.6	-7.9	-0.7
<i>Oral Care – US</i>	164	-12.3	-12.3	–
<i>Oral Care – International</i>	220	-1.3	-2.2	+0.9
Total Oral Care	384	-6.3	-6.8	+0.5
<i>Woundcare/Other – US</i>	139	-12.0	-12.0	–
<i>Woundcare/Other – International</i>	110	-18.5	-18.5	±0.0
Total Woundcare/Other	249	-15.0	-15.0	±0.0
<b>Total Consumer</b>	<b>3,567</b>	<b>-10.6</b>	<b>-10.2</b>	<b>-0.4</b>
Consumer – US	1,277	-24.5	-24.5	–
Consumer – International	2,290	-0.3	+0.4	-0.7

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

Division	Third-quarter sales (US\$ millions)	Change (%)	Operational change (%)	Currency effect (%)
Medical Devices & Diagnostics	5,920	+1.3	+1.9	-0.6
Pharmaceutical	5,495	+4.7	+5.9	-1.2
Consumer	3,567	-10.6	-10.2	-0.4
<b>Total Johnson &amp; Johnson</b>	<b>14,982</b>	<b>-0.7</b>	<b>+0.1</b>	<b>-0.8</b>

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

son's chairman and chief executive officer, said McNeil was "revamping" the Fort Washington facility to bring both its equipment and procedures "up to the high standards we set for ourselves". It was spending US\$100 million "across McNeil" on facilities and equipment, he added, and Johnson & Johnson as a whole was restructuring its quality and operations responsibilities (*OTC bulletin*, 10 September 2010, page 31).

In the wake of the recalls and subsequent congressional investigation, Johnson & Johnson announced that Colleen Goggins would step down as worldwide chairman of the company's Consumer division on 1 March 2011 (*OTC bulletin*, 29 September 2010, page 25).

Weldon said at the time that the succession plans for what he described as a "critical position" would be announced in a timely manner. He stressed that Goggins, 56, had had a "successful and distinguished" career with Johnson & Johnson spanning almost 30 years.

Meanwhile, sales declines in all but one of the other categories in Johnson & Johnson's Consumer division meant the firm was unable to offset the impact of the problems at the OTC & Nutritionals business. Worldwide Consumer sales fell back by 10.6% to US\$3.57 billion, as an operational decline of 10.2% was made even worse by a negative currency effect of 0.4%.

The OTC recalls had impacted Consumer's operational result by six percentage points, Mehrotra noted, while the devaluation of Venezuela's currency and divesting two oral care brands at the end of last year had had a negative impact on operational growth of "just over one point each".

US Consumer turnover slipped back by 24.5% to US\$1.28 billion, while international sales dropped by 0.3% to US\$2.29 billion.

The Consumer division's Skin Care business posted worldwide sales down by 5.0% to US\$800 million, as the firm began implementing equipment upgrades, which led to a temporary reduction in shipments of certain products. The upgrade process was expected to continue into the fourth quarter, the company noted.

US Skin Care sales declined by 15.9% to US\$311 million, wiping out the 3.6% rise in international sales to US\$489 million. International Skin Care sales had been lifted by the Da-

boa skincare range in China, the firm said.

Baby Care was the only Consumer category to enjoy a positive quarter, with sales rising by 4.0% to US\$566 million. Powders and cleansers boosted international sales, which grew by 4.5% to US\$462 million, while the babycentre.com website pushed up US turnover by 2.0% to US\$104 million.

The Women's Health business reported sales down by 8.6% to US\$459 million, due primarily to a 14.8% slide in US sales to US\$121 million. International turnover dropped back by 6.1% to US\$338 million.

Worldwide Oral Care sales fell by 6.3% to US\$384 million, as US sales declined by 12.3% to US\$164 million. The US performance was blamed on lower sales of toothbrushes and slower growth in the mouth-rinse category, as well as the sale of the Efferdent and Effergrip brands at the end of 2009. The US drop was compounded by a 1.3% slide in international sales to US\$220 million.

Woundcare/Other posted worldwide turnover down by 15.0% to US\$249 million, with double-digit declines in both US and international sales. International sales tumbled by 18.5%, with the entire drop reported at an operational level, while sales fell by 12.0% in the US.

#### Group sales down by 0.7%

The Consumer division accounted for 23.8% of Johnson & Johnson's worldwide sales in the third quarter of 2010, which dropped by 0.7% to US\$15.0 billion (see Figure 2). The fall was entirely due to a 0.8% negative currency impact, which wiped out an operational gain of 0.1%.

The dominant Medical Devices & Diagnostics division posted sales up by 1.3% to US\$5.92 billion, while turnover at the Pharmaceuticals division moved forward by 4.7% to US\$5.50 billion.

Pre-tax profits fell back by 0.6% to US\$4.22 billion, as cost of goods sold and research and development costs both increased.

Following the close of the quarter, a jury in Louisiana, US, ruled that Johnson & Johnson owed the state US\$258 million for mis-selling its diabetes drug Risperdal. The company said it would appeal the ruling.

#### Regulatory Affairs

## Reckitt faces £10.2mn fine

Reckitt Benckiser has agreed to pay a fine of £10.2 million (€11.6 million), after admitting to abusing its dominant position in the supply of alginate and antacid heartburn drugs through the UK's National Health Service (NHS).

The fine follows an investigation by the UK's Office of Fair Trading (OFT) into an allegation that the firm had limited generic competition through the NHS to its Gaviscon brand, when a patent had expired.

The OFT noted that the fine had been reduced from £12 million to reflect Reckitt Benckiser's admission and its decision to cooperate as part of an early resolution agreement.

As part of the early resolution agreement, Reckitt Benckiser admitted to infringing UK and European competition law by withdrawing and delisting Gaviscon Original Liquid from the NHS prescription channel in 2005.

The OFT's Statement of Objections issued during February of this year (*OTC bulletin*, 17 March 2010, page 5) claimed that Reckitt Benckiser had deliberately timed the withdrawal of Gaviscon Original Liquid to ensure general practitioners' prescribing software identified only its successor Gaviscon Advance Liquid, rather than a generic. The Advance product has patent protection until 2016.

John Fingleton, the OFT's chief executive, said the case underlined his organisation's "determination to prevent firms with a dominant position in a market from using their strength to seek to restrict competition from rivals".

"The imposition of penalties should serve to deter firms from engaging in anticompetitive behaviour of this sort in future," he added.

Prior to the OFT's investigation, Reckitt Benckiser had denied accusations made by the BBC current affairs television show *Newsnight* that it had unfairly hindered generic competition to its Gaviscon brand, thereby costing the NHS approximately £40 million since 1999 (*OTC bulletin*, 17 March 2008, page 11).

—OIC

#### IN BRIEF

■ **SIGMA PHARMACEUTICALS** said exclusive negotiations with **Aspen Pharmacare** over the A\$900 million (€639 million) sale of its Pharmaceuticals division would continue until 29 October 2010.

—OIC

Third-Quarter Results

# Innovation holds key for GSK in the US

Innovation will be the key to GlaxoSmithKline Consumer Healthcare turning around its sales in the US, according to the company's chief executive officer Andrew Witty.

The UK-based firm's Consumer Healthcare business posted US sales down by 4% at constant exchange rates to £249 million (€281 million) in the third quarter, as consumers continued to avoid buying premium-priced "non-essential OTC and oral healthcare products".

Witty said that although Consumer Healthcare's competitive performance in the US was "not too bad", the weak economic environment had hit consumer confidence, which in turn had impacted on sales of its higher-priced products. He pointed out that the weight-loss medicine Alli – which retails at between US\$40.00-US\$65.00 (€28.70-€46.63) – had been "hurt quite a bit".

Asked how GlaxoSmithKline intended to turn the US consumer business around, Witty stressed that innovation was "the key to going forward in the US".

Backed by increased investment, the US Consumer Healthcare business had been challenged to step up its "brand innovation dimension", Witty pointed out.

Highlighting the oral-care brand Sensodyne as a major opportunity in the US in the next couple of years, Witty held up Nicorette Mini Lozenges as an example of how innovation

Region	Third-quarter sales (£ millions)	Change 2009/2010 (%)	
		£	CER*
Rest of World	520	-25	+15
Europe	491	-3	-2
US	249	±0	-4
<b>Total Consumer Healthcare</b>	<b>1,260</b>	<b>+8</b>	<b>+4</b>

\* CER is at constant exchange rates

Figure 1: GlaxoSmithKline Consumer Healthcare's third-quarter 2010 sales by region (Source – GlaxoSmithKline)

could pay-off. Since its launch earlier this year (OTC bulletin, 14 May 2010, page 21), the product had done well in terms of market share and competitiveness, Witty noted, despite a decline in the smoking-cessation market overall.

Outside of the US, Consumer Healthcare's sales in Europe dropped by 2% at constant exchange rates to £491 million (see Figure 1), reflecting the post-launch success of Alli in the previous year (OTC bulletin, 30 October 2009, page 1). Excluding Alli, the division's underlying sales in Europe had increased by 1%, GlaxoSmithKline noted.

In contrast to Europe and the US, Consumer Healthcare's Rest of World region experienced double-digit sales growth during the third quarter. Rest of World turnover had risen by 15% at constant exchange rates to £520 million, the firm said, following growth across all major categories.

This double-digit rise in Rest of World sales offset the falls in Europe and the US, pushing up Consumer Healthcare's total third-quarter sales by 4% at constant exchange rates to £1.26 billion.

Excluding the impact of Alli on European sales, Consumer Healthcare's underlying turnover had moved ahead by 5%, GlaxoSmithKline noted, outpacing the worldwide market growth of 3%.

Operating profit increased by 7% at constant exchange rates to £313 million. The operating margin was 24.8%.

Within Consumer Healthcare's largest product category, OTC Medicines, sales edged up by 1% at constant exchange rates to £601 million (see Figure 2), reflecting lower sales of Alli in both the US and Europe.

The company did not release Alli's quarterly sales figures, but in Europe the brand suffered from a difficult comparison with the prior-year quarter, when it generated sales of £29 million following its launch across 24 European markets in April 2009 (OTC bulletin, 30 April 2009, page 1). As previously mentioned, Alli's sales in the US declined due to the difficult trading environment.

Excluding Alli, OTC Medicines turnover had improved by 5%, GlaxoSmithKline said, driven by "positive momentum in other OTC categories" and "strong growth" in the Rest of World region.

OTC Medicines accounted for 47.7% of Consumer Health's total turnover, with Oral Healthcare generating a further 31.7% and Nutritional Healthcare the remaining 20.6%.

Sales of Oral Healthcare products grew by 4% at constant exchange rates to £400 million, thanks to Sensodyne's sixth consecutive quarter of double-digit sales growth.

Nutritional Healthcare posted the biggest gain in the quarter, with turnover rising by 12% at constant exchange rates to £259 million. GlaxoSmithKline said the performance had been driven by a combination of "innovation,

Business	Third-quarter sales (£ millions)	Change 2009/2010 (%)	
		£	CER*
OTC Medicines	601	+5	+1
Oral Healthcare	400	+7	+4
Nutritional Healthcare	259	+16	+12
<b>Total Consumer Healthcare</b>	<b>1,260</b>	<b>+8</b>	<b>+4</b>

\* CER is at constant exchange rates

Figure 2: GlaxoSmithKline Consumer Healthcare's third-quarter 2010 sales by business (Source – GlaxoSmithKline)

	Third-quarter (£ millions)	Change 2009/2010 (%)		Proportion of total (%)
		£	CER*	
<b>Sales</b>				
Pharmaceuticals	5,553	-1	-3	82
Consumer Healthcare	1,260	+8	+4	18
<b>Total</b>	<b>6,813</b>	<b>+1</b>	<b>-2</b>	<b>100</b>
<b>Operating profit</b>				
Pharmaceuticals	1,988	-	-16	86
Consumer Healthcare	313	-	+7	14
<b>Total**</b>	<b>1,958</b>	<b>-5</b>	<b>-10</b>	<b>100</b>

\* CER is at constant exchange rates \*\* Including corporate costs of £182 million and restructuring costs of £171 million

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

Trading Update

# Omega Pharma buoyed by French gain

Omega Pharma's French business posted a rise in quarterly sales for the first time in two years, as the company reported total group sales up by 6% to €200 million in the third quarter of 2010.

Sales at Omega's French business moved forward by 2% to €35.1 million (see Figure 1) over the three months. This marked the business' first positive quarterly-sales result since it reported a 1% gain in the second quarter of 2008 (*OTC bulletin*, 31 July 2008, page 9).

The result comes after an 8% decline in French sales over the first half of 2010, with first-quarter turnover dropping by a tenth and second-quarter sales falling by 6% (*OTC bulletin*, 30 April 2010, page 5; *OTC bulletin*, 30 July 2010, page 10).

Commenting on the turnaround in France, the Belgian firm said that a new management team appointed at the start of the year, coupled with a more focused sales and marketing approach and the launch of a number of new products had all contributed to the result.

The Clément-Thékan, Dermalex, Phytosun Arômes and XL-S Medical brands had driven the French performance, Omega noted, adding that it was confident the "necessary fundamen-

geographic expansion and enhanced marketing behind the Horlicks brand".

Consumer Healthcare accounted for 18% of GlaxoSmithKline's total third-quarter sales, which slipped back by 2% at constant exchange rates to £6.81 billion. As reported, sales edged up by 1%.

Turnover at the dominant Pharmaceuticals business dropped by 3% at constant exchange rates to £5.55 billion. The fall was a less severe 1% as reported, while operating profit tumbled by 16% to £1.99 billion.

GlaxoSmithKline's total operating profit fell by 10% at constant exchange rates – 5% as reported – to £1.96 billion. The company noted that it had booked restructuring charges of £171 million during the quarter.

Asked about GlaxoSmithKline's acquisition policy, Witty noted that any cash left after the company had boosted its dividend would be channelled towards bolt-on acquisitions. These would be typically in the consumer, emerging markets, and vaccines areas, he insisted, noting that "classic, big acquisitions" were not on the company's agenda.

tals" were now in place for its French business to "deliver sustainable growth".

Following the close of the quarter, Omega expanded its French business, by acquiring the French natural products firm Laboratoire de la Mer for €69 million in cash (see front page).

Marc Coucke, Omega's chief executive officer, said that thanks to its "talented and enthusiastic team", the French business now complemented the growth seen in the company's other regions.

## Emerging Markets grew quickest

Emerging Markets was the company's fastest-growing region in the third quarter, as positive sales results in "practically all countries" led to turnover jumping by 18% to €26.8 million.

Coucke said the growth had been driven by "better sales structures" – which he claimed had "generated 25% more visits" to pharmacies – along with "local and corporate initiatives".

Australia, the Adriatic, the Baltics, Poland, Russia, Turkey and Ukraine had all delivered double-digit turnover advances in the period, Coucke said, adding that both Omega's local products and its global brands had done well in the firm's Emerging Markets region.

Solid growth had been delivered in the company's home market, Omega pointed out, with Belgian sales rising by 8% to €58.4 million. The company had benefited from a "solid market position" and ongoing OTC product innovation, Omega noted, adding that in the generics segment it held a 60% market share, together with its partner Eurogenerics.

In Western Europe – Omega's biggest region

in terms of sales – turnover improved by 3% to €80 million, as the majority of countries in the region delivered positive results.

Switzerland and the Nordic countries had reported double-digit sales growth, Omega said, while the UK and Ireland had also performed strongly, thanks primarily to the Jungle Formula insect repellent brand and the Paranix Double Action head-lice treatment.

Jungle Formula was backed by a £1.0 million (€1.1 million) UK television campaign during the summer, which was the first significant consumer advertising for the brand in years (*OTC bulletin*, 11 June 2010, page 8).

Following the close of the quarter, Omega expanded its presence in the Nordic region by acquiring for €3.1 million the ACO vitamin and nutritional supplements range from Johnson & Johnson Consumer Nordic (see front page).

Commenting on Omega's on-going product roll-out programme, the company said that the Paranix brand was now the leading head-lice treatment in the Czech Republic and had taken third place in the Turkish head-lice treatment market, despite only having been launched in both markets during the summer.

Looking ahead, Omega said that in the fourth quarter it would introduce "new and improved" Silence Anti-Snoring products and a "non-addictive sleeping aid" called Silence Calm & Sleep in a limited number of countries.

Ongoing country-by-country product roll-outs, coupled with the impact of investments made earlier in the year and a successful third quarter, meant Omega could re-affirm its previous forecast of a 4% rise in full-year sales.

	Third-quarter sales (€ millions)	Change 2009/2010 (%)	Proportion of total (%)
Western Europe	80.0	+3	40
Belgium	58.4	+8	29
France	35.1	+2	18
Emerging Markets	26.8	+18	13
<b>Omega Pharma</b>	<b>200.3</b>	<b>+6</b>	<b>100</b>

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

OIC

We also publish *Generics bulletin*

[www.generics-bulletin.com](http://www.generics-bulletin.com)

Mergers & Acquisitions

# Alliance Boots to obtain Anzag

Continued from front page

-pansion in Europe and beyond”.

Under the terms of the deal, Alliance Boots will pay around €69 million for Sanacorp’s 24.99% stake in Anzag and €39 million for Celesio’s 14.15% holding. The company has also agreed to pay approximately €35 million for Phoenix’ 12.50% stake.

Smaller wholesalers Noweda and MediQ hold the bulk of Anzag’s remaining shares, but neither company has said whether they are willing to sell their respective stakes.

The deal for Anzag comes four years after Sanacorp – which is Germany’s fourth-largest pharmaceutical wholesaler – was prevented from taking a majority stake in the firm due to competition concerns (*OTC bulletin*, 16 October 2006, page 3).

Alliance Boots, however, is unlikely to face such issues, as its only presence in the German wholesaling market is through its Megapharm subsidiary, which offers a range of wholesaling and logistics services for oncology products.

In the year ended 31 March 2010, Germany accounted for under 3% of total sales at Alliance Boots’ Pharmaceutical Wholesale division, which stood at £12.4 billion (€14.0 billion) (*OTC bulletin*, 31 May 2010, page 5).

Third-Quarter Results

# Boiron’s sales boosted by international performance

Sales by the French homoeopathy specialist Boiron edged up by 4.0% to €147 million in the third quarter of 2010, as a double-digit rise in international turnover offset a decline in domestic sales.

International sales grew by 13.4% to €71.1 million, driven solely by a 21.1% increase to €58.8 million in sales for Europe excluding France (see Figure 1).

### Better European performance

The better European performance had been due mainly to improved sales in Russia, Boiron pointed out. During the first half of 2010, Boiron’s Russian sales had fallen by 8.9% after a poor winter flu season hit sales of the company’s Oscillococcinum flu brand (*OTC bulletin*, 10 September 2010, page 11).

Outside of Europe, North American sales declined by 11.9% to €11.0 million, while in Boiron’s other markets, turnover slipped back by 21.7% to €1.35 million.

Meanwhile, in Boiron’s home market, sales dropped back by 3.5% to €75.7 million. This followed a first-half when Boiron’s French sales had only edged up by 0.3%, after a 1.3% second-quarter rise had offset a 1.1% decline

Business	Third-quarter sales (€ millions)	Change (%)
France	75.7	-3.5
Europe*	58.8	+21.1
North America	11.0	-11.9
Other countries	1.3	-21.7
<b>Boiron</b>	<b>146.8</b>	<b>+4.0</b>
Non-proprietary	65.0	-2.5
OTC specialties	81.7	+10.1
Other	0.1	-55.2

\* Excluding France

Figure 1: Breakdown of Boiron’s sales in the third quarter of 2010 (Source – Boiron)

in the opening three months of the year.

Sales of Boiron’s OTC specialties grew by 10.1% to €81.7 million, but sales of non-proprietary homoeopathic medicines slipped back by 2.5% to €65.0 million.

Looking ahead, Boiron said it expected that difficult market conditions would affect its performance in 2010, which would fall short of the €526 million in sales and €91.8 million operating profit achieved in 2009 (*OTC bulletin*, 31 March 2010, page 8).

Mergers & Acquisitions

# Omega completes two deals in Europe

Continued from front page

skincare line that Omega bought in 2004 (*OTC bulletin*, 15 September 2004, page 1).

Established in 1939, the ACO portfolio of skincare products, vitamins and nutritional supplements was split in 1992, when Kabi-Pharmacia – now part of Pfizer – sold the ACO skincare division.

However, Kabi-Pharmacia retained the rights to use the ACO brand name in some categories, such as vitamins and supplements. When Pfizer sold its OTC business to Johnson & Johnson in 2006, the rights shifted to Johnson & Johnson Consumer Nordic.

Commenting on the Laboratoire de la Mer deal, Omega said it would expand its presence in the cough/cold sector, as well as add around €25 million to sales and €8 million to earnings before interest, tax, depreciation and amorti-

sation (EBITDA) during the whole of 2011.

Based around a range of seawater-containing products, Laboratoire de la Mer’s portfolio includes the Hydrasense, Nasalmer, Physio-mer and Sinoclear nasal-care products, as well as the Audiclean earcare brand and Opticalm eyecare line.

The company also offers the Lipozone slimming products and the Varidraîne heavy-legs line, as well as distributing the Algodentyl oral and dental-care brand.

Laboratoire de la Mer’s brands are available in 50 countries worldwide through distribution partners including Omega, which sells the products in Australia, the Benelux countries, Greece, New Zealand, Poland and Romania. Around 85% of the company’s sales are generated in markets outside of France.

Coucke said Laboratoire de la Mer’s flagship

brands would expand the company’s position in the natural care market while its “expertise and assets in the fast-growing cough and cold segment” fitted exactly with Omega’s strategy.

The two acquisitions come after Omega announced in March that it would consider buying innovative brands or businesses with global potential as part of its drive to become one of the world’s top 10 OTC players (*OTC bulletin*, 31 March 2010, page 2).

Acquisitions would play a part, Omega noted, in expanding its five new business categories of Classics, Cough & Cold, Derma, Multi-Locals and Parasites. Focusing on just the five business areas would enable Omega to shift away from niches with sales of €50 million to €100 million, the company said, to large categories like dermatology and cough/cold.

Omega claims to be the 13th biggest OTC company in the world with sales of €814 million in 2009 and a presence in 35 countries (*OTC bulletin*, 10 February 2010, page 11).

Regulatory Affairs

# EFSA rejects majority of claims in third batch

Most of the 808 submissions in the third batch of general-function health claims assessed by the European Food Safety Authority (EFSA) have been rejected.

EFSA has now said no to 80% of the 1,745 general-function health claims assessed to date.

Only a handful of the 416 submissions in the second batch were given the okay (*OTC bulletin*, 17 March 2010, page 11). And just a third of the 500-plus health claims in the first batch received a positive opinion (*OTC bulletin*, 16 October 2009, page 11).

As with the first two batches, EFSA said its panel on Dietetic Products, Nutrition and Allergies (NDA) had issued negative opinions for many of the claims in the third batch “due to the poor quality of the information provided”.

EFSA pointed out that the positive opinions mainly involved vitamins and minerals. However, they also referred to claims for specific dietary fibres related to blood-glucose control, bowel function or weight management; to fatty-acid claims related to brain function, vision or heart health; and to claims related to live yoghurt cultures and lactose digestion.

Discussing the negative opinions, EFSA said one problem was an inability to identify the specific substance on which the claim was based. It cited as an example claims for “dietary fibre” that did not specify the particular fibre.

Another problem highlighted by EFSA was a lack of evidence that the claimed effect was indeed beneficial to the maintenance or improvement of body functions. Claims about renal “water elimination” were given as an example by EFSA.

Lack of precision regarding the actual health claim was also an issue, continued EFSA, citing claims referring to terms such as “energy” and “vitality”. And a lack of human studies with reliable measures of the claimed health benefit was also an issue.

EFSA has now assessed just over a third of the 4,637 health claims compiled by European Union member states and the European Commission. The authority said it intended to finalise evaluations for all general-function health claims – other than botanicals – by the end of June 2011.

To provide additional guidance to applicants, EFSA is organising a series of consultations on specific topics. The first of these on 2 Decem-

ber 2010 will focus on health claims related to gut and immune functions.

The June 2011 deadline is in line with the European Commission’s modified process for adopting general-function health claims (*OTC bulletin*, 15 October 2010, page 1).

The Commission said earlier this month that the community list of permitted general-function health claims for foods would now be established in two steps. The list for all substances other than botanicals would be adopted in a single step, it explained, with claims for botanicals considered once the first step had been completed. The Commission noted that it would “immediately” follow up with the necessary legislative measures.

The move comes after industry and some member states complained about the Commis-

sion’s progressive approach whereby claims were set to be adopted in a number of series.

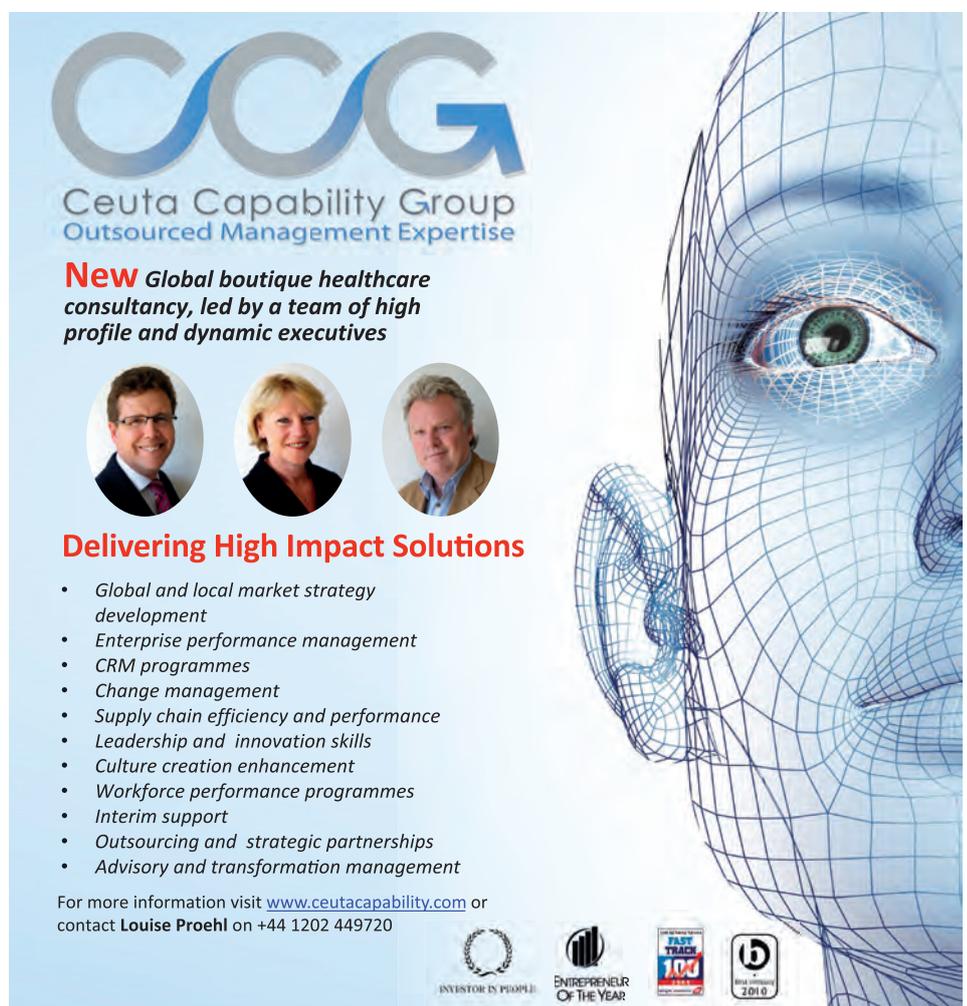
The community list of permitted general-function health claims for foods – covered by Article 13.1 of the European Union’s Regulation 1924/2006 on nutrition and health claims for food – should have been completed by 31 January 2010. However, it became clear some time ago that the deadline would not be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

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

Meanwhile, EFSA’s NDA panel has rejected three Article 13.5 health claims. One application from Yakult involved a claim that *Lactobacillus casei* strain Shirota could maintain upper respiratory tract defences against pathogens, while another from Synbiotec involved a claim that two bacterial strains could maintain and improve intestinal wellbeing.

A third from Milte Italia was for silymarin Bio-C and involved increased production of breast milk after childbirth.

OTC



**CCG**  
Ceuta Capability Group  
Outsourced Management Expertise

**New Global boutique healthcare consultancy, led by a team of high profile and dynamic executives**



**Delivering High Impact Solutions**

- Global and local market strategy development
- Enterprise performance management
- CRM programmes
- Change management
- Supply chain efficiency and performance
- Leadership and innovation skills
- Culture creation enhancement
- Workforce performance programmes
- Interim support
- Outsourcing and strategic partnerships
- Advisory and transformation management

For more information visit [www.ceutacapability.com](http://www.ceutacapability.com) or contact **Louise Proehl** on +44 1202 449720



# Tell the **right people** what you want to **buy** and **sell**

**WE KNOW** the people who want to in-license, out-license, buy or sell your OTC products, brands or technologies. We know them because they are registering with us at the SourceOTC website. Reach the SourceOTC community by posting your own message.

**New cost-effective rates** apply for 2010, so there has never been a better time to use the SourceOTC website to tell the right people what OTC assets you want to buy and sell. The new entry-level service means you can post up to five business opportunities on the SourceOTC website for three months for just £495 (plus VAT where applicable). And there is no success fee to pay.

This gives companies of all shapes and sizes a cost-effective way of getting their message across to the right people.



in association with **OTCbulletin**  
[www.OTC-bulletin.com](http://www.OTC-bulletin.com)

**New cost-effective rates apply for 2010**

 [sourceotc.com](http://sourceotc.com)

 [sourceotc.com](http://sourceotc.com)

 [sourceotc.com](http://sourceotc.com)

Visit [www.SourceOTC.com](http://www.SourceOTC.com) to find out more or contact Deborah Wilkes on 01564 777550 or [deborah.wilkes@SourceOTC.com](mailto:deborah.wilkes@SourceOTC.com)

**DEALS TO DRIVE YOUR BUSINESS**

## Regulatory Affairs

# UK's MHRA steps up its OTC codeine restrictions

More restrictions have been placed on codeine-containing OTC medicines by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

The agency has said that oral liquid OTC medicines containing codeine – all of which have pharmacy-only status – should no longer be used to treat cough in children and young people aged under 18 years. Moreover, these medicines should be supplied in child-resistant containers.

The latest move follows a review that resulted in a package of measures restricting the OTC use of codeine last year (*OTC bulletin*, 16 September 2009, page 1). These measures included restrictions on indications, controls on advertising, limits on pack sizes and prominently-positioned addiction warnings on the label and in the patient information leaflet.

"It is clear," the MHRA says in its latest public-assessment report, "that there is little evidence to support the use of codeine to relieve cough caused by the common cold in children."

And on safety, it adds: "There are serious concerns which need to be taken into account when assessing the risk/benefit balance of codeine-containing products."

Concluding that the risks outweigh the benefits of these medicines, the MHRA notes that their packaging and leaflets are being updated with the new advice that they are not for use in children and young people under 18 years.

This new information will begin to appear in pharmacies from April 2011, it adds, and in the meantime existing medicines will continue to be sold as before. Pharmacists, however, have been asked to consider the new advice when recommending cough medicines for children.

OTC

## Legal Cases

## CVS/pharmacy settles on pseudoephedrine

CVS/pharmacy – the retail arm of CVS Caremark – has agreed to pay the US government US\$75 million (€53 million) in civil penalties and US\$2.6 million in profit forfeitures to settle allegations that the company unlawfully sold pseudoephedrine.

The agreement settles allegations made by the US Drug Enforcement Administration (DEA) and US Attorneys' Offices for the central district of California and the district of Nevada that in 2007 and 2008 certain CVS/pharmacy stores within the two states sold excessive amounts of pseudoephedrine-based products because of the flawed implementation of an electronic monitoring system.

### Vulnerable to criminals

As implemented in California, Nevada and certain other states, the electronic monitoring system had failed to prevent multiple purchases of pseudoephedrine that totalled more than the federal daily legal limit, the company admitted. This had made certain CVS/pharmacy stores vulnerable to criminals who intended to purchase large amounts of the decongestant, which can be used to manufacture the illegal drug methamphetamine.

CVS/pharmacy also admitted that a distribution centre in California had failed to monitor and report excessive pseudoephedrine sales by CVS/pharmacy stores.

In 2006, the US placed limits on large-scale purchases of pseudoephedrine-containing OTC medicines to try and prevent the illegal manufacture of methamphetamine (*OTC bulletin*, 17 March 2006, page 9).

According to the measures, consumers requiring a product containing more than 60mg of pseudoephedrine must supply the seller with official identification, and the seller must log the name, address, product name and quantity sold along with date and time. No more than 3.6g of the product can be sold daily to the same purchaser.

Thomas Ryan, chairman and chief executive officer of CVS Caremark, said that to make certain this kind of lapse never happened again the company had strengthened its internal controls and compliance measures and had made substantial investments to improve its handling and monitoring of pseudoephedrine by implementing enhanced technology and making other improvements in stores and distribution centres.

OTC

## Regulatory Affairs

# Qualiphar sent warning by FDA

Qualiphar has received a Warning Letter from the US Food and Drug Administration (FDA) about its manufacturing plant in Bornem, Belgium.

The FDA said an inspection in May of this year had identified "significant violations" of current Good Manufacturing Practice (cGMP) regulations for finished pharmaceuticals. It added that a response from Qualiphar dated 28 May 2010 "lacks sufficient corrective actions".

Furthermore, the FDA said that Qualiphar was neither registered nor had it listed every product in commercial distribution in the US.

Until the problems had been resolved, said the FDA, approval of any new applications or supplements listing Qualiphar as a drug product manufacturer might be withheld. In addition, the agency noted that it would be refusing admission of articles manufactured at the Bornem plant to the US.

Qualiphar has to respond to the FDA within 15 working days of receiving the letter dated 30 September 2010.

OTC

## Publications

## BPI makes changes to German compendium

An improved structure and indexing system has been added to the Pharma Kodex compendium of German laws and regulations affecting medicines – including rules covering their production and promotion – offered by the association of the German pharmaceutical industry, the BPI.

The guide comes as five paperback books, each covering specific areas such as advertising and Europe's legal framework. Prices start from €63.00. An online version is available.

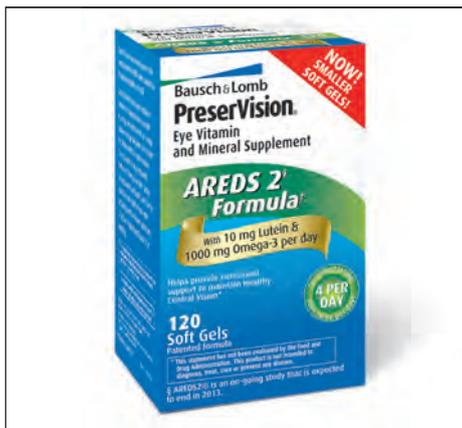
■ Contact BPI Service, Friedrichstrasse 148, 10117 Berlin, Germany (Tel: +49 30 279 09 136; Fax: +49 30 279 09 336; E-mail: infomedien@bpi-service.de. Website: [www.pharma-kodex.de](http://www.pharma-kodex.de)).

OTC

### IN BRIEF

■ **THE IRISH MEDICINES BOARD** has published a **guide to switching** the legal status of medicines on its website.

OTC



Bausch & Lomb has relaunched its PreserVision Eye Vitamin AREDS 2 Formula with smaller softgel capsules in the US, following the recent recall of the vitamin and mineral supplement for eye health.

Consumers should take two of the softgels, twice a day. The dosage for the original larger softgels was one softgel, twice a day.

The eye-health specialist voluntary recalled the food supplement containing omega-3 and lutein in July (OTC bulletin, 30 July 2010, page 13).

At the time, Bausch & Lomb said it had received a "small number of reports predominantly within a specific age group – age 70 and older – of difficulty swallowing or a choking sensation when taking the softgel".

A strapline on the packaging of the new design reads: "Now! Smaller Soft Gels!"

OIC

Launches

## Cinfa offers Spanish innovative rub cream

Laboratorios Cinfa has launched the Respirub and Respirub Infantil balsamic rub cream in Spain.

The company pointed out that the products came in an "innovative" dispensing stick. They can be used either as a traditional rub cream, inhaled directly from the stick, or inhaled as vapours after pouring into warm water.

The adult formulation is based on menthol, eucalyptus and camphor, while the children's version contains eucalyptus, pine and lavender.

OIC

### IN BRIEF

■ **PRESTIGE BRANDS** is backing its **Ultra Chloraseptic Anaesthetic Throat Spray** in the UK with a consumer marketing campaign worth £0.5 million (€0.6 million) this winter. The company said it would air its existing television commercial – which is built around the theme "Real relief. Real fast" – on satellite channels from November until January. Television advertising will be supported by public relations activity, and point-of-sale material.

OIC

Launches

# Principle aims Vit Heroes at kids in western Europe

Principle Healthcare has entered the children's vitamins market in the UK with a trio of additive-free, chewable food supplements shaped like teddy bears.

Vit Heroes will initially be available from Asda and Morrisons stores in the UK. However, Principle Healthcare plans to launch the range outside of the UK, starting with other western European countries.

In the UK, the Vit Heroes brand currently comprises Calcium & Vitamin D, Multivitamin, and Vitamin C variants. However, Principle Healthcare said it would extend the trio with "other varieties".

Available in "natural fruit tastes that should appeal to children", the range is said to be "entirely free from artificial colours, flavours, preservatives, sweeteners, and flavour enhancers".

The packaging features drawings of superhero characters.

The company said it would back Vit Heroes with an "exciting" multimedia marketing campaign. This will include television advertising, point-of-sale material and a consumer website, which will "bring the brand's characters to life



Principle Healthcare's Vit Heroes food supplements for children are initially available in the UK

and create a dialogue with parents and children".

Principle Healthcare said it was looking to achieve further distribution through other supermarkets, as well as pharmacies and independent health shops in the UK.

A month's supply of Vit Heroes, which are suitable for children aged three to 12 years, has a recommended retail selling price of £2.99 (€3.40) in the UK. Children should take one gummy bear a day.

Principle Healthcare's portfolio includes the BioCalth and Boost food supplements.

OIC



Novartis Consumer Health has extended its Tixylix range of children's medicines for coughs and colds in the UK with a syrup containing honey, lemon and glycerol.

According to Novartis, Tixylix Honey, Lemon & Glycerol was the "first branded paediatric product of its kind to market". The company noted that the launch was a response to the Department of Health's recommendation that the first line of treatment for children aged over one year with coughs should be a simple mixture containing glycerol, honey and lemon (OTC bulletin, 31 March 2008, page 1).

Tixylix Honey, Lemon & Glycerol is a general-sales list (GSL) medicine that is suitable for children aged one year and over.

It is supplied in a 100ml pack with a recommended retail selling price of £3.05 (€3.45). A strapline on the packaging points out that the oral solution provides "soothing relief of coughs and sore throats".

The Tixylix range also includes saline nasal drops, toddler syrup, baby syrup, a chesty cough medicine, and a vapour fan.

OIC

### IN BRIEF

■ **ACTAVIS** and **Omega Pharma** have teamed up in the UK to create a new trading partnership targeting the pharmacy sector. Omega Pharma said the additional focus on its sales

operation would help to foster a stronger sense of co-operation with pharmacies. Actavis noted it would continue to focus on its OTC brands.

OIC

Launches

# Boots Pharmaceuticals brand offers everyday health ranges

Boots said a wide range of everyday healthcare products for all the family would be available in the UK under its new Boots Pharmaceuticals brand.

The country's largest pharmacy chain claimed that the selection of "proven medicines and natural alternatives" would provide consumers with "convenient access to effective, affordable healthcare solutions".

A spokesperson for the retailer said the aim was for the Boots Pharmaceuticals brand to encompass the vast majority of its existing and new own-label healthcare products. It would eventually cover hundreds of products, added the spokesperson.

Two new ranges have been launched under the Boots Pharmaceuticals banner. One tackles men's sexual wellbeing and includes products for premature ejaculation and erectile dysfunction, while the other is aimed at people suffering from very dry skin.

Boots Pharmaceuticals also encompasses the retailer's existing NicAssist smoking-cessation range, as well as insect repellents and vitamin supplements. The company said the full range

would continue to be rolled out over the coming months.

Boots pointed out that the new Men's Sexual Wellbeing range consisted of five "innovative" and "discreetly packaged" products. These include condoms and a device to delay ejaculation, as well as a support ring for erectile dysfunction, a lubricating gel and a food supplement carrying the on-pack claim "Helps support vascular health including the genital area".

The retailer said research it had carried out with the consumer magazine *Men's Health* had found that a significant proportion of men in the UK experienced premature ejaculation and erectile dysfunction. Over two-thirds of men, 68%, had ejaculated earlier than they or their partners would have liked, said Boots, and almost one in five, 19%, had experienced difficulty in getting or maintaining an erection to enable satisfactory intercourse.

Boots is supporting the Mens Sexual Wellbeing range with information and advice on sexual wellbeing at its [www.boots.com](http://www.boots.com) website.

The retailer also offers a service for men aged 30-65 years who are suffering from erec-

tile dysfunction called The Boots Erectile Dysfunction Service (OTC *bulletin*, 27 February 2007, page 18). This includes supply of Pfizer's prescription-only drug Viagra (sildenafil).

Robert Gilbert, director of Boots Pharmaceuticals for Boots UK, said that "by providing a range of products and advice from our pharmacy team in stores, as well as online, Boots is making it easy for sufferers of sexual concerns to receive accessible guidance and support when they need it".

Recommended retail selling prices range from £2.99 (€3.35) for a 60g pack of lubricating gel up to £29.99 for either the 30-sachet pack of the supplement or the device.

Meanwhile, the new Derma Care range is claimed to introduce a "holistic approach to managing very dry skin". It is backed by the promise that it provides "A wall of protection for dry skin".

Designed to offer a "complete daily moisturising regime", the Derma Care range consists of a daily moisturising cream, light daily moisturising lotion, daily moisturising shower cream, emollient cream, itch relief cream, hydrocortisone 1% cream, and hydrocortisone 1% ointment.

Boots said the range was supported by "in-store advice from specially-trained healthcare advisers, who could provide support and advice on the management and maintenance of exceptionally dry skin conditions, such as eczema and dermatitis".



The new Boots Pharmaceuticals brand in the UK includes a line of products for men's sexual wellbeing as well as a range of formulations for dry skin

OTC

Discontinued Products

## McNeil discontinues Zocor Heart-Pro

"Limited consumer demand" has led McNeil Products to discontinue its Zocor Heart-Pro medicine in the UK.

The 2004 launch of the pharmacy (P) medicine containing 10mg simvastatin was a landmark development for the OTC industry. The UK was the first country in the world to switch a cholesterol-lowering statin from prescription-

only to pharmacy (POM-to-P) status (OTC *bulletin*, 28 November 2003, page 1).

Furthermore, Zocor was the first blockbuster prescription drug switched to OTC status for the long-term prevention of a chronic disease.

Commenting on the withdrawal, McNeil remarked: "We explored many options for the future management of Zocor Heart-Pro before mak-

ing this difficult decision." "Patients and healthcare professionals who are currently using the medicine can be assured that it remains an effective cholesterol-lowering treatment with a favourable safety profile," the company added.

McNeil pointed out that medicines containing 10mg simvastatin would still be available without a prescription in the UK from other manufacturers.

Bristol Laboratories markets a P medicine containing 10mg simvastatin.

OTC



Trebbling the life of the product and delivering a precisely-measured single dose are two of the benefits offered by a pump delivery system attached to bottles of Bausch & Lomb Laboratoire Chauvin's new Ophthalmicfree eye drops in France.

The preservative-free addition to Chauvin's Ophthalmic range of anti-allergy eyecare products can be used for up to three months once opened. In comparison, Chauvin's regular bottle of Ophthalmic can only be used for up to 28 days.

Chauvin said that the Ophthalmicfree pump automatically dispensed precisely the right amount of solution each time it was used. Before using the product for the first time, around 15 pumps are needed to activate the device and begin dispensing solution.

Ophthalmicfree is a non-reimbursable, non-prescription medicine. The retail price without tax for a 10ml bottle of the 2% sodium cromoglycate solution is €4.10.

The product is suitable for adults and children over 15 years of age and should be used between two and six times per day depending on the severity of symptoms. Ophthalmic is also available in packs of 10 x 0.35ml single-dose containers or in a 10ml bottle.

OIC

## Marketing Campaigns

## Dolormin campaign focuses on life's beautiful moments

Beautiful moments in life that are made possible by reliable pain relief are the theme of Johnson & Johnson's latest television advertising for its Dolormin analgesics in Germany.

Johnson & Johnson has chosen the slogan "Das Leben ist zu schön für Schmerzen", which translates as "Life is too beautiful for pain".

A 30-second commercial opens with a smiling man being hit on the head by his young son, who he is carrying on his shoulders. "His daddy just had a headache," a voiceover explains.

The action then changes to an older man energetically waving a wasp away from an ice cream. "He used to find moving painful," the voiceover comments.

A third scene shows a young woman enjoying an exercise class. "At midday, she had period pains," the voiceover notes.

The commercial then points out that Dolormin – "the pain specialist" – offers targeted relief for different complaints, including Dolormin Extra for headaches, Dolormin GS for joint pain and Dolormin für Frauen for menstrual pain. It ends with the campaign slogan.

An 18-second version highlights Dolormin Extra tablets that use the salt ibuprofen lysine to deliver relief from headaches in just 15 minutes.



Johnson & Johnson has revamped the German website for its Dolormin pain relievers

Meanwhile, Johnson & Johnson has enlisted the Plan.Net agency to revamp its brand website at [www.dolormin.de](http://www.dolormin.de). "We want Dolormin to be a competent source on the subject of pain and to make our new slogan of 'Das Leben ist zu schön für Schmerzen' come alive online," explained brand manager Myriam Bloess.

The revamped website offers comprehensive information on Dolormin products; the active ingredient in most of the range, ibuprofen; and types of pain. Tips, leaflets and brochures for download are aimed not only at consumers but also at pharmacists and doctors.

OIC

## Marketing Campaigns

## Stiefel backs Oilatum with online video

Stiefel Laboratories is backing its Oilatum skincare products in the UK with an online video showing parents how to use emollient moisturisers more effectively to treat their child's eczema.

Available on the website of the National Eczema Society at [www.eczema.org](http://www.eczema.org), the video is part of a wider campaign from Stiefel called 'Soak and Smooth to Soothe'. The company said the name of the campaign reminded parents that there were two important steps to follow when using emollients.

These two steps, said Stiefel, were shown in the video that aimed "to help parents understand that a daily soak in the bath, with a fragrance-free emollient added, followed by the smoothing on of a fragrance-free cream will help to soothe and hydrate their child's skin".

Based around a woman applying emollients to a girl's body, the video demonstrates how

they work and the importance of using them. It also includes step-by-step instructions on how to use emollients during and after a bath or shower.

Stiefel said research had found that emollients could be underused, and many people



An online video offering parents practical guidance on how to apply emollients to their child's skin is the latest tool Stiefel Laboratories is using to support its Oilatum brand in the UK

did not understand why they were so important in treating eczema.

The company also highlighted that a survey had found that the majority of pharmacists had never given patients written information on how to treat a child's eczema, or demonstrated how to apply emollient creams.

Stiefel said that it was "urging pharmacists to help educate their customers on the importance of regular and correct use of emollients" through a trade public relations campaign.

### Advertising in women's magazines

In addition, the company is backing Oilatum with a consumer public relations campaign, and will run press advertising in women's magazines during December and January.

A company spokesperson added that Stiefel planned to offer parents additional educational materials, and further advertising would be unveiled next year.

The Oilatum range of emollients includes Junior Bath, Junior Cream and Shower Gel.

OIC

Launches

# Swiss company Mepha enters herbals market

Mepha Pharma is building on its position as Switzerland's leading generics player by launching a range of herbal medicines sold by their active ingredient.

The first two herbal medicines introduced by Mepha are coated tablets containing 20mg monk's pepper (agnus castus) extract for premenstrual syndrome, and St John's wort (hypericum) coated tablets in 250mg and 500mg strengths for anxiety and mild depression.

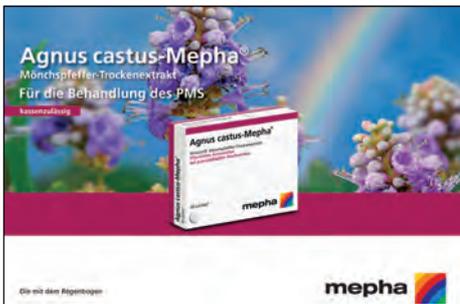
Next year, the Swiss company intends to launch herbal remedies for joint pain and ner-

vous heart complaints. "Further products are in the pipeline," Mepha added.

The Swiss firm believes herbal medicines are a strategically sound addition to its portfolio of generics, value-added generics and branded OTC and prescription drugs. "Mepha is responding to the growing trend for natural therapies," stated the company, which had revealed earlier this year that it planned to push into herbals (*OTC bulletin*, 10 February 2010, page 2).

Mepha plans to market its herbal medicines, which will be reimbursed by Switzerland's health insurance funds, through pharmacies and, where applicable, drugstores and self-dispensing doctors.

According to the Swiss company, its retail selling prices for Agnus castus-Mepha and Hypericum-Mepha are comparable with other leading products containing the same active ingredients. The monk's pepper product retails at CHF20.65 (€15.45) and CHF53.65 for packs of 30 and 90 tablets respectively, while prices for the St John's wort remedy range between CHF16.80 and CHF57.60.



Agnus castus-Mepha is one of two herbal medicines just launched in Switzerland by Mepha

Neue, große  
**TV-Kampagne**  
ab Oktober!

Bringt das innere Gleichgewicht zurück

ARD

Großer Werbedruck (330 Millionen Kontakte)

Starke Aufmerksamkeit in der Zielgruppe Frauen 40+

Hohe, getestete Kaufaktivierung

Entspannen am Tag. Schlafen in der Nacht.

Neurexan

wirkt schnell und natürlich

Biologische Heilmittel Heel is investing "a seven figure sum" in a new television campaign for its Neurexan homeopathic anxiety remedy in Germany. Since 11 October, a 30-second commercial – developed by the BrawandRieken agency in Hamburg – has been running on the ARD and ZDF channels.

By using images of a woman walking along a quiet beach, BrawandRieken said it was creating "an oasis of calm amid commercial breaks". The key visual image of a flying seagull – said to symbolise inner balance and coasting above troubles – also appears on revamped packaging.

Heel is also supporting Neurexan – a formulation including passionflower, oat and coffee-bean dilutions – with press advertising, including a trade-press campaign that highlights the television commercial's appeal to the brand's target audience of women aged 40 years and older.

Line Extensions/Marketing Campaigns

# McNeil adds colour to Nicorette Inhalator in the UK

McNeil Products is offering Britons black and blue mouthpieces for its Nicorette Inhalator smoking-cessation aid as well as the original white version.

Commenting on "the more comprehensive colour range", the company said that it should "broaden the product's appeal, by improving the look of the inhalator and providing more op-

tions to support smokers in their quit attempt".

McNeil is currently backing Nicorette Inhalator with a multimedia marketing campaign, including a television and cinema commercial, trade-press advertising and a microsite at [www.nicorette.co.uk](http://www.nicorette.co.uk).

First seen in May, the commercial recreates "memorable" film scenes with actors using inhalators rather than cigarettes. Created by the agency AMV BBDO, it includes scenes from a western, a romance, and a 'teen' movie.

Furthermore, visitors to the main Nicorette website can register for a money-off coupon, which enables them and up to three friends to receive £1.00 (€1.14) off a pack of 42 Nicorette Inhalator cartridges.

A pack containing the new blue and black mouthpieces has a recommended retail selling price of £1.99. Consumers can also buy the black mouthpiece together with 42 cartridges in a pack priced £21.99.

Another new addition to the Nicorette range



McNeil Products has extended its Nicorette Inhalator with black and blue mouthpieces in the UK

ACTIVE INHALATION HAND TO MOUTH ACTION OCCUPIES THE HAND

NICORETTE Inhalator sure is effective, partner

Acts like a cigarette replacement, and helps control cravings. Up to 1 in 3 smokers remained abstinent at 12 weeks.\*

A multimedia marketing campaign for Nicorette Inhalator is based around recreated scenes from movies with cigarettes replaced by inhalators

will soon be introduced in the UK.

# OTC Marketing Awards

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](http://www.otc-bulletin.com/awards)  
to find out more



Sponsored by



OTC Marketing Awards 2011

# Don't miss the deadline for our headline Awards

Urgent action required. The entry deadline for **OTC bulletin's** OTC Marketing Awards 2011 is fast approaching. Friday, 3 December 2010 is just five 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.

Entry Information Packs can be downloaded from the Awards website at [www.otc-bulletin.com/awards](http://www.otc-bulletin.com/awards).

Companies of all sizes – from the biggest down to the smallest – have the opportunity to win one of **OTC bulletin's** prestigious OTC Marketing Awards 2011.

Nineteen categories cover a wide range of disciplines in the OTC industry, including internet advertising, out-of-home advertising, television advertising, trade advertising, pharmacy training, public relations initiatives and packaging design. And retailers could win the Award

for Best OTC Multiple Retailer of the Year.

The 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 – 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](mailto:jenna.lawrence@otc-bulletin.com) or [val.davis@otc-bulletin.com](mailto:val.davis@otc-bulletin.com)). Or visit the Awards website at [www.otc-bulletin.com/awards](http://www.otc-bulletin.com/awards).

**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**

**Visit the Awards website at**  
**[www.otc-bulletin.com/awards](http://www.otc-bulletin.com/awards)**

**IN BRIEF**

■ **JOHNSON & JOHNSON** is supporting its **Compeed** footcare products in the UK with a consumer public relations campaign offering tips to women on how to maintain their feet while partying in high heels during the festive season. Firstly, the company recommends Compeed Overnight Cracked Heel Cream, which it said “intensively moisturises to regenerate and revitalise the appearance of cracked heels while you sleep”. It then urges women to “be prepared for blisters” with Compeed blister patches, which “seal the wound completely”, and Compeed Anti-Blister Stick, which “utilises a special lubricant to help prevent friction and blistering”. In addition, the firm suggests avoiding ill-fitting shoes, varying shoe types and varying heel heights from day-to-day.



People who feel tired and have trouble concentrating, such as students and sportspeople, are the target users of CioGen, a dietary supplement drink launched into German and Swiss pharmacies by Germany's 2o2pharma.

Launch trade-press advertising claims that CioGen concentrate – when mixed into water or fruit juice – helps the body to make better use of the oxygen breathed in normally. Users, the Heidelberg-based firm insists, will have “more energy and will generally feel fitter and more active”.

The supplement is based on two ‘natural’ ingredients: alpha-ketoglutaric acid (AKG), a key substance in the citric-acid cycle that is claimed to “increase oxygen saturation in cells”; and 5-hydroxymethylfurfural, an organic compound found in dried fruit, milk, wine and honey that 2o2pharma says supports the function of AKG.

A 500ml bottle of CioGen – sufficient for five or six days – has a recommended retail price of €28.75.

The German firm plans to use the CioGen brand to launch in Germany a more highly concentrated dietetic food that employs the same formula. The product is already available in Austria under the Sanopal name.

**1. Wahl bei ersten Anzeichen\***  
denn Umckaloabo® packt den Infekt\* an der Wurzel!

- Verstärkt die Virenabwehr
- Hemmt die Bakterienvermehrung
- Löst zähen Schleim

Massive PRINT-WERBUNG ab Oktober 2010!

Auch als Tabletten

**Umckaloabo**  
FÜR MICH NATÜRLICH BESSER

Umckaloabo's unusual name is the focus of the latest consumer-press advertising for the pelargonium-root remedy unveiled by Germany's ISO-Arzneimittel.

A headline states "Unaussprechlich, aber ausgesprochen gut", which translates as "Unpronounceable, but unspeakably good".

Current trade-press advertising for the bronchitis treatment highlights the consumer campaign, which is running in women's, pharmacy-customer and television-listing magazines. It also claims that Umckaloabo is "the first choice at the first sign" of illness because the pharmacy-only herbal medicine "attacks the roots of the infection".



Sachets of granules that can be taken without water are the latest addition to the Eunova multivitamin brand marketed by Stada's Hemopharm in Germany.

From this month, packs of 20 and 40 Eunova Multi-Vitalstoffe Direkt are available from German pharmacies with recommended retail prices of €8.95 and €16.60. The granules provide not only vitamins and minerals but also lutein.

Hemopharm is promoting the newcomer through a brand advertising and public-relations campaign featuring heavyweight boxing champions Vitali and Wladimir Klitschko (OTC bulletin, 29 September 2010, page 17).

**IN BRIEF**

■ GALEN said its **Laxido Orange** treatment for chronic constipation and faecal impaction in the UK was now sugar-free. The pharmacy (P) medicine – which contains macrogol 3350, potassium chloride, sodium chloride and sodium hydrogen carbonate – is supplied in single-dose sachets of powder that should be dissolved in water and taken as a drink.

Line Extensions

# Benylin Mucus Cough gains two new variants in the UK

McNeil Products has extended its Benylin Mucus Cough in the UK with decongestant and menthol versions in the run up to the product's second winter season.

The company pointed out one of the newcomers – Benylin Mucus Cough Plus Decongestant Syrup – was the only medicine in the Benylin portfolio to combine guaifenesin with pseudoephedrine.

Straplines on the packaging highlight that the pharmacy-only (P) medicine "Reduces nasal & chest congestion" and "Thins and loosens chest mucus".

Benylin Mucus Cough Plus Decongestant Syrup comes in a 100ml bottle with a recommended retail selling price of £3.49 (€3.95). Each 5ml of liquid contains 30mg of the decongestant pseudoephedrine hydrochloride together with 100mg of the active ingredient in original Benylin Mucus Cough, guaifenesin.

The second new addition – Benylin Mucus Cough Menthol – is claimed to contain a "unique extra menthol formula" which provides a "soothing sensation and invigorating taste".

Noting the newcomer had "a max strength formula you can really feel", McNeil said that it "works deep down to loosen phlegm, clear bronchial congestion, and make your cough more productive".

The general-sales list (GSL) medicine has a recommended retail selling price of £5.09 for a 150ml bottle. Each 5ml of cough syrup contains 100mg guaifenesin.

McNeil said that it would back the expanded Benylin Mucus Cough range this winter with an "extensive" marketing campaign.

An updated version of the "mucus monkey" television commercial will run from November until January on terrestrial and satellite channels. The 30-second commercial will comprise a 20-second section backing Benylin Mucus Cough followed by a 10-second tag supporting Benylin Mucus Cough Menthol.

In the original commercial, which made its debut last year, the problems caused by mucus are portrayed by the mucus monkey clinging onto a man's chest (OTC bulletin, 30 November 2009, page 16).

Benylin Mucus Cough Menthol is also sponsoring primetime television programme *The Alan Titchmarsh Show* on ITV until the end of this year. The deal includes spots aired around the show based on the theme "get it off your

**A max strength, unique formula you can really feel**

NEW

Benylin MUCUS COUGH MENTHOL 100 mg/5 ml Syrup

Reduces Chest Congestion

Thins and loosens chest mucus with an immediate menthol sensation and invigorating taste.

**Get it off your chest**

Benylin McNeil

UK trade-press advertising for new Benylin Mucus Cough Menthol highlights that the medicine provides an "immediate menthol sensation and invigorating taste"

Benylin MUCUS COUGH Plus DECONGESTANT SYRUP

Guaifenesin & Pseudoephedrine

Nasal & Chest Congestion Relief

Thins and loosens chest mucus

REDUCES NASAL & CHEST CONGESTION

A decongestant syrup containing pseudoephedrine and guaifenesin is one of two new additions to McNeil Products' Benylin Mucus Cough medicine in the UK this winter

chest", and a quiz on coughs at [www.itv.com](http://www.itv.com).

Furthermore, McNeil is backing the brand with press advertising in women's weekly magazines, as well as trade-press advertising and advertorials. The company also plans to launch a Facebook application allowing consumers to share experiences of coughs, colds and flu.

Other activity for the brand includes a public relations campaign fronted by celebrity doctor Hilary Jones, point-of-sale material, in-store activity, and training and educational materials for pharmacists and their staff.

Meanwhile, McNeil has introduced a larger 300ml bottle of Benylin Mucus Cough to accompany the original 150ml pack.

## NOVEMBER

8-9 November

■ **EuroPLX 44**

Barcelona, Spain

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

Contact: RauCon.

Tel: +49 6222 9807 0.

Fax: +49 6222 9807 77.

E-mail: [meetyou@europlx.com](mailto:meetyou@europlx.com).

Website: [www.raucon.com](http://www.raucon.com).

8-10 November

■ **Pharmaceutical Regulatory Affairs in Latin America**

London, UK

Arturo González-Martínez, Glaxo-SmithKline's director of regulatory affairs for Mexico, will chair this three-day meeting.

Contact: Management Forum.

Tel: +44 1483 730071.

Fax: +44 1483 730008.

E-mail: [registrations@management-forum.co.uk](mailto:registrations@management-forum.co.uk).

Website: [www.management-forum.co.uk](http://www.management-forum.co.uk).

18 November

■ **ASMI Conference**

Sydney, Australia

'Bringing self-care to life' is the theme of this one-day conference, organised by the Australian Self-Medication Industry (ASMI).

Contact: ASMI.

Tel: +61 2 9922 5111.

Fax: +61 2 9959 3693.

E-mail: [conference2010@asmi.com.au](mailto:conference2010@asmi.com.au).

Website: [www.asmi.com.au](http://www.asmi.com.au).

22 &amp; 23-24 November

■ **Regulatory Affairs in Emerging Economies**

London, UK

A pre-conference workshop entitled 'Emergence of Mexico, Argentina, Turkey and the Middle East: practical regulatory advice' will accompany this two-day event.

Contact: Informa UK.

Tel: +44 20 7017 7481.

Fax: +44 20 7017 7823.

E-mail: [registrations@informa-ls.com](mailto:registrations@informa-ls.com)

Website: [www.informa-ls.com](http://www.informa-ls.com).

24 November

■ **Basics of Regulatory Affairs**

Brussels, Belgium

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

Contact: TOPRA.

5-8 November

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

Chinese Taipei

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

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

Contact: 2010 WSMI Secretariat.

Tel: +886 2 8226 1010. E-mail: [2010wsmi.tw@gmail.com](mailto:2010wsmi.tw@gmail.com).

Website: [www.2010wsmi-taiwan.org](http://www.2010wsmi-taiwan.org).

Tel: +44 20 7510 2560.

Fax: +44 20 7537 2003.

E-mail: [meetings@topra.org](mailto:meetings@topra.org).

Website: [www.topra.org](http://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](mailto:workshop@eas.eu).

Website: [www.eas.eu](http://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](mailto:h.wolf-klein@forum-institut.de).

Website: [www.forum-institut.com](http://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](mailto:meetings@topra.org).

Website: [www.topra.org](http://www.topra.org).

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](mailto:registrations@management-forum.co.uk).

Website: [www.management-forum.co.uk](http://www.management-forum.co.uk).

## JANUARY 2011

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](mailto:h.wolf-klein@forum-institut.de).

Website: [www.forum-institut.com](http://www.forum-institut.com).

## FEBRUARY 2011

1-2 February

■ **AESGP Conference**

Brussels, Belgium

This two-day conference – organised by the Association of the European Self-Medication Industry, the AESGP – will focus on food supplements and herbal medicinal products.

Contact: AESGP.

Tel: +32 2 735 51 30.

Fax: +32 2 735 52 22.

E-mail: [l.gits@aesgp.be](mailto:l.gits@aesgp.be).

Website: [www.aesgp.be](http://www.aesgp.be).

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](mailto:weurope_customerservice@economist.com).

Website: [www.economistconferences.com](http://www.economistconferences.com).

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](mailto:meetyou@europlx.com).

Website: [www.raucon.com](http://www.raucon.com).

## MARCH 2011

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](mailto:ptaylor@chpa-info.org).

Website: [www.chpa-info.org](http://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](mailto:h.wolf-klein@forum-institut.de).

Website: [www.forum-institut.com](http://www.forum-institut.com).

28-30 March

■ **DIA Annual EuroMeeting**

Geneva, Switzerland

Christelle Anquez-Traxler of the Association of the European Self-Medication Industry, the AESGP, will be one of the speakers at this three-day conference that is 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](mailto:diaeurope@diaeurope.org).

Website: [www.diahome.org](http://www.diahome.org).

# Review finds few faults with Dutch distribution

*The three-tier classification system for non-prescription medicines in the Netherlands has emerged relatively unscathed from a review commissioned by the government. Deborah Wilkes reports.*

No significant problems have emerged in the Netherlands in the three years since the country's new classification system for non-prescription medicines was introduced, according to a report commissioned by the government. The Nivel Report recommends that the three-tier classification system – whereby non-prescription medicines are authorised as either pharmacy-only, pharmacy/drugstore or general-sale products – should be retained.

Furthermore, the Nivel Report into the three-tier classification system that was introduced on 1 July 2007 sees no reason to change the rules on self-selection displays for pharmacy-only and pharmacy/drugstore medicines. Introduced in 2001, these permit self-selection displays in drugstores, pharmacies and supermarkets with a drugstore licence.

However, the Nivel Report – from the Neth-

erlands Institute for Health Services Research – does demand changes. Consumers should be made more aware of the safe use of non-prescription medicines, insists the report, which also raises concerns about the quality of advice and information provided to consumers by druggists and pharmacists. It suggests that this could be improved by introducing a country-wide mystery shopper programme combined with enforcement.

### Highlighted by television programme

Bernard Mauritz – director of Neprofarm, the Dutch OTC manufacturers' association – told *OTC bulletin* that this issue had been highlighted in a recent television programme in the Netherlands. The majority of druggists and pharmacists had failed to respond to mystery shoppers in the correct way, he noted.

And on a more negative note, the Nivel Re-

port also calls for long-term research into the extent, causes and consequences of misuse of non-prescription medicines, particularly those containing paracetamol.

The report points out that the number of reports of overdoses with self-medication products – particularly paracetamol and ibuprofen – increased between 1999 and 2008. It highlights that the use of important types of self-medication products, such as paracetamol, has also grown. This is mainly due to increasing sales in supermarkets, it maintains.

However, the Nivel Report acknowledges that a direct relationship has not been established between the increase in sales of paracetamol in supermarkets and the rise in the number of overdoses.

Mauritz says a study carried out for Neprofarm by market researcher IMS Health confirmed that sales of small packs of paracetamol in general-sale retail outlets had increased. But sales of large packs of paracetamol in drugstores and pharmacies had also risen, he adds.

Neprofarm hopes that the findings of the Nivel Report will be accepted by the new coalition government led by prime minister Mark Rutte, which has just taken power in the Netherlands. Health minister Edith Schippers is currently evaluating the report before passing her recommendations to parliament for debate.

If the findings of the Nivel Report are accepted by parliament, then this will bring "stability" to the non-prescription market, states Mauritz. Such stability could also encourage supermarkets to step up their investment in the general-sale category, he notes.

The arrival of a new organisation providing an e-learning option for people to obtain a druggist licence could also drive change, he adds, noting that the e-learning option is less expensive than the programme offered by the druggists' association. Mauritz says the e-learning option could provide a cost-effective way for supermarkets to add to the number of drugstores within their outlets.

He points out, for example, that the largest supermarket chain in the Netherlands, Albert Heijn, has a relatively small presence in the non-prescription medicines market at present.

Meanwhile, Neprofarm is hoping to capitalise on the new government's stated intention of driving healthcare out of hospitals and into general practitioners' offices. The industry body aims to show general practitioners how greater self-medication and self-care can free up their time and resources. Mauritz notes that the preliminary results of a study commissioned by Neprofarm into the amount of time spent by general practitioners on minor ailments was due to be presented on 27 October at a meeting organised by the Association of the European Self-

Distribution channel	Sales in 2009 (€ millions)	Change in sales 2008/2009 (%)	Proportion of total (%)
Drugstores (not in supermarkets)	489.8	+0.1	75.2
Pharmacies	103.8	+12.0	15.9
Supermarkets	58.0	+14.0	8.9
<b>Total self-medication market</b>	<b>651.6</b>	<b>+3.0</b>	<b>100.0</b>

Figure 1: Self-medication sales of non-prescription products in Dutch drugstores, pharmacies and supermarkets in 2009 at retail selling prices. Drugstores refers only to stand-alone drugstores and does not include drugstores within supermarkets. Supermarkets covers drugstores within supermarkets as well as supermarkets offering a range of general-sale medicines and/or unlicensed healthcare products, including food supplements (Source – Neprofarm/IMS Health)

Product category	Sales in 2009 (€ millions)	Change in sales 2008/2009 (%)	Proportion of total (%)
Vitamins/minerals	132.1	-2.2	20.3
Cough/cold/pharyngeal	131.4	+6.3	20.2
Analgesics	131.0	+1.0	20.1
Skincare/haircare	67.8	+18.2	10.4
Gastrointestinal	55.3	+12.0	8.5
Genitourinary tract	27.3	-3.7	4.2
Others	106.7	-2.2	16.4
<b>Total self-medication market</b>	<b>651.6</b>	<b>+3.0</b>	<b>100.0</b>

Figure 6: Self-medication sales of non-prescription products by category in Dutch drugstores, pharmacies and supermarkets in 2009 at retail selling prices (Source – Neprofarm/IMS Health)

Product category	Sales in 2009 (€ millions)	Change 2008/2009 (%)
Analgesics	62.6	+4.1
Vitamins/minerals	60.5	+2.4
Cough/cold/pharyngeal	57.9	+6.5
Skincare/haircare	30.7	+25.0
Gastrointestinal	20.7	+7.0
Genitourinary tract	11.0	+6.0
Others	41.9	+3.0
<b>Total chain drugstores</b>	<b>285.3</b>	<b>+6.2</b>

Figure 2: Self-medication sales of non-prescription products by product category in those chain drugstores in the Netherlands that were not in supermarkets in 2009 at retail selling prices (Source – Nephrofarm/IMS Health)

Product category	Sales in 2009 (€ millions)	Change 2008/2009 (%)
Cough/cold/pharyngeal	22.1	+8.4
Analgesics	19.4	+7.4
Skincare/haircare	13.5	+12.2
Vitamins/minerals	13.4	+8.0
Gastrointestinal	13.1	+51.9
Genitourinary tract	3.7	+5.0
Others	18.6	+5.5
<b>Total pharmacies</b>	<b>103.8</b>	<b>+12.0</b>

Figure 4: Self-medication sales of non-prescription products by category in Dutch pharmacies in 2009 at retail selling prices (Source – Nephrofarm/IMS Health)

Medication Industry, the AESGP.

Before the three-tier classification system was implemented on 1 July 2007, all non-prescription medicines were available from both pharmacies and licensed drugstores in the Netherlands. Supermarkets could only sell medicines if they had either a full drugstore licence or a special licence permitting them to sell a limited selection of up to 20 different non-prescription medicines. All supermarkets could sell food supplements.

This pharmacy/drugstore category was joined on 1 July 2007 by two new categories – pharmacy-only and general-sale. Medicines in the general-sale category are available in a broad range of retail outlets, including supermarkets, convenience stores and petrol stations.

On 1 July 2007, all non-prescription medicines were automatically placed in the pharmacy/drugstore category. Companies with products eligible for the general-sale category had to apply for authorisation from the Dutch Medicines Evaluation Board (MEB).

Both the pharmacy-only and general-sale categories have since proved highly controversial. Decisions over the former have provoked the OTC industry, while druggists have had problems with the latter from the start.

The Nivel Report draws attention to the fact that stakeholders queried the MEB's criteria for

classification. It notes that several legal proceedings have been started, but maintains that progress has been made.

At present, only a handful of medicines are in the pharmacy-only category. At the start of 2008, VSM Geneesmiddelen's Hyperiplant St John's wort product became the first medicine to be given pharmacy-only status in the Netherlands (*OTC bulletin*, 25 January 2008, page 8). It has since been joined by a second St John's wort medicine.

Domperidone has pharmacy-only status, as does GlaxoSmithKline Consumer Healthcare's weight-loss medicine Alli (orlistat), which was switched to non-prescription status via Europe's centralised authorisation procedure.

#### Status of proton-pump inhibitors

However, Nycomed's 20mg pantoprazole tablets, which like Alli gained non-prescription status through Europe's centralised procedure, were put into the pharmacy/drugstore category. Another switched proton-pump inhibitor, omeprazole, is also available from both pharmacies and drugstores.

Dextromethorphan will be taken out of the pharmacy/drugstore category and reclassified as pharmacy-only at the beginning of 2011. The Council of State, which is the highest administrative court in the Netherlands, ruled earlier

Product category	Sales in 2009 (€ millions)	Change 2008/2009 (%)
Vitamins/minerals	45.3	-12.1
Analgesics	36.4	-10.2
Cough/cold/pharyngeal	34.4	+2.1
Skincare/haircare	20.0	+9.4
Gastrointestinal	14.5	-5.8
Genitourinary tract	12.0	-13.7
Others	41.9	-11.1
<b>Total independent drugstores</b>	<b>204.5</b>	<b>-7.3</b>

Figure 3: Self-medication sales of non-prescription products by product category in those independent drugstores in the Netherlands that were not in supermarkets or drugstore chains in 2009 at retail selling prices (Source – Nephrofarm/IMS Health)

Product category	Sales in 2009 (€ millions)	Change 2008/2009 (%)
Cough/cold/pharyngeal	17.0	+12.1
Vitamins/minerals	12.9	+7.7
Analgesics	12.7	+14.5
Gastrointestinal	7.0	+15.9
Skincare/haircare	3.5	+45.6
Nicotine replacement therapies	0.5	+12.3
Others	4.4	+17.3
<b>Total supermarkets</b>	<b>58.0</b>	<b>+14.0</b>

Figure 5: Self-medication sales of non-prescription products by product category in Dutch supermarkets in 2009 at retail selling prices (Source – Nephrofarm/IMS Health)

this year that dextromethorphan could be abused and could cause significant side-effects in young children if used incorrectly (*OTC bulletin*, 14 May 2010, page 19).

The decision brought to an end a chain of events that began over two years ago when the MEB decided that all non-prescription medicines containing dextromethorphan should be switched from the pharmacy/drugstore category to pharmacy-only. Several companies appealed against the reclassification, but their concerns were rejected by the MEB. Legal action was then taken by Bayer Healthcare, Daro, Novum Pharma and Procter & Gamble.

Meanwhile, some pack sizes of non-steroidal anti-inflammatory drugs (NSAIDs) look set to join the pharmacy-only category. Oral formulations containing the NSAIDs diclofenac, ibuprofen, ketoprofen and naproxen have non-prescription status in the Netherlands, and form one of the biggest product categories in the Dutch self-medication market.

The MEB recently rejected industry appeals against the reclassification of some pack sizes from the pharmacy/drugstore category to pharmacy-only status. However, the regulatory body also dismissed a move by druggists to halt the reclassification of packs containing up to 12 x 200mg ibuprofen tablets from the pharmacy/

■ Continued on page 22

Continued from page 21

drugstore to general-sale status.

Two years ago, a government committee recommended that these NSAIDs should all be put in the pharmacy-only category. But just under a year ago, the MEB recommended different approaches for different NSAIDs.

The MEB said that packs containing up to 12 x 200mg ibuprofen tablets should have general-sale status, packs of up to 48 x 200mg ibuprofen should be in the pharmacy/drugstore category, and larger packs should be pharmacy-only. For 400mg ibuprofen tablets, packs of up to 24 should be in the pharmacy/drugstore category and larger packs should have pharmacy-only status.

The agency also recommended that 25mg diclofenac tablets and 550mg naproxen tablets should be restricted to pharmacy-only status, while 12.5mg diclofenac tablets and 275mg naproxen tablets should be in either the pharmacy/drugstore or pharmacy-only category depending on the pack size.

Explaining its recommendations, the MEB said diclofenac had more cardiovascular side-effects than ibuprofen, and naproxen had more gastrointestinal side-effects.

**Companies appealed against the decision**

Bayer and Novartis appealed against the MEB's decision to place greater restrictions on diclofenac and naproxen. In addition, druggists appealed against the move to classify 12-tablet packs of 200mg ibuprofen as general-sale.

The MEB's list of active ingredients suitable for general-sale status – which includes aciclovir, cetirizine, loperamide, loratadine and paracetamol – has proved controversial with druggists. The druggists' association failed in an attempt to get cetirizine removed.

The effects of reclassifying non-prescription medicines in the Netherlands are still having an impact on the Dutch self-medication market.

Figures released by Nprofarm in conjunction with IMS Health show that total self-medication sales of non-prescription products, in-

cluding food supplements, in drugstores, pharmacies and supermarkets moved ahead by 3.0% to €652 million at retail selling prices in the Netherlands during 2009 (see Figure 1 on page 20). This compares with a rise of 1.8% in 2008 (OTC bulletin, 30 June 2009, page 10), and 1.4% in the previous year (OTC bulletin, 30 June 2008, page 10).

Meanwhile, prescription-generated sales of non-prescription medicines – mostly private prescriptions with the patient paying for the medicine – reached about €73 million during 2009. This lifted the total market for non-prescription products to €725 million.

**Drugstores remain dominant**

In terms of distribution channels, drugstores remained the most important for self-medication sales of non-prescription products, generating three-quarters of total sales. However, sales through drugstores only edged ahead by 0.1% to €490 million.

More than half of this figure, 58.2%, was generated by the chain drugstores – including Kruidvat and Etos – which reported sales up by 6.2% to €285 million (see Figure 2 on page 21). The remainder came from independent drugstores, which saw a 7.3% decline in sales to €205 million (see Figure 3 on page 21).

Pharmacies did well following the launch of Alli, with sales increasing by 12.0% to €104 million. As can be seen from Figure 4 on page 21, the arrival of Alli pushed gastrointestinal sales up by 51.9%.

But sales in supermarkets, including the Albert Heijn and C1000 chains, recorded the strongest growth, rising by 14.0% to €58.0 million. All of the most important product categories, except vitamins and minerals, achieved double-digit sales growth during the year (see Figure 5 on page 21).

Vitamins and minerals remained the largest seller in drugstores, pharmacies and supermarkets during 2009, despite a 2.2% drop in sales to €132 million. Cough, cold and pharyngeal products were close behind in second place,

Distribution channel	Outlets
Drugstores – multiples	1,442
Drugstores – independents	1,279
Total drugstores	2,721
Pharmacies – multiples	493
Pharmacies – independents	1,473
Total pharmacies	1,966
Total supermarkets	3,830
<b>Total retail outlets</b>	<b>8,517</b>

Figure 7: Retail outlets for non-prescription products in the Netherlands in 2009. Drugstores refers only to stand-alone drugstores and does not include drugstores within supermarkets. Supermarkets covers drugstores within supermarkets as well as supermarkets offering a range of general-sale medicines and/or unlicensed healthcare products, including food supplements. Around 400 supermarkets employ a qualified druggist and may sell pharmacy/drugstore medicines. A further 1,700 sell general-sale medicines. The rest only sell unlicensed healthcare products including food supplements. The figures do not include approximately 250 petrol stations selling general-sale medicines (Source – Nprofarm/IMS Health/KNMP)

with sales up by 6.3% to €131 million. And analgesics, including NSAIDs, were in third place, with sales up by 1.0% to €131 million (see Figure 6 on page 20).

The market data released by Nprofarm and IMS Health includes sales of non-prescription medicines; unlicensed self-medication products such as vitamins, minerals and supplements; herbal remedies; homoeopathic medicines; and self-care medical devices. It also encompasses retailers' own-label ranges.

At the end of 2009, the Netherlands had 2,721 drugstores – 1,442 in a chain and 1,279 independents – together with 1,966 pharmacies and 3,830 supermarkets (see Figure 7 on this page). Around 400 of the supermarkets had a drugstore licence, allowing them to sell pharmacy/drugstore medicines as well as general-sale medicines and unlicensed healthcare products. A further 1,700 supermarkets only sell general-sale medicines.

OIC

Retailers

**NPA appoints Holden as chief executive**

Michael Holden will take over as the new chief executive officer of the UK's National Pharmacy Association (NPA) in 2011.

He replaces John Turk, who left the trade body earlier this year, just two years after joining the NPA (OTC bulletin, 16 April 2010, page 23).

A qualified pharmacist, Holden has spent 30 years in community pharmacy. He is cur-

rently chief officer of the Hampshire and Isle of Wight Local Pharmaceutical Committee, where he is responsible for more than 340 community pharmacies and their interface with the UK's National Health Service (NHS).

He also sits on a number of strategic advisory boards and national committees, including the National Public Health Leadership Forum for Pharmacy.

Commenting on Holden's appointment, the NPA's chairman Ian Facer, said: "He has a clear vision of how community pharmacy can achieve its potential and a strong track record in driving positive change to deliver benefits to patients and to pharmacies."

**Critical time for pharmacy**

Holden added there could not be a "more critical time" to be chief executive of the NPA in view of the "transformational change" expected within the NHS.

OIC

Regulatory Agencies

## Schwerdtfeger is new BfArM boss

Germany's cabinet has named **Dr Walter Schwerdtfeger** as president of the country's federal institute for drugs and medical devices, BfArM. He will take up the post on 1 November 2010, replacing **Professor Johannes Löwer**, who is to retire.

Schwerdtfeger – who lectures at the medical faculty of the University of Bonn – currently leads the medicines and pharmacies department within Germany's federal ministry of health. In this role, he contributed significantly to restructuring BfArM.

He joined the ministry in 1992, having previously worked at the Max Planck Institute for brain research in Frankfurt and the Paul Ehrlich Institute in Langen, which has federal responsibility for vaccines and biological drugs.

Löwer became the temporary director of BfArM three years ago while he was still in charge at the Paul Ehrlich Institute (*OTC bulletin*, 30 November 2007, page 23). He took permanent charge of the regulatory agency towards the end of last year (*OTC bulletin*, 18 December 2009, page 23).

OTC

Retailers

## Boots UK adds to management team

Boots UK – the UK retailing arm of Alliance Boots – has appointed **Sarah Carpenter** as director of commercial development.

A spokesperson for Boots UK told *OTC bulletin* that Carpenter would be responsible for strategy formulation and report to the company's commercial director **Ken Murphy**.

Carpenter had worked with Boots UK in a consultancy capacity for the past few years, the spokesperson added, after she had left the retail group Home Retail.

OTC

### IN BRIEF

■ **CRN** – the US Council for Responsible Nutrition – has given Apple Awards to **Jon Benninger** of Virgo Publishing, **Vasilios Frankos** of Herbalife and **John Wise** of Natural Alternatives International in recognition of their considerable contributions to both the CRN and the dietary supplement industry.

OTC

Manufacturers

## Day is to depart Reckitt but no successor in place

**Colin Day**, Reckitt Benckiser's chief financial officer for the past 10 years, is to leave the rapidly-expanding UK firm on 31 March 2011 to "focus on his portfolio of non-executive positions and other career interests".

Claiming that "effective succession management" was an important business principle within Reckitt Benckiser, the firm said that Day's successor would be announced "in the next few months".

Day's leaving date had been agreed to "ensure a smooth transition and an effective hand-over", Reckitt Benckiser added.

When it was formed a little over a decade ago at the end of 1999, Reckitt Benckiser had annual sales of just over £3.0 billion (€3.37 billion), of which the Health & Personal Care division accounted for just under £400 million (*OTC bulletin*, 29 March 2000, page 4).

Ten years later in 2009, its turnover had more than doubled to £7.75 billion, but its Health & Personal Care sales were five-times larger at just over £2.0 billion (*OTC bulletin*, 26 February 2010, page 4).

Completing its £2.54 billion deal for the UK's SSL International will add another third to Health & Personal Care, taking the business unit's turnover to about £2.8 billion (*OTC bul-*



Colin Day

*letin*, 15 October 2010, page 3).

Commenting that it was a "good time" to appoint a successor to Day who was "keen to focus on leading the company's finance function in support of the next stage of Reckitt Benckiser's growth", the firm's board said Day had made a "significant contribution" to the performance of the business.

"Our appreciation is, in particular, for ensuring strong financial management and control, overseeing excellent cash generation and working with the leadership team on a number of key strategic acquisitions," the board stated, noting Day's successor would inherit a firm in a "strong financial position".

OTC

Manufacturers

## Bélingard leaves Ipsen over strategy

Ipsen said **Jean-Luc Bélingard** was stepping down as chairman and chief executive officer due to "strategic differences" with the board.

The privately-held French pharmaceutical company has appointed **Marc de Garidel** as its new chairman and chief executive officer with effect from 22 November 2010.



Jean-Luc Bélingard

Described by Ipsen as an "industry veteran" with an in-depth knowledge of speciality medicine and experience in overseas business development, de Garidel joins from US biotechnology firm Amgen.

De Garidel would lead the implementation of the company's new strategy, Ipsen pointed out, which included strengthening its operations in the US and emerging markets.

In his 15-year career with Amgen, de Garidel has held numerous senior management positions including vice-president and general manager for France, and vice-president for south-western Europe encompassing Belgium, France, Portugal and Spain. In his current position, he also has responsibility for the emerging markets of Africa, Latin America and the Middle East.

OTC

# OTC *bulletin*

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Finding information is easy these days

But finding **GOOD** information  
is just as tough as ever

That's why **OTC *bulletin*** is  
**Essential Reading**

Published 20 times a year, **OTC *bulletin*** is supplied in a printed format designed to provide you with a regular briefing on the business of consumer healthcare.

Your annual subscription also offers the added value of *news@OTCbulletin* – a free weekly\* electronic newflash which keeps you fully updated with the biggest stories breaking in the consumer healthcare sector.

\* Published around 45 times a year

## SUBSCRIPTION FORM

### PLEASE TICK APPROPRIATE BOXES

I would like \_\_\_\_\_ annual subscription/s to **OTC *bulletin*** at the rate of £595 (£625 outside Europe) for single copies and £345 (£375 outside Europe) for additional copies to the same address

### PAYMENT OPTIONS

I enclose a cheque for £\_\_\_\_\_, or the equivalent in Euros \_\_\_\_\_, drawn on a UK bank  
Cheques should be made payable to **OTC Publications Ltd**

Please send me an invoice

Please debit my credit card for £\_\_\_\_\_

VISA     MASTERCARD     AMERICAN EXPRESS

Card No:

Three/four-digit security code:

Cardholder signature \_\_\_\_\_

Expiry date: \_\_\_\_\_ Date \_\_\_\_\_

### DELIVERY ADDRESS

Name \_\_\_\_\_ Position \_\_\_\_\_

Company \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Tel \_\_\_\_\_ Fax \_\_\_\_\_

E-mail address for *news@OTCbulletin* \_\_\_\_\_

Please return form to:

**OTC *bulletin***, Bulletin Publishing Group, OTC Publications Ltd,

54 Creynolds Lane, Solihull B90 4ER, UK. Or Fax to: +44 (0)1564 777524

Telephone enquiries: +44 (0)1564 777550 E-mail: [info@OTC-bulletin.com](mailto:info@OTC-bulletin.com)

Registered Office: As above. Registered in England No 2765878. VAT No GB 608 0432 69

For more information visit our website at [www.OTC-bulletin.com](http://www.OTC-bulletin.com)