30 June 2010

OTC bulletin

THE BUSINESS NEWSLETTER FOR EUROPE'S CONSUMER HEALTHCARE INDUSTRY

Sanofi-Aventis to catch Canadian firm Canderm

Sanofi-Aventis is set to double the size of its Consumer Health Care business in Canada by acquiring the skincare specialist Canderm Pharma for an undisclosed sum.

The French pharmaceutical firm said that buying the privately-held company would increase its Consumer Health Care sales in Canada to around CA$50 million (€40 million). Canderm reported turnover of CA$24 million in 2009, which represented approximately 10% of Canada's non-prescription anti-ageing skincare market.

Hugh O'Neill, president and chief executive officer of Sanofi-Aventis Canada, said the company planned to consolidate its dermatology portfolio under the Canderm umbrella to create a Canadian leader in medical dermatology.

Canderm's existing portfolio includes cosmeceuticals, physician-recommended dermatological products, physician-practised cosmetic procedures and OTC brands. These include the Cliniderm line of "irritant free" products for sensitive skin and scalp, the NeoStrata anti-ageing range, Rosacure+ for facial redness, and the Lipsorex Plus medicated cold-sore gel.

Canderm is Sanofi-Aventis' second major OTC acquisition in North America this year.

In March, the company entered the US OTC market by paying approximately US$1.9 bil-

■ *Continued on page 27*

Sigma seeks buyer for its Herron brand

Australia's Sigma Pharmaceuticals has put its Herron brand of OTC medicines and food supplements up for sale as it seeks to raise funds to pay off its debts.

Brian Jamieson, Sigma's newly-appointed chairman, said a "competitive" sale process for the Herron brand – which includes products in 16 healthcare categories – had already begun.

■ *Continued on page 26*

McNeil warns on OTC supply

McNeil Consumer Healthcare does not expect to have sources of supply for most of the products made at its Fort Washington manufacturing facility in the US before the end of this year.

The Johnson & Johnson subsidiary stressed that the majority of its US OTC business was

■ *Continued on page 27*

46th AESGP Annual Meeting

Key issues facing Europe's OTC industry were debated at the 46th AESGP Annual Meeting in Croatia. Turn to page 20 for the first part of our conference coverage.

Mergers & Acquisitions

GSK strengthens in Latin America

GlaxoSmithKline has strengthened its business in Latin America by paying US$253 million (€209 million) for Argentine branded-generics firm Laboratorios Phoenix.

Described by GlaxoSmithKline as a "leading Argentine pharmaceutical company focused on developing, manufacturing, marketing and sales of branded generic products", Phoenix generated sales of approximately £70 million (€85 million) in 2009.

Branded prescription generics accounted for the majority of its turnover, with less than 10% coming from its portfolio of non-prescription products, which includes antiseptics, gastrointestinal remedies, and food supplements.

Includes the Plenovit vitamin brand

The company's non-prescription brands include the digestive product AgioFibras and the Plenovit line of vitamins, which offers vitamin C, vitamin E, ginseng, magnesium, melatonin and multivitamin variations.

The deal includes Phoenix' manufacturing facility near Buenos Aires and its established primary-care salesforce.

GlaxoSmithKline's existing Argentine unit, which markets consumer healthcare brands as well as prescription pharmaceuticals and vaccines, posted 2009 sales of around £100 million.

GSK Argentina and Phoenix would remain as two separate legal entities, GlaxoSmithKline noted, and Phoenix would keep its name.

Abbas Hussain, president of emerging markets at GlaxoSmithKline, said that acquiring Phoenix was an "important step forward" in the company's strategy to grow its business in Latin America, a region he described as containing a "key group of emerging markets".

The deal was announced less than a month after GlaxoSmithKline agreed to pay £73.9 million for a 9.9% stakeholding in South Korea's Dong-A Pharmaceutical (**OTC *bulletin***, 31 May 2010, page 3).

OTC

IN BRIEF

■ **ASDA** – the UK supermarket chain owned by Walmart of the US – has agreed to acquire all 193 of Danish retailer Dansk Supermarked's **Netto** stores in the UK for £778 million (€932 million). Asda has 374 stores in the UK at present.

OTC

Licensing Agreements

GlaxoSmithKline makes double cold-sore swoop

GlaxoSmithKline Consumer Healthcare has strengthened its dermatology portfolio by striking two deals that expand its range of cold-sore products.

The UK-based company has acquired the exclusive rights to market Medivir's Xerclear topical cold-sore treatment as a non-prescription medicine in a number of markets. It has also snapped up from Beiersdorf-owned Labtec the exclusive marketing rights to a new topical patch for treating cold sores.

GlaxoSmithKline's existing range of OTC cold-sore products includes the Abreva (docosanol) brand in North America and the Zovirax (aciclovir) brand in a number of markets around the world.

Under the terms of the deal with Medivir, GlaxoSmithKline has gained exclusive rights to commercialise and distribute non-prescription Xerclear – 50mg/g aciclovir and 10mg/g hydrocortisone – under its Zovirax brand name across multiple markets. The two companies said Xerclear was the "first and only topical cold-sore treatment clinically proven to help prevent cold-sore lesions appearing".

GlaxoSmithKline will pay Medivir up to €3.0 million in upfront and pre-launch milestones, as well as up to double-digit royalties on sales. It will also fund ongoing and future commercial development of Xerclear in all territories covered by the deal.

The Xerclear agreement covers Australia, Europe, India, Japan, New Zealand and Russia, but excludes China, Israel, North America, South America and South Korea. GlaxoSmithKline noted that Medivir had retained the rights to prescription Xerclear in all markets.

A spokesperson for GlaxoSmithKline told **OTC *bulletin*** that the product had not yet been approved for non-prescription sale in all of the markets covered by the deal, but non-prescription status would be sought in those markets as soon as possible.

Launches in those markets where Xerclear already had non-prescription status should begin in 2011, the spokesperson pointed out.

Xerclear was authorised in 14 countries in Europe last year through a European licensing procedure. The product has now been approved for sale as a non-prescription medicine in five out of the 14 markets, and as a prescription-only medicine in a further six. The remaining three countries have yet to decide the status of Xerclear.

Medivir launched non-prescription Xerclear in Sweden earlier this year (**OTC *bulletin***, 20 January 2010, page 14).

John Clarke, worldwide president of GlaxoSmithKline Consumer Healthcare, said the deal demonstrated the company's "ongoing commitment to invest in and expand" its OTC business. "It will help strengthen our dermatology portfolio across multiple territories including several key emerging markets," he added.

Meanwhile, GlaxoSmithKline has secured from Labtec the exclusive marketing rights to a new topical patch for treating cold sores.

Details of the markets covered by the deal were confidential, GlaxoSmithKline said.

The agreement gives GlaxoSmithKline access to a patch which Labtec explained could be applied easily and conveniently to the delicate surface of the lip. It had been designed to promote the healing process by maintaining a "moist and optimal healing environment".

Under the terms of the agreement, Labtec has been designated the exclusive manufacturer of the patch for GlaxoSmithKline.

A GlaxoSmithKline spokesperson told **OTC *bulletin*** that Labtec's topical patch was another good addition to the company's substantial cold-sore offering, but it was too early to say how the product would be used.

Three cold-sore deals in quick succession

GlaxoSmithKline has struck three deals in the cold-sore category in a little over six months. In January, the company signed an exclusive licensing agreement with NanoBio Corporation for OTC use of NB-001 – a patented compound that GlaxoSmithKline said had "significant antimicrobial activity against the virus that causes cold sores" – in the US and Canada (**OTC *bulletin***, 20 January 2010, page 2).

GlaxoSmithKline announced in February that it would expand its Consumer Healthcare business by adding a Dermatology unit (**OTC *bulletin***, 26 February 2010, page 1). The new unit brings together GlaxoSmithKline's existing OTC dermatology brands with the consumer dermatology brands gained by acquiring Stiefel Laboratories in April of last year (**OTC *bulletin***, 30 April 2009, page 1).

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Mergers & Acquisitions

Valeant to merge with Canada's Biovail

US-based Valeant Pharmaceuticals is set to merge with Canada's Biovail in a move that both companies claim will create a "leader in speciality pharmaceuticals".

The combined US$1.75 billion (€1.42 billion) operation, they said, would have a "significantly expanded presence in North America and operations in eight other countries". It would work across four growth platforms, they added, and would have the financial strength to pursue "substantial growth opportunities".

Biovail shareholders will hold a 50.5% stake in the combined firm, with Valeant's shareholders taking the remaining 49.5%.

Operating under the name Valeant Pharmaceuticals International, the enlarged company will combine Valeant's existing portfolio of neurology and dermatology products – which includes OTC brands – with Biovail's drug-development operations focused on central nervous system conditions. The new Valeant will also benefit from Biovail's portfolio of third-party prescription products that contain its proprietary drug-delivery technologies.

A spokesperson for Valeant told **OTC *bulletin*** that the merger "should not have any impact" on the firm's OTC business, which includes the CeraVe and Hissyfit skincare brands.

Under the terms of the merger agreement, the combined company will retain Biovail's corporate structure and "related financial efficiencies", the two companies noted.

In exchange for their shares, Valeant stockholders will receive a one-time special dividend of US$16.77 per share and 1.7809 shares of Biovail stock. The deal is expected to close before the end of 2010, subject to approval by both sets of shareholders as well as the regulatory authorities in the US and certain other foreign jurisdictions.

Proforma sales of the new entity would have been US$1.75 billion for the year ended 31 March 2010. Annual cost synergies of at least US$175 million are expected from the second year of operation.

All four of the new Valeant's "key growth platforms" – speciality central nervous system products, dermatology, the Canadian market and branded generics in emerging markets – had experienced proforma double-digit growth, Valeant and Biovail pointed out.

Michael Pearson, Valeant's chairman and chief executive officer, will serve as the new company's chief executive officer, with Bill Wells, chief executive officer of Biovail, serving as non-executive chairman.

The merger comes after a 2009 in which Valeant grew its sales by 26% to US$831 million (**OTC *bulletin***, 31 March 2010, page 3).

This reflected a year dominated by acquisition activity, which saw the company buy Canada's Laboratoire Renaud (**OTC *bulletin***, 18 December 2009, page 7), and Australia's Private Formula International (**OTC *bulletin***, 16 October 2009, page 3). It also made acquisitions in Poland, including gel specialist Emo-Farm (**OTC *bulletin***, 15 May 2009, page 9).

Product sales by the company's Specialty Pharmaceuticals division – including its OTC brands – grew by a third to US$404 million. Sales of branded generics in Latin America improved by 14% to US$155 million, but in Europe they fell by 1% to US$152 million.

Two Brazilian acquisitions

Income from continuing operations was US$258 million, compared with an operating loss of US$207 million a year earlier.

Prior to announcing the merger with Biovail, Valeant agreed to acquire two Brazilian OTC and branded generics firms (**OTC *bulletin***, 31 March 2010, page 3; **OTC *bulletin***, 30 April 2010, page 3), and Canadian OTC dermatology specialist Vital Science Corp (**OTC *bulletin***, 14 May 2010, page 3).

Biovail reported turnover of US$820 million in 2009 – a rise of 8% – with net income falling by 12% to US$177 million. Its business is generated primarily in Canada and the US.

These results followed an operational review in 2008, which led Biovail to switch its focus to developing pharmaceuticals that addressed unmet medical needs in speciality central nervous system disorders.

Built on sales of prescription products that use the company's proprietary drug-delivery technologies – including GlaxoSmithKline's Wellbutrin XL, Sanofi-Aventis' Aplenzin and Ortho-McNeil's Ultram ER – Biovail also owns the promotion and distribution rights to GlaxoSmithKline's Zovirax cold-sore ointment and cream in the US – where it is available on prescription – and markets a range of generics.

IN BRIEF

■ **BASF** is set to acquire specialty chemicals company **Cognis in a deal worth €3.1 billion**. The German firm said the purchase would give it a leading position in personal-care ingredients, strengthen its leading position in value-added products for home care and establish a strong position in health and nutrition.

■ **DANONE** is set to expand its presence in the US nutrition market by acquiring **Medical Nutrition USA** for approximately US$62 million (€50 million). Medical Nutrition's portfolio, including the Pro-Stat drinks brand, is focused on the "long-term care channel". The company posted sales of US$16.0 million in the year ended 31 January 2010. Danone said the deal should close in the third quarter.

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Legal Cases

Supreme Court to hear Matrixx

The US Supreme Court will hear Matrixx Initiatives' appeal against the re-opening of a lawsuit that accuses the firm of not telling investors that its Zicam nasal sprays could cause a loss of sense of smell, or anosmia.

A district court judge had dismissed the lawsuit in 2005, after ruling that the adverse events reported were not statistically significant enough to link the Zicam products to anosmia. However, the ninth circuit appeals court disagreed and re-opened the case last year.

In its filing to the Supreme Court, Matrixx argues that reviving the case had "immense consequences" for pharmaceutical companies, investors and consumers.

The company said that under the appeals court's ruling, a pharmaceutical company that failed to disclose a small number of adverse-event reports could be sued even if the reports were not statistically significant enough to link a drug to the adverse event.

In turn, this would mean all pharmaceutical companies would have to inform investors and consumers of every adverse event reported.

The Supreme Court will rule in the autumn whether the ninth circuit court was correct in disagreeing with the US first, second and third circuit courts, which have all held that drug companies have no duty to disclose adverse event reports until the reports provide statistically-significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use.

Appeals court's decision was in error

William Hemelt, president and chief executive officer of Matrixx, said the company was "pleased" the Supreme Court had agreed to hear the company's case as he believed the appeals court's decision "was in error".

Meanwhile, Matrixx is facing numerous consumer and investor lawsuits after it voluntarily withdrew two of its Zicam Cold Remedy products from the US market.

The withdrawals came after the US Food and Drug Administration (FDA) issued the company with a Warning Letter last year citing consumer reports that the intranasal products could cause a loss of sense of smell (**OTC *bulletin***, 19 June 2009, page 15).

The FDA has so far rejected two requests from Matrixx to withdraw the Warning Letter (**OTC *bulletin***, 17 March 2010, page 8).

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Business Strategy

Merck turns to Adcock in South African market

Merck & Co and Adcock Ingram have joined forces in South Africa to promote a number of Merck's prescription medicines and OTC products.

The two companies have agreed a five-year strategic collaboration to co-promote and distribute the established products in South Africa.

OTC products covered by the deal include the nasal decongestants Afrin and Drixine; the antihistamines Clarityne, Neoclarityne and Deselex; the cough, cold and flu brand Demazin; and the antifungal Tinaderm. Merck obtained these when it acquired Schering-Plough last year (**OTC *bulletin***, 17 March 2009, page 1).

Prescription medicines include Cozaar for hypertension, Fosamax for osteoporosis, Singulair for asthma and Zocor for high cholesterol.

The collaboration will be managed by a joint operating committee comprising representatives from both US-based Merck and South Africa's Adcock Ingram. No financial details of the deal were disclosed.

Stefan Oschmann, president of emerging markets at Merck, said the collaboration was part of the company's long-term expansion strategy. "We will strive to expand our presence across emerging markets by actively seeking local collaborations," he said.

Jonathan Louw, chief executive officer of Adcock Ingram, said the deal would enhance the company's diverse portfolio and broaden its offering in the marketplace.

Emerging markets such as South Africa were expected to account for over 25% of Merck's global pharmaceutical and vaccine sales by 2013, the company pointed out.

To achieve this goal, Merck said it intended to "continue successfully to launch new products, and optimise its robust in-line portfolio of medicines, vaccines, follow-on biologics and consumer-care products". The firm added that it would "fully leverage the market for branded generics with its portfolio of mature brands as well as targeted business development".

OTC

Business Strategy

BPI boss invests in OrganoBalance

German probiotic bacteria specialist OrganoBalance has secured "substantial investment" from Bernd Wegener, chairman of the association of the German pharmaceutical industry, the BPI.

OrganoBalance said Wegener – who is also executive chairman of biotech firm BRAHMS – would take a "position of responsibility" in the company's management team. The size of his stake has not been disclosed.

By focusing on developing bacterial strains and its Oassys microbiological screening, OrganoBalance is developing "new biological products in the area of pharmaceuticals, preventive healthcare, nutrition and cosmetics".

The Berlin-based company last year launched with BASF a product called pro-t-action that uses *Lactobacillus paracasei* bacteria that is said to bind to and eliminate the *Streptococcus mutans* bacteria that cause tooth decay. According to BASF, the active ingredient can be "easily integrated into everyday consumer products like toothpaste, mouthwash, candies, lozenges and chewing gums".

OrganoBalance also last year agreed a partnership with bioanalysis specialist Chemel.

"We are truly delighted that an expert of Dr Wegener's immense scientific distinction and experience will join our team," commented Christine Lang, managing director of OrganoBalance.

Developing new active substances

"With his support and commitment, we will be able to pursue our strategy of developing new active substances for the pharmaceutical industry much more rapidly and efficiently than previously planned," Lang insisted.

Wegener believed the "patentable micro-organisms" that OrganoBalance was developing would lead to "new diagnostic and therapeutic concepts and procedures, particularly for hitherto inadequately treatable indications".

Before founding BRAHMS in 1994, Wegener worked for companies including Boehringer Ingelheim, Degussa, Marion Merrell Dow and Henning Berlin.

OTC

Mergers & Acquisitions

Celesio and Phoenix in Dutch tie-up

Celesio and Phoenix Pharmahandel have agreed to combine their Dutch pharmacy businesses to create the country's second-largest pharmacy chain with 115 fully-owned stores and 40 franchise-partner pharmacies.

The joint venture will see Celesio's Lloyds Apotheken chain transferred to Phoenix' Brocacef Holding subsidiary, which comprises the Escura Apotheken pharmacy chain and Brocacef wholesaling unit. Celesio will receive a 45% stake in Brocacef Holding.

The enlarged Brocacef Holding will generate annual sales in excess of €1.1 billion, and employ more than 1,600 people.

Celesio said the deal would not affect its Apotheek DocMorris, Movianto Nederland or Celesio Finance businesses in the Netherlands.

Fritz Oesterle, chairman and chief executive officer of Celesio, said the partnership "set the right course for remaining competitive and successful in the Dutch market in future".

In January of this year, Oesterle said that Celesio was "evaluating whether to continue its pharmacy operations" in Ireland, Italy and the Netherlands, after it had cut goodwill valuations across all three countries by over €200 million (**OTC *bulletin***, 20 January 2010, page 6).

Celesio cut the goodwill valuation of its Dutch pharmacy chain by €87 million in October of last year, following the introduction of generics tendering in all but name, which the company claimed had reduced the earning power of Dutch pharmacies (**OTC *bulletin***, 16 October 2009, page 1).

Celesio said that once the joint venture had been approved by the Dutch anti-trust authorities and other relevant bodies the 62 Lloyds Apotheken stores would be merged with the Escura outlets to produce the second-largest pharmacy chain in the Netherlands. The enlarged chain will have 115 fully-owned stores and 40 franchise-partner pharmacies operating under the Escura name.

The Netherlands' leading pharmacy chain, Mediq, had 206 pharmacies at the end of 2009.

Frank Große-Natrop and Johan Eeken will retain their positions as chief executive officer and chief financial officer of Brocacef. Bart Tolhuisen, managing director of Lloyds Apotheken, will take responsibility for the enlarged retail operation.

Oesterle said the joint venture would "significantly improve" the service portfolio and performance of both Celesio and Phoenix in the Netherlands without the need for additional capital investment.

He added that the deal was in line with Celesio's decision to "reassess its activities in the pharmacy business in countries where it has a rather small market share". The firm would then determine its next strategic steps, he said.

Brocacef Holding currently generates annual turnover of €1.0 billion from the Escura pharmacy chain and Brocacef wholesale business.

Meanwhile, Celesio's Dutch pharmacy chain reported sales of €173 million in 2009 from 67 stores across the Netherlands. The chain accounted for 5.4% of total sales by Celesio's Retail Pharmacies business, which reported turnover of €3.18 billion (**OTC *bulletin***, 31 March 2010, page 4).

Medco joint venture in Europe

Celesio has also announced a pan-European joint-venture with the US-based pharmacy benefit manager Medco Health Solutions.

Starting in Germany, Medco Celesio would focus on providing integrated pharmacy solutions to improve care for patients with chronic and complex health conditions such as asthma, diabetes, high-cholesterol and heart disease, the company said.

The 50/50 joint venture would then be rolled out into other major European markets, the company noted, including France, Italy, Spain and the UK. Going forward, the plan was to introduce the joint-venture into as many as 27 European Union member states plus Norway and Switzerland, the company said, depending on the respective market needs.

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Business Strategy/Results Forecast

Stada to slash 800 full-time jobs

Stada Arzneimittel says it will cut around 10% of its workforce – or 800 full-time positions – as it aims to double its net profit to €215 million by 2014. The job losses will fall in "all company divisions and regions", although the bulk of the cuts will come outside of the German group's home market.

Redundancy costs will form part of an expected €50 million in expenses related to the group's 'Build the future' cost-optimisation project, which Stada expects to complete in 2013. Additional investments linked to the project are slated to be around €20 million.

By cutting its operating costs, the German group expects by 2014 to improve its earnings before interest, tax, depreciation and amortisation (EBITDA) by 54% – equivalent to an average 9% annual gain – to €430 million.

Stada also foresees an average 6.5% annual turnover growth over the next five years, rising from €1.57 billion in 2009 (**OTC *bulletin***, 16 April 2010, page 4) to €2.15 billion by 2014. The forecasts are based on organic growth and assume no significant disposals as well as constant exchange and interest rates. This year, Stada expects to achieve sales growth as well as an improvement in all key earnings figures, adjusted for one-time special effects.

The company unveiled its long-term targets ahead of its annual general meeting during which its shareholders rejected an option for Stada to buy up to 10% of its own shares.

In April, Hartmut Retzlaff, Stada's chairman and chief executive officer, said that the company's board was open to takeover offers or partnership deals involving "significant capital investment". He added that he would not be surprised if parties interested in strengthening in Germany looked at Stada.

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Mergers & Acquisitions

Recordati enters Romanian market

Recordati has moved into Romania after snapping up marketing and distribution company ArtMed International and its portfolio of five prescription and OTC brands for an initial €1.2 million.

The Italian pharmaceutical firm said ArtMed was one of the first independent companies in Romania to offer "integrated marketing and promotional services for prescription and OTC products" targeting physicians and pharmacists.

Under the terms of the deal, Recordati will pay €1.2 million for ArtMed, plus an earn-out based on the gross profit of the five brands ArtMed markets under licence.

Two of ArtMed's five brands – Dills Digestive Mints and the EQI weight-control product – are available OTC in Romania.

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Business Strategy

Mentholatum invests £10m to treble Scottish capacity

Mentholatum has trebled the manufacturing capacity at its plant in Scotland to 42 million tubes of product a year.

The company has spent £10 million (€11 million) developing its European headquarters near Glasgow, where the topical analgesics Deep Heat, Deep Freeze and Deep Relief are among the products made.

Andrew Tasker – Mentholatum's UK managing director and vice-president in charge of the UK, Europe, the Middle East and Africa – said the investment would help expand both the company's UK and global export businesses. Mentholatum intended to increase its annual sales by a third to around US$400 million (€325 million) by 2013, he promised.

As well as investing in "new generation plant", added Tasker, Mentholatum had created an "advanced research and development facility". He stated that the company aimed to bring "world-class innovation steeped in the very latest science, ingredients and delivery technology to consumer healthcare".

Mentholatum recently launched the Regenovex range of joint-health products in the UK.

An advanced research and development facility has been created at Mentholatum's European headquarters near Glasgow, Scotland, says Andrew Tasker, Mentholatum's UK managing director and vice-president in charge of the UK, Europe, the Middle East and Africa

The oral capsules, topical gel and patch contain a combination of hyaluronic acid and the green-lipped mussel extract Bionovex Oil (**OTC *bulletin***, 30 April 2010, page 15).

The plant in Scotland is one of seven factories owned by Mentholatum's parent company, Rohto, which has annual sales of around US$1.1 billion. The Japanese company has five research and development facilities.

OTC

Licensing Agreements

Boehringer licenses antiviral nasal spray

Boehringer Ingelheim is set to expand its Mucosolvan cough and cold brand with an antiviral nasal spray after signing a licensing agreement with development firm Marinomed Biotechnologie.

The German firm has acquired the rights to market Marinomed's nasal spray for treating the common cold under the Mucosolvan name in Australia, Europe – excluding Austria and the UK – Russia and the Commonwealth of Independent States, South America and parts of Asia.

Sigmapharm Arzneimittel has launched the spray under its Coldamaris brand in Austria; Biotis has launched it in Israel; and Liba Laboratuarlari has introduced it in Turkey.

Class IIa medical device in Europe

Austria-based Marinomed said the spray was based on its "mavirex" antiviral respiratory technology platform, which it had used to develop therapies that target more than 200 different respiratory virus strains. The product is a Class IIa medical device in the European Union.

Use of the mavirex platform for treating influenza and in combination products was not included in the agreement, Marinomed pointed out.

Under the terms of the deal, Boehringer will make an upfront payment in the "million Euro range" to Marinomed, as well as milestone and royalty payments.

Boehringer Ingelheim's ambroxol-containing Mucosolvan range for productive cough already offers a dual-action syrup, dual-action soft lozenges, a syrup for children and one-a-day capsules, as well as effervescent and standard tablets.

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Switches

UK MHRA consults on GSL 5% minoxidil

A stronger minoxidil-based hair-regrowth solution for men will soon be available on general sale in the UK, if a switch consultation from the Medicines and Healthcare products Regulatory Agency (MHRA) is given the go-ahead.

Johnson & Johnson's McNeil Products subsidiary is seeking to switch 5% w/v minoxidil cutaneous solution from pharmacy to general-sale list (GSL) status. GSL status already applies to 2% minoxidil formulations.

The stronger GSL medicine would continue to be sold under the Regaine for Men Extra Strength Scalp Solution brand name.

The MHRA's ARM 67 consultation document notes Regaine for Men Extra Strength Scalp Solution would be indicated for "treatment of alopecia androgenetica in men aged between 18 and 65".

ARM 67 points out the Regaine for Men Regular Strength and Regaine for Women Regular Strength – both of which contain 2% minoxidil – have been available as GSL medicines since 2002 and there has not been "any detectable change in the safety profile" since the reclassification.

For any topical minoxidil product to be effective it must be used regularly and continuously, ARM 67 continues, adding that if use is discontinued "hair loss reverts to the level it would have reached had the product never been used".

Therefore, argues the consultation document, wider availability of Regaine for Men Extra Strength will benefit patients in terms of convenience and its presence on the shelf in retail outlets will prompt patients to purchase when they might otherwise have forgotten and thereby assist compliance.

Addressing the removal of professional advice from the sale process, the ARM 67 document says that GSL availability of the product will also be convenient to those consumers who might suffer embarrassment when asking for a treatment for their hair loss.

Given the safety precedent already established, this benefit is considered sufficient to "outweigh any advantage gained from professional advice at point of sale", the document explains.

■ Comments on ARM 67 should be sent by 6 July 2010 to Veronica Alexander, Reclassification Unit, Medicines and Healthcare products Regulatory Agency, Room 14-138 Market Towers, 1 Nine Elms Lane, London SW8 5HQ, UK (E-mail: reclassification@mhra.gsi.gov.uk).

OTC

Industry Initiatives

BAH's green scheme wins marketing prize

Germany's medicines manufacturers' association, the BAH, has won a prize for a campaign to promote its 'green prescription' scheme, whereby German doctors write recommendations for non-reimbursable, non-prescription medicines on notes that look like prescribing pads.

The jury for the Health Media Award – organised by EEC Network and Stiftung Gesundheit – said there was strong evidence that the promotional push had influenced the behaviour of doctors.

The campaign included waiting-room posters and order forms, many of which were distributed through the doctors' magazine *Ärzte Zeitung*. Furthermore, the pharmacists' magazine, *Pharmazeutischen Zeitung*, was used to encourage pharmacists to order green prescribing pads and forward them to doctors.

According to the BAH, approximately 15 million green prescription forms had been distributed to general practitioners in Germany since it started a push a year ago to encourage doctors to use the scheme (**OTC *bulletin***, 30 April 2009, page 15).

Quoting IMS Health data, the industry association said the number of recommendations for non-prescription medicines via the scheme had increased by a tenth in 2009 and by 15% in the fourth quarter of the year.

"Almost 70% of all general practitioners now use green prescriptions in their practice," the BAH stated.

Meanwhile, the association added that a survey conducted by Institut für Demoskopie Allensbach had discovered that 56% of Germans were aware of the scheme, which has been running since 2004.

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Switches

New Zealand gives okay to non-prescription rizatriptan

Merck & Co's Maxalt Melt 5mg rizatriptan wafers will have non-prescription status in New Zealand from July.

The Medicines Classification Committee has given the go-ahead for the medicine to be switched from prescription to pharmacist-only status for the acute treatment of migraine with or without aura.

Two triptans – GlaxoSmithKline Consumer Healthcare's sumatriptan tablets and AstraZeneca's zolmitriptan nasal spray – are already available as pharmacist-only medicines for migraine in New Zealand.

Merck & Co pointed out that unlike the other products, Maxalt Melt was supplied as an orally-disintegrating tablet that could be taken without water. The company noted that the format was more palatable to some people than conventional oral tablets.

At its meeting in April – for which minutes have just been released – the Medicines Classification Committee said the safety profile of rizatriptan was "not significantly different" from that of other triptan medicines that had recently been reclassified.

The committee also noted that the wafer had advantages over tablets and capsules, as migraine was often accompanied by nausea and vomiting. It agreed that consumer convenience would be enhanced if a range of similar medicines were sold with the same classification.

Johnson & Johnson's application to switch its Imodium (2mg loperamide) antidiarrhoeal from pharmacy-only to general-sale medicine was given the go-ahead by the committee.

However, the committee turned down Reckitt Benckiser's application to switch Strepfen (8.75mg flurbiprofen) sore-throat lozenges from pharmacy-only to general-sale status. It also rejected Johnson & Johnson's application to switch its Regaine for Men (5% minoxidil) hair-regrowth product from pharmacy-only to general-sale status.

Meanwhile, the Medicines Classification Committee said it had not considered switching topical medicines containing calcipotriol from prescription to pharmacist-only status (**OTC *bulletin***, 26 February 2010, page 12). An application had been incorrectly published in its agenda for the April meeting, it said.

The committee has, however, decided that calcipotriol should be classified as a prescription medicine except when a maximum of 30g or 30ml was sold by a pharmacist to an adult with mild to moderate psoriasis that had previously been diagnosed by a doctor.

The move followed a submission from the retail group PharmacyBrands for calcipotriol cream, ointment and scalp formulations.

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IN BRIEF

■ **MELDEX INTERNATIONAL** has signed up **Al-Mawarid Drug Store** to sell and distribute its Menoflavon range of menopause supplements in Jordan. The UK-based firm has also agreed a global licensing agreement for its Kudos range of vitamins and herbal products with **Meadow Laboratories**, which will see the products introduced into Serbia this year and other export markets at a later date.

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Markets

British OTC market still sluggish in 2009

Sluggish is a good way to describe the progress of the British OTC market last year, judging by the figures just released by the Proprietary Association of Great Britain (PAGB) in conjunction with market research agency IRI. British OTC sales of non-prescription medicines and food supplements increased by just 0.7% to £2.36 billion (€2.87 billion) at retail selling prices in 2009.

The market performance was in line with 2008, when sales crept forward by 0.5% (**OTC *bulletin***, 30 June 2009, page 8). However, it was sluggish compared with 2007 and 2006, when sales grew by 4.8% and 1.8% respectively.

Martin Wood, business unit director of IRI, said the market had been boosted by the launch of GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine, but had been held back by the recession and declining sales of cough, cold and flu products.

Wood pointed out that Alli had been the most successful prescription-only to pharmacy (POM-to-P) switch of the past 20 years in terms of standard IRI launch criteria. As can be seen from Figure 1, the arrival of the weight-loss medicine containing the active ingredient orlistat pushed up sales of weight-management products by 52.9% to £71.7 million.

Other newcomers driving overall market growth, added Wood, were Novartis Consumer Health's Voltarol Pain-Eze, Reckitt Benckiser's Optrex ActiMist, and some food supplements in the women's health sector. Optrex ActiMist – a premium-priced spray-on product for dry eyes – helped lift sales of eyecare treatments by 15.1% to £55.7 million in 2009.

Commenting on the impact of the recession, Wood said there had been "strong growth" in sales of own-label OTC products. "Consumers are increasingly well-informed about price," he maintained.

Wood added that people had cut back on purchasing generally, and they were probably using up existing household stocks rather than buying ahead. He noted that IRI had also identified this trend in the toiletries market.

Furthermore, he continued, there had been a decline in volume sales in some categories that had previously seen steady sales growth. This trend was particularly apparent for travel and indigestion products, he said.

Increasing unemployment was also having an effect, remarked Wood. "Patients have more time and less money," he explained "and free prescriptions make OTC purchases less attractive, especially for more expensive lines."

Product category	OTC sales in 2009 (£ millions)	Change 2008/2009 (%)
Adult oral analgesics	369.4	+0.4
Paediatric analgesics	72.4	-1.6
Topical analgesics	67.6	+4.3
Oral lesions/toothache	32.6	-4.4
Total pain-relief products	**542.0**	**+0.3**
Cold, flu, decongestants	216.1	-4.2
Medicated confectionery	125.4	+0.7
Cough liquids	95.8	-6.9
Total cough, cold, sore-throat products	**437.2**	**-3.5**
Medicated skincare	82.0	-9.2
Dry skin treatments	73.0	+4.4
Antifungals	70.0	+1.8
Infestation (head lice and worm treatments)	31.2	-2.8
Cold-sore treatments	27.1	-4.7
Feminine care/lubricant jelly	25.3	+6.3
Antiseptic liquids	23.7	+4.6
Antihaemorrhoids	22.3	-0.3
Verucca/wart treatments	18.5	-4.2
Antiseptic creams	17.9	-1.7
Insect bite/antiseptic sprays	13.3	+3.4
Scalp treatments	11.1	-3.9
Cystitis	4.8	-2.6
Total skin-treatment products	**420.1**	**-1.2**
Total vitamins and minerals (inc anti-tiredness)	**324.2**	**+0.7**
Indigestion remedies	123.9	-1.9
Laxatives	49.3	+0.9
Antidiarrhoeals	45.2	-1.1
Stomach upset remedies	19.3	-3.2
Infant gastro	8.9	-4.2
Travel sickness	6.5	-5.5
Irritable bowel syndrome	4.9	+1.0
Total gastrointestinal products	**258.1**	**-1.5**
Smoking-cessation aids	**102.8**	**+2.1**
Hayfever remedies	**87.9**	**+3.9**
Weight-management products	**71.7**	**+52.9**
Eyecare treatments	**55.7**	**+15.1**
Sleep aids (including herbal sleep aids)	**38.7**	**+4.5**
Medicated mouthwash/sprays	**26.2**	**-4.9**
TOTAL BRITISH OTC MARKET	**2,364.6**	**+0.7**

Figure 1: Self-medication or OTC sales of non-prescription medicines and food supplements through all pharmacy and most supermarket and grocery outlets including multiple impulse outlets in Britain in 2009. Figures are at retail selling prices and include own-label and generic products, but do not cover prescription-generated sales, sales in Northern Ireland, sales in healthfood outlets and food discounters, and sales via mail order and internet-only vendors (Source – PAGB/IRI)

He drew attention to the fact that the smoking-cessation category – a major OTC driver during the past 10 years – had seen sales stall. By contrast, the prescription-generated sales of these products had grown strongly in 2009, according to data from IMS Health.

Changes in the VAT rate had also curbed value sales in 2009, said Wood. The standard VAT rate had been 17.5% for most of 2008, but had been 15.0% in 2009, he said.

Wood noted that the biggest single influence on year-on-year development of the OTC market was the winter flu season. There had been unusually high incidence levels in December 2007 and 2008, he said, and it had been anticipated that the H1N1 swine flu pandemic

Government Measures

Greek government delists non-prescription medicines

All non-prescription medicines have been delisted from reimbursement in Greece with effect from 1 June.

The move was welcomed by the Greek OTC industry association, EFEX, which believes that there is now an urgent need for free pricing of all non-prescription medicines.

Greece has applied strict price controls to both reimbursable and non-reimbursable non-prescription medicines for many years. Most member states of the European Union, by contrast, allow free pricing for non-reimbursable non-prescription medicines.

George Dokios, director general of EFEX, pointed out that the strict government controls meant prices of non-prescription medicines in Greece were among the lowest in Europe. The market was underdeveloped due to low promotional budgets, he added, and companies were not motivated to launch new and innovative products.

"For the self-care market in Greece to develop, manufacturers of non-prescription medicines should be free to set their own prices," insisted Dokios.

In May of this year, Greece introduced substantial price cuts for all medicines, including non-prescription products. In addition, the VAT rate was increased from 10% to 11%.

Price cuts ranged from 0% to 27%, depending on the wholesale price of medicines. Medicines with a wholesale price above €20.00 faced cuts of either 23%, 25% or 27%. Those with prices ranging from €5.01 to €20.00 were subjected to cuts of 20%, while those with prices ranging from €1.01 to €5.00 experienced cuts of 3%. Medicines with a wholesale price below €1.00 were not affected.

The Ministry of Economy, Competitiveness and Shipping said at the time that there was "a necessity to temporarily regulate the prices of medicinal products because of the financial difficulties that the country faces, caused by its public deficit and debt". It claimed that a "remarkable" proportion of medicines introduced in Greece had higher prices than those in other European Union countries "based on the average of the three lowest prices for medicinal products in the European member states".

According to figures from IMS Consumer Health, sales of non-prescription medicines in Greece increased by 5.6% to €337 million at wholesale prices in 2009.

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would increase incidence further and stimulate demand for OTC treatments.

"Mild outbreaks spread rapidly in July, but OTC sales never exceeded the normal seasonal variation, and the anticipated epidemic in late 2009 never materialised," he commented, adding that "low seasonal flu incidence in December 2009 led to a sharp year-on-year decline in the winter peak OTC sales of cold/flu treatments and analgesics – 30 million packs lower in December alone."

The end result was that sales of cough, cold and sore-throat products dropped back by 3.5% to £437 million in 2009.

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IN BRIEF

■ **FDA** – the US Food and Drug Administration – has warned Americans that some liquid **vitamin D supplements** are sold with droppers that could "allow excessive dosing of vitamin D to infants". The agency has also advised manufacturers that droppers accompanying these products should be clearly and accurately marked for 400 international units (IU). In addition, the FDA has recommended that droppers accompanying products intended for infants should hold no more than 400 (IU).

■ **MHRA** – the UK's Medicines and Healthcare products Regulatory Agency (MHRA) – has published a new enforcement strategy. The MHRA said it was "actively considering extending its toolkit of sanctions" after a recent review had found that the range of sanctions available to regulators was "too limited and predicated on criminal prosecution".

■ **NBTY** said that its **worldwide sales** in May had increased by a tenth to US$246 million (€203 million).

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Regulatory Affairs

Level playing field a must for herbals

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) should take steps to ensure that registered traditional herbal medicinal products are not left at a competitive disadvantage, according to Schwabe Pharma UK.

Paul Kerry, Schwabe Pharma's UK managing director, told **OTC *bulletin*** that the MHRA should take a "proactive rather than a reactive approach" to enforcing marketing claims for herbal products. Noting that the transition period for European directive 2004/24/EC would end on 30 April 2011, Kerry stressed the importance of creating a "level playing field" in the herbal sector.

Kerry's comments came after the MHRA upheld a competitor's complaints about Schwabe's marketing initiatives for two of its registered traditional herbal medicinal products, Echinacold and Kaloba. The MHRA's decisions were "fair", he said, but unlicensed herbal products continued to be backed by similar claims, particularly on websites, and little or no action was taken against them.

The MHRA investigated Schwabe's marketing following a complaint from rival herbal products company Bioforce. Kerry commented that a level playing field could only exist if the MHRA proactively monitored the entire herbal sector and did not just respond to trade complaints. Failure to enforce the law could put public health at risk, and was the main reason for the phasing in of registered herbal products, he said.

Bioforce's complaint about advertising for Echinacold on Schwabe's website was upheld by the MHRA. Schwabe claimed the herb echinacea was a "powerful immune system booster" and was "safe". Furthermore, the advertised indication was broader than the registered indication.

An editorial feature for Echinacold in *Chemist & Druggist* magazine also caught the attention of Bioforce. Schwabe acknowledged that a draft press release had been issued in error by its public relations agency, and said steps had been taken to ensure that this type of mistake did not happen again.

Bioforce also objected to two consumer-press advertisements for Kaloba. Schwabe told the MHRA that it would modify its claim to state that "Kaloba is the best researched herbal cough and cold medicine in the world" and avoid using the word "natural".

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Regulatory Affairs

Europe's EMA releases herbal medicines plan

The European Medicines Agency (EMA) plans to increase significantly the "quality and number" of Community herbal monographs and list entries produced by its Committee on Herbal Medicinal Products (HMPC).

By the end of 2011, the EMA expects that the HMPC will have sent the European Commission another 10 entries for inclusion in the Community list of herbal substances, preparations and combinations for use in traditional herbal medicinal products. Furthermore, the HMPC should have released 10 more entries for public consultation.

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

The HMPC proposes entries to the Commission, which then adds them to the Community list.

The EMA notes in a new action plan for herbal medicines, however, that the targets for Community list entries can only be achieved if a solution is found to the problems surrounding genotoxicity data.

In 2008, the European Commission's final report on directive 2004/24/EC identified the availability and quality of genotoxicity data for herbal substances as a "major" problem (**OTC *bulletin***, 17 October 2008, page 18).

According to the EMA's action plan, an "orientation concerning the genotoxicity data situation" will be decided in 2010. "Possible options include the use by the HMPC of unpublished data available on a national level and labelling that is transparent with regard to genotoxicity information," states the action plan.

In addition to the progress with Community list entries, the EMA expects the HMPC to finalise a further 20 Community herbal monographs and release 20 for public consultation during 2010 and 2011.

To date, a total of only 63 monographs have been finalised (**OTC *bulletin***, 11 June 2010, page 13). In contrast to list entries, the monographs are finalised by the HMPC.

To improve the output of the HMPC, the EMA said it intended to "adjust the priority list of herbal substances, preparations and combinations thereof for assessment to the needs of the market operators and allocate member states' resources accordingly".

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

System for tracking registrations

The EMA's action plan also sets out a system for tracking the registration of traditional herbal medicines at the national level. In collaboration with the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the agency will publish and update on a six-monthly basis an overview of applications received, applications under evaluation, and registrations granted per member state of the European Union.

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Retailing

BAH and pharmacists create online training

An online training programme for pharmacists to test their knowledge of herbal and homoeopathic remedies has been developed by Germany's medicines manufacturers' association, the BAH, in conjunction with 13 pharmaceutical companies and the German pharmacists' marketing association, the MGDA.

The programme – called Competence Center Naturarznei – comprises 21 online modules that are aimed at all pharmacy staff. The cost for one year's participation is €59.00.

All pharmacies that take part will receive a promotional pack, which includes printed polo shirts, stickers, flyers and a poster.

According to the MGDA, using the programme to position themselves as natural remedy specialists is an ideal way for German pharmacies to "combat the low-price positioning of certain pharmacy franchises".

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Product Recalls

Procter & Gamble recalls twice in US

Procter & Gamble has announced two voluntary product recalls involving its Vicks Sinex and Scope brands in North America.

The company said Vicks Sinex 4-hour decongestant nasal spray had been recalled because the "product formulation may not meet the expiration dates on the package". It stressed that the recall was not the result of consumer complaints.

Prior to June 2009, the decongestant was also sold as Vicks Sinex Nasal Spray.

Meanwhile, the Scope recall applies to "a small percentage" of one-litre bottles of Scope Original Mint and Scope Peppermint mouthwash in Canada and the US with malfunctioning child-resistant caps.

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IN BRIEF

■ **MEAD JOHNSON NUTRITION** is discontinuing its **Enfagrow Premium** chocolate toddler drink in the US following some "misunderstanding and mischaracterisation of the intended user of the product. There had been reports that some parents felt a chocolate-flavoured drink for toddlers was inappropriate because of high childhood obesity. The firm said the drink had a "superior nutritional profile".

OTC

Product Recalls

McNeil's product recall woes just won't go away

McNeil Consumer Healthcare has recalled five lots of Benadryl and Tylenol products that, according to the Johnson & Johnson subsidiary, were "inadvertently omitted" from a previous recall.

Earlier this year, McNeil recalled certain lots of Benadryl, Motrin, Rolaids, Simply Sleep, St Joseph Aspirin and Tylenol products made at its Las Piedras plant in Puerto Rico.

The company has now added to that recall four product lots of 100-count Benadryl Allergy Ultratab tablets sold in the US, and one lot of 50-count Extra Strength Tylenol Rapid Release Gels sold in Bermuda, Puerto Rico, Trinidad and Tobago, and the US.

The initial recall was sparked by consumer complaints about an "unusual mouldy, musty or mildew-like odour that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events".

McNeil stated that the problem had been caused by trace amounts of a chemical called 2,4,6-tribromoanisole, which could result from the breakdown of a wood-treatment chemical used on the wooden pallets that transport and store products.

At the same time as the recall in January, the US Food and Drug Administration (FDA) sent McNeil a Warning Letter about its Las Piedras manufacturing plant (**OTC *bulletin***, 10 February 2010, page 22).

The new recall comes in the midst of an investigation by the Committee on Oversight and Government Reform of the US House of Representatives into McNeil's recall of more than 40 OTC medicines for infants and children in May (**OTC *bulletin***, 14 May 2010, page 1). It was the sixth significant recall implemented by McNeil in North America during an eight-month period.

Operations at the company's Fort Washington manufacturing plant in the US were suspended in connection with the recall.

Considering criminal charges

Earlier this month, the FDA announced another McNeil-related recall and said that it was considering further action, including criminal charges, against McNeil in light of the recent recalls. The recall involved the McNeil-made children's OTC brand, Blacksmith Brands' PediaCare (**OTC *bulletin***, 11 June 2010, page 1).

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Marketing Campaigns

Freederm sponsors UK's *Big Brother*

A group of young people checking out their reflections in a bathroom mirror is how Dendron is promoting its Freederm products for spot-prone skin to followers of *Big Brother* in the UK.

Working with its advertising agency Bray Leino, Dendron has come up with 56 different 'idents' for its sponsorship of the last-ever series of the reality television show. All include a strapline and a voiceover stating: "*Big Brother* is sponsored by Freederm skincare for spot-prone skin".

The company pointed out the idents "mimic the two-way mirror in the *Big Brother* house and capture some funny, confident, exhibitionist, and sometimes strange behaviour".

The idents are running throughout the 13-week series, which kicked off on 9 June.

In addition, Dendron has launched a competition on the Freederm website at www.freederm.co.uk, giving people the chance to win VIP tickets to attend the weekly eviction nights for *Big Brother*.

To enter, people have to upload photographs of themselves that link in with the weekly themes, such as "Best pose" or "Best 'morning hair'". The winner is the person whose photograph attracts the most votes from visitors to the website.

Meanwhile, current trade-press advertising for Freederm urges pharmacists to "Be a part of the brand that all eyes will be on", and to "Stock up ready for a giant boost in demand".

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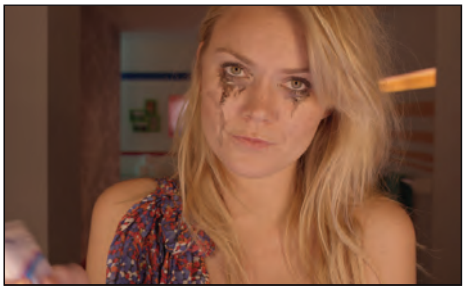

Dendron has created 56 different 'idents' for Freederm's sponsorship of *Big Brother* in the UK

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Launches

Ratiopharm UK offers two new OTC brands

German generics firm Ratiopharm has expanded its OTC portfolio in the UK with three medical devices sold under two brands.

Dissolving patches for cold sores and mouth ulcers have been launched under the Algopain-Eze banner, while a treatment for fungal nail infections is now available under the ClearFeet brand name.

The launches come a year after Ratiopharm entered the branded sector of the UK's non-prescription market with the Life's-Biotic probiotic food supplement, which is positioned as a pharmacy-exclusive product. At the time, Ratiopharm said that Life's-Biotic was "the first of many OTC brand offerings" (**OTC *bulletin***, 15 May 2009, page 15).

Rob Hall, head of OTC at Ratiopharm UK, said the Algopain-Eze brand would be developed over time into an "effective range of pain relieving products" that offered pharmacists "good profit-on-return". "You're only a patch away from pain relief," is the brand slogan.

More launches in the pipeline

The patches for cold sores and mouth ulcers should soon be joined by products for joint and muscle pain (**OTC *bulletin***, 26 February 2010, page 13).

The company is initially backing the dissolving patches with public relations activity, a website at www.algopaineze.co.uk, point-of-sale material, and information leaflets for consumers and pharmacy staff. Samples of both patches are included in the leaflet aimed at pharmacy staff.

According to Ratiopharm, the Algopain-Eze Herpatch Dissolving Cold Sore Patch was the "first product of its type available to contain therapeutic ingredients to treat the cold-sore problem directly".

Noting that the patch contained topical zinc sulphate, ß-1,3-D-glucan and a sulfated polysaccharide, Ratiopharm claimed that it relieved pain and discomfort, hid unsightly blisters, protected the cold sore, and promoted healing. The company said users could wear lipstick and/or sunblock over the patch.

Meanwhile, the Algopain-Eze Dissolvable Mouth Ulcer Patch contains hyaluronic acid, *Rhizophora mangle* aqueous bark extract, and cellulose. Ratiopharm said the patch protected the mouth ulcer from further damage and irritation, and promoted healing.

Both products are supplied in packs of eight single-use patches, which can be applied two times a day, or more if necessary. Straplines on the packs highlight the patches are "Handy for home and away".

A pack of cold-sore patches has a recommended retail selling price of £8.99 (€10.75), while the pack of mouth-ulcer patches retails at £8.25.

Both patches would be available from independent pharmacies, chain pharmacies, supermarkets and online retailers, Ratiopharm said.

Ratiopharm has launched the two patches after acquiring the exclusive UK marketing and distribution rights from the Belgian company Sylphar. Ratiopharm said that it was considering taking on the products in a number of other countries.

It also has exclusive UK marketing and distribution rights to the ClearFeet AF Nail Fungus Treatment, which was developed by the Dutch company Serrix Consumer Health. The newcomer is positioned as a "unique bio-active fungal blocker".

Supplied with a "unique brush-on applicator", the product is said by Ratiopharm to deliver a specific dose of non-toxic, fragrance-free ingredients – rye ferment filtrate, pentylene glycol, dimethyl isosorbide and hydroxyethylcellulose.

Ratiopharm is positioning new ClearFeet AF Nail Fungus Treatment in the UK as a "unique bio-active fungal blocker"

"In one laboratory test, the treatment killed 90% of fungus in only eight days, and at 10 days there was no fungus remaining," said the company, adding: "In one user trial, nearly three-quarters of sufferers with mild to moderate toe-nail fungal infection had no detectable nail fungus after four weeks of treatment."

Ratiopharm is supporting the launch with public relations activity, a consumer information leaflet and a product website located at www.clearfeet.co.uk.

Suitable for adults and children aged four years and above, ClearFeet AF Nail Fungus Treatment comes in a pack containing a 4ml tube of the solution with a brush-on applicator, 10 nail files, a nail template to monitor treatment progress and a reminder treatment schedule. The pack retails at £14.95.

Consumers should use the nail fungus treatment twice a day for at least a month.

Ratiopharm noted that ClearFeet would be available from independent pharmacies, chain pharmacies, and supermarkets.

Ratiopharm has also launched an athlete's foot cream containing 1% terbinafine hydrochloride, which will be brought under the ClearFeet brand next year.

In March of this year, Israel's Teva Pharmaceutical Industries signed a definitive agreement to pay €3.63 billion for Ratiopharm. The deal is expected to complete at the end of this year (**OTC *bulletin***, 31 March 2010, page 1).

Two topical patches containing "therapeutic ingredients" have just been launched in the UK under Ratiopharm's Algopain-Eze brand

One-a-day omega-3 fatty acid capsules are the latest addition to Queisser Pharma's Doppelherz System range of pharmacy-exclusive food supplements in Germany.

Packs of Doppelherz System Omega-3 Konzentrat stress that each capsule contains 60% omega-3 fatty acids – providing 300mg eicosapentaenoic acid and 200mg docosahexaenoic acid – as well as 14mg vitamin E.

Packs of 30 and 60 capsules have recommended retail selling prices of €8.95 and €15.95 respectively.

Launch trade-press advertising carries the headline "In der Konzentration liegt die Kraft", or "The power lies in concentration". This message is reinforced by an image of a droplet of yellow oil carrying the words "60% omega-3".

It also cites Nielsen data showing that the company is already Germany's OTC market leader by value for omega-3 products.

Switches

Bayer takes omeprazole into French self-medication arena

Bayer Santé Familiale will launch a non-prescription heartburn medicine based on omeprazole in France in July, following the switch of the proton-pump inhibitor from prescription-only status.

Branded Mopralpro, the non-prescription medicine contains 20mg omeprazole per caplet and is indicated for short-term treatment of heartburn and acid regurgitations. It is available in packs of seven or 14 caplets.

The company told **OTC *bulletin*** the launch would be backed by a comprehensive marketing campaign, including training for pharmacy staff, pharmacy-press advertising, public relations activity, and consumer advertising. The campaign is still under development.

Current trade-press advertising alerts pharmacists to the imminent arrival of Mopralpro through the message "Bientôt disponible sans ordonnance!" or "Soon available without a prescription".

Advertising points out that one caplet lasts for 24 hours. It also highlights Mopralpro's "unique" multiple-unit pellet system (MUPS), which is a patent-protected formulation that can be taken dispersed in water or fruit juice.

Bayer already markets Mopral – a prescription-only medicine containing omeprazole – in France under licence from AstraZeneca.

Advertisements in the French pharmacy press highlight the imminent launch of Bayer's Mopralpro non-prescription medicine containing omeprazole

Last year, Bayer announced an exclusive licensing agreement with AstraZeneca covering the launch of a non-prescription medicine containing omeprazole under the Antra brand in Germany. The deal also included the option for Bayer to market omeprazole as a non-prescription medicine in other countries following the first launch in Germany (**OTC *bulletin***, 31 July 2009, page 21).

Business Strategy/Launches

Brunel strikes deal with Fortuna in UK

Fortuna Healthcare has gained the rights to distribute Brunel Healthcare's Vertese range of gelatin-free food supplements to independent pharmacies in the UK.

In addition, Brunel has launched a supplement that targets skin, hair and eyes under the Vertese brand name, after identifying "a gap in the market for a vegan-friendly and vegetarian beauty supplement".

Noting that Fortuna Healthcare employed over 20 local sales managers in the UK, Brunel said Vertese would benefit from a "much larger distribution force".

Meanwhile, Brunel is positioning its latest addition – Vertese Skin, Hair and Eyes – as a "unique, good looking supplement" that aimed to introduce new consumers to the brand. The company noted the launch was its first foray into the "beauty from within" sector.

A month's supply of 30 capsules has a recommended retail selling price of £4.99 (€6.00). One strapline on the packaging highlights the product contains lutein, while a second makes the claim "Helping to maintain healthy skin, hair and eyes".

Brunel revamped the Vertese range earlier this year with an on-pack promise of "Help your body help itself" (**OTC *bulletin***, 10 February 2010, page 20). The range – which includes products based on omega oils, evening primrose oil and flaxseed oil – is approved by the Vegetarian Society.

A spokesperson for Brunel told **OTC *bulletin*** that the company distributed Vertese to multiple retailers including Boots.

Brunel Healthcare has entered the "beauty from within" sector of the food supplements market in the UK with Vertese Skin, Hair and Eyes

Pharmacists notice Solpadeine launch

A new Solpadeine variant caught the eye of pharmacists in June, judging by the results of Pharmacy viewpoint – our monthly survey of UK pharmacists' attitudes to OTC sales and marketing, which is published exclusively in OTC bulletin courtesy of the Intr@PharmQ service from IMS. However, Alli and Flomax Relief were the best performers across the board.

Trade-press advertising for the latest addition to GlaxoSmithKline's Solpadeine pharmacy-only pain relievers caught the attention of pharmacists in June

Voting was tight in our **Pharmacy *viewpoint*** survey in June, with three brands notching up wins.

GlaxoSmithKline Consumer Healthcare's Alli weight-loss medicine recaptured its familiar position at the top of the tables, achieving two wins and two second places (see Figures 1, 2, 3, and 4).

Boehringer Ingelheim's Flomax Relief – backed by the humorous 'P' marketing campaign – also did well, notching up two wins, a second place and a fourth spot. However, its performance was not as good as in May, when it recorded a clean sweep of wins in all four sections of **Pharmacy *viewpoint*** (**OTC *bulletin***, 11 June 2010, page 16).

The third brand to grab a pole position was GlaxoSmithKline Consumer Healthcare's Solpadeine. As can be seen from Figure 1, when IMS Consumer Health surveyed UK pharmacists between 1 and 24 June 2010 through its Intra@PharmQ service, around one in seven of them said the pain reliever was backed by the best current trade-press advertising for an OTC medicine or dietary supplement.

Current pharmacy-press advertising for the brand highlights the addition of a soluble version of Solpadeine Max to the range of codeine combination medicines. New Solpadeine Max Soluble tablets provide 500mg paracetamol, 12.8mg codeine and 30mg caffeine, and are backed by the claim "gets to work twice as fast as ordinary paracetamol tablets" (**OTC *bulletin***, 14 May 2010, page 23).

A full-page advertisement for Solpadeine Max Soluble carries a large heading stating that the product is a "new unique formulation from the number one selling pharmacy pain brand". It also highlights that the medicine has pharmacy-only status.

The company has also placed an advertorial about "Codeine and its place in pharmacy" in *Pharmacy Magazine*. This explains to pharmacists how strong pain relievers can continue to be used responsibly in line with the tighter controls for non-prescription medicines containing codeine that were recently introduced in the UK market (**OTC *bulletin***, 16 September 2009, page 1).

Meanwhile, the top spot in the television section of **Pharmacy *viewpoint*** went to Flomax Relief with 17% of the best-advertising vote (see Figure 2).

Alli led the way in the rankings for best current pharmacy-support package, attracting 15% of the vote (see Figure 3).

The weight-loss medicine had to share the top spot with Flomax Relief in the section for best current representative detailing. Each attracted 10% of the vote (see Figure 4).

OTC

Two high-profile switches from prescription-only to pharmacy status – GlaxoSmithKline Consumer Healthcare's Alli (pictured above) and Boehringer Ingelheim's Flomax Relief (right) – dominated the pharmacy viewpoint rankings this month

Intr@PharmQ and Pharmacy *viewpoint*

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

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

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

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

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

PHARMACY *viewpoint*

BEST CURRENT TRADE-PRESS ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Solpadeine	GlaxoSmithKline	Oral analgesic	14
2=	Alli	GlaxoSmithKline	Weight-loss medicine	11
	Nurofen	Reckitt Benckiser	Oral/topical analgesic	11
4	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	9
5=	Bonjela	Reckitt Benckiser	Mouth-ulcer treatment	5
	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	5
7=	Benadryl	McNeil Products	Allergy remedy	3
	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	3
	Vitabiotics	Vitabiotics	Food supplement	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 1: Unprompted response of UK pharmacists between 1 June and 24 June 2010 when they were asked the question: "In your opinion, what is the best current trade-press advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT TELEVISION ADVERTISING

Rank	Brand	Company	Product type	Pharmacists (%)
1	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	17
2	Alli	GlaxoSmithKline	Weight-loss medicine	16
3	Nurofen	Reckitt Benckiser	Oral/topical analgesic	14
4=	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	7
	Solpadeine	GlaxoSmithKline	Oral analgesic	7
6	Canesten	Bayer Consumer Care	Antifungal	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 2: Unprompted response of UK pharmacists between 1 June and 24 June 2010 when they were asked the question: "In your opinion, what is the best current television consumer advertisement for an OTC medicine/dietary supplement?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT PHARMACY-SUPPORT PACKAGE

Rank	Brand	Company	Product type	Pharmacists (%)
1	Alli	GlaxoSmithKline	Weight-loss medicine	15
2	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	14
3	Solpadeine	GlaxoSmithKline	Oral analgesic	11
4	Nurofen	Reckitt Benckiser	Oral/topical analgesic	9
5	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	6
6	Canesten	Bayer Consumer Care	Antifungal	4
7=	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	3
	Vitabiotics	Vitabiotics	Food Supplement	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 3: Unprompted response of UK pharmacists between 1 June and 24 June 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best pharmacy-support package (consumer/trade advertising, bonus deals, profit margin, training, etc)?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

BEST CURRENT REPRESENTATIVE DETAILING

Rank	Brand	Company	Product type	Pharmacists (%)
1=	Alli	GlaxoSmithKline	Weight-loss medicine	10
	Flomax	Boehringer Ingelheim	Benign prostatic hyperplasia	10
3	Solpadeine	GlaxoSmithKline	Oral analgesic	9
4	Nurofen	Reckitt Benckiser	Oral/topical analgesic	8
5	NiQuitin	GlaxoSmithKline	Smoking-cessation aid	5
6	Seven Seas	Seven Seas	Food supplement	4
7	Piriton/Piriteze	GlaxoSmithKline	Allergy remedy	3

Base: 100 pharmacists who named a brand of OTC medicine or food supplement

Figure 4: Unprompted response of UK pharmacists between 1 June and 24 June 2010 when they were asked the question: "In your opinion, which OTC medicine/dietary supplement is currently backed by the best representative detailing?" (Source – OTC *bulletin*/IMS' Intr@PharmQ service)

Launches

Biology inspires Bausch's Biotrue

"Inspired by the biology of your eyes," is the on-pack claim for a new contact lens solution from Bausch & Lomb.

The company has already launched Biotrue in the US, and said the multipurpose product would be available in Europe from October.

According to Bausch & Lomb, Biotrue had been developed following an "intensive study on how the eye naturally works to clean, hydrate and keep itself healthy". The product was based on "three bio-inspired innovations", the company maintained.

Firstly, Biotrue was "pH-balanced to match healthy tears". "In clinical trials," the company pointed out, "81% of patients who tried the solution said it felt like their natural tears."

Secondly, the product contained hyaluronan which, according to Bausch & Lomb, "helps attract water to envelop lenses in a moisture-rich cushion and to stabilise the tear film and reduce friction". "Even after 20 hours, hyaluronan has been shown to remain on both hydrogel and silicone-hydrogel lenses, helping to provide all-day comfort," said the firm.

Bausch & Lomb is launching Biotrue in the US and Europe this year

Thirdly, continued Bausch & Lomb, Biotrue kept certain beneficial tear proteins active for longer. "Testing has shown that Biotrue maintains over 13 times more active lysozyme than other solutions," it said.

Biotrue comes in a clear bottle that allows users to track how much solution remains. It is available in the US in a 2 oz bottle with a recommended retail selling price of US$1.89 (€1.54), a 4 oz bottle priced US$5.19 and a 10 oz bottle priced US$8.60.

Beiersdorf is backing its Elastoplast Invisible Protection first-aid plaster in the UK with a website aimed at women seeking an "aesthetic alternative to everyday plasters".

Visitors to the website located at www.elastoplast-invisibleprotection.co.uk can view videos offering beauty tips. In addition, they can request a free product sample, enter a competition to win a spa break and read "beauty blogs".

The company is also supporting the plaster with promotional activity in women's magazine *Glamour*. The August issue will include a coupon offering £0.50 (€0.60) off the price of a pack of the plasters, and the chance to win a spa break.

Launched in the UK in March, the plasters are also available in Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, France, Germany, Greece, the Middle East, the Netherlands, Portugal, Slovenia, Sweden and Switzerland under Beiersdorf's Elastoplast and Hansaplast brands.

In the UK, Beiersdorf is positioning the plaster – which even has a transparent wound pad – as "the first-ever totally transparent plaster". The company added that it was "just like a second skin".

A pack of 12 assorted plasters has a recommended retail selling price of £2.99 in the UK.

OTC

IN BRIEF

■ **SEVEN SEAS** is backing its **Multibionta** probiotic multivitamin supplements in the UK with a money-back guarantee. Special Multibionta Challenge packs encourage consumers to "try for 14 days or your money back".

■ **GLAXOSMITHKLINE** Consumer Healthcare is investing £1.0 million plus (€1.2 million plus) in television and consumer-press advertising for its **Panadol Advance** pain relievers in the UK. The established "visible man" commercial from the agency Ogilvy returns to screens for a nine-week burst starting 28 June. The company said the campaign, which takes in both terrestrial and satellite stations, would target programmes and time slots expected to appeal to ABC1 housewives. Press advertising will appear in 11 titles including *Woman's Own* and *Take a Break*. Quoting data from Nielsen for the 12 months ended 20 April 2010, GlaxoSmithKline said sales of Panadol had grown by 9% in value terms and 19% in volume terms.

■ **ASA** – the UK Advertising Standards Authority – has upheld a complaint about press advertising for **Magno-Pulse's** knee support.

OTC

Marketing Campaigns

Wartner appeals to Britons with happy fingers and toes

Feet, toes and fingers are transformed into appealing personalities in Omega Pharma's new advertising campaign for its Wartner cryotherapy in the UK.

Created by the advertising agency VCCP, the "happy fingers and toes" campaign features a series of characters that should appeal to a broad range of wart and verruca sufferers. The heel of a foot becomes a surfing dude with a mop of blond hair, for example, while a finger is a schoolgirl with her hair in bunches and a tie around her neck. The toes of a foot, meanwhile, represent a family of five, with the big toe as dad, the second toe as mum, and the other three as children.

The campaign, which was scheduled to kick off as **OTC *bulletin*** went to press, comprises digital, outdoor and trade-press advertising.

Andy Wines, marketing director for Omega Pharma in the UK, pointed out that millions of searches for warts and verrucas were made on the internet each year in the UK. He said the company was "investing a television-sized budget in digital media because that is where people are looking for information".

The digital campaign includes banners and a new microsite at www.easyfreezeywartner.co.uk, while the outdoor campaign comprises wall posters and floor advertisements in swimming pools.

"It's easy to freeze off warts and verrucas using Wartner's new measuring tool," is a key message of the campaign, which positions Wartner as the "Easy Freezey" option. "Measured it. Freezed it. Verruca gone," the campaign tells consumers and healthcare professionals.

Introduced earlier this year, the Wartner measuring tool allows users to choose the correct treatment time for different-sized warts and verrucas.

The new campaign for Wartner is part of Omega Pharma's strategy of doubling the size of its UK business over the next four years through a combination of organic growth, acquisitions and licensing deals. Managing director Nigel Bathurst said recently that the company had been a "sleeping giant" in the UK OTC market, but was now working to "unlock the potential of its existing brands through an approach rooted in consumer insight" (**OTC *bulletin***, 11 June 2010, page 8).

VCCP – the advertising agency behind the memorable "meerkat" campaign for compare themarket.com – was appointed at the start of this year.

Wall and floor advertisements in swimming pools are part of Omega Pharma's new marketing campaign for its Wartner brand in the UK

The Wartner cryotherapy range in the UK offers separate products for warts and verrucas

OTC

DIARY DATE.....DIARY DATE.....DIARY DATE.....DIARY DATE

The OTC Marketing Awards 2011

will be held in London on Thursday 10th March 2011

AUGUST

4 August

■ **Basics of Regulatory Affairs**

London, UK

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

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

26-28 August

■ **Natural Products Expo Asia 2010**

Wan Chai, Hong Kong

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

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

30-31 August

■ **All About Regulatory Affairs in Europe**

Heidelberg, Germany

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

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

SEPTEMBER

8 September

■ **OTC Approval and Marketing Strategies**

Bonn, Germany

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

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

26-27 October

■ **How Can Non-Prescription Medicines Best Contribute to Public Health?**

Antwerp, Belgium

Speakers at this two-day conference – organised by the Association of the European Self-Medication Industry, the AESGP – include: Xavier de Cuyper of the Belgian Federal Agency for Medicines and Health Products; Dagmar Roth-Behrendt of the European Parliament; Eric Abadie of the Committee for Human Medicinal Products (CHMP); Noël Wathion of the European Medicines Agency (EMA); and Kent Woods of the UK Medicines and Healthcare products Regulatory Agency (MHRA).

***Contact**: Association of the European Self-Medication Industry, the AESGP.*
Tel: +32 2 735 51 30. Fax: +32 2 735 52 22.
E-mail: l.gits@aesgp.be. Website: www.aesgp.be.

27 September

■ **The Borderline Between Medicines and Foods**

London, UK

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

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

29 September-2 October

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

Austin, Texas, US

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

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

OCTOBER

4-5 October

■ **Herbal Medicines**

Bonn, Germany

This one-day meeting conducted in German will cover quality data for approval and registration.

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

4-6 October

■ **The 7th TOPRA Annual Symposium**

London, UK

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

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

7-10 October

■ **Expopharm 2010**

Munich, Germany

International pharmaceutical trade fair and conference.

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

5-8 November

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

Chinese Taipei

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

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

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

25-26 & 27 October

■ **Nutraceuticals and Functional Foods**

London, UK

Topics for discussion at this two-day meeting include global perspectives and evolution of functional foods, marketing opportunities, nutrition and health claims, nanotechnology, and probiotics. The meeting will be followed by a half-day workshop entitled 'Protecting product innovation'.

***Contact**: Samantha Graves,*
SMi Group.
Tel: +44 20 7827 6052.
Fax: +44 87 0909 0712.
E-mail: sgraves@smi-group.co.uk.
Website: www.smi-online.co.uk.

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.
Website: www.raucon.com.

8-10 November

■ **Pharmaceutical Regulatory Affairs in Latin America**

London, UK

This three-day seminar will focus on Latin America's regulatory environment for pharmaceuticals.

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

DECEMBER

6-7 December

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

London, UK

This two-day conference is organised by the European Medicines Agency (EMA) and The Organisation for Professionals in Regulatory Affairs (TOPRA).

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

Regulatory Affairs

Centralised procedure is a 'game changer'

Europe's centralised licensing procedure is a launch route that can no longer be ignored by the OTC industry, according to Andy Tisman, IMS Consulting's senior principal for Consumer Health. "It is a game changer," he told delegates attending the recent 46th AESGP Annual Meeting.

Tisman pointed out that it had taken around 25 years for Reckitt Benckiser's Nurofen to become a pan-European brand. The first switch of the ibuprofen-based pain reliever from prescription-only to non-prescription status in 1983 in the UK, he recalled, had been followed by "a slow country-by-country process". Nevertheless, Nurofen was now available in 24 countries in Europe, added Tisman, where it now had annual sales of €108 million.

Very different experience to Nurofen

GlaxoSmithKline Consumer Healthcare's experience with the Alli weight-loss medicine, which gained non-prescription status through the centralised procedure in early 2009, had been very different. "Alli obtained one marketing authorisation in 28 countries in one day," he stressed, adding that Alli had achieved sales close to those of Nurofen in 2009.

Alli was initially launched in 24 countries across the European Union in April 2009 (**OTC *bulletin***, 30 April 2009, page 1), and was introduced in the others soon afterwards. GlaxoSmithKline reported that the brand had generated sales of £105 million (€130 million) in Europe in the nine months following its launch (**OTC *bulletin***, 10 February 2010, page 1).

Discussing Alli's launch at the AESGP Annual Meeting, James Hallatt – vice-president and general manager of GlaxoSmithKline Consumer Healthcare in the UK – said IMS Review Plus ranked Alli as the number six OTC brand across Europe in the nine months to the end of 2009.

In January of last year, the 60mg orlistat capsules became the first non-prescription medicine to be licensed through the centralised procedure (**OTC *bulletin***, 29 January 2009, page 1). Only one other medicine – Nycomed's 20mg pantoprazole formulation for heartburn – has managed to gain non-prescription status via the centralised procedure (**OTC *bulletin***, 19 June 2009, page 1).

However, two applications involving non-prescription medicines have been withdrawn. The first was announced in late 2008, when Pfizer pulled the plug on its application to switch the erectile dysfunction drug Viagra (sildenafil citrate) from prescription to non-prescription status (**OTC *bulletin***, 28 November 2008, page 1). The second came at the start of this year, when Wyeth Consumer Healthcare – now part of Pfizer – decided not to pursue its application to licence a new combination containing the existing non-prescription medicines ibuprofen and diphenhydramine hydrochloride (**OTC *bulletin***, 10 February 2010, page 1).

Tisman stressed that the centralised procedure was "not an easy option". "The process and execution are complex, and success is not guaranteed," he remarked, adding: "There is one process but not one individual solution."

Describing Europe's member states as "27 disparate markets", Tisman said there were "different levels of pharmacy supervision, different advertising regulations, and different consumer cultures and habits". He noted the pharmacy-channel mix also varied across Europe.

However, he reminded delegates that the European market presented a "great opportunity". One consistent marketing message could be presented to half a billion people, he said.

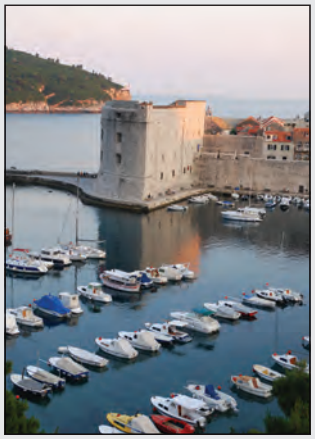
Europe's centralised licensing procedure offers great opportunities, but the process and execution are complex, says Andy Tisman, IMS Consulting's senior principal for Consumer Health

Tisman added that the European supply chain consisted of around 160,000 pharmacies, and these were visited by around 46 million pharmacy shoppers every day. Wholesalers and retailers operating on a pan-European basis were increasing in importance, he added.

"Furthermore," he warned, "if you don't recognise the potential of your molecule in the European Union, then someone else may."

Tisman pointed out that the performance of Alli had shown that "the scale is large enough to be of interest to non-traditional OTC players". "A lot of traditional pharmaceutical companies are now taking a look," he added.

OTC



46th AESGP Annual Meeting

"Connecting with self-care – the future of self-medication in the new Europe" was the theme of the 46th Annual Meeting of the Association of the European Self-Medication Industry, the AESGP, held in Dubrovnik, Croatia, from 9-11 June 2010.

Around 400 people from 44 countries attended the meeting.

The first part of OTC *bulletin*'s comprehensive report appears on pages 20-23 of this issue, with more to follow in forthcoming issues.

The 47th AESGP Annual Meeting will be held in Rome, Italy, from 8-10 June 2011.

Regulatory Affairs

Revise the rules for switch originators

When 27 non-prescription medicines – all containing a proton-pump inhibitor – were launched in a six-month period in Germany, both pharmacists and consumers were confused, according to Etienne de Laroullière, who is the worldwide head of Nycomed's OTC business unit.

Starting in August of last year, pharmacists and consumers in Germany were bombarded with an array of advertising campaigns, often using fire or flames to portray heartburn (**OTC *bulletin***, 31 August 2009, page 1).

Germany by far the most crowded

Germany was by far the most crowded marketplace for non-prescription proton-pump inhibitors. However, de Laroullière noted that four non-prescription medicines containing a proton-pump inhibitor had been launched in Poland during the past year, and the same number had been introduced in Finland. Austria and France had each seen three arrivals, he added.

One of the non-prescription medicines in these countries was Nycomed's 20mg pantoprazole formulation, which had gained non-prescription status through Europe's centralised licensing procedure earlier in the year (**OTC *bulletin***, 19 June 2009, page 1). Licensed under five brands names, including Pantozol Control, it had not been granted any exclusivity.

De Laroullière told delegates attending the 46th AESGP Annual Meeting that a lack of data exclusivity when a new category was switched could lead to confusion in the marketplace.

Although European legislation allows innovative switches to obtain a one-year period of data exclusivity, this is proving very difficult to get in practice. Neither of the two centralised switches to date – GlaxoSmithKline Consumer Healthcare's Alli 60mg orlistat capsules and Nycomed's 20mg pantoprazole tablets – have been successful.

In the US, by contrast, switch originators can – and often do – gain three years of market exclusivity.

James Hallatt – the vice-president and general manager of GlaxoSmithKline Consumer Healthcare in the UK – also highlighted the lack of data exclusivity as a problem. He stressed that companies needed a sufficient incentive to justify the huge investment required for a switch.

The lack of data exclusivity was one of two important hurdles facing switch originators in Europe, according to de Laroullière. The second was the authorised indication, which could make it difficult to differentiate a switched medicine from competitors.

At the European level, the permitted indication for Nycomed's non-prescription proton-pump inhibitor is "short-term treatment of reflux symptoms", complained de Laroullière. This contrasts with some countries, notably the US, where non-prescription proton-pump inhibitors are indicated for frequent heartburn.

De Laroullière said an indication of frequent heartburn would have allowed Nycomed to differentiate its proton-pump inhibitor from other heartburn remedies.

He also maintained that the phrase "short-term" was confusing. Consumers thought short-term meant one or two days, he stated, while doctors thought it meant one or two months.

"Indications should be in consumer understandable language," de Laroullière insisted, calling for the European regulators to "revise the rules".

On a positive note, de Laroullière said all member states of the European Union, including Italy and Spain, had given the "green light to full OTC status" for Nycomed's 20mg pantoprazole tablets.

By contrast, GlaxoSmithKline Consumer Healthcare's Alli did encounter some nationally-imposed restrictions.

In Italy, for instance, Alli was placed in the country's controversial category of non-advertisable, non-prescription medicines. This stopped GlaxoSmithKline advertising Alli to consumers (**OTC *bulletin***, 19 June 2009, page 1).

Italy's move came despite the fact that there is no legal basis for a ban on consumer advertising of non-prescription medicines that are not reimbursable.

In France, GlaxoSmithKline was not allowed to run television advertising for Alli for a year, but the company could use posters and press advertisements to reach consumers.

Efficient and predictable regulation

Commenting on the pan-European switch of Alli, Hallatt stressed the importance of "efficient and predictable regulation".

He also highlighted that Europe's Committee for Human Medicinal Products (CHMP) had limited experience of non-prescription medicines. However, the latter problem has recently been addressed through procedural advice on the appointment of rapporteurs and co-rapporteurs for non-prescription medicines.

Urging pharmacists to "step up to play their role" for major switches, Hallatt said pharmacists in some countries had engaged more fully with the obesity category than those in others. He also drew attention to the "inconsistency" in the role of pharmacists across Europe with regard to self-medication. This was apparent in the practice, culture, perceptions and organisation of healthcare systems, he said.

Regulation of digital content across Europe is not keeping pace with consumer behaviour, according to James Hallatt, vice-president and general manager of GlaxoSmithKline Consumer Healthcare in the UK

Permitted indications for non-prescription medicines should be in "consumer-understandable language", says Etienne de Laroullière, worldwide head of Nycomed's OTC business unit

Hallatt was also concerned about the "uneven playing field" for Alli compared with competitors that were unlicensed products or medical devices.

Furthermore, Hallatt maintained that regulation of digital content was "not keeping pace with consumer behaviour". Only nine markets allowed discussion boards on the Alli website, he said, and it was not possible to get interactive tools everywhere. There was also the question of how companies could contribute to discussions on all types of websites, he added, asking whether it should be within defined parameters, based on pre-approved statements adjusted for context, or through regular reviews with regulatory agencies.

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Traditional Herbal Medicinal Products

Herbal registrations rise to 162 in Europe

Over 160 products have now been registered using the simplified procedure for traditional herbal medicinal products introduced by European Union directive 2004/24/EC.

This is a significant improvement on the position a year ago, when the total number of registrations in the European Union stood at 66 (**OTC *bulletin***, 19 June 2009, page 19).

According to the new edition of the AESGP's legal and regulatory framework for herbal medicines, the number of registrations had reached 162 when the publication went to press in April of this year. All European Union member states, except Lithuania and Luxembourg, are included in the publication.

As can be seen from Figure 1, the UK led the way with 56 registrations, followed by Austria with 26 and Sweden with 22.

More than a quarter of the registrations were for combination products.

Registrations covered several herbal ingredients, including *Arnicae flos*, *Capsici fructus*, *Echinacea purpurea herba*, *Lupuli flos*, *Pelargonii radix*, *Harpagophyti radix*, *Hyperici herba*, *Passiflorae herba*, *Salvia folium* and *Valerianae radix*.

With the transition period for the directive set to end in April 2011, the low number of registrations in most member states is a cause for concern.

The European Medicines Agency (EMA) has just announced an action plan (see page 10) to increase significantly the "quality and number" of Community herbal monographs and list entries produced by its Committee on Herbal Medicinal Products (HMPC). Since directive 2004/24/EC came into force six years ago, only seven entries have been added to the Community list (**OTC *bulletin***, 31 May 2010, page 15) and only 63 monographs have been finalised (**OTC *bulletin***, 11 June 2010, page 13).

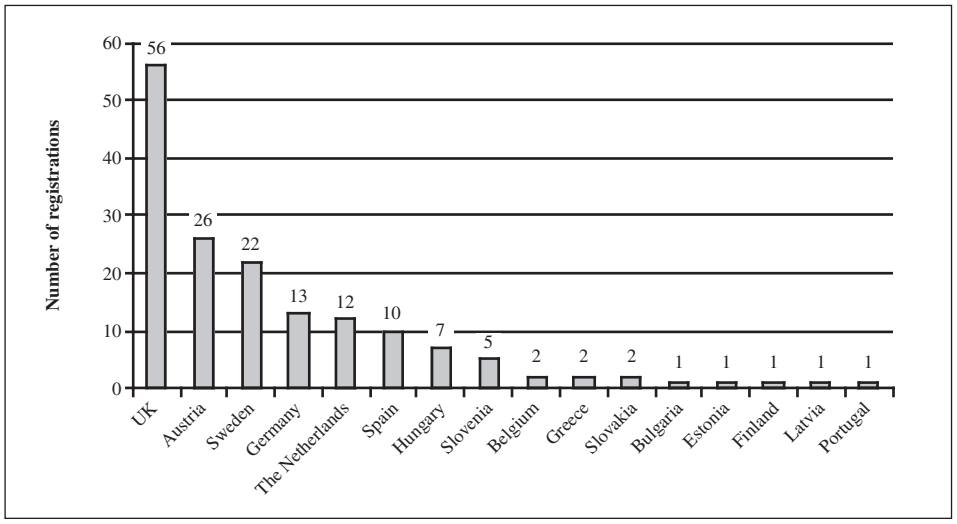

Figure 1: Breakdown by member state of the number of products registered using the simplified procedure for traditional herbal medicinal products introduced by European Union directive 2004/24/EC (Source – AESGP)

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

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

The European Parliament's influential Environment, Public Health and Food Safety (ENVI) committee recently endorsed a proposal that would have made Community herbal monographs legally binding on member states. If the proposal had been adopted, directive 2001/83/EC would have been amended to say that Community herbal monographs "shall be complied with" by member states.

However, **OTC *bulletin*** understands that the amendment has been dropped from the current version of the pharmacovigilance proposal.

Launched in 2009, the AESGP's framework publication for herbal medicines has now been extended beyond Europe. The 2010 edition covers Australia, Canada, China, India, Japan and the US, as well as 29 countries in Europe. The national chapters give details of dossier requirements, the evaluation process, product information, trade names, advertising and distribution channels.

■ Copies of the 'Legal and regulatory framework for herbal medicines in Europe' can be obtained, priced €150 plus postage, from the AESGP, 7 Avenue de Tervuren, 1040 Brussels, Belgium (Tel: +32 2 735 51 30; Fax: +32 2 735 52 22; E-mail: info@aesgp.be).

OTC

Publications

AESGP updates framework book

An updated version of the 'Economic and legal framework for non-prescription medicines' – the standard reference for anyone interested in self-medication and self-care – is now available.

Published by the Association of the European Self-Medication Industry, the AESGP, the 16th edition includes regulatory developments over the past year.

The 500-page book provides detailed information on the regulatory climate in 26 European countries and 15 other countries around the world, as well as giving an overview of the main European Union legislation affecting non-prescription medicines.

■ Copies of the 'Economic and legal framework for non-prescription medicines' can be obtained, priced €150 plus postage, from the AESGP, 7 Avenue de Tervuren, 1040 Brussels, Belgium (Tel: +32 2 735 51 30; Fax: +32 2 735 52 22; E-mail: info@aesgp.be).

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European Parliament

Call for television ban

A ban on advertising non-prescription medicines on television has been proposed by Carl Schlyter, a Swedish member of the European Parliament.

Schlyter is seeking to amend the European Commission's proposed legislation on information to patients, which does not apply to non-prescription medicines. He argues that television commercials are too short to convey relevant information and warnings.

The amendment is unlikely to be approved.

OTC

Manufacturers

Unsworth will head Bausch Asia-Pacific

Rod Unsworth – the former president of Schering-Plough's Asia-Pacific region – will succeed **David Edwards** as president of Asia-Pacific at US-based eye-health specialist Bausch & Lomb on 1 July.

Edwards, who has resigned "to pursue other activities", will continue to advise the company during an unspecified transition period.

Hassan and Saunders

Unsworth's appointment follows that of Schering-Plough's former chairman and chief executive officer, Fred Hassan, and its former Consumer Health Care chief, Brent Saunders, as Bausch & Lomb's chairman and chief executive officer respectively (**OTC *bulletin***, 31 March 2010, page 23).

Prior to becoming Schering-Plough's Asia-Pacific head in 2004, Unsworth held a variety of positions at Pharmacia, including president of Asia-Pacific, and global vice-president of ophthalmology and metabolic diseases. He had become managing director of Pharmacia & Upjohn Australia, after Upjohn had acquired in 1992 the Australian pharmaceuticals company, Delta West, that he had founded 20 years earlier.

Unsworth has a degree in pharmacy.

Meanwhile, Saunders has been elected to the Upstate New York Regional Advisory Board of the Federal Reserve Bank of New York.

OTC

Manufacturers

Albrecht takes the helm at generics firm Actavis

Former Ratiopharm head **Claudio Albrecht** has been appointed chief executive officer of the Icelandic generics company Actavis with immediate effect.

Claudio Albrecht

Albrecht replaces **Sigurdur Oli Olafsson**, who is standing down after seven years in senior management positions, including the past two as chief executive officer following the departure of Robert Wessman (**OTC *bulletin***, 29 August 2008, page 27).

Albrecht, 51, is an Austrian citizen and holds a doctorate in law. He started his career with Sandoz in 1987, and he went on to serve as the firm's managing director in the Netherlands, Germany and the US.

In 2000, he became Ratiopharm's global chief executive, a role in which he doubled the German company's sales to make it the third-largest generics player by the time he left at the end of 2005 (**OTC *bulletin***, 30 November 2005, page 21).

In 2008, Albrecht set up Cometh, a consultancy that advised companies – including Actavis – on their growth strategies.

"Actavis has one of the best research and development pipelines in the industry, but it still needs to grow its market presence in many of the big markets," commented Albrecht, adding that "strong geographic expansion and better market penetration, especially in southern Europe and the emerging markets, will be our goal for the future".

Actavis is currently seeking a "central location" where its senior team can be based in one place. "Following a number of acquisitions over the past decade," said the firm, "senior management is spread across five different locations."

Iceland would remain a key site for manufacturing, research and development and the third-party sales division Medis, the company pointed out.

OTC

Regulatory Agencies

EMA board re-elects Ireland's O'Mahony

The management board of the European Medicines Agency (EMA) has re-elected **Pat O'Mahony**, chief executive of the Irish Medicines Board, as its chair for a second term of three years. He originally replaced Finland's Hannes Wahlroos in 2007 (**OTC *bulletin***, 15 June 2007, page 23).

Accepting his re-election, O'Mahony underlined the importance of ensuring the "network model of which we are all part" worked to the full benefit of the European public.

One of the issues facing the board is the way the EMA handles potential conflicts of interests of experts involved in evaluating medicines. The agency is due to adopt an updated policy in October 2010.

It is looking for a better balance between restricting the involvement of experts with conflicts of interest in the EMA's activities, and ensuring the availability of the best scientific expertise. A key aspect of its proposed policy will be systematically to publish on its website all declarations of interests from experts.

Pat O'Mahony

OTC

Obituary

Dieter Zeh

Dieter Zeh, managing director of German herbal medicines company Salus Haus, has died after a lengthy illness.

Between 1991 and 2007, Zeh was chairman of the phytomedicines committee within Germany's medicines manufacturers' association, the BAH. He was also the industry association's deputy chairman from 2004 to 2009.

Furthermore, Zeh had since May 2006 been the spokesperson for Kooperation Phytopharmaka, a Bonn-based scientific society dedicating to promoting herbal medicine.

OTC

Manufacturers

Bayer's Main moves from Consumer to Medical Care

Alan Main – the European head of Bayer HealthCare's Consumer Care division – will become worldwide head of the German company's Medical Care division with effect from 1 July. He will also be a member of Bayer HealthCare's executive committee.

Main will be replaced by **Jörg Ohle**, North American president and general manager of Bayer HealthCare's Animal Health division. Ohle will be based at Consumer Care's European headquarters in Basel, Switzerland.

Alan Main

Jörg Ohle

Thirty-two years with Bayer

During his 32-year career with Bayer, Ohle has worked for the company's Animal Health, Consumer Care and Pharmaceuticals divisions. His first job was in the company's pharmaceuticals business in Germany.

Between 1992 and 1996, he held several marketing positions at Bayer's Consumer Care business in Germany. He then moved to Singapore, and subsequently became head of Bayer HealthCare for the Asia-Pacific region.

Ohle was born in Bayer's home town of Leverkusen, and holds a business degree from Bayer's International Management School in Leverkusen.

Main has spent more than 25 years in the OTC industry, working for Stafford-Miller and Roche Consumer Health. He joined Bayer in 2005 when the company acquired Roche Consumer Health.

Main is a board member and vice-president of the Association of the European Self-Medication Industry, the AESGP.

OTC

Industry Associations

ASMI names Schoombie's replacement

The Australian Self-Medication Industry (ASMI) has appointed **Steven Scarff** as regulatory and scientific affairs director.

He replaces **Deon Schoombie**, who will succeed **Juliet Seifert** as executive director when she retires in August (**OTC *bulletin***, 26 February 2010, page 23). Schoombie had been the ASMI's scientific director since mid-2004.

Steven Scarff

A qualified solicitor as well as a scientist, Scarff has more than 20 years of industry experience. This includes over 10 years working in regulatory affairs on the OTC products of major ASMI member companies, latterly as a regulatory affairs consultant. Scarff has also participated in ASMI meetings, providing legal guidance in trade practices compliance.

Prior to becoming a solicitor, he had held increasingly senior regulatory roles at both Pfizer Consumer Healthcare and Johnson & Johnson Pacific.

OTC

Manufacturers

Phytopharm takes on drug developer

Phytopharm has appointed **Tim Sharpington** as its new chief executive officer and board director from 6 July.

He will succeed interim chief executive officer **Sandy Morrison**, who will revert to the role of non-executive director.

Sharpington joins Phytopharm – which describes itself as a development company with "a residual portfolio of functional foods" – after nearly 20 years in drug development.

In 2006, he founded Serentis, where he raised £15 million (€18 million) of venture capital and developed two dermatology products to Phase II. Previously, he had spent three years as development director of Arakis before its £107 million sale to Sosei.

Meanwhile, Phytopharm is still talking to "major branded companies" about developing its *Hoodia gordonii* extract which it claims is a novel appetite suppressant (**OTC *bulletin***, 11 June 2010, page 3).

Consumer products giant Unilever had been a partner until 2008, when the two firms agreed mutually to terminate their arrangement to develop and commercialise the extract (**OTC *bulletin***, 28 November 2008, page 4). Unilever commented that the extract, which Phytopharm licenses from the South African Council for Scientific and Industrial Research (CSIR), had not met its safety or efficacy standards.

OTC

IN BRIEF

■ **BAYER's** worldwide head of Consumer Care, **Gary Balkema**, 54, has accepted an invitation to join the board of security-product firm Brady Corporation from 19 July.

■ **CELESIO** is recruiting an **OTC category manager** to develop trade-marketing initiatives for its Gehe Pharma Handel wholesaling operation in Germany.

■ **ANZAG** will appoint **Ralf Lieb**, 46, as its chief financial officer from September 2010. The former Sandoz employee currently holds a similar position at building supplies group VBH Holding.

■ **THE BLACKSTONE GROUP** said that **Arthur Higgins**, former chairman of the board of management at Bayer HealthCare, had joined the investment firm's healthcare group.

OTC

Divestments

Australia's Sigma seeks a buyer for its Herron brand

■ *Continued from front page*

The company was "very happy with the level of interest" shown in the brand and a number of other non-core assets it was looking to divest, he added.

The news comes shortly after Sigma announced that South Africa's Aspen Pharmacare was undertaking due diligence ahead of a possible A$1.49 billion (€1.06 billion) acquisition of the company (**OTC *bulletin***, 11 June 2010, page 5). The troubled Australian firm pointed out at the time of the announcement, however, that it would continue with its previously outlined asset-sale programme.

Sigma noted that it would not consider any other takeover offers until 5 July to allow Aspen to complete the process.

In April, Sigma wiped A$49.1 million off the goodwill valuation of the Herron range following a poor performance in the grocery channel (**OTC *bulletin***, 16 April 2010, page 2).

Commenting on the reasons why it reduced the goodwill valuation of the Herron brand, Sigma admitted that additional investment to raise brand awareness in the grocery channel had not paid off, as indicated by the company's cash-flow forecasts for the brand.

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

Most of the Herron range is vitamins and supplements, but it also offers Herron Paracetamol and Herron Blue Ibuprofen.

In addition to the Herron write-down, Sigma cut A$375 million off the A$819 million goodwill valuation placed on its Arrow business after the two companies merged in 2005 (**OTC *bulletin***, 16 September 2005, page 5).

The total of A$424 million in goodwill cuts led to Sigma reporting a net loss of A$389 million for the year ended 31 January 2010. Sales increased by 4.5% to A$3.22 billion.

In the wake of the results announcement, Sigma's chief executive officer Elmo De Alwis and chief financial officer Mark Smith stepped down from their posts.

The company recently announced that its former chief financial officer Mark Hooper would replace De Alwis as managing director and chief executive officer in September. Hooper is rejoining Sigma four years after leaving his position as chief financial officer to take up a similar role at Symbion Health. He left Symbion in 2008, and for the past two years has served as chief financial officer for paper company PaperlinX.

Commenting on Sigma's performance in the four months to the end of May, Jamieson said it had been "sound in most business areas", with the Consumer, Manufacturing, Medical and Retail businesses all performing "largely in line with expectations".

Wholesaling – Sigma's largest division in terms of sales – had reported turnover up by a tenth year-on-year, Jamieson noted, but the Generics division had suffered in what he described as a "really tough and volatile market". Jamieson pointed out that "intense competition" and "massive discounting" over the four-month period meant earnings before interest and tax by the Generics division was A$6.4 million below expectations.

Given this performance, along with the one-off costs associated with the Aspen bid and other non-recurring expenses, there was "considerable uncertainty" that Sigma would meet its profit target for the year ended 31 January 2011, Jamieson warned.

Sigma had hoped that its net profit after tax would return to about AS$80 million, the figure it reported for the year ended 31 January 2009.

OTC

Retailers

GNC promotes Berg

General Nutrition Centers (GNC) has promoted **David Berg** – executive vice president of global business development and chief operating officer of its international operations – to the newly-created role of chief operating officer at the global retailer of nutritional products. He will continue to report to Joe Fortunato, chief executive officer of GNC.

Prior to joining GNC, Berg was with the retailer Best Buy International for seven years, serving as chief operating officer from 2008.

OTC

Manufacturers

Ransom allows Whitcomb back on board of directors

William Ransom & Son has appointed **Frederick Whitcomb** to its board as a non-executive director. The move comes just 18 months after Whitcomb failed in an attempt to remove the existing board of the troubled UK-based natural healthcare company.

An executive director of Ransom between June 2005 and December 2007, Whitcomb has a 13.98% stake in the company.

In January of last year, Whitcomb and fellow shareholder Stephen Quinn tabled a motion at Ransom's annual general meeting to remove the existing board (**OTC *bulletin***, 29 January 2009, page 8). If the proposal had succeeded Whitcomb and Quinn would have been named executive directors, with former executive director David Wilkie and Frank Lewis in non-executive roles.

At the time, Ransom was five months into a turnaround plan launched by chief executive officer Ivor Harrison, who had taken over in May 2008. The aim of the plan was to streamline the business and return it to profitability (**OTC *bulletin***, 29 September 2008, page 6).

Commenting on Whitcomb's return to the board, David Suddens, chairman of Ransom, said Whitcomb had requested representation on the board and had emphasised his desire to work with the existing board and management to drive shareholder value.

Having given the request careful consideration, and having taken account of Whitcomb's sizeable shareholding, the board felt it was appropriate to grant the request and welcome Whitcomb onto the board in a non-executive capacity, Suddens said.

Ransom recently announced that its finance director Robert Denton had left the company after less than a week in the post (**OTC *bulletin***, 14 May 2010, page 26).

OTC

Mergers & Acquisitions

Sanofi-Aventis to catch Canderm

■ *Continued from front page*

-lion (€1.5 billion) for Chattem (**OTC *bulletin***, 17 March 2010, page 9). Announcing the acquisition in December, the company said it was considering expanding its Canadian Consumer Health Care business by introducing Chattem's products into Canada (**OTC *bulletin***, 20 January 2010, page 20).

Less than a month ago, Sanofi-Aventis announced it was set to acquire Nepentes in a deal that valued the Polish OTC company at PLN420 million (€105 million) (**OTC *bulletin***, 31 May 2010, page 1).

Canderm and Nepentes are the latest in a series of OTC acquisitions by Sanofi-Aventis, which helped push up sales by the company's Consumer Health Care business by 44.8% – 42.5% at constant exchange rates – to €491 million in the first quarter of 2010 (**OTC *bulletin***, 14 May 2010, page 8).

Sanofi-Aventis says that it is the fifth-largest consumer healthcare player in the world.

Meanwhile, Sanofi-Aventis is set to establish a generics joint venture in Japan with leading Japanese generics company Nichi-Iko. The French firm will hold a majority 51% stake.

OTC

Product Recalls

McNeil warns on OTC supply in US

■ *Continued from front page*

not affected by the ongoing suspension of manufacturing at Fort Washington in the wake of recent product recalls.

Nevertheless, it pointed out that the products made at Fort Washington had recorded average annual sales of around US$650 million (€530 million) for the past three years. This represented just over a fifth of McNeil's US OTC & Nutritional sales in 2009, which were US$2.49 billion (**OTC *bulletin***, 10 February 2010, page 6).

Meanwhile, McNeil has expanded a previously announced recall of OTC products (see page 12).

OTC

Industry Associations

GSK's Hallatt now president of PAGB

GlaxoSmithKline Consumer Healthcare's **James Hallatt** has been elected president of the Proprietary Association of Great Britain (PAGB), succeeding Pfizer Consumer Healthcare's **John Smith** who had performed the role for the previous two years.

Hallatt – who succeeded Roger Scarlett-Smith in 2008 as vice-president and general manager of GlaxoSmithKline's UK Consumer Healthcare operation (**OTC *bulletin***, 31 July 2008, page 27) – said increased self-care had the potential to free resources and help the National Health Service (NHS) reach its target of making £20 billion (€25 billion) in efficiency savings by 2013-2014.

James Hallatt

"There are currently 57 million general practitioner consultations every year for minor ailments that could be self-treated. This results in every general practitioner spending on average an hour a day seeing patients with minor ailments at an estimated cost to the NHS of £2 billion," he said, asking: "In these straitened times, is this really an appropriate use of the health service?"

Hallatt pointed out that 990 million packs of OTC medicines had been sold in the UK during 2009 compared with just over a billion prescriptions. "There is no doubt that self-medication continues to play a key part in UK healthcare, but we need to continue to innovate and develop products that are modern, relevant and meet consumer needs."

Pane and Reidla are vice-presidents

The PAGB's vice-presidents are Reckitt Benckiser's **Camillo Pane** and Bayer HealthCare's **Meelis Reidla**. Honorary vice-president **Clive Dixon** continues as treasurer.

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