OTC bulletin

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THE BUSINESS NEWSLETTER FOR THE CONSUMER HEALTHCARE INDUSTRY

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OTC bulletin

THE BUSINESS NEWSLETTER FOR THE CONSUMER HEALTHCARE INDUSTRY

US removes age block to emergency contraception

A US court has ordered that all levonorgestrel-based emergency contraceptives, including Teva's Plan B One-Step product, be made available OTC to women of all ages. The ruling removes the need for women aged 16 and under to obtain a prescription for the products.

The ruling handed down by a New York district court overturns the US Food and Drug Administration's (FDA's) decision to twice deny a Citizen Petition originally filed by the Center for Reproductive Rights in 2001, which sought OTC access to all emergency contraception for women of all ages.

It also undoes a 2011 decision by Kathleen Sebelius, secretary of the US Department of Health and Human Services (HHS), to deny Teva's application to make Plan B One-Step available OTC to women of all ages (**OTC *bulletin***, 19 December 2011, page 8).

In his ruling issued on 5 April 2013, district court judge Edward Korman said that he believed that the current obstructions in the the path of women – specifically adolescents – in obtaining emergency contraceptives under the current behind-the-counter regime had a "practical effect of making contraceptives unavailable without a doctor's prescription".

"Consequently, the decision of the FDA denying the Citizen Petition is reversed," Korman said, "and the case is remanded to the FDA with the instruction to grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within 30 days."

Korman described both the FDA's actions, in regards to the Citizen Petition and Sebelius' denial of Teva's application as "arbitrary, capri-

■ *Continued on page 23*

Dr Kade grabs Takeda's German brands

Dr Kade has acquired Takeda's portfolio of OTC brands in Germany and signed an exclusive deal with the Japanese company to sell its Pantozol Control OTC heartburn medicine in the country.

The family-owned German firm said the deal had given it a number of well-established German OTC brands, including the Faktu haemorrhoid treatment, Buer and Sanostol vitamin lines and the Riopan heartburn brand.

In addition, Dr Kade said it had acquired from Takeda an exclusive licence to sell the pantoprazole-based Pantozol Control in Germany. Pantozol Control was previously sold as an OTC medicine in Germany by Nycomed, which Takeda acquired in 2011 (**OTC *bulletin***, 30 May 2011, page 1).

The deal would also see Dr Kade add Takeda's German pharmacy salesforce to its Avenda sales subsidiary, the company noted.

Felix König, director of Dr Kade, said the brands would be a "useful addition" to its already "successful OTC portfolio", which included the market-leading haemorrhoid brand Posterisan and the thrush treatment KadeFungin.

OTC sales accounted for around a third – €20 million – of Dr Kade's domestic sales, which stood at €60 million in 2011. Group sales in 2011, including domestic and international turnover, were approximately €80 million.

The acquisition supported the company's long-term growth plans, König pointed out, and better prepared it for the challenges the healthcare market was set to face.

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Business Strategy

Bausch & Lomb set to go public

Privately-held US-based eye health specialist Bausch & Lomb looks set to return to the public markets after its holding company WP Prism filed a registration statement for a proposed initial public offering.

Although the registration statement had been filed with the US Securities and Exchange Commission, the number of shares to be offered and the price range for the proposed offering had yet to be determined, Bausch & Lomb noted.

The move comes three months after Bausch & Lomb confirmed that it had been approached by companies showing a "strategic interest" in the business (**OTC *bulletin***, 18 January 2013, page 5).

Approached by interested parties

At the time, the company said it was "regularly contacted" by interested parties and continued to "aspire to a return to the public markets". However, Bausch & Lomb was firmly focused on "building the best global eye health company", the firm added.

In January, Merck & Co's chief executive officer Kenneth Frazier admitted that his company might be interested in Bausch & Lomb, telling *Bloomberg News* that acquiring the firm was "something worth thinking about".

Private-equity firm Warburg Pincus took Bausch & Lomb private five and a half years ago in a deal worth over US$4 billion (€3 billion) including debt (**OTC *bulletin***, 28 September 2007, page 5). Bausch & Lomb pushed through the deal despite a late bid from rival eyecare company Advanced Medical Optics.

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Licensing Agreements

Church & Dwight gets Futura CSD500 condom

Church & Dwight is set to launch Futura Medical's CSD500 erection-maintaining condom under its Trojan brand name after snapping up the rights to the product in North America and certain European markets.

Adrian Huns, president of international consumer products at the US-based company, said that CSD500 was a "genuinely novel condom" that represented a "major breakthrough in condom technology".

"We look forward to working with Futura on the successful completion of the required approvals necessary, ahead of the launch in Europe and North America of a completely new type of condom from a highly trusted brand," Huns added.

Under the terms of the deal, Church & Dwight has gained the rights to manufacture, market and distribute CSD500 in North America and a "number of key European markets".

Although the financial details of the deal have not been disclosed, Futura pointed out that it would receive an upfront payment and royalties on all product sales, along with certain minimum performance guarantees.

James Barder, Futura's chief executive officer, said the UK-based development company was pleased that this "pivotal deal" would see CSD500 marketed under "one of the world's biggest condom brands and the number one brand in North America".

The deal was also in line with the licensing strategy adopted by Futura after it regained the rights to CSD500 from Reckitt Benckiser last year (**OTC *bulletin***, 28 September 2012, page 6), Barder pointed out. This strategy, he noted, focused on licensing the product on a geographic basis to condom distributors with leading positions in their regions.

"We continue to negotiate CSD500 rights for other major territories and believe that this strategy will create optimal value for shareholders," Barder added.

Futura said at the end of March that it was preparing to announce the first of several licensing deals for CSD500 (**OTC *bulletin***, 29 March 2013, page 3).

CSD500 – which contains the erectogenic gel Zanifil – would "fundamentally change the condom market" due to its "highly innovative 'disruptive technology'", Futura claimed, and would command a "significant price premium over existing condoms".

Furthermore, CSD500's "appealing proposition and unique claims" would help grow the overall condom category, the company insisted, adding that it expected the product to gain a market share "significantly in excess of 10%" in the UK and the US.

Three marketing claims for the product had been approved by regulatory authorities, Futura pointed out, including the maintenance of a firmer erection; increased penile size; and a longer-lasting sexual experience for women.

Futura had also been granted patents or was in the process of being granted patents related to CSD500 in 36 countries worldwide, the company said, including key markets in Europe and North America.

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Business Strategy/Annual Results

Oxford targets high value categories

A fresh round of fundraising has left Oxford Pharmascience "excellently placed" to take its OTC and prescription drug-delivery technologies into "more attractive and higher value" categories, according to the company's chairman David Norwood.

The UK-based development firm had raised £5.0 million (€5.9 million) in March, Norwood pointed out, through a new share placing. This had resulted in Invesco Asset Management holding an 18.6% stake in the business.

These new funds would allow the company to develop its OXP Zero taste-masking technology for a range of non-steroidal anti-inflammatory drugs (NSAIDs), he noted, and accelerate development of its OXP Target controlled-release technology for use with statins.

The company had made "significant progress" in 2012, Norwood insisted, with sales in Brazil of chewable vitamins based on its OXP Chew soft-chew technology continuing to grow.

The trick now, Norwood said, was to repeat the success of OXP Chew with OXP Zero and OXP Target by converting them into "real, exciting products" that the industry wanted in the "more attractive and higher-value areas of NSAIDs and statins".

Throughout 2013, the company would look to take to market new products which utilised OXP Zero and OXP Target as "quickly as possible", Norwood pointed out, and secure further commercial licensing deals with "major pharmaceutical partners".

At the end of last year, Oxford Pharmascience announced that it had struck a deal with an unnamed pharmaceutical company to develop a range of undisclosed "on-the-go" consumer products using its OXP Zero taste-masking technology (**OTC *bulletin***, 18 December 2012, page 4).

Under the terms of the deal, the company will produce a range of "non-tablet products" that could be used "on-the-go" for market research testing to determine the best versions.

Upon the successful conclusion of a feasibility study, the unnamed company would have an option to take an exclusive worldwide licence to sell the products under one of its main brands, Oxford Pharmascience pointed out.

At the same time, the firm also announced that it was set to use its OXP Chew technology to develop a dietary supplement for another unnamed major pharmaceutical company.

Oxford Pharmascience said that it had reached a "feasibility and option agreement" with the unnamed company to develop prototype products using OXP Chew technology.

Under the terms of the agreement, the unnamed company had the option to negotiate an exclusive licensing agreement to sell the products under its main multivitamin brand, the firm noted.

The two deals came at the end of a productive year for Oxford Pharmascience. In March, the company announced that its OXP Zero technology was set to appear in a range of ibuprofen-based products from Hermes Pharma after the two companies signed a 'heads of terms' agreement (**OTC *bulletin***, 30 March 2012, page 8).

Two months later, the company signed a 10-year licensing agreement with Bayer Consumer Care, which would see the German firm use OXP Chew technology to manufacture a calcium and vitamin D soft-chew product (**OTC *bulletin***, 31 May 2012, page 11).

Sales in Brazil of the Inellare vitamin chew, based on Oxford Pharmascience's OXP Chew technology, increased rapidly in 2012

Oxford Pharmascience also pointed out that product sales in 2012 had grown by 39% to £393,000, driven by its deal with Aché Laboratórios Farmacêuticos in Brazil.

The company uses its OXP Chew technology to produce a calcium and vitamin D product which Aché sells in Brazil under the Inellare brand name (**OTC *bulletin***, 29 April 2011, page 3). The OXP Chew calcium and vitamin D product is also currently marketed in the UK and Middle East.

Overall turnover for the year – including licensing, development and grant income, as well as product sales – rose by 65% to £466,000.

The company's net loss had shrunk by 15% to £783,000 in 2012, Oxford Pharmascience said, noting that as of 31 December 2012 it had £2.2 million in cash resources.

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IN BRIEF

■ **VITAMIN SHOPPE** said that its **first international franchise store** had opened in Panama City, Panama. The US-based retailer said the new store had been opened by Reprico, a local firm with a long history in health and wellness retailing. The store offered Panamanians an "unrivalled selection of brands and products", Vitamin Shoppe claimed, and stocked over 800 products in more than 70 lines ranging from vitamins and supplements to herbal remedies and beauty aids. Vitamin Shoppe recently expanded into Canada by opening two of its own stores in the Greater Toronto area under the Vitapath banner (**OTC *bulletin***, 8 February 2013, page 3).

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Business Strategy

Sanofi invests US$75 mn in Vietnam

Sanofi is investing US$75 million (€59 million) in a new manufacturing facility in Vietnam that will produce a range of the French firm's prescription and consumer healthcare products.

The new plant in Ho Chi Minh City would help Sanofi meet the growing demands of the Vietnamese pharmaceutical market, the company noted, as well as serve as an export platform to other members of the Association of South East Asian Nations (ASEAN).

Christopher Viehbacher, Sanofi's chief executive officer, said that the new plant represented the largest investment by the company in Vietnam and illustrated its commitment to bringing "high-quality medicines to a broader population" across the country.

Scheduled to be fully operational by the end of 2015, the plant would have an initial capacity of 90 million units per year, Sanofi said, with the potential to expand the capacity to up to 150 million units.

Sanofi Vietnam was the leading pharmaceutical firm in the country, Sanofi claimed, with a market share of 4%.

The subsidiary also had a strong partnership with local pharmaceutical firm Vinapharm, the company said.

OTC

Annual Results

Nepstar strategy boosts turnover

China Nepstar's strategy of optimising product offerings, diversifying into non-pharmaceutical categories and closing underperforming stores had led to a rise in sales in 2012, according to chief executive officer Fuxiang Zhang.

The Chinese drugstore company reported 2012 sales up by 2.4% to CNY2.55 billion (€320 million), with same-store turnover rising by 9.1% compared to the previous 12 months.

Operating income had increased even quicker, Nepstar said, growing by 21.5% to CNY46.9 million, as cost control measures reduced operating expenses.

OTC drugs had accounted for 39.1% of the firm's sales in 2012, Nepstar noted, with convenience and other products generating 20.9%. Prescription drug sales were responsible for a further 20.4%, nutritional supplements 15.7% and traditional Chinese products 3.9%.

The company's private-label products represented 26.8% of sales in the 12 months, the company noted, down from 30.0% in 2011.

As of 31 December 2012, Nepstar was operating 2,132 stores across China, having opened 56 new stores and closed 319 over the year.

Looking ahead, Zhang said that the company remained "cautiously optimistic".

"We believe the strategic changes we have implemented to drive sales, control costs and improve store efficiencies will help us remain competitive," Zhang pointed out.

The company continued to see opportunities in the OTC drugs and convenience product categories, Zhang noted, while cost-control measures had started to reduce expenses. These two positives, coupled with continued improvements in same-store sales and the efforts of the firm's management team, should lead to a better performance in 2013, he added.

OTC

IN BRIEF

■ **LITHA HEALTHCARE** said that its **sales had decreased** by 18% to R1.43 billion (€120 million) in 2012, while pre-tax operating profit had grown by 56% to R216 million. In July last year, the South African firm acquired Pharmaplan from Canada's Paladin Labs (**OTC *bulletin***, 15 June 2012, page 4). Commenting on the deal, Litha said that merging Pharmaplan's portfolio with its own products would complement its generics and OTC businesses.

OTC

Mergers & Acquisitions

Adcock keeps open mind despite rejecting Bidvest

Adcock Ingram has rejected an "unsolicited" takeover offer from Bidvest, a South African conglomerate that already owns 2.54% of Adcock's shares.

However, Adcock said it would "keep an open mind" on any revised proposal from Bidvest, which wants to raise its stake in the South African pharmaceuticals group to 60.0% through a cash-and-equity offer valued at around R6.3 billion (€531 million).

Khotso Mokhele, Adcock's chairman, said Bidvest had made "nothing more than a non-binding proposal" and had "provided no insight into the strategic rationale for its proposal and the potential benefits" or areas of synergy.

Having consulted with shareholders representing almost two-thirds of Adcock's issued shares, the South African firm's independent board had "fundamental legal and material concerns" about Bidvest's offer.

Bidvest's approach was opportunistic

The timing of Bidvest's approach was "opportunistic", Mokhele believed, as Adcock had recently completed a ZAR1.5 billion upgrade of its facilities, won a "significant slice" of South Africa's antiretrovirals tender and completed acquisitions of both Ghana's Ayrton Drug and India's Cosme Farma (**OTC *bulletin***, 27 July 2012, page 8).

Bidvest has offered almost two-times Adcock Ingram's sales in its financial year ended 30 September 2012, which grew by 3.3% to R4.60 billion (see Figure 1), as OTC sales in Southern Africa increased by more than a tenth to R1.79 billion (**OTC *bulletin***, 18 December 2012, page 7). But the firm's operating profit dipped by 19% to R869 million.

Adcock said the double-digit growth at its Southern African OTC business had been driven by acquisitions, reducing its reliance on scheduled OTC products and strong brands.

Acquiring NutriLida and its portfolio of vitamin, mineral and supplement (VMS) brands in July 2011 (**OTC *bulletin***, 15 April 2011, page 6) had added R162 million (€14.2 million) to the company's OTC sales in Southern Africa, Adcock pointed out.

Adding NutriLida – along with the ADDvance "brain health" supplements in late 2011 – had made Adcock number one in the VMS category of the fast-moving consumer goods (FMCG) of the same market, the firm noted.

Furthermore, the contribution from NutriLida's brands meant that, for the first time, over half – 53% – of the company's OTC sales in South Africa had been generated by "unscheduled products", Adcock said. The firm defines unscheduled products as schedule 0 listed medicines, complementary alternative medicines and personal care brands.

Quoting IMS data, Adcock noted that sales of unscheduled products in its home market of South Africa had advanced by 31% in the year ended September. Turnover from schedule 1 products – pharmacy-only – had improved by 5%, compared to 9% in the prior year, the company pointed out, while sales of schedule 2 products – sold only by a pharmacist – had advanced by just 6%, down from 13% growth a year earlier.

The big rise in sales of unscheduled products had been driven by more people taking a "proactive approach" to their health, Adcock noted.

Adcock's OTC sales in Southern Africa had also been boosted by better performances from key brands, the firm said.

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Business	Annual sales (R millions)	Change (%)	Operating profit (R millions)	Change (%)
OTC	*1,792*	*+11*	*660*	*-3*
Prescription	*1,520*	*-7*	*372*	*-23*
Hospital	*1,124*	*+6*	*213*	*+5*
Southern Africa	4,436	+3	1,246	-9
Rest of Africa and India	296	+15	76	+20
Intra-company/other	-132	–	-452	–
Total Adcock Ingram	**4,599**	**+3**	**869**	**-19**

Figure 1: Adcock Ingram's sales and operating profit in the year ended 30 September 2012, broken down by business (Source – Adcock Ingram)

Annual Results

International growth spurt boosts OTC sales at CFR

Chile's CFR Pharmaceuticals said its K2 Health & Wellness division had posted a double-digit increase in sales in 2012, thanks to strong growth across key international markets.

Turnover at K2 – the firm's OTC healthcare and beauty products division, which operates in eight Latin American countries – had advanced by 17.8% to US$39.6 million (€30.9 million), CFR said, primarily as a result of higher sales in Colombia, Peru and Venezuela.

Colombia had been the division's best-performing market, with sales more than trebling to US$5.7 million in the 12 months, the company noted, while turnover in Peru advanced by 13.1% to US$16.5 million. In Venezuela, sales improved by 28.1% to US$2.4 million.

Turning to K2's three leading brands – which accounted for 47% of the division's total sales – CFR said that the Caprimida range of calcium products had grown quickest, with sales rising by 20.3% to US$9.2 million.

Niofen analgesics had posted turnover up by 14.2% to US$3.3 million, the company added, while the sales of the Sugafor sweetener range had increased by 13.8% to US$6.1 million.

K2 represented 6.9% of CFR's total group sales, which grew by 16.3% to US$571 million. On a local currency basis, the rise was 17.3%.

The majority of CFR's remaining sales were primarily generated by its range of "off-patent and locally unpatented" branded speciality pharmaceutical products and complex injectables, spread across four core divisions (see Figure 1).

CFR noted that it was set to simplify its reporting structure to just four segments – Complex Therapeutics, Health & Wellness, Specialty Pharma and Other – in the coming year after acquiring the Colombian generics and OTC firm Lafrancol at the end of 2012.

Under the new structure, Health & Wellness would account for 8.7% of CFR's total 2012 sales, the company noted, with Specialty Pharma generating the majority (see Figure 2).

Commenting on the US$562 million Lafrancol deal, CFR said that it was now the "leading pharmaceutical company in Colombia", holding the number one spot in the country's branded generics market and the number four spot in the generics market overall.

Expanded OTC offering

The deal also boosted the company's OTC offering, CFR pointed out, with a wide portfolio of "leading brands", which accounted for 20% – US$40 million – of Lafrancol's annual sales of around US$200 million.

Alejandro Weinstein, CFR's chief executive officer, said the "transformational acquisition" of Lafrancol gave the company a "great platform for future growth" in a "attractive and rapidly-growing" market.

Furthermore, the deal would be immediately accretive, Weinstein noted, and offered a number of revenue and cost-synergy opportunities.

Colombia was a "key" pharmaceutical market within Latin America, Weinstein said, with a population of approximately 47 million and a growing middle class. The Colombian pharmaceutical market was worth almost US$4 billion annually, he added, and was expected to grow by 10% per year from 2012 to 2016.

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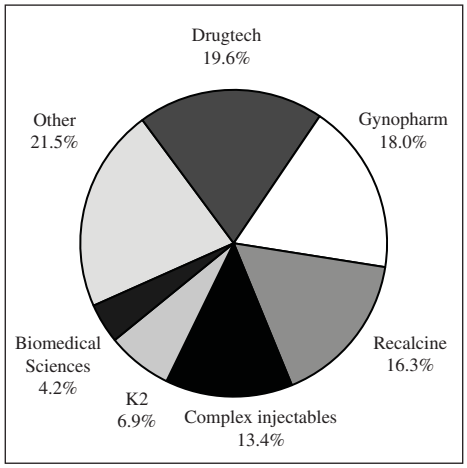

Figure 1: Breakdown of CFR's 2012 sales – US$71 million – by division (Source – CFR)

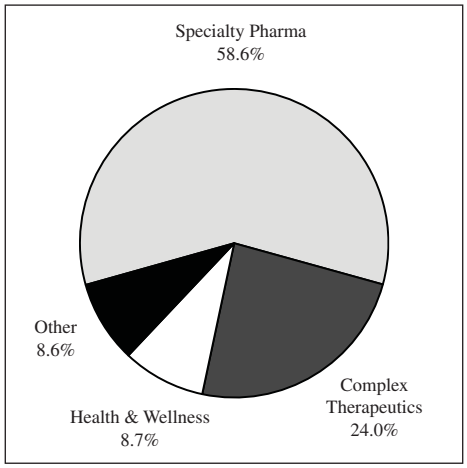

Figure 2: CFR's 2012 sales using the firm's new streamlined reporting structure (Source – CFR)

Annual Results

Sinupret Extract helps Bionorica

Introducing the Sinupret Extract extension to its market-leading herbal respiratory brand helped Germany's Bionorica to pass group sales of €200 million for the first time last year.

Having secured approval from Germany's federal institute for drugs and medical devices, BfArM, Bionorica in October last year launched Sinupret Extract in its home market (**OTC *bulletin***, 26 October 2012, page 15).

The line extension to "Germany's most-successful herbal medicine" contains the same combination of five herbs as other Sinupret variants. However, the cold remedy offers "a four-times higher concentration of natural active ingredients".

"In just three months, the market share by value of Sinupret Extract in Germany rapidly rose to 5.5%," Bionorica claimed, quoting IMS Health data for pharmacy sales. Two-thirds of German pharmacies were currently stocking the line extension, the company added.

During 2012, the herbal medicines firm increased the total number of Sinupret packs sold in Germany by about 15% – or by 1.2 million – to 9.3 million. This had raised the brand's market share by value to 19.7%.

Announcing the German launch, Bionorica had said that it would seek marketing authorisations for its patented Sinupret Extract in the firm's "key international markets".

"Growth in international core markets" complemented the German group's double-digit domestic sales rise in 2012. Quoting Insight Health data, Bionorica said it had improved its domestic sales by 15.3%, whilst the local OTC market had advanced by barely 1%.

According to Bionorica, clearly outperforming its OTC competitors in Germany stemmed in part from its "unique pharmacy sales concept", the Phytothek. These are dedicated areas of pharmacies in which herbal medicines are exclusively presented by indication to consumers.

Having started to roll out its store-in-store concept in March 2012 (**OTC *bulletin***, 16 April 2012, page 7), Bionorica said that, by the end of last year, it had installed a Phytothek display unit in 209 German pharmacies.

The firm intends to install around 300 units per year in Germany, while 16 Phytothek pilot projects are also underway in Russia and Ukraine, where Bionorica is a leading supplier of herbal remedies.

OTC

Business Strategy

Scheske's Infirst raises launch funds

Infirst Healthcare has raised £25 million (€30 million) to help launch its cocoa-flavoured OTC cough medicine in Europe and commercialise its pipeline of non-prescription products.

The UK-based company – led by Manfred Scheske, former European president of GlaxoSmithKline Consumer Healthcare – said the funding from Invesco Asset Management would enable the firm to enter the "US$20 billion (€16 billion) cough, cold and pain consumer healthcare markets".

Scheske pointed out that cough, cold and pain were the "largest and most prevalent conditions in the consumer health sector" and represented an "enormous opportunity" for Infirst to bring "innovation and efficacy" to a market which had seen few new products and only "marginal innovation" over the past few decades.

Speaking to **OTC *bulletin***, Scheske said the new funding demonstrated the value in Infirst's philosophy of "known drugs – made better".

OTC companies continued to see switching as the main path to innovation in the OTC sector, Scheske said, but there was significant value to be found in making established ingredients work harder and better.

This strategic focus would allow Infirst rapidly to develop new products that would be faced with minimal regulatory burdens, Scheske said, but would still produce valuable intellectual property and offer real benefits.

Infirst plans to launch the cocoa-flavoured cough medicine under its own brand name in a "key European market" sometime in 2014.

In this first key market, the product would be based on a combination of diphenhydramine hydrochloride and levomenthol, Scheske pointed out. However, the product's active ingredients could be changed in individual markets to suit the regulatory environment, he added.

US launch handled by Pernix

Outside of Europe, Infirst has licensed the cocoa-flavoured cough liquid to Pernix Therapeutics in the US.

Pernix said that it planned to launch the product under the Dr Cocoa brand name "in time for the 2013/2014 cough and cold season".

The Dr Cocoa product range would include daytime, nighttime, cough, cold and fever formulations, the US-based firm pointed out.

Turning to other products in Infirst's pipeline, Scheske said the development of a new presentation of ibuprofen was "on schedule".

The ibuprofen product would not be just another headache product, Scheske noted, but a product focused specifically on inflammation.

A brand name had already been chosen, Scheske said, adding that the product would mostly likely be rolled out in Europe first.

Commenting on how Infirst decided which areas of the OTC market to target, Scheske said that the company had very strict criteria.

There needed to be an unmet need in the category, preferably a symptomatic need, Scheske said, and the company had to be sure its potential product could make a difference.

Asked about potential partnership opportunities, Scheske said that the company was "very open" to deals with big pharmaceutical firms, as well as "horizontal" partnerships with companies similar to itself.

OTC

Business Strategy

Boots changes BCM approach

Alliance Boots has unveiled a "new strategic approach" for its BCM contract manufacturing business, including a shake-up of operations at its factory in Nottingham, UK.

The programme – which will lead to the loss of around 200 jobs – would refocus the Nottingham facility on activities where it had a sustained competitive advantage, Alliance Boots said, including production of the group's beauty and skincare brands.

BCM would exit certain unprofitable areas of third-party manufacturing, the company pointed out, but would also benefit from investment in new product technologies to enable greater flexibility and better support for Boots' own product-development activities.

This shift would address a reduction in manufacturing volumes, the company claimed, due to a fall in external market demand for contract manufacturing and an increase in regulatory compliance requirements.

It would also position BCM to "seize growth opportunities generated by the further internationalisation of the group's brands, including the US market", Alliance Boots said.

The reorganisation of BCM would cost just over £30 million (€35 million), the firm noted, all of which would be booked in its 2012/2013 financial year.

One of the largest contract manufacturers in Western Europe, BCM manufactures consumer health and beauty products for internal supply as well as third-party brands. The company also produces special prescription medicines for individual use.

In addition to its operations in Nottingham, the firm operates BCM Cosmetique in France – which specialises in skincare and cosmetic brands – and BCM Kosmetik in Germany, which produces colour cosmetics. BCM Specials manufactures sterile and non-sterile bespoke unlicensed medicines for patients in the UK.

OTC

IN BRIEF

■ **GRINDEKS** said that its **sales had improved by 5%** in the opening two months of 2013, keeping it on track to achieve its sales target of approximately LVL100 million (€145 million) by the end of the year. The Latvian firm noted that it had also opened talks with potential export partners in Southeast Asia.

OTC

Annual Results

ProPhase Labs promises next generation products

ProPhase Labs is set to reveal the "next generation" of Cold-EEZE cold and flu products in time for the 2013/2014 cough, cold and flu season, according to chairman and chief executive officer Ted Karkus.

Speaking as ProPhase reported 2012 sales up by 28.4% to US$22.4 million (€17.4 million), Karkus said that the new products would be available in the autumn and would not just be new flavours of lozenge.

The next generation of Cold-EEZE products would feature "new delivery forms", Karkus revealed, that not only shortened the duration of the common cold but also provided "additional health benefits".

Much like in 2012, the firm's aim looking ahead, Karkus pointed out, was to launch products that efficiently leveraged its marketing budget and its improved distribution platform.

After net sales had "bottomed" in 2010, ProPhase developed and implemented a long-term strategy to improve the business, Karkus said.

This included improving the core Cold-EEZE homoeopathic lozenge range, expanding distribution and overhauling the company's approach to marketing and in-store merchandising, he noted.

The result had been a 20.3% increase in net sales in 2011 and a 28.4% rise in 2012, Karkus pointed out – results achieved despite a "significant decline in the incidence of upper respiratory illness" in the US over the two years.

ProPhase announced its 2012 results a month after Matrixx Initiatives – owner of the rival Zicam Cold Remedy brand – withdrew its takeover offer for the company (**OTC *bulletin***, 22 February 2013, page 8).

Ted Karkus, ProPhase Labs' chairman and chief executive officer, said the next generation of Cold-EEZE products would be available in the autumn

Matrixx ended its interest shortly after ProPhase secured a share equity line with investment fund-management company Dutchess Opportunity Fund (**OTC *bulletin***, 18 December 2012, page 6).

In October last year, Matrixx made an improved US$1.60 per share bid for ProPhase, after having had its initial US$1.40 per share offer rejected (**OTC *bulletin***, 26 October 2012, page 6). At the time, the improved offer valued ProPhase at US$24 million.

OTC

Annual Results

Alliance Pharma reports sales decline

Alliance Pharma said it remained on the look out for further acquisitions, despite striking a number of deals in 2012 and posting a 2% decline in annual sales to £44.9 million (€52.9 million).

The UK-based speciality pharmaceutical company blamed the drop in turnover on generic competition to its key Deltacortril steroid brand and the decision by Sanofi Pasteur Canada to suspend production of the cancer drug ImmuCyst, which Alliance distributes in the UK and Ireland.

Excluding Deltacortril and ImmuCyst, sales from its range of dermatology, nutrition and oncology products improved by 13%.

Operating profit, Alliance said, had slipped back by 0.2% to £12.3 million.

During the year, Alliance expanded its non-prescription offering by acquiring the Quinoderm acne treatment and Ceanel shampoo from Ferndale Pharmaceuticals (**OTC *bulletin***, 23 January 2012, page 3).

Looking ahead, Alliance said it was confident of achieving sales growth in 2013, thanks to the underlying strength of its product portfolio and a full year's contribution from its 2012 acquisitions.

OTC

Market Research

Sales rise at UK independent pharmacies

Independent community pharmacies sell approximately 12% of all OTC medicines and vitamins in the UK, according to recent research by SymphonyIRI Group.

This figure is up by 1.9% compared to a total market increase of OTC sales of 1.6%, the research by the market measurement and consultancy firm reveals.

According to the research, growth has been driven by sales of seasonal products such as decongestants as well as specialist skin products.

Over 20% of total non-prescription sales within independent pharmacies are represented by products available only through pharmacy, requiring advice or assistance from the pharmacist or pharmacy staff, such as for dry skin treatments and sleeping aids, the research shows (see Figure 1).

Martin Wood, Business Unit Director, Health and Beauty at SymphonyIRI Group, said that whilst the National Health Service (NHS) encouraged doctors to recommend OTC medicines to save money, tranaction dynamics were different in community pharmacy.

He pointed out: "Advice, which may include guidance on price points and the benefits of generic alternatives, is more important."

Pre-planned purchase decision-making is less important in the pharmacy compared with self-selection from the general-sale list shelves as part of a supermarket shop. So a different approach to pricing and product ranging is required by OTC firms, as is communication through good channels including the trade press and an in-house of third-party salesforce."

Meanwhile, the findings reveal that independent pharmacies still account for a "healthy" 40% of pharmacy outlets in the UK. Their numbers are growing despite the long-term trend of pharmacies opening in major multiple supermarkets such as Tesco, Sainsbury and Asda, and the growth of bigger pharmacy chains, such as Boots and the Co-operative Pharmacy.

This growth, together with increased footfall in all pharmacies driven by increased prescriptions from doctors, the research notes, has led to the rise in OTC medicine sales.

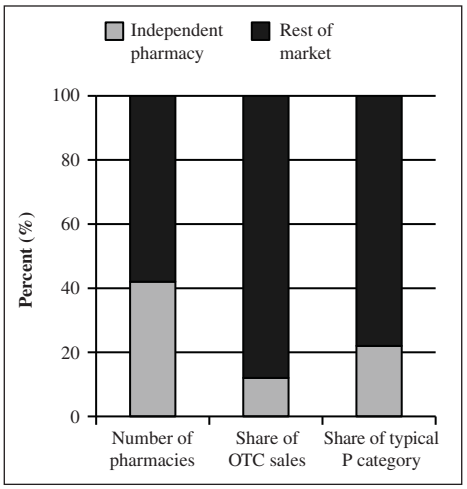

Figure 1: Relative numbers and performance of independent pharmacies in the total UK market in the year ended 6 October 2012 (Source – SymphonyIRI Group)

OTC

Regulatory Affairs

FDA needs more supplement data

More information is needed by the US Food and Drug Administration (FDA) to identify possible safety concerns associated with dietary supplements, according to a report by the country's Government Accountability Office (GAO). This could be achieved by obtaining data from poison centres, it recommends, which are shown to have received a higher number than the FDA of adverse event reports (AERs) from consumers and healthcare professionals.

Another suggestion in the report – which analysed FDA data on AERs for dietary supplements received from January 2008 and December 2011, and again between 1 January and 30 September 2012 – is that the FDA finalises guidance clarifying whether a liquid product may be labelled and marketed as a dietary supplement or as a conventional food.

Furthermore, the FDA should show that AERs are being used to their fullest extent, the report suggests. It should systematically collect information on when AERs are used to "support and inform consumer protection actions", such as inspections, consumer alerts and recalls.

OTC

Regulatory Affairs

FDA proposes changes to NRT labelling

Some warnings in the labelling of nicotine replacement therapy (NRT) products are unnecessary and can be removed, according to the US Food and Drug Administration (FDA).

Certain warnings and limitations are no longer necessary to ensure safe and effective use to quit smoking, the agency believes.

FDA Commissioner Margaret Hamburg said: "The FDA hopes the recommended changes will allow more people to use these products effectively for smoking cessation and that tobacco dependence will decline in this country."

She added that the changes addressed concerns from public health groups that the existing labelling could stop consumers trying to quit smoking from using the products.

Proposed changes to the labelling include removing the warning that consumers should not use an NRT product if they are still smoking, chewing tobacco, using snuff or any other product that contains nicotine, such as another NRT.

Furthermore, a warning on the duration of use – directing consumers to stop using the NRT product at the end of a recommended treatment period – has also been modified, based on evidence showing no additional safety risks from long-term use (see Figure 1).

The changes, the FDA said, reflected decades of research and use showing that non-prescription NRT products did not have significant potential for abuse or dependence.

A review on NRT labelling and safety was conducted by the FDA as a result of three Citizen Petitions filed between 2008 and 2010. The petitions requested changes to the labelling of non-prescription NRT products, including instructions covering the duration of use and use with other nicotine-containing products.

Meanwhile, the FDA has compiled a report for Congress recommending how best to regulate, promote and encourage innovative smoking-cessation treatments. The report relates to implementing section 918 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act (**OTC *bulletin***, 29 March 2013, page 13).

A number of NRT products have been made available OTC in the US in the past two decades. NRT gums and patches were switched from prescription to OTC status between 1996 and 2002, while nicotine lozenges were approved directly for OTC use in 2002, with mini-lozenges following suit in 2009.

Current Drug Facts labelling	Proposed Drug Facts labelling
Warnings: **Do not use** if you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products	None. The "Do not use" statement would be deleted
Directions: Stop smoking completely when you begin using [the NRT product]	***Directions:*** Begin using [the NRT product] on your quit day
It is important to complete treatment. Stop using [the NRT product] at the end of [a specified number of] weeks. If you still feel the need to use [the NRT product], talk to your doctor	It is important to complete treatment. If you feel you need to use [the NRT product] for a longer period to keep from smoking, talk to your health care provider

Figure 1: Proposed changes to labelling of OTC nicotine-replacement therapy products in the US (Source – FDA)

Regulatory Affairs

ASMI welcomes new staged OTC approach

The "staged approach" to introducing changes to the administrative processes for the evaluation of OTC medicines in Australia and New Zealand has been welcomed by the Australian Self-Medication Industry (ASMI).

Changes to how OTC medicines are authorised in Australia and New Zealand will be introduced from 15 April 2013 (**OTC *bulletin***, 29 March 2013, page 9) and rolled out over a period of 12 months.

The changes – proposed in a consultation document published in September 2012 (**OTC *bulletin***, 28 September 2012, page 1) – include creating monographs for OTC medicines as well as a series of risk-related OTC categories.

The ASMI said the staged approach would assist sponsors to "get it right" without losing their application fee.

Market Research

Aspirin linked to drop in oral cancer risk

Taking a regular low dose of aspirin could reduce head and neck cancers by almost a quarter, according to a new study.

People that consume aspirin on a weekly and monthly basis are 22% less likely to develop head and neck cancers, the study published in the *British Journal of Cancer* reveals, with throat cancers affected most from regular aspirin use.

Dr Nigel Carter, chief executive officer of the British Dental Health Foundation, says: "Mouth cancers are increasing, so this piece of research is encouraging. Regular aspirin use has been linked with preventing a number of cancers and if it is a particularly successful practice for warding off mouth cancer, it should act as a springboard for more research."

The report is based on a large-scale study conducted by a specialist team at the Queen's University Belfast in Northern Ireland. The study analyses the effect of aspirin and ibuprofen on head and neck cancer risk using data from the US National Cancer Institute's Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial.

According to the findings, a "significant" reduction of head and neck cancer risk is shown for those aged between 55-74 years who take aspirin on a weekly and monthly basis.

IN BRIEF

■ **MHRA** – the UK Medicines and Healthcare products Regulatory Agency – has warned that aqueous cream for conditions such as eczema may cause skin reactions such as burning, stinging, itching and redness in some people, particularly children. It says these reactions are not usually serious, but advice from a medical professional should be sought if skin irritation occurs.

Market Research

Survey shows fall in trust among French consumers

French consumer confidence in non-prescription medicines fell at the start of 2013, according to a survey conducted by market researcher Ipsos on behalf of local pharmaceutical industry association Les Enterprises du Médicament (LEEM).

Of a representative sample of just over 1,000 consumers surveyed in January 2013, just two-thirds – or 66% – said they trusted non-prescription medicines, compared to 70% in 2012. For non-reimbursed medicines in general, the figure was 74%, which was three percentage points lower than the previous year. The decline came against the backdrop of an overall rise in French consumers' trust in medicines, which advanced by three percentage points to 87%, Ipsos found.

Among the more than 500 French general practitioners also surveyed by Ipsos, confidence in non-prescription medicines was lower than for consumers. Just 41% of general practitioners had faith in non-prescription products and 56% trusted non-reimbursed medicines in general.

When asked about their buying habits, 22% of consumers said they bought at least one non-prescription medicine per month, usually for coughs, colds, headaches or migraine. While 69% said they asked the advice of their pharmacist when buying a self-medication product, more than half said they did "habitually".

Almost all of those consumers surveyed – 96% – said they read the label when buying a self-medication product for the first time.

However, Ipsos noted, following the recent introduction of French measures to allow certain 'free access' self-selection medicines to be sold online (**OTC *bulletin***, 18 January 2013, page 8), just 11% of those surveyed said they expected to order non-prescription medicines online "in the coming months".

OTC

Regulatory Affairs

Australia reviews cetirizine labels

Labels for non-prescription medicines containing cetirizine for oral use should include new warnings on drowsiness and pregnancy, according to Australia's Therapeutic Goods Administration (TGA).

It has proposed two advisory statements for drowsiness and one for pregnancy. Comment on the advisory statements is being sought from interested parties by 3 May 2013.

Proposed warnings include: "This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol" or "This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery."

For expectant mothers, the proposed warning reads: "If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine."

OTC

Advertising Complaints

NAD issues two claims warnings

Two US firms – Alde Associates and Hello Life – have been warned by the country's National Advertising Division (NAD) not to continue making unsupported advertising claims.

Alde Associates had made claims that its daniPro nail polish product treated or prevented nail fungus, while Hello Life claimed that its Synaptol homoeopathic remedy treated or relieved symptoms of attention deficit disorder (ADD) or attention deficit/hyperactivity disorder (ADHD).

Although the watchdog acknowledged that Alde Associates' daniPro product contained the anti-fungal agent undecylenic acid, it recommended that the firm "clearly and conspicuously disclose" in its advertising that the product was not effective in "preventing or treating fungus of the nails", and remove testimonials attesting to this.

The firm was also warned that statements such as "keeps nails looking healthy" and "natural and organic" should no longer be used.

A number of claims made in the advertising for the product had been challenged by Adwill Labs, which markets "Dr's Remedy" nail polish.

Meanwhile, the authority recommended that testimonials claiming that Hello Life's Synaptol could be used as a replacement or alternative to prescription treatments for ADD or ADHD should be discontinued.

In its response to the recommendations, Hello Life said that several claims for Synaptol had voluntarily been discontinued, including statements that it "quickly" relieved ADD/ADHD symptoms, provided "fast" relief and was "non-addictive".

However, the firm said that the remaining claims for the product were "substantiated by competent and reliable scientific evidence" from texts that were "based upon the expertise of homoeopathic professionals". The product's label "clearly" disclosed that its indications were based on the material, it added.

Previous reviews of advertising claims made for homoeopathic products, the authority noted, had required "support beyond homoeopathic provings, including competent and reliable scientific testing on the product itself". Hello Life had not provided this, it said, recommending that any claims that Synaptol treated or relieved the symptoms of ADD/ADHD be discontinued.

Both companies said future advertising would take into account the recommendations.

OTC

Re-branding

Lanes Health says Gopo is new name for Litozin brand

Gopo Joint Health has replaced Litozin Joint Health in the UK as the brand name for Lanes Health's rose-hip based supplement. The re-branding was an effort to "maximise the high consumer and media awareness" of Gopo's active ingredient – glycoside of mono- and diglycerol – which had been marketed under the Litozin name since 2006, the firm said.

Claiming that the product was the only rose-hip based supplement in the UK to contain the active ingredient and be backed by 10 years of "extensive peer-reviewed and published clinical research", the company insisted there was "confusion" among consumers who assumed the findings from these studies applied to all rose-hip based products.

"With an increasing number of unproven rose-hip based supplements flooding the UK market, we felt it was an opportune time to re-brand and make it easier for consumers who read about the efficacy of Gopo to find it in store," commented Dave Cole, sales and marketing director at Lanes Health.

An exclusive deal with Danish firm Hyben Vital – the original supplier of the compound – meant that Lanes Health was the sole UK distributor, the firm noted. It was "really important" that consumers looked for the Gopo logo when purchasing a rose-hip supplement, it added.

Lanes Health says customers purchasing a rose-hip supplement should look for the Gopo logo (above left) which features on the packaging for its re-branded Gopo Joint Health product (above right)

Lanes Health noted that the product's website had also been re-named as gopo.co.uk, while a heavyweight public relations campaign would "communicate" the supplement's re-branding through pharmacy and consumer publications. Case studies from brand advocates would feature in consumer press to attract new users, it added.

Previously manufactured in Denmark, the capsules will now be made in the UK. The firm has also reduced the recommended retail prices of the capsules from £20.42 (€24.10) for 120 capsules to £17.99. Prices for packs of 200 capsules have been lowered to £26.99 from £30.63.

OTC

Product Launches

Merck supplement sustains French energy

Merck Médication Familiale has added to its Bion range of food supplements in France with the launch of Bion Energie Continue. Aimed at sustaining energy throughout the day, the product boasts an "exclusive extended-release technology" that releases a range of vitamins and minerals over the course of six hours.

Television advertising for Bion Energie Continue features a man walking a dog in the morning and evening. In the morning, the man drags the dog along with its lead, but in the evening the dog still has the energy to pull its owner along the pavement.

The dog in the television advertising for Bion Energie Continue still has energy at the end of the day

"When you need energy for the day, the problem is that it doesn't last all day," the advertisement states, highlighting the "unique" prolonged-release technology that allows Bion Energie Continue to work over a six-hour period. Merck said it expected the advertisement – which is being shown on major terrestrial channels in France – to reach an audience of around 12 million.

One tablet of Bion Energie Continue should be taken each day at breakfast, Merck advises. The product is available in both pharmacies and parapharmacies, in bottles or packs each containing 30 tablets.

OTC

Product Launches/Business Strategy

Omega to make Benegast the gastrointestinal answer

Omega Pharma is aiming for its Benegast range of products to be "the first and only complete brand covering all gastrointestinal symptoms" when it is launched across its main European markets, the firm told **OTC *bulletin***.

Carrying the slogan: "Naturally powered to regain and maintain digestive health", the line comprises four class IIa medical devices under the Benegast banner: Dimexanol for diarrhoea; Reduflux for heartburn; Redugas for flatulence and bloating; and Regulamine for irregular bowel activity.

Noting an "increasing prevalence" of people suffering from gastrointestinal conditions, Omega said the products were "designed to be the only ones that not only fix the symptoms, but also work in a way that brings consumers back to gastrointestinal balance".

Currently, the range is available in Belgium, under the existing Phytosun aromatherapy brand name. This would be unique to its home market, Omega noted.

"In Belgium, Phytosun is known to provide effective but natural and safe treatments, so we already benefit from consumer awareness," the firm pointed out.

It added that Switzerland and the Netherlands would be the first countries to see the roll out of the Benegast range, although it did not say when the launches would take place.

Since the Phytosun name didn't have the same "heritage" in other countries, the international brand umbrella would be Benegast, unless there was a "strong local brand available as a brand carrier", the firm explained. The idea was to "build a new brand as the gastrointestinal specialist", it added.

The Benegast range of four class IIa medical devices aims to "regain and maintain digestive health"

Noting that market research in Belgium had found that 72% of people surveyed preferred the taste of Reduflux to that of Gaviscon, Omega said the products would be competing against the "respective segment leaders" in the 'big four' gastrointestinal categories for each country they would enter. The Regulamine product was also "unique" in that it combined both soluble and insoluble fibres to provide "higher efficacy in restoring regular transit", it added.

Promotional activity in Belgium, the company said, initially targeted doctors and pharmacists with point-of-sale materials and training. "We foresee a strong consumer campaign," it added, noting that a television campaign would commence "very soon".

OTC

Distribution Agreements

CamNutra takes Ateronon to Asia

CamNutra's one-a-day supplement Ateronon – comprised primarily of a modified lycopene – is to be distributed across the Far East under an international agreement signed with BFA Exim International. Further markets are expected to follow this year.

Tim Dye, chief executive officer of CamNutra said the company was delighted to be exporting Ateronon across the Far East. He told **OTC *bulletin*** that the firm had plans to distribute Ateronon in more markets in 2013. "Registration is currently underway with agreed suppliers in Saudi Arabia, the US, Bulgaria and Israel," he said.

A spokesperson from BFA Exim International said the company was pleased to be stocking Ateronon as Asia had started to see an increase in heart problems, with more people being diagnosed with type II diabetes and high cholesterol.

The distribution of Ateronon has been aided by a recent study from Cambridge University led by cardiovascular medicine expert Joseph Cheriyan showing that a modified version of lycopene, a key nutrient naturally found in tomatoes and red fruit, could potentially prevent or slow down the effects of heart disease by improving flexibility of blood vessels by up to 50% (**OTC *bulletin***, 18 January 2013, page 8).

According to Dye, secondary data was expected from the Cambridge study and further studies were underway including one led by Professor Howard Sesso from Harvard University in the US, which was at the analysis stage.

Hong-Kong based trading company BFA Exim International will distribute Ateronon for three years across Hong Kong, Taiwan and Macau. CamNutra has existing distribution agreements for the supplement in Greece, Nigeria, Ghana and Pakistan, Dye pointed out.

CamNutra's Ateronon allows lycopene to be readily taken into the bloodstream

OTC

Young users of Reckitt Benckiser's (RB's) Nurofen analgesics brand in Germany now have another option. The company has just introduced 200mg ibuprofen soft-gel capsules that are intended for children aged from six years, as well as for adults.

Launch trade-press advertising for Nurofen Weichkapseln states that the soft-gel capsules are "especially for young people in pain".

A strapline on the advertising maintains that the capsules are "klein, weich [und] leicht zu schlucken", which translates as "small, soft and easy to swallow".

Having established Nurofen liquids in Germany as an analgesic range for infants and young children, RB and its marketing partner Klosterfrau have positioned the brand's lemon-flavoured 200mg orodispersible tablets as the ideal choice when children have 'grown out' of paediatric ibuprofen liquids.

A pack of 10 Nurofen Immedia 200mg soft-gel capsules has a recommended retail price of €5.75. Trade-press advertising claims that the small pack size ensures the pharmacy-only medicine is used responsibly.

OTC

Marketing Campaigns

Herbalife backs US triathlete

Herbalife has announced an exclusive sponsorship deal with triathlete Lukas Verzbicas, who has twice been the world junior duathlon and triathlon champion. The one-year global deal will make the US-based direct-selling supplement firm Verzbicas' primary sponsor.

Verzbicas planned to compete in the US, Europe and Latin America, the firm said, and would also represent the company when he performed in the Herbalife Triathlon in Los Angeles in October.

Brian McKinley, Herbalife's senior director, corporate alliances, said Verzbicas represented "the future of the sport".

In addition to racing, Verzbicas would assist the firm in developing new performance nutrition products for its Herbalife24 range by providing feedback on formulas and prototypes in development. The company declined to comment on how much the deal was worth.

OTC

An unlicensed foot cream that is said to alleviate dry and toughened skin is the latest addition to Dr August Wolff's Linola dermatology range in Germany.

Linola Fuß-Milch is an oil-in-water emulsion that has a lipid content of 27%. Like the rest of the Linola range, it is based on linolenic acid, while the addition of glycerine is said to improve the skin's elasticity.

Current trade-press advertising invites pharmacists to order a counter display unit that – like the advertising – features the animated blue brand mascot, Lino. The brand also benefits from television advertising.

A 100ml tube has a recommended retail price of €10.95.

OTC

Advertising Campaigns

Pharmacist appears in Omega's UK commercial

Omega Pharma is featuring a pharmacist in the latest television advertisement for its Prevalin nasal-barrier treatment. The Belgium-based company claims it is the first time an OTC medicines manufacturer has used a pharmacist in its television advertising in the UK.

Nick Kaye, an independent community pharmacist from Newquay, appears in the 30-second spot, which the company says "highlights the different options for hayfever treatments". He points out that Prevalin – registered as a medical device – acts "five-times faster" than hayfever tablets.

"The unique formula is so effective because it diffuses pollen rapidly, supports fast clearance of allergens, and forms a micro-gel barrier against further irritation," Kaye goes on to explain.

The creative will run on a number of channels – including Channel 4, Channel 5, ITV and Sky – in 'prime time' slots until the middle of May, and will also be shown in Ireland. It is part of a £2 million (€2.4 million) campaign, mainly aimed at pharmacists, which will also include an 'allergy trainer' as well as point-of-sale materials.

Omega said it hoped the promotional activity would "give both customers and healthcare professionals the confidence to select and recommend fast and effective treatments, like Prevalin and Beconase, to manage hayfever symptoms".

Community pharmacist Nick Kaye points out that Omega Pharma's Prevalin works "five-times faster" than hayfever tablets

Beconase is one of GlaxoSmithKline's non-core OTC brands in Europe that Omega gained as part of a €470 million deal last year (**OTC *bulletin***, 16 March 2012, page 1).

The hayfever category was one of Omega's main priorities, Neil Lister, UK and Ireland general manager told **OTC *bulletin***, while the firm's overall objective was to become "the number one OTC player in Western Europe" (**OTC *bulletin***, 29 June 2012, page 8).

OTC

Product Launches

Venus Remedies launches first OTC product

Indian generics company Venus Remedies has entered the OTC arena in its home market for the first time with the launch of its Ezenus herbal candy product, which it claims is "effective for acute as well as chronic stress management". Plans to launch the candy internationally in all of the firm's 60 markets would begin from April 2014, it said.

Containing five "potent" herbs – *andrographis paniculata, boerhavia diffusa, berberis aristata, tinospora cordifolia* and *rubia cordifolia* – as its active ingredients, Ezenus is said to reduce stress by more than 60% in 30 days "without a change in lifestyle".

The low-calorie, sugar-free product would be rolled out in stages throughout its home country, Venus Remedies said, with a view to making it available "pan-India" within the calendar year. It would use its existing network of 50,000 pharmacists to distribute the product nationwide, the Indian company added.

Noting its main competitors – including Himalaya Healthcare's StressTea, Sunova's Ashwagandha capsules, and SRS Pharma's Stressnil Syrup – the company said its ambition was for the supplement to acquire "5% of the US$100 million (€77.8 million) direct market in India for stress management, other than lifestyle disorders, within three years of its launch".

Two-stage promotional campaign

An "aggressive" two-stage promotional campaign – totalling approximately US$7million – would support the launch, the firm said. Stage one would use digital media – such as banner and text advertisements and social networking sites – and advertisements on FM radio. The second stage would add television commercials and print advertising to the marketing mix.

OTC

MAY

2-3 May

■ **2013 Regulatory Scientific and Quality Conference**

Washington DC, US

'Delivering consumer healthcare products in a dynamic environment' is the theme of this two-day conference organised by the US Consumer Healthcare Products Association (CHPA).

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13, 14-15 May

■ **Filing Variations**

Brussels, Belgium

A pre-conference briefing on 'Implementing a regulatory strategy for filing variations' will accompany this two-day meeting.

***Contact:** Informa UK.*
Tel: +44 20 7017 7481.
Fax: +44 20 7017 7823.
Email: registrations@informa-ls.com.
Website: www.informa-ls.com/filing.

13-17 May

■ **GMP Masterclass for the Pharmaceutical Industry**

London, UK

A five-day course on good manufacturing practice (GMP).

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

14-16 May

■ **Vitafoods Europe**

Geneva, Switzerland

A three-day exhibition and conference focusing on nutraceuticals, and functional foods and drinks.

***Contact:** Informa Exhibitions.*
Tel: +44 20 7017 6482.
Fax: +44 20 7017 7818.
Email: chris.lee@informa.com.
Website: www.vitafoods.eu.com.

16 May

■ **The Decentralised Procedures**

Frankfurt, Germany

Speakers at this one-day seminar will include Dr Peter Bachmann and Dr Klaus Menges of the German federal institute for drugs and medical devices, BfArM.

***Contact**: Dr Henriette Wolf-Klein, Forum Institut für Management.*
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21-23 May

■ **Russian Pharmaceutical Forum**

St. Petersburg, Russia

Speakers from GlaxoSmithKline, IMS Health, Johnson & Johnson, Pfizer, Sanofi and Takeda will take part in this three-day conference.

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23-24 May

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

London, UK

Countries covered at this two-day meeting will include Bahrain, Egypt, Israel, Lebanon, Libya, Saudi Arabia, Sudan and Yemen.

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Tel: +44 1483 730071.
Fax: +44 1483 730008.
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30 May

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

Brussels, Belgium

'The key steps to a successful product launch' will be discussed at this one-day meeting.

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

JUNE

10-11 June

■ **EuroPLX 52**

Munich, Germany

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

***Contact**: RauCon.*
Tel: +49 6222 9807 0.
Email: meetyou@europlx.com.
Website: www.europlx.com.

5-7 June

■ **49th AESGP Annual Meeting**

Lisbon, Portugal

'Realising the Self-Care Potential' is the theme of this three-day event run by the Association of the European Self-Medication Industry, the AESGP.

There will be sessions on: 'How to be successful in self-care. The industry leadership's vision for the self-care sector's future'; 'Switch: a key driver of innovation in self-care'; and 'The role and potential of the medical devices sector in self-care'.

Speakers will include: Basil Mathioudakis and Salvatore D'Acunto of the European Commission; Werner Knöss of the European Medicines Agency (EMA); Catherine Geslain-Lanéelle of the European Food Safety Authority (EFSA); Dagmar Roth-Behrendt, member of European Parliament; June Raine of the UK's Medicines and Healthcare products Regulatory Agency (MHRA); Briain de Buitleir of PGT Healthcare; Roger Scarlett-Smith of GlaxoSmithKline Consumer Healthcare Europe; Erica Mann and Joerg Ohle of Bayer Consumer Care; Brian McNamara of Novartis Consumer Health; Vincent Warnery of Sanofi; and Andy Tisman of IMS Consumer Health.

***Contact**: Association of the European Self-Medication Industry, the AESGP.*
Tel: +32 2 735 51 30. Fax: +32 2 735 52 22.
Email: b.klimka@aesgp.eu. Website: www.aesgp.eu/49.

10-12 June

■ **Pharmacovigilance**

London, UK

Drug safety monitoring in Europe, Japan and the US will be covered at this three-day course.

***Contact:** Management Forum.*
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Website: www.management-forum.co.uk.

12-14 June

■ **Advanced European Regulatory Affairs**

London, UK

A three-day event covering European regulatory affairs legislation, pharmacovigilance and labelling.

***Contact:** Informa UK.*
Tel: +44 20 7017 7481.
Fax: +44 20 7017 7823.
Email: registration@pti-global.co.uk.
Website: www.pti-global.co.uk/advreg.

24-25 June

■ **Pharmaceutical Regulatory Affairs in Africa**

London, UK

Countries to be discussed at this two-day seminar will include Algeria, Ghana, Morocco, Nigeria, South Africa, Tanzania, Tunisia and Uganda.

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Website: www.management-forum.co.uk.

25-27 June

■ **Shaping the Future**

London, UK

This three-day pharmaceutical market research conference is organised by the European Pharmaceutical Market Research Association (EphMRA).

***Contact:** MCI Suisse.*
Tel: +41 22 33 99 636.
Fax: +41 22 33 99 601.
Email: ephmra.reghot@mci-group.com.
Website: www.ephmra2013.org.

27 June

■ **Basics of Pharmaceutical 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.
Email: meetings@topra.org.
Website: www.topra.org.

JULY

1-4 July

■ **Strategic Pharma Marketing Asia**

Singapore

This four-day meeting will look at expanding market share across multiple Asian regions.

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Europe needs new switch culture

As the US breaks new ground, becoming the first major market in the world to approve an OTC switch for an overactive bladder treatment, questions on the viability of Europe's switch climate are being raised. Sonia Kalsi reports.

Merck & Co's groundbreaking effort to switch Oxytrol for Women from prescription to non-prescription status was approved in January, making the US the first country in the world to authorise oxybutynin as an OTC active ingredient (**OTC *bulletin***, 8 February 2013, page 1). Simultaneously, questions were raised over Europe's ability to sanction OTC indications of such a groundbreaking nature.

Speaking at the UK's Self Care Conference in February, Dr Steve Mann, ex-vice president of European research and development at McNeil, stated his frustration at the US approving an overactive bladder (OAB) treatment for women ahead of Europe.

"In Europe, we've been talking about approving a non-prescription OAB medicine since 2001. It was one of the case studies sponsored by the European Commission, and presented as part of a report by the Association of the European Self-Medication Industry, the AESGP, on potential new indications," he said. An OTC treatment for OAB was a major unmet need in Europe, he pointed out (**OTC *bulletin***, 15 March 2013, page 18).

Mann, who led the UK switch of Zocor Heart-Pro, told **OTC *bulletin*** that the "commercial history of recent switches in Europe is not inspiring", adding that "the enthusiasm of companies to embark on reclassification must also be tempered by the uncertainty that now prevails in the European regulatory environment".

Many newer medicines – that have accumulated sufficient market experience to allow them to be considered for reclassification in Europe – would have been approved by the centralised system and had to be considered for reclassification by the same route, he noted.

However, all European Union (EU) member states did not feel the same way about the role of non-prescription medicines, Mann stressed, or about the ability of pharmacists to contribute to medicines management, or even about how such medicines should be labelled compared to their prescription counterparts.

He said that these were not only the reasons why an OAB treatment had yet to be approved in Europe, but were also the main reasons why there could be a "major brake" on the number of expected switches.

Manfred Scheske, ex-European president of GlaxoSmithKline Consumer Healthcare and now chief executive officer of Infirst Healthcare, said: "Whether we have a supportive switch climate in Europe is debatable."

"The process remains cumbersome," he told **OTC *bulletin***, "and the outcome on the legal status as well as on the commercial result remains uncertain and unattractive."

"Without addressing the commercial risk – by offering incentives to those firms willing to accept a leadership role – I don't see why anybody should volunteer to become a sponsor for switching a drug in Europe unless the remaining patent lifetime is favourable," Scheske said.

"There doesn't seem to be a joint political and commercial will," he continued, "to drive for more impactful change, to accept that only commercial incentives can make the industry drive for switch and deliver on the expectations which one should have from switches." The EU centralised procedure carried the same inequality of commercial rewards and uncertainty/risks, but on a much larger scale, he added.

According to Scheske, the "success rate" of prescription to non-prescription switches in the UK, France and Germany over the past five years had been "rather limited".

The UK had been the most proactive, but detailed questionnaires and algorithms had made switches fail, Scheske said. Meanwhile, Germany, which has also been a more liberal switch environment, had produced switches with slightly better commercial results in the absence of strict algorithms, Scheske noted.

In contrast, he said, France as well as Mediterranean countries with their sizeable 'semi-ethical' markets – non-prescription products which are being prescribed and reimbursed – had been more conservative on switches.

Tim Brooks, director at growth and strategy consultancy Muzeable, agreed with Scheske, believing the success rate of prescription to non-prescription switches in the UK, France and Germany in the past five years had been "poor", with meagre commercial returns. He told **OTC *bulletin*** that in the UK, in his own experience, "none" of the switches had really been worth the money spent.

Need commercially-viable model

Looking ahead at new switch indications, Brooks said that before indications were switched from prescription to OTC status in Europe, "a better model or framework" to enable them to be "commercially viable" was needed.

According to Scheske, the next line of switches would have to challenge the criteria requiring illnesses to be "self diagnosable" and usage to be temporary, rather than long-term or chronic.

Self diagnosis is a key issue for Mike Munley, who as a former GlaxoSmithKline director has led teams responsible for switching. "Developments in self-diagnosis and 'remote diagnosis' will have a major impact on the definition of an OTC condition," he believed, noting the strides taken in personal genomic testing. "There's a huge wave coming and industry is asleep," he maintained.

Currently writing a book of "*Switch Stories*", based on interviews with global OTC industry leaders and strategic thinkers, Munley* noted that self-diagnosis/self-treatment was one of the three regulatory pillars needed for a switch – the others being the safety and effectiveness of an OTC dose.

There was growing evidence, he pointed out, that self-assessment drove motivation and changed behaviour, particularly where lifestyle conditions, such as smoking and diabetes, were concerned. Such behavioural changes influenced treatment and adherence in an OTC context and thus drove efficacy, he said, noting that one of the key issues in future would be ownership of the test data. "Things are hap-

Year	Active ingredient	Brand name	Purpose	Company	Date approved
2013	Oxybutynin	Oxytrol for Women	Overactive bladder	Merck & Co	25 January
2011	Fexofenadine hydrochloride	Allegra Allergy	Allergy treatment	Sanofi	24 January
2009	Lansoprazole	Prevacid 24 hr	Acid reducer	Novartis	18 May
2009	Omeprazole	Zegarid OTC	Acid reducer	Merck & Co	12 January
2007	Orlistat	Alli	Weight-loss aid	GlaxoSmithKline	7 February
2007	Cetirizine	Zyrtec Allergy	Antihistamine	McNeil	16 November

Figure 1: Breakdown of major prescription-to-OTC switches in the US from 2007 to date (Source – FDA)

pening that will converge with what we call switch," he forecasted.

Despite the problems in Europe, Mann pointed out that it would be curious if more new indications for self-care started to appear first in the US, where non-prescription medicines could be purchased without pharmacist or healthcare professional approval.

"If Europe started to lag behind the US in providing more new indications to the OTC market, then industry should ask what is going wrong," he said.

While Europe contemplates its switch procedures, the US has also been looking at potential new regulatory approaches. A public hearing in March 2012 was held by the US Food and Drug Administration (FDA) to gain comments on a proposed new paradigm on safety – the Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative – to expand which drugs could be considered OTC.

The agency told **OTC *bulletin*** that it was supportive of switches and recognised that consumers could benefit from having broader OTC access to certain drugs for common conditions.

Decisions to switch, it said, would be based on adequate evidence that the product was safe and effective for use under the proposed OTC conditions, and that consumers could safely diagnose the target condition as well as select and use the drug without consulting a medical professional.

Due to the absence of a medical professional in the administration of certain OTC medicines, the US regulator is particularly concerned with marketeers proving that consumers can understand the product labelling.

The approval of Oxytrol for Women in the US could have been made sooner if the product label had met adequate standards. In a FDA advisory committee meeting last November, committee members voted narrowly against approval, citing that consumers would not "appropriately self select" Oxytrol in an OTC setting. They added, however, that labelling modifications would have changed their vote (**OTC *bulletin***, 23 November 2012, page 1).

Label modifications were subsequently made and January this year saw the agency become the first to approve an OAB skin-patch treatment.

Nine studies involving more than 5,000 subjects had been performed by Merck to show that consumers could use the drug safely in an OTC setting, the regulator said.

Merck noted at the time that there were "no plans to pursue OTC Oxytrol in countries outside of the US".

While Mann hopes to see an OTC OAB treatment in Europe this year, he said that if it involved a centralised switch then it "may not happen easily or quickly" as some countries would see the indication as controversial.

Product	Approval date
Rabeprazole 10mg gastro-resistant tablets *Parietis (Eisai prescription brand)*	January 2012
Ibuprofen 1% lotion *Soleve Sunburn Relief (Diomed)*	August 2011
Diclofenac potassium 25mg tablets *Voltarol Pain-eze Extra Strength (Novartis)*	May 2011
Diclofenac sodium 140mg medicated plaster *Algopain-eze (Teva)*	November 2010
Diclofenac diethylammonium 1.16% gel (extend treatment for pain relief in non-serious arthritic conditions to 21 days) *Voltarol Emulgel (Novartis)*	April 2010
Tranexamic acid 500mg tablets *Cyklo-F tablets (Meda)*	March 2010
Tamsulosin 4mg tablets *Flomax Relief MR (Boehringer Ingelheim)*	December 2009
Domperidone 10mg tablets (extension for relief of nausea and vomiting) *Motilium 10 (McNeil Products)*	November 2009
Alclometasone dipropionate 0.05% cream *Diprolieve Eczema and Dermatitis Cream (Merck & Co)*	September 2009
Pantoprazole 20mg tablets (via EU centralised procedure) *Pantoloc Control (Takeda)*	June 2009
Orlistat 60mg capsules (via EU centralised procedure) *Alli (GlaxoSmithKline)*	January 2009
Azithromycin 500mg tablets *Clamelle (Actavis)*	August 2008
Diclofenac potassium tablets 12.5mg *Voltarol Pain-eze (Novartis)*	June 2008
Naproxen 250mg enteric-coated tablets *(Perrigo)*	February 2008
Chloramphenicol 1% eye ointment *Brochlor (Sanofi)* *Optrex Infected Eyes (Reckitt Benckiser)* *Galpharmvision Antibiotic Eye (Perrigo)*	June 2007

Figure 2: Breakdown of major UK prescription-only to pharmacy-only reclassification applications approved from 2007 to date, showing OTC brand name and brand owner (Source – MHRA)

Commenting on the switch of GlaxoSmithKline's Alli (orlistat 60mg) for weight loss – which had used Europe's centralised procedure – Scheske said that the procedure "was not a strategic choice, but clearly a default necessity" as orlistat had been approved in that way in 1998.

According to Brooks, the centralised procedure was beneficial for Alli as the safety profile of the drug was well established in Europe. Consistent usage on prescription, coupled with consumers being able easily to understand the nature of obesity, made the Alli switch achievable and helped to get consensus relatively fast, he believed.

However, not all switches using the centralised procedure would be as straightforward. Local differences would be more pronounced and existing prescription usage would be more variable, he warned. This would make embarking on the process less attractive and riskier for manufacturers.

Scheske noted stakeholders across all EU states had been comprehensively consulted and involved "prior, during and after" the Alli switch. However, Brooks admitted that more could have been done on marketing the drug to consumers.

Consumers ultimately wanted benefits, Brooks said, and where the answer was "behaviour change" a tablet couldn't do it alone. While Alli was never marketed as a "magic pill", consumers did not like the idea of a "drug-based programme" for weight loss, he noted.

In Alli's case, Brooks said, GlaxoSmithKline used a 'big bang' branding and advertising launch whereas a slower, behaviourally-driven approach may have been better.

Furthermore, as pharmacists were generally not trained to deliver broad-based programmes, encouraging a behaviour change among consumers could have been delivered "above pharmacy interaction" through more involvement by GlaxoSmithKline, he believed.

Alli was switched to OTC status in the US in July 2007 (see Figure 1 on page 16) while the UK followed suit through the European centralised procedure in January 2009 (see Figure 2 on page 17).

However, Scheske said that a successful switch in the US did not necessarily mean that Europe would follow accordingly. "The very successful US switch of Prilosec could not even motivate licence holder Procter & Gamble to follow suit in Europe," he noted.

"Only commercial incentives can make the industry drive for switch and deliver on the expectations which one should have from switches"

"The US switch environment is more supportive," Scheske explained, "because of pre-switch brand awareness from direct-to-consumer advertising of prescription medicines. More importantly, however, switched products benefit from three years of Waxman/Hatch exclusivity. This helps to balance risks and rewards for the sponsor and gives the leading sponsor the chance to build a brand before generics follow behind."

In comparison, he added, the 12-months exclusivity offered in Europe was not a realistic incentive, even if it was awarded.

According to Brooks, the authorities in Europe were using the "wrong metric" in measuring the purpose of a switch. They were seeing a successful outcome as the switch itself, rather than patient/consumer numbers leaving the prescription environment or trading up from existing OTC medicines for better results, he said.

Commenting at the recent Self Care Conference on recent switches in the UK the Medicines and Healthcare products Regulatory Agency's (MHRA's) self-medication specialist Colette McCreedy said: "From a regulatory perspective, tamsulosin (Flomax Relief), sumatriptan (Imigran Recovery) and simvastatin (Zocor Heart-Pro) are successful reclassifications because a positive benefit-risk ratio for non-prescription availability of these products has been clearly demonstrated."

However, Scheske pointed out: "One cannot really look at switches with a checklist which tallies the number of legal changes."

"The commercial success, exemplified by consumer penetration and repeated use; and cost reductions for payers – including keeping patients with minor ailments away from congesting the primary infrastructure – have to be taken into account. We must conclude [using these criteria] that the UK switches of triptans and statins have failed," he pointed out.

While the 2004 UK launch by McNeil of Zocor Heart-Pro (10mg simvastatin), as an OTC medicine was the first in the world of a cholesterol-lowering statin (**OTC *bulletin***, 28 November 2003, page 1), poor support from pharmacists was partly to blame for it being discontinued in the UK towards the end of 2010 (**OTC *bulletin***, 29 October 2010, page 13).

Meanwhile, commenting on the switch of Boehringer Ingelheim's Flomax Relief (tamsulosin 4mg) in December 2009, Anna Maxwell, ex-marketing director at Boehringer Ingelheim and author of new book *Switch Dynamics*, blamed both lengthy sales protocols for pharmacists and the short duration of time for measuring the success of the switch as reasons for its failure.

"Building new self-care categories with conventional marketing models requires time. A five to 10-year investment programme is more realistic than a shorter one," she said. The switch also demonstrated that pharmacists found lengthy sales protocols hard to grasp, she insisted.

Maxwell added about Flomax Relief: "Pharmacists and the self-care industry have not quite figured out how to commercialise the product in the OTC setting yet. Some say that it is ahead of its time."

According to Mann, orlistat and tamsulosin had been successful in terms of introducing entirely new concepts to consumers, while Brooks highlighted the switch of Optrex Infected Eyes (chloramphenicol 1% eye ointment) as the most successful in recent years. "The umbrella branding meant that its relative lack of scale was less critical as it supported the core brand," he noted.

Mann agreed that complicated pharmacy protocols were one of the main reasons for unsuccessful switches in the UK. These were demanded by regulators and advisory committees who did not fully understand the self-care environment in pharmacies.

It would be curious if more new indications for self-care started to appear first in the US, where non-prescription medicines could be purchased without pharmacist or healthcare professional approval

He also cited pharmacists lacking in confidence about switches, as well as the apparent inability of doctors to recommend effective self-care options. The lack of explicit public-health support from government was also an issue, he said.

A lack of success in switches could be due to unrealistic and short-term definitions of commercial success, Mann added, creating "failures" that were not supported for the long term.

Meanwhile, the mandatory intervention of the pharmacist when selling a newly-switched medicine in the UK could be seen as an additional barrier to access – particularly if the pharmacy was expected to administer a questionnaire or complicated algorithm.

According to Brooks, a small number of pharmacists "get it" and had stepped up to a broader primary healthcare provider role. The vast majority, however, had failed to do this.

Pharmacists were too cautious in using new products, he noted, conflicted by their role as retailer and pharmacist. They were often too quick to sell a cheaper alternative, even if it was less efficacious, leaving the newly-switched medicine as a "last resort".

High promotional costs were also an issue, Brooks said. Switched brands really needed to get above £7 million (€8.2 million) and close to £10 million in ex-factory sales, he noted. "This makes the success hurdle high and, for some interesting switches, too high," he explained.

However, if the switched product could be launched as a "new product variant" within an existing brand, he added, that viable sales target reduced dramatically. The switch of a £2 million to £3 million addition within an existing brand would be an attractive brand extension.

Brooks also highlighted that pharmaceutical companies could do more to aid successful switches. Ideally the pharmaceutical player should switch the brand internally to the consumer business, or manage the transition "pre-patent loss" coherently, he said.

Furthermore, Brooks noted, pharmaceutical companies needed to develop more robust validation methods to quantify the real size of the opportunity and the best route to market. This would ensure investment levels were appropriate. They should also allow "digital and e-commerce business models" to be developed to market switch products direct to consumers, he said.

Scheske remains sceptical of recent efforts in the UK to improve the country's switch procedure (**OTC *bulletin***, 18 December 2012, page 9).

The switch landscape would not massively change, he noted, as meaningful commercial incentives had not been addressed. "Even if we will see more switches, I don't expect these to be of commercial, public-health or healthcare-budget significance," he stressed.

*** Mike Munley would like to speak to any OTC *bulletin* reader with views on switching.**
He can be contacted at mike.munley@me.com.

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Harnessing pricing power lifts profits

In a tough market, it pays to dig deeper into pricing, and put pricing strategy at the forefront of brand management, argues Simon-Kucher. OTC firms may then capitalise on the full potential of their portfolios. Matt Stewart reports.

Pricing is too important to only be done at the time of product launch. At a time when OTC companies face numerous challenges that threaten their profitability, pricing should be more than an activity carried out in isolation at launch, according to strategy and marketing consultant Simon-Kucher & Partners.

"Taking advantage of a dedicated pricing function is essential when over 80% of companies face increased pricing pressure from customers or their competitors," comments Ram Subramanian, who is a director at the firm's Boston, Massachusetts office.

"Our experience shows that OTC manufacturers can increase their pricing power and find new sources of profit growth, even when the market is becoming more competitive and less forgiving," he adds.

Subramanian points out that within OTC manufacturers today there is generally no single function or department that is responsible for sophisticated pricing analytics. This when national retailers have more power than ever to negotiate lower prices, and competition from private-label brands continues to intensify.

"OTC manufacturers are at risk," he says, "when they do not craft a pricing strategy that is aligned with the overall brand strategy, but instead simply determine a price".

In the US, he notes, sales of private-label OTC brands grew by 8.7% in 2011 and accounted for over a quarter of the overall OTC market, according to the OTC industry body, the Consumer Healthcare Products Association (CHPA).

Meanwhile, prescription-to-OTC switches and launches of innovative new products – the events that drive growth in the OTC market – are few and far between. Subramanian's colleague, senior consultant Matt Adkins, says that there were 27 such events in the US between 2000 and 2011, or about 2.3 on average annually over the 12 years.

Moreover, Adkins notes, this figure included not only new OTC brands, but also new formulations of existing OTC products. There were only one or two new brands each year over the period, and these were confined to a limited number of OTC categories.

Taking the 27 launches as a whole, just over a quarter were of cold and cough-related products and 15% were in the heartburn category. Another tenth involved allergy products.

Against this background, according to Subramanian, OTC manufacturers should have been improving their profitability by:

- bringing discounts into line with customer loyalty, and incentivising retailers to increase their volumes;
- adopting product pricing strategies that aligned with the overall brand strategy from the start; and
- incorporating a centralised 'pricing and profitability' function intent on optimising profit margins across the portfolio.

Addressing the first of these, Subramanian highlights the "self-inflicted wounds" from unnecessary discounting and overuse of favourable terms and conditions, as well as ineffective retailer incentives.

While acknowledging that OTC manufacturers often have "robust knowledge and firm control" of where their costs are incurred and how top-line revenue is "whittled down" into bottom-line profitability, he insists that "very few manufacturers have the same level of knowledge and governance in place to oversee the 'pricing waterfall' from list prices to the prices actually paid by the retailer" (see Figure 1).

Explaining that a price waterfall is a graphical depiction of all the transactional factors involved in reducing the list price of a product to the 'net-net price' – the price actually paid for the product – Subramanian says price-waterfall analysis can show exactly how much money on-invoice discounts and off-invoice rebates are costing a company, compared with more transparent discounting methods like standard percentage discounts.

Implement regular pricing audits

"Our experience suggests that larger players in the market stand to gain enormously in additional profitability every year by regularly auditing their pricing practices," he maintains, adding that the source of the potential profit improvement can come from several areas.

"Pricing audits we undertake often uncover that manufacturers frequently give some of their worst customers – those with minimal sales and poor loyalty – some of the best discounts and most favourable terms and conditions."

Taking a close look at these customers and putting policies in place to force the sales function to better justify high discounts to 'bad customers', Adkins says, can lead to significant additional profit through capturing higher net prices (see Figures 2 and 3).

Adkins points out that pricing analytics often uncover patterns like the one shown. Little to no correlation exists between the pricing that a customer gets and that customer's sales volume.

"Customers, or retailers in this case, have little incentive to sell more volume," comments Subramanian. "Limiting the amount of discount given to underperforming customers can create a strong incentive for customers to grow," he adds, noting the impact of implementing a more consistent customer-pricing framework.

Pricing analytics often uncover that certain discounting mechanisms are well-governed and monitored, limiting misuse, acknowledges Adkins. Other pricing mechanisms, however, can

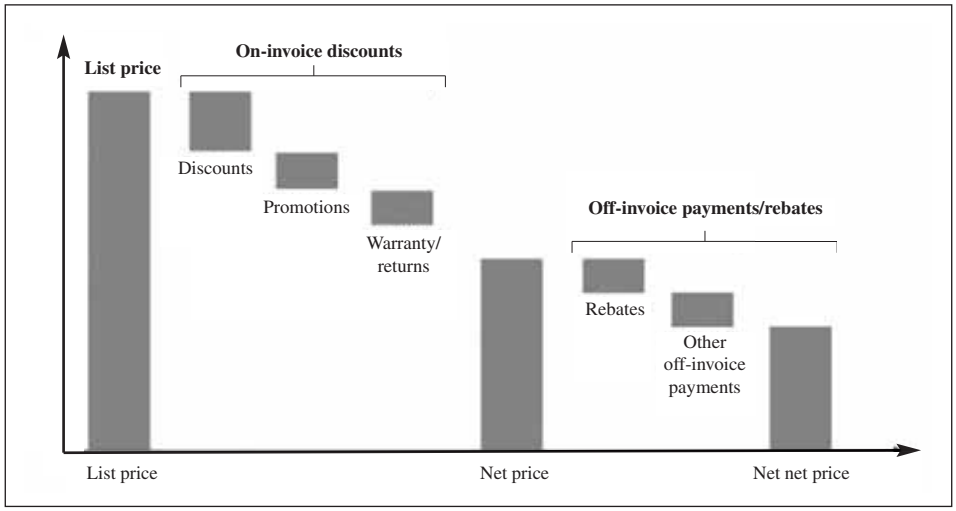
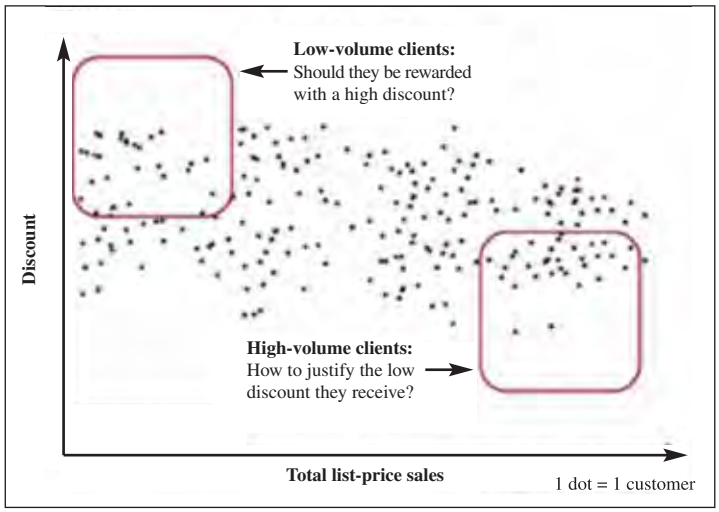


Figure 1: The 'pricing waterfall', showing how a cascade of discounts and rebates turns list prices into prices actually paid (Source – Simon-Kucher)



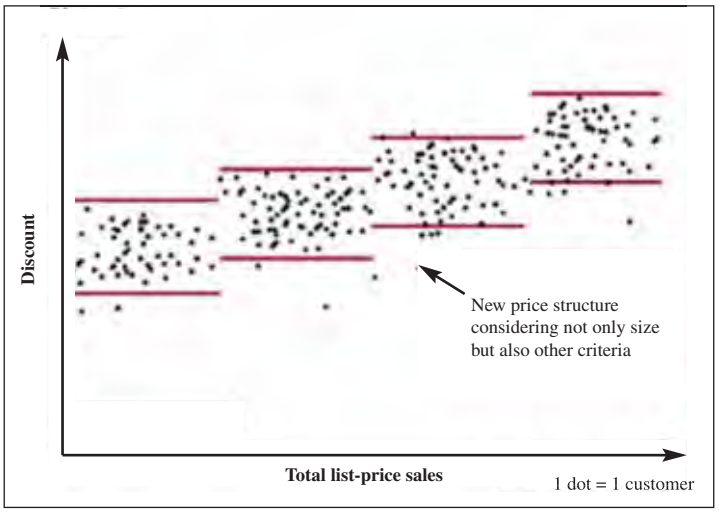


Figure 2 (above left): Distribution of customer pricing versus customer spending for a typical OTC company; Figure 3 (above right): Adopting a consistent customer framework (Source – Simon-Kucher)

remain unmonitored, increasing the risk that salesforces unnecessarily give away potential profits. "In the absence of regular pricing analysis and monitoring, such 'loopholes' may not even be known to management," he says.

Ineffective retailer incentives and terms are another potential cause of profit leaks, continues Subramanian. "Our experience in other retail-focused industries has shown that manufacturers often provide discounts or trade terms that either do not incentivise the right behaviour from retailers or that have a much larger impact than originally intended on a company's bottom line," he insists.

Routine pricing analysis can also identify other potential pricing problems. Examples include unintentional list-price inconsistencies among stock-keeping units (SKUs) within a brand, and unprofitable SKUs.

Subramanian quotes the example of a recent Simon-Kucher 'Mystery Shopper' study of US retail pharmacy prices. This uncovered a pricing inconsistency in OTC allergy drugs.

He explains that Sanofi/Chattem markets both a 12-hour and a 24-hour version of Allegra (fexofenadine) in a standard formulation as well as in a decongestant formulation known as Allegra-D.

"On a per unit basis, the 12-hour standard product was priced higher than the 24-hour standard product. However, this trend was reversed for the 'D' formulations, where Allegra-D 12-hour was priced lower than the 24-hour version."

These types of price inconsistencies can cause unintended consumer behaviour, Subramanian insists, and are potentially a source of lost profits for manufacturers.

"In our experience, most OTC manufacturers do not consistently perform this type of advanced pricing analysis and as a result may be leaving millions of dollars in unrealised profits on the table," states Subramanian, who notes that many of the corrective actions identified through this type of analysis are readily implementable and can lead to near-term profit realisation with little upfront investment.

Turning to pricing strategy, Adkins maintains that companies with "world-class pricing" set and execute pricing against a corporate pricing strategy. "These companies carefully position products within their portfolios and craft a strategy that fits within that context," he says.

However, pricing for OTC manufacturers is "most often a decision taken by the brand manager". It is not always optimised in the context of the manufacturer's broader portfolio.

Two "critical areas" deserve more attention, according to Adkins. These are launch pricing and managing prices after launch.

> ***Not adapting a brand's pricing strategy to changes in its value proposition and market positioning represents a wasted opportunity for additional profit growth***

"Getting the price right at launch is critically important," says Subramanian, "and decisions must be made which align the pricing strategy with the overall brand strategy, over the full lifecycle of the product."

In launch pricing, he says, too much emphasis is often placed on uptake at launch to achieve volume targets for the brand. But this can lead to problems.

Adkins highlights in-depth interviews conducted by Simon-Kucher with OTC industry executives in the US that found pressure from larger retailers can make it difficult for companies to change prices on leading products once they are set in the market. "This effectively locks companies into sub-optimal pricing," he notes.

"Manufacturers need fully to understand the value proposition of their new products in the context of the broader portfolio, enabling the optimal launch price to be determined," says Subramanian. "By better understanding the value story of new products prior to launch, manufacturers can more effectively position products within their broader portfolios and develop the right pricing strategy to execute that positioning at launch."

Managing prices after launch is just as important as launch pricing, they both believe, because the value proposition of products can change drastically over the lifecycle of the product. "Manufacturers must adjust their products' pricing strategy to account for such market changes," they say, citing categories with recent prescription-to-OTC entrants as good examples.

"Former market leaders, such as the heartburn remedy Zantac (ranitidine) and the allergy treatment Benadryl (diphenhydramine), now play significantly different roles in the market than they did before the launch of newer generation products," notes consultant Dan Greenwald. "Thanks to the launch of next-generation OTC medications like Prilosec (omeprazole) and Claritin (loratadine), Zantac and Benadryl now each have a more niche position and their pricing should reflect this change."

Not adapting a brand's pricing strategy to changes in its value proposition and market positioning, he says, represents a tremendous wasted opportunity for additional profit growth.

"A product's pricing strategy should depend on both the value provided and the stage it has reached in its lifecycle," insists Adkins. Innovative prescription-to-OTC switches should aim to maintain a high net price by limiting channel promotion.

As the product progresses through its lifecycle, concessions can be given on price and discounting. But when a product nears the end of its lifecycle or becomes a legacy product,

manufacturers should look to raise the price and limit discounting.

"Our experience shows that end-of-lifecycle and legacy products present a tremendous unrealised opportunity to boost profitability," says Subramanian. "Significant price increases on these products can lead to higher profitability as remaining users tend to have high brand loyalty. Some converters, meanwhile, will switch to higher-margin, next generation products."

Manufacturers can also more easily implement such price changes, he adds, as the changes are isolated and focused primarily on brands that are often not top-spend items for retailers.

Greenwald highlights Benadryl as an excellent example of this opportunity. "Next-generation allergy medications have launched at significant price premiums and have converted the vast majority of the market over to these newer products in the past several years."

"However, a recent Simon-Kucher study of retail pharmacy OTC pricing revealed that Benadryl has maintained its significant price discount with respect to the next-generation products," he observes (see Figure 4).

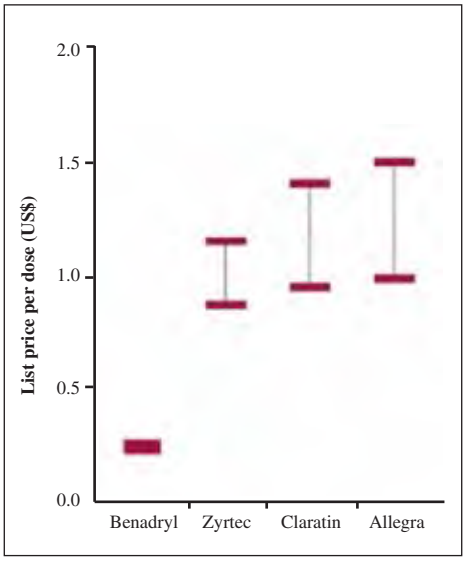


Figure 4: Benadryl has maintained a significant price discount with respect to next-generation products (Source – Simon-Kucher)

Increase the price of Benadryl

"This disconnect may represent an opportunity for the manufacturer of Benadryl, McNeil Consumer Healthcare, to gradually reduce the price gap through consistent price increases on Benadryl, especially given that McNeil markets one of the next-generation allergy medications, and can potentially benefit from converting customers to higher-margin Zyrtec (cetirizine)."

By mapping the road to profitability, OTC manufacturers would improve their profit margins, he insists, noting that the road starts at launch with a well-understood value proposition, and continues over the course of the product lifecycle by adapting the pricing strategy to changing market conditions.

But such mapping cannot be accomplished efficiently and effectively unless OTC firms incorporate the right internal structure. "Within OTC manufacturers today," Subramanian says, "there is generally no single function or department that is responsible for sophisticated pricing analysis. This leads companies to overlook pricing as a potential area for profit growth."

"Profitability gains are likely to erode over the long-term if an organisation is not set up to incorporate a pricing function as a core component of product and portfolio strategy."

Subramanian believes OTC manufacturers usually think of pricing as an organisational function, not as an activity. As such, pricing is typically one among several activities that fall under the responsibilities of the brand manager.

Adkins takes over the story: "Brand managers may spend time on product pricing at the launch of a new product and as part of updates to the annual brand plan, but this focus on pricing is not a sophisticated analysis." The risk for OTC manufacturers, he adds, is that they are merely fixing on a price rather than developing a pricing strategy that is aligned with the overall brand strategy.

But it is not only the brand context that can get overlooked. Pricing at the portfolio level and price positioning within a portfolio of brands is also ignored. "This aspect probably receives even less attention than individual product pricing," contends Subramanian.

"The lack of a dedicated pricing and profitability function prevents tracking of product profitability across a franchise in a systematic way, with the end result that profit gains erode in the long-term and the organisation does not capitalise on the full potential of their product portfolios," he says.

Marketing and sales departments within most OTC manufacturers typically divide up pricing responsibilities. Often, they do not collaborate enough to align strategy-setting with strategy-execution, Subramanian argues.

"Marketing teams craft the value story for a brand and manage the profit and loss aspect. They are responsible for product positioning and recommending an appropriate launch price. However, the sales team manages discounts and rebates and the overall channel strategy, which has a direct impact on profit margins."

"Without a pricing and profitability function that spans the marketing and sales teams," he insists, "it is extremely difficult to co-ordinate an optimal strategy for the franchise."

Subramanian's recipe for success in a pricing and profitability function requires a very analytical and data-driven approach to problems. This combines financial rigour with marketing creativity.

> ***The risk for OTC manufacturers is that they are merely fixing on a price rather than developing a pricing strategy aligned with the overall brand strategy***

"The goal of a pricing and profitability role is to ensure the highest profitability in line with the long-term franchise strategy, while detecting and eliminating any 'profit leaks' in the portfolio," he states.

Referring to a recent global study conducted by Simon-Kucher, Subramanian suggests that a dedicated pricing function gives OTC companies their greatest chance to survive and prosper in today's low-growth climate.

After talking to over 2,700 executives and managers from over 50 countries across a variety of industries, he says, Simon-Kucher has concluded that companies with a dedicated pricing organisation are:

- more likely to have "high pricing power";
- more often successful in achieving price increases; and
- more likely to command higher margins after a price increase.

Expanding on these findings, Subramanian explains that high pricing power results when executives at the top level within a company take an active role in pricing. "High pricing power makes companies more likely to raise prices, more likely to make those increases stick, and more confident about future profit growth," he maintains.

Subramanian adds that companies where top executives are directly involved in pricing are much more likely to have created a dedicated pricing function than companies in which top management does not have pricing on the agenda.

"A dedicated pricing role or function within the organisation needs to do the day-to-day pricing work that ensures strategic pricing decisions are implemented," he remarks, noting that a dedicated pricing function is crucial to taking advantage of high pricing power when many companies are struggling with greater pricing pressure from both customers and competitors.

"Pricing is simultaneously one of the most powerful and underutilised tools for profit improvement among OTC manufacturers," says Subramanian, "We believe that by following our recommendations, OTC manufacturers can increase their pricing power and find new sources of profit growth."

OTC

Regulatory Affairs

US emergency contraception

■ *Continued from front page*

-cious, and unreasonable".

The FDA had "engaged in intolerable delays in processing the petition", Korman pointed out. Indeed, the agency's actions could accurately be described "as an administrative agency filibuster", he noted.

Meanwhile, Sebelius' decision to deny Teva's application to widen access to Plan B One-Step – despite the FDA backing the move – had been "politically motivated, scientifically unjustified and contrary to agency precedent", Korman said.

Although the FDA's recommendations are normally followed by the government, Sebelius insisted at the time that Teva had not submitted sufficient evidence to support the move.

"The label comprehension and actual-use studies did not contain data for all ages for which this product would be available for use," Sebelius stated.

As women of reproductive age could be as young as 11 years old, Sebelius said she was not satisfied that all potential OTC purchasers of Plan B One-Step would "understand the label and use the product appropriately".

Surrounded by controversy

Emergency contraceptives have been surrounded by controversy since they arrived on the OTC scene. After dragging its heels for three years, the FDA finally approved the switch of Teva's Plan B – which consists of two 0.75mg levonorgestrel tablets – from prescription to OTC status in August 2006 (**OTC *bulletin***, 31 August 2006, page 1).

The product was the first dual-label OTC/prescription medicine in the US. Originally, it was only available as an OTC medicine for sale to women aged 18 years and over. Furthermore, the FDA imposed point-of-sale restrictions, including distribution through pharmacies only.

In 2009, Korman ordered the FDA to make Plan B available OTC to 17 year-olds as well as older women, finding that the FDA had acted in a "capricious and arbitrary" manner during the five-year switch of the product (**OTC *bulletin***, 31 March 2009, page 11).

That same year, the FDA approved Teva's Plan B One-Step product – which consists of one 1.5mg levonorgestrel tablet – for OTC sale to women aged 17 years and above (**OTC *bulletin***, 31 July 2009, page 24).

OTC

Manufacturers

Beiersdorf set to lose head of Europe/North America

Beiersdorf – owner of the Nivea and Eucerin global brands – has announced that **Peter Feld**, member of its executive board with responsibility for Europe and North America, would leave the German company on 31 July 2013 at his own request.

Until further notice, Feld's responsibilities would be taken on by the company's chief executive officer **Stefan Heidenreich**, Beiersdorf noted. Heidenreich already holds direct responsibility for the firm's Asia/Emerging Markets region.

Professor Reinhard Pöllath, chairman of Beiersdorf's supervisory board, said the firm regretted that Feld had decided not to renew his contract and wished him well for the future.

Prior to joining Beiersdorf in 2010 (**OTC *bulletin***, 11 June 2010, page 22), Feld was management board chairman of Johnson & Johnson's German subsidiary, with responsibility for the US company's consumer and OTC business segments. He had also served as an area managing director covering Austria, the Benelux countries, Germany and Switzerland. This had followed similar responsibilities for Procter & Gamble.

Beiersdorf said that during his tenure, Feld had made a "decisive contribution to the company's progress" in Europe and North America.

Feld would leave behind an "excellent" base for further growth in what was a core business region, Beiersdorf said. He had "strengthened" and reorganised all areas of management and workforce in the region, the company added, while improving customer relations and the company's market position with consumers.

Peter Feld

Stefan Heidenreich

OTC

Regulatory Agencies

Pharmacopoeia elects Dr Robert as chair

The European Pharmacopoeia Commission has elected **Dr Jean Louis Robert** as its chair for a three-year term starting in June 2013.

Dr Robert will take over from **Dr Marianne Ek**, who has held the position for the past three years.

Head of the Department of Control of Medicines at Luxembourg's Laboratoire National de Santé, Dr Robert has been a member of the European Medicines Agency's (EMA's) Committee for Human Medicinal Products (CHMP) since 1995.

For the past 18 years, Dr Robert has served as chairman of the EMA's joint Quality Working Party of both the CHMP and the Committee for Medicinal Products for Veterinary Use (CVMP).

Dr Robert also serves as a pharmaceutical expert at the World Health Organization (WHO) and is a "membre correspondant étranger" at the French national academy for pharmacy, the Académie Nationale de Pharmacie.

Developed and published by the European Directorate for the Quality of Medicines and Healthcare (EDQM), the *European Pharmacopoeia* lists a wide range of active substances and excipients used to prepare pharmaceutical products in Europe.

It includes more than 2,000 specific and general monographs, including various chemical substances, antibiotics and biological substances; vaccines for human or veterinary use; herbal drugs; homoeopathic preparations and homoeopathic stocks.

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