27 May 2016

OTC bulletin

THE BUSINESS NEWSLETTER FOR THE CONSUMER HEALTHCARE INDUSTRY



# Poland's Adamed claims first OTC sildenafil switch

**Men in Poland are the first in the world able to buy the erectile-dysfunction drug sildenafil without a prescription.**

The country's regulator approved in April Adamed's prescription-to-OTC switch application for 25mg sildenafil under the brand name MaxOn Active. The product is now shipping to pharmacies.

The switch had been granted, a spokesperson for the Polish firm explained to **OTC *bulletin***, thanks to a questionnaire that was included in every pack. This allowed users to "make a safe decision" by educating them about sildenafil and its contraindications.

The questionnaire was also available in pharmacies and online, the spokesperson pointed out, to enable men to make sure the product was suitable for them before they purchased it.

An observational clinical study had been carried out to prove the effectiveness of the questionnaire, the spokesperson added, with the results of the study forming the basis of the switch application.

Poland is the first country in the world to approve a 'true' prescription-to-OTC switch of sildenafil. Pfizer tried and failed to switch the ingredient – which is the basis for its blockbuster drug Viagra – through the European Union's (EU's) centralised procedure in 2008 (**OTC *bulletin***, 28 November 2008, page 1).


**Adamed's MaxOn Active is the world's first OTC sildenafil brand**

Pfizer withdrew its Viagra application in the EU following "some concerns" – including a lack of medical supervision, potential for unintentional misuse and possible abuse of the drug for recreational purposes – at the European Medicines Agency (EMA).

The EMA's Committee for Medicinal Prod-

■ *Continued on page 14*

# Greece reveals general-sale plans

Plans for allowing OTC medicines to be sold outside of pharmacies for the first time were unveiled by the Greek government on 18 May.

Selling OTC medicines through mass-market channels is currently forbidden in Greece, but last week the Ministry of Health added a provision allowing general sale of OTC medicines to a bill awaiting a Parliamentary vote.

The measure is restricted to a sub-group of the country's OTC List, referred to by the Ministry as "Medicines for general availability". The sub-group currently comprises 216 forms, and criteria for deciding the list – and adding to it in future – were also spelled out.

As **OTC *bulletin*** went to press, however, the names of the medicines in the sub-group had not been officially published and were said to be still under discussion. Active substances known to be in the sub-group include acetylsalicylic acid, glucosamine, glycerol, hexetidine, paracetamol and retinyl palmitate.

Some supermarkets and local Greek firms have already expressed interest in supplying such OTC medicines, which in turn has raised the possibility of store brands.

The official position of EFEX, the Greek self-care industry association, is that OTC medicines must be sold by pharmacists, thereby ensuring consumer safety and safeguarding the role of pharmacists as health advisors. The views of George Dokios, director-general of EFEX, can be found on page 28.

However, EFEX has also emphasised that the association's "primary vision" is to est-

■ *Continued on page 15*

*Mergers & Acquisitions*

# C&D denies RB takeover talks

Church & Dwight has categorically denied it is engaged in takeover talks in response to rumours that Reckitt Benckiser (RB) is poised to acquire the US-based firm for US$23 billion (€20 billion).

The manufacturer of Arm & Hammer toothpaste, Trojan condoms and Vitafusion vitamins insisted that the reports of an impending takeover by RB – published by Madrid-based news website *Negocios* – were "market speculation".

"The company believes that it is prudent to advise its employees and investors," commented Church & Dwight, "that it is not engaged in discussions with, nor has it received any proposal or communication concerning a potential bid for the company or any of its business units, and is not otherwise aware of any information supporting these rumours."

"The company notes," continued the firm, "that this statement is an exception to its policy of not commenting on market rumours, and that in the future it will maintain its policy of not commenting on rumours except as required by law."

RB declined to comment on the reports that a deal was imminent.

Church & Dwight posted sales of US$3.39 billion in 2015 and recorded an operating profit of US$683 million.

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*Business Strategy/First-Quarter Results*

# Retailer GNC considering putting itself up for sale

Health and wellness products retailer GNC has revealed its board is weighing up a "wide range of strategic and financial alternatives", including the potential sale of the business, in an effort to "increase shareholder value".

The move came just days after GNC posted first-quarter sales that the company described as "unacceptable".

"After careful consideration, including discussions with a range of shareholders, we believe it is an appropriate time to undertake a comprehensive review of the company's strategic and financial alternatives," commented Michael Hines, GNC's chairman.

A "thorough evaluation of the company's current operating plan" would be undertaken during the review, the US-based retailer said. "Potential value-maximising alternatives such as accelerated refranchising strategies, capital structure optimisation, partnerships and other value-creating collaborations, or a potential sale of the company" would be considered.

"We are in the early stages of a broad review," Hines explained, "and we will take the time we need to thoroughly evaluate our opportunities to achieve the best result for our shareholders, business partners, and associates."

"While the review is ongoing, GNC will continue to act with the necessary urgency to deliver improved financial performance by addressing our near-term challenges and continuing to execute our strategic initiatives," he added.

Announcing its first-quarter results, GNC reported turnover down by 1.8% to US$669 million (€585 million), as sales fell at the company's Retail and Franchise operations. Adjusted net income dropped by 23.0% to US$50.8 million.

Turnover at the Retail division – including company-owned stores and e-commerce – declined by 1.5% to US$496 million, due to a slip in same-store sales.

The company's Franchise revenue dropped even faster, with sales down by 5.6% to US$116 million. Poor performances in Australia and Turkey were highlighted by the firm.

On a more positive note, turnover at the Manufacturing/Wholesaling division improved in the three months, moving forward by 3.5% to US$57.5 million.

"We are not pleased with the reported results for the quarter and find them unacceptable," admitted chief executive Mike Archbold. "While we are making progress on our strategic evolution which we started in 2014, the turnaround is taking longer than expected and the progress is insufficient."

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*Business Strategy/First-Quarter Results*

# Problems in Europe frustrate Perrigo

"Lower sales in certain markets" caused Perrigo's European OTC operation to post first-quarter results which "fell considerably short of top-line expectations", according to chief financial officer Judy Brown.

Speaking as the store-brand specialist reported the results of its first quarter ended 2 April 2016, Brown said Perrigo's Branded Consumer Healthcare unit – which consists of the Omega Pharma business and the basket of brands the firm acquired from GlaxoSmithKline last year (**OTC *bulletin***, 12 June 2015, page 1) – had posted sales of US$318 million (€280 million), which were "organically flat compared to the prior-year period".

Adjusted operating income was US$25 million, giving the business an adjusted operating margin of 7.8%.

As a result of Branded Consumer Healthcare's "net sales miss" against expectations, Brown said Perrigo had changed its guidance for the business for 2016.

The company had also identified a pre-tax non-cash impairment charge of approximately US$467 million, Brown noted, "related to intangible assets acquired in conjunction with the Omega transaction".

"The primary impairment indicators included the decline in the company's 2016 performance expectations and a reduction in Branded Consumer Healthcare's long-range revenue growth forecast," she explained, "particularly in the lifestyle and natural health/vitamins, minerals and supplements (VMS) brands."

"This is clearly a disappointment," Brown admitted, "but steps are being taken to correct the underperformance in Branded Consumer Healthcare, including changes in leadership."

"While many steps have already been taken, it is important to note that it will take time to fully realise the true value of the actions we are taking," she added.

Perrigo revealed earlier this year that it was experiencing problems at Branded Consumer Healthcare when the business posted fourth-quarter results that recently-departed chairman and chief executive officer, Joseph Papa, described as a "personal disappointment" (**OTC *bulletin***, 4 March 2016, page 1).

John Hendrickson – who replaced Papa as chief executive officer last month (**OTC *bulletin***, 6 May 2016, page 1) – said that while Branded Consumer Healthcare was facing "some challenges", he remained "optimistic" about the "power of the platform".

Noting that he had been working to "develop a deeper understanding of the day-to-day operations" of the Branded Consumer Healthcare business, Hendrickson said Perrigo was now "fully and effectively" integrating the unit into the firm's existing leadership structure.

"We are building upon the team's core sales and marketing strengths and implementing our own strong operational controls and structures," he explained.

While the firm was unhappy with Branded Consumer Healthcare's performance in the first quarter, the addition of Omega Pharma and the ex-GSK brands to the company's portfolio helped to lift Perrigo's total sales by 32% to US$1.38 billion (see Figure 1).

Group turnover had also been boosted, Perrigo said, by a solid performance from its store-brand Consumer Healthcare unit, which posted sales up by 2% to US$700 million.

Better sales of smoking-cessation products and infant formula had been the main drivers of Consumer Healthcare's growth in the three months, the firm noted.

Perrigo's Consumer Healthcare and Branded Consumer Healthcare divisions accounted for 74% of group turnover in the first quarter. The remainder was generated by the firm's Prescription Pharmaceuticals and Specialty Sciences divisions, plus 'other' sales.

| Business | First-quarter sales (US$ millions) | Change (%) | Operating income (US$ millions) | Change (%) |
|---|---|---|---|---|
| Consumer Healthcare | 700 | +2 | 122 | +1 |
| Branded Consumer Healthcare | 318 | – | 25 | – |
| Prescription Pharmaceuticals | 257 | +2 | 117 | -3 |
| Specialty Sciences/Other | 108 | – | 71 | – |
| **Total Perrigo** | **1,383** | **+32** | **335** | **+7** |

**Figure 1: Perrigo's sales and operating income in the three months ended 2 April 2016 (Source – Perrigo)**

*Mergers & Acquisitions*

# Blackmores pays A$23mn for TCM firm

Australian natural-health firm Blackmores has paid A$23 million (€14.8 million) to acquire Global Therapeutics, which is said to be the country's leading provider of traditional Chinese medicines (TCMs).

As a result of the deal, Blackmores has gained fellow Australian company Global Therapeutics' full product portfolio – including its two "highly-respected" brands, Fusion and Oriental Botanicals – and more than 40 staff members.

Blackmores pointed out that the Fusion brand had a leading position in health-food stores, while Oriental Botanicals was the top TCM line in pharmacies.

Both brands, however, would not be sold under the Blackmores name, the firm noted.

Founded in 1999, Global Therapeutics had invoiced approximately A$20 million in sales in the past 12 months solely in Australia, Blackmores highlighted, and generated earnings before interest, tax, depreciation and amortisation (EBITDA) of A$3 million.

Commenting on the acquisition, Christine Holgate, Blackmores' chief executive officer, said that the deal – which is expected to be accretive within a year – would give the firm a "foothold in the rapidly-growing Chinese herbal medicine market".

Noting that there was a "growing use of Chinese herbs in self-selection channels" – and 4,700 TCM practitioners in Australia – Holgate added that Global Therapeutics would deepen the firm's understanding of TCMs.

"The deal will bring us closer to our Chinese customers in Australia, which will underpin our growth success internationally," Holgate explained, "and it will give us further scale to boost our operational effectiveness."

Holgate added that Global Therapeutics would in the future provide Blackmores with a new product portfolio to sell through its "existing distribution networks in Asia".

The acquisition also meant that Blackmores now had leading brands in pharmacy, health-food stores – where the company had been "a little bit weaker in the last 10 years" – and practitioner channels in Australia, Holgate claimed.

*Business Strategy/First-Quarter Results*

# Mylan defends Meda's results

Mylan is committed to its planned acquisition of Meda, and the Swedish firm is continuing to perform as anticipated, according to the generics giant's chief executive officer Heather Bresch.

Meda's first-quarter results – which saw the firm's sales fall by 6% to SEK4.32 billion (€467 million), translating to an organic drop of 2% – were "in line with our expectations for the business", Bresch reassured investors, calling Meda a "scarce high-quality asset".

Mylan's offer for Meda, due to be completed by the end of September, values the company at SEK83.6 billion (**OTC *bulletin***, 19 February 2016, page 3).

At the time the deal was announced, Mylan said it was set to create a US$1 billion (€875 million) global OTC business and a "foundation for further expansion in the market".

In the first quarter of 2016, Meda's sales fell in Germany as well as in parts of Asia, where the drop was "mainly related to fluctuations in distributor buying patterns".

Turnover declined at a double-digit rate in the US, due to lower sales of certain prescription medicines.

Excluding non-recurring items – including a SEK121 million negative impact related to the Mylan offer – Meda's earnings before interest, tax, depreciation and amortisation (EBITDA) dropped by just over a tenth to SEK1.26 billion, giving the group an EBITDA margin 1.5 percentage points lower at 29.1%.

"We remain fully committed to and look forward to closing this transaction," Bresch affirmed, insisting that Meda's dynamics were "well-known and understood by us".

"As we've always said, it's not what the company's doing on a standalone basis, it's what we're going to do as a combined platform," Bresch pointed out. "And we believe the Mylan-Meda platform will continue to be one of the most diversified and differentiated ones in our industry."

"As we bring in Meda and establish a US$1 billion OTC franchise, we will be able to think about the best ways to continue to grow that channel throughout the globe," she added.

Mylan – which has just appointed Kenneth Parks to become chief financial officer from 6 June, replacing John Sheehan – saw its own group sales increase by 17% to US$2.19 billion in the first quarter.

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*Business Strategy*

# J&J is back in the market for Consumer acquisitions

Johnson & Johnson is "committed" to growing its Consumer business inorganically through acquisitions and partnerships, according to Jorge Mesquita, worldwide chairman of the unit.

Speaking at a recent analysts' day, Mesquita said that after spending the past few years divesting brands and "pruning" the Consumer portfolio, Johnson & Johnson was now back in the market for acquisition opportunities to expand the business.

"We've been very disciplined over the past few years in pruning our portfolio as needed," Mesquita pointed out, "to concentrate our business on the categories that we want to compete in. We've offloaded brands such as K-Y lubricants, Benecol food products and Splenda sweeteners, but now we're turning to focus on growth."

This change of focus had already begun to bear fruit, Mesquita noted, with Johnson & Johnson in March picking up the Hipoglós nappy-rash brand from Procter & Gamble (**OTC *bulletin***, 25 March 2016, page 3), and a month later US-based skin-care company NeoStrata (**OTC *bulletin***, 6 May 2016, page 3).

### More deals to come

These deals were just the start, he insisted, and there were "more to come".

Noting that the firm had an "ambitious programme to grow the business through acquisitions", Mesquita said Johnson & Johnson would focus its efforts on "building scale in OTC globally, strengthening our leadership in Baby Care and growing in Skin Care".

In addition, the company would go after "regional and country-specific opportunities", he revealed, and look to secure licensing deals and partnerships.

Johnson & Johnson was "actively shaping" its Consumer portfolio to "capture growth opportunities", Mesquita insisted, adding that the firm had a "strong track record of creating value through acquisitions".

Since acquiring Neutrogena in 1995, Johnson & Johnson had more than tripled the brand's sales to over US$1 billion (€895 million), Mesquita pointed out. In addition, sales of Aveeno had grown from around US$30 million in 1999 – when it was added to the Consumer portfolio – to over US$700 million in 2015, he noted.

Commenting on the types of acquisitions Johnson & Johnson would pursue, Sandi Peterson, group worldwide chairman, said the firm would target individual brands, new technologies and small- and medium-sized consumer healthcare companies.

While these were the primary targets, Johnson & Johnson would not rule out going after a "big company" if such a deal "made sense", she added.

"We will look at all of those options," Peterson insisted. "We are focusing on a number of critical spaces – OTC, Skin Care and Baby Care – as well as on tuck-in acquisitions to expand geographically."

Meanwhile, Mesquita noted that while Johnson & Johnson had put together a plan to grow Consumer inorganically, the firm was also focused on securing organic growth.

To do this, Mesquita said the company was "investing heavily" in e-commerce to drive up sales of its Consumer brands online.

"We see a huge opportunity in e-commerce," he insisted. "In the consumer packaged goods (CPG) industry, online sales are growing twice as fast as traditional bricks and mortar sales."

The company was also committed to transforming its approach to innovation, he revealed, to concentrate on "fewer, bigger ideas".

"Previously, we were working on too many projects that were too small to have an impact on the business," Mesquita explained. "We are now focusing on the ideas that truly have a point of difference, a competitive advantage and a bigger global appeal."

Meanwhile, asked by analysts if Johnson & Johnson would consider spinning off Consumer into a separate company to take the business to the next level, Mesquita revealed he was against such a move.

"I can tell you with great confidence," Mesquita said, "that the Consumer business is far better off as part of Johnson & Johnson than as a standalone company."

"I cannot see any disadvantages for the Consumer business if it stays within the group," he claimed. "We have all the autonomy in the world that we need to compete in the consumer healthcare industry."

"In addition, the business can access Johnson & Johnson's innovation ecosystem, which it would not be able to do if it were a standalone company," Mesquita pointed out. "For me, it's a no-brainer [to stay together]."

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*Business Strategy/First-Quarter Results*

# Stada counters investor-driven shake up

Stada Arzneimittel has countered a move by an activist investor to replace three members of the company's supervisory board by announcing it will put forward its own candidates for election.

The investor – Active Ownership Capital, which holds a 5% stake in the German firm – had originally come to an agreement with Stada on 13 May to let shareholders vote on a proposal to replace a third of the nine-member supervisory board with Active Ownership's candidates.

However, Stada said a "special nomination committee" of the current supervisory board would now put forward "at least three" of its own candidates for election.

"In selecting suitable candidates," commented Stada, "the supervisory board's nomination committee will place particular emphasis on the potential candidates' relevant expertise and experience in the fields of generic pharmaceuticals and OTC products, their expertise in finance, audit and legal matters as well as on their personal independence."

The vote to elect new board members will take place at the firm's annual general meeting, which has been rescheduled from 9 June to 26 August. Stada said it had delayed the meeting "to ensure an orderly and transparent selection process".

Despite postponing the meeting, Stada noted that all items on the agenda would remain unchanged, including a vote on an additional proposal by Active Ownership to reclassify registered shares with restricted transferability to registered shares.

Commenting on its decision to shake up its supervisory board, Stada said it wanted to find the "best possible candidates" to support its growth strategy. "In recent years, Stada has successfully pursued a strategy of internationalisation and diversification," the firm pointed out, "and these steps are designed to respond to this development."

Following Stada's move, the candidates nominated by Active Ownership indicated that they would need a "reflection period to consider taking part in the selection process".

| Country | Group sales (€ millions) | Change (%) | Branded Products' sales (€ millions) | Change (%) | Branded Products' share in Stada (%) |
|---|---|---|---|---|---|
| Germany | 135 | +17 | 60 | +31 | 44 |
| Italy | 49 | +12 | 10 | +65 | 20 |
| Russia | 38 | -14 | 18 | -40 | 47 |
| UK | 37 | -14 | 33 | -8 | 89 |
| Spain | 32 | ±0 | 5 | +24 | 16 |
| Belgium | 30 | +11 | 3 | +31 | 10 |
| Other | 176 | – | 61 | – | 35 |
| **Total Stada** | **497** | **+2** | **190** | **+3** | **38** |

**Figure 1: Breakdown of sales by Stada and its Branded Products division in the first quarter of 2016, together with the proportion of group sales accounted for by Branded Products (Source – Stada)**

Putting forward its original proposal to shake up the supervisory board, Active Ownership had said a change of leadership was required to "develop the company further".

Noting that it had identified "substantial value-creation potential" for Stada, Active Ownership claimed that the company had over the past 10 years "substantially underperformed against its peers".

In addition, the €2.3 billion spent on acquisitions and investments in that period had failed to "yield satisfying shareholder returns", the investment firm insisted.

Stada announced its plans to refresh its supervisory board shortly after it reported first-quarter sales at its Branded Products unit up by 3% to €190 million, as turnover improved in four of its six biggest markets.

In Stada's home market of Germany, sales of Branded Products – under the Stadavita and Stada GmbH brand names – increased by 31% to €60 million (see Figure 1).

"High seasonal orders" had been behind the double-digit improvement, Stada noted.

Branded Products' turnover accounted for 44% of group sales in Germany, which advanced by 17% to €135 million.

In Italy, turnover from Branded Products had jumped by 65% to €10 million, Stada reported, thanks to acquisitions and good performances from existing brands.

Branded Products accounted for 20% of total turnover in Italy, which moved forward by 12% to €49 million.

Stada's Branded Products turnover in Spain improved by 24% to €5.3 million, accounting for 16% of total sales, which were flat at €32 million.

In Belgium, Stada reported Branded Products' turnover up by 31% to €3 million, as the business overcame distribution problems that had hit sales in the prior-year period.

Branded Products' turnover accounted for 10% of group sales in Belgium, which advanced by 11% to €30 million.

Meanwhile, Branded Products' sales had been held back, Stada noted, by weaker performances in both Russia and the UK.

An "ongoing reluctance to buy among consumers" in Russia, due to the economic situation, had caused sales of Branded Products to slip by 40% to €18 million, the firm said. Lower sales had also been compounded by negative currency effects related to the Russian rouble.

Branded Products accounted for 47% of group sales in Russia, which declined by 14% to €38 million.

In the UK, where Stada acquired OTC firm Thornton & Ross in 2013 (**OTC *bulletin***, 23 August 2013, page 1), Branded Products' sales dropped back by 8% to €33 million.

A "weak cold season" had hit sales of key brands, Stada explained, most notably the Covonia cough medicine range, which had suffered a double-digit sales decline.

Branded Products accounted for 89% of UK turnover, which fell by 14% to €37 million.

Branded Products generated 38% of Stada's total sales in the first quarter of 2016. These advanced by 2% to €497 million (see Figure 2). Stada's dominant Generics business accounted for the bulk of the remainder.

| Business | First-quarter sales (€ millions) | Change 2015/2016 (%) | Operating profit (€ millions) | Change 2015/2016 (%) |
|---|---|---|---|---|
| Generics | 296 | +2 | 49 | +35 |
| Branded Products | 190 | +3 | 29 | -14 |
| Commercial | 11 | -2 | 0.2 | -13 |
| Group/Other | – | – | -22 | – |
| **Total Stada** | **497** | **+2** | **56** | **+12** |

**Figure 2: Stada's sales and operating profit in the first quarter of 2016 by business (Source – Stada)**

*Business Strategy/First-Quarter Results*

# Pfizer keen on "valuable" OTC business

Pfizer's Consumer Healthcare business is "a very valuable asset" which the company wants to hold on to for the immediate future, according to chief executive officer Ian Read.

Speaking as the US-based firm announced its first-quarter results, Read said Consumer Healthcare was "growing well" as part of Pfizer, and the company planned to "continue to add to the business".

However, circumstances could change in the future, Read admitted, and Pfizer was not ruling anything out.

"All of Pfizer is aware internally," Read noted, "that we continually look at all of our different assets, and we're always focused on creating shareholder value."

"At this moment, I think the best way of creating shareholder value is the plan we have with Consumer Healthcare growing inside the group," he insisted.

"But as facts change," Read added, "we are always willing to look at those facts."

Were Pfizer to put its Consumer Healthcare unit on the market, it would be a prized asset, with Reckitt Benckiser's (RB's) chief executive officer, Rakesh Kapoor, openly admitting late last year that his UK-based company would be "interested" in the business (**OTC *bulletin***, 11 December 2015, page 1).

"If the Pfizer consumer business were to come up [for sale] for any number of reasons, would RB be interested to look at it? Yes," Kapoor revealed to *Bloomberg*. "I would be very interested in looking at it."

| Business | First-quarter sales (US$ millions) | Change 2015/2016(%) | Proportion of sales (%) |
|---|---|---|---|
| Global Established Pharmaceutical | 5,972 | +17 | 46 |
| Global Innovative Pharmaceutical | 3,640 | +18 | 28 |
| *Global Vaccines* | *1,570* | *+18* | *12* |
| *Global Oncology* | *1,001* | *+90* | *8* |
| *Consumer Healthcare* | *822* | *+2* | *6* |
| Global Vaccines, Oncology and Consumer Healthcare | 3,393 | +27 | 26 |
| **Total Pfizer** | **13,005** | **+20** | **100** |

**Figure 1: Pfizer's sales in the first quarter of 2016 broken down by business (Source – Pfizer)**

Turning to Pfizer's first-quarter results, the company reported Consumer Healthcare sales up by 2% to US$822 million (€719 million). Operationally, sales advanced by 10%.

The operational rise in Consumer Healthcare's sales had been "primarily driven" by "strong demand" for Nexium 24HR following increased promotional support and the launch of a tablet format line extension in the three months (**OTC *bulletin***, 8 April 2016, page 14).

Higher sales of Nexium 24HR in the US helped to push up Consumer Healthcare's turnover in the country by 16% to US$468 million.

Turnover in the US had also been boosted by better sales of its Advil range of products, Pfizer said, which had benefitted from a "late surge in the cough and cold season".

In contrast to the growth recorded in the US, International Consumer Healthcare turnover dropped by 13% to US$355 million due to negative currency effects.

Operationally, sales had improved by 3%, Pfizer pointed out, driven mainly by growth in China and Latin America.

This growth had been partially offset, the company noted, by lower sales in Canada and Saudi Arabia.

Consumer Healthcare accounted for 24% of Pfizer's Global Vaccines, Oncology and Consumer Healthcare division's sales, which advanced by 27% to US$3.39 billion in the three months (see Figure 1).

With the company's Global Established Pharmaceutical and Global Innovative Pharmaceutical businesses both also gaining ground, Pfizer's total group sales jumped by 20% to US$13.0 billion.

OTC

*Mergers & Acquisitions*

# Piramal picks up brands from Pfizer

India's Piramal Enterprises is set to bolster its Consumer Products business in its domestic market by acquiring four OTC brands from Pfizer for INR1.10 billion (€14.5 million). The closure of the transaction is subject to regulatory approvals.

The deal will add to Piramal's OTC portfolio in India the Ferradol dietary supplement, Neko medicated soap, Sloan's analgesic and the Waterbury's Compound expectorant.

Piramal is also set to gain from Pfizer the trademark rights to Ferradol and Waterbury's Compound in Bangladesh and Sri Lanka.

Having been sold in India for over 30 years, all four brands had a "rich legacy" in the country, the company claimed, and enjoyed a "high consumer pull".

Commenting on the deal, Kedar Rajadnye, chief operating officer of Piramal's Consumer Products unit, insisted the products had "huge potential to become power brands in their respective categories".

"We expect these four brands to leverage the strong sales and distribution capability that we have built over the years," Rajadnye explained, "and also to help us improve our profitability margins."

Nandini Piramal, executive director of Piramal, said the Pfizer brands were a good "fit" with the firm's consumer healthcare portfolio and would help the company to "move closer" to realising its objective of becoming a top-three player in India's OTC market by 2020.

Noting that Piramal currently ranked as the seventh-largest player, Nandini Piramal said "strategically acquiring accretive brands" would play an important role in helping the firm to achieve its target.

Commenting on its decision to offload the products, Pfizer said that by removing these four "non-core" brands from its Indian consumer healthcare portfolio it could better focus its efforts on growing its "power brands".

The deal with Pfizer is Piramal's third consumer healthcare acquisition in recent months. In November, the company picked up the Little's baby-care brand, and the following month it snapped up five OTC brands from Merck & Co's Indian subsidiary Organon India (**OTC *bulletin***, 15 January 2016, page 4).

The Merck deal gave Piramal the gastrointestinal brands Farizym, Lactobacil and Naturolax, plus the Lynoral oral contraceptive and Pregcolor pregnancy test.

OTC

*Annual Results*

# Takeda enjoys domestic rise

Higher sales of its top-five OTC brands helped to lift turnover at Takeda's Japanese Consumer Healthcare division by 8.9% to ¥80.1 billion (€649 million) in the 12 months ended 31 March 2016, the company reported.

The unit's best-selling brand, Alinamin vitamin tablets, had been the stand-out performer in the period, Takeda pointed out, posting sales up by 22.1% to ¥25.2 billion.

Alinamin tonics remained the second best-selling brand, with sales edging up by 0.4% to ¥14.9 billion.

Sales of Benza cold remedies advanced by 1.7% to ¥9.8 billion in the 12 months, while turnover from the Biofermin range of gastro-intestinal treatments moved forward by 6.1% to ¥8.6 billion.

Rounding out the top-five, the Borraginol haemorrhoid brand posted sales up by 8.9% to ¥4.5 billion.

Operating profit grew even faster than sales, rising by 10.0% to ¥18.9 billion.

Consumer Healthcare accounted for 4.4% of Takeda's total group sales in the 12 months, which improved by 1.7% to ¥1.81 trillion.

During the period, Takeda announced plans to spin off its Japanese Consumer Healthcare division into a wholly-owned subsidiary, in a move the firm claimed at the time would enable it to "accelerate" the business' growth (**OTC *bulletin***, 19 February 2016, page 1).

Expected to begin operations in April 2017, the new subsidiary – the Takeda Consumer Healthcare Company – will be headquartered in Osaka, Japan.

"Through the planned spin-off," the company explained, "the Takeda Consumer Healthcare Company will gain a more agile business model in the consumer healthcare market, with the goal of accelerating growth by responding faster to changes in the market."

Masashi Sugimoto, president of Takeda's Japanese Consumer Healthcare unit, said the spin-off would leave the business better placed to "respond rapidly" to both "business opportunities" and the needs of consumers.

"We will continue to contribute to the expectations of our customers to live longer and have healthier lives with brands such as Alinamin and Benza," Sugimoto explained, "and, at the same time, we aim to become a leading company in the consumer healthcare markets of the Asia region, focusing primarily on Japan."

OTC

*Business Strategy/Annual Results*

# Prestige open to entering adjacent OTC categories

Prestige Brands will consider entering adjacent OTC categories away from its core portfolio as long as they meet the firm's strict criteria, according to president and chief executive officer Ron Lombardi.

Speaking as the US-based firm announced its results for the year ended 31 March 2016, Lombardi said that Prestige did not "target categories for acquisition opportunities".

"We focus on brands that have a strong heritage with consumers and that compete in categories and spaces that we can win in," he explained. "We look for brands with new product development and innovation opportunities and brands that will respond to increases in advertisement and promotion."

"Those attributes can be applicable to the dietary supplements space," Lombardi pointed out, "the sports nutrition area, and other categories that are close to the OTC space."

"We would be open to adjacent categories, but we will start by looking for brands that meet our criteria," he added.

Lombardi's comments came as Prestige reported North American OTC sales up by 16.0% to US$658 million (€582 million) in the 12 months, driven by better sales of core OTC brands and the acquisition of DenTek Oral Care (**OTC *bulletin***, 11 December 2015, page 5).

Commenting on the firm's North American OTC business, Lombardi said that its focus on core OTC brands had driven "consumption and share growth".

The performance of the firm's three largest brands – Monistat, Clear Eyes and BC/Goody's – had been "particularly strong", Lombardi pointed out, adding that the company expected its OTC brands to "continue to outgrow the categories they compete in".

Turning to new product development, Lombardi revealed that Prestige planned to launch "three to five meaningful new products each year".

"When we speak of innovation," he continued, "we are looking to create meaningful line extensions of existing core brands that match each brands' unique positioning in the market and at the same time make a difference in the lives of consumers."

Over the past 12 months, Prestige had added a non-drowsy variant to its Dramamine motion-sickness line, Lombardi said, and introduced a product to the Compund W range featuring new technology to better target warts.

Furthermore, the company had launched a liquid-drop variant of its Fiber Choice supplement, added new flavours to the Goody's line of headache powders and expanded the Little Remedies range with a product for colic.

Asked about the growing influence of the e-commerce channel in North America, Lombardi admitted that e-commerce only generated a "small part" of the firm's sales.

"Our focus is, first of all, to make sure we're available every place that the consumer might show up to buy the products," Lombardi said.

"Going forward, we think products like DenTek might fit naturally in the e-commerce channel and that shoppers might look in that channel for the product," he noted, "so DenTek is a bit of a first step in that direction for us and it will evolve slowly over time."

International OTC turnover fell back by 0.2% to US$57.7 million, but excluding negative currency impacts, sales increased by 16.2%.

Lombardi stated that Prestige continued to "feel good" about its international business – which is built around the Care business in Australia (**OTC *bulletin***, 26 July 2013, page 3) – and that the firm had adopted the same brand-building strategy in its international markets as it operated in the US.

The firm's three biggest international OTC brands – Fess, Hydralyte and Murine – were growing "very well", Lombardi claimed, along with the company's fledgling UK business, which had been boosted over the year by product launches.

OTC sales accounted for 89% of Prestige's total annual turnover, which increased by 12.8% to US$806 million. The remainder was generated by the Household Cleaning unit, which posted sales up by 0.8% to US$90.7 million.

OTC

## IN BRIEF

■ **THE CLOROX COMPANY** – the US-based consumer packaged-goods player – has grown its dietary supplements offering by **acquiring Renew Life** for around US$290 million (€259 million). Generating annual sales of about US$115 million, Renew Life's portfolio includes fibre and fish-oil supplements, probiotics, digestive enzymes and herbal cleansers.

OTC

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*Business Strategy/Annual Results*

# Taisho plots to grow Japanese dominance

Developing new products, enhancing consumer communications and introducing innovative line extensions to key ranges will drive growth at Taisho Pharmaceutical's domestic OTC business over the next 12 months, according to the Japanese firm.

Reporting its annual results for the year ended 31 March 2016, the country's largest OTC player said it was crucial for the firm to "steadily grow and develop" its domestic business in the face of "intensified" competition from its peers.

To help drive demand for its OTC products in Japan, the firm revealed it was "increasing co-ordination between marketing and sales activities" and "working to enhance direct communication with consumers by expanding into new distribution channels, such as mail order".

Furthermore, the company would look to respond to the "heightened health consciousness" of consumers, Taisho noted, by developing products in "new fields" and bolstering its existing brands.

| Business | Annual sales (¥ billions) | Change (%) | Forecast sales (¥ billions) | Change (%) |
|---|---|---|---|---|
| Japan | 148.1 | +1.7 | 153.8 | +3.8 |
| *International OTC drugs* | *18.4* | *+4.8* | *18.5* | *+0.6* |
| *International energy drinks* | *10.3* | *+9.5* | *9.7* | *-6.1* |
| *International other* | *1.2* | *–* | *0.8* | *–* |
| International | 29.9 | +6.9 | 29.0 | -2.9 |
| Others | 2.7 | -0.7 | 2.6 | -4.4 |
| **Total Self-Medication** | **180.7** | **+2.5** | **185.4** | **+2.6** |
| **Prescription operations** | **109.4** | **-4.2** | **99.6** | **-9.0** |
| **Total for Taisho** | **290.1** | **-0.1** | **285.0** | **-1.8** |

**Figure 1: Taisho Pharmaceutical's sales in the year ended 31 March 2016. Forecasted sales are for the year ending 31 March 2017 compared with actual sales in the previous year (Source – Taisho Pharmaceutical)**

### Increase value of key brands

By introducing line extensions, Taisho said it hoped to "further increase the value" of its key brands – including Lipovitan tonics and nutrient drinks, Pabron cold remedies and RiUP hair-regrowth products – which it had spent "many years" nurturing.

To that end, the firm had rolled out a number of line extensions in its domestic market in the 12 months, Taisho pointed out, including the Rhinitis Attack product under its Pabron brand and a Plus variant for its RiUP range (**OTC *bulletin***, 6 November 2015, page 22).

During the year, Taisho achieved domestic sales at its Self-Medication division up by 1.7% to ¥148.1 billion (€1.21 billion) (see Figure 1), as good performances from RiUP and Vicks cold remedies offset lower sales of analgesics, energy drinks and other products.

RiUP had "performed solidly" in the 12 months, Taisho said, with turnover growing by 10.9% to ¥16.5 billion (see Figure 2).

Sales of Vicks moved forward by 3.9% to ¥3.6 billion, while turnover from Colac laxatives edged up by 0.2% to ¥3.3 billion.

By contrast, domestic sales of Taisho's core Lipovitan brand slipped back by 2.5% to ¥60.5 billion during the 12 months.

Turnover from Lipovitan D dropped by 3.5% to ¥38.6 billion, while sales of other Lipovitan products fell by 0.8% to ¥21.9 billion.

Sales of the Pabron cold remedies brand had declined by 1.5% to ¥24.8 billion, the firm pointed out, with both mainstay general cold remedies and nasal decongestants hit by an unusually mild winter.

Overall turnover at Taisho's Self-Medication division advanced by 2.5% to ¥181 billion in the 12 months, driven by the increase in domestic sales and a 6.9% rise in international turnover to ¥29.9 billion. Other sales accounted for the remainder of the unit's turnover.

International sales of the division's OTC drugs improved by 4.8% to ¥18.4 billion in the 12 months, while international turnover from energy drinks grew by 9.5% to ¥10.3 billion. Other sales generated ¥1.2 billion.

Taisho noted that during the period it had continued to "proactively develop" its international business, particularly in South-East Asian countries such as Indonesia, Malaysia, the Philippines and Thailand.

Commenting on its plans to grow the business further, Taisho explained that it would work hard to "strengthen" its product development capabilities and invest behind its newly-acquired brands.

In addition, the company would strive to "further expand" the footprint of the international business across South-East Asia, Taisho revealed, and into other regions where it identified "high growth potential".

Back in 2014, Taisho's president and chief executive officer, Akira Uehara, said he wanted the business to account for a significant proportion of the Self-Medication unit's sales in the future (**OTC *bulletin***, 24 October 2014, page 6).

| Business | Annual sales (¥ billions) | Change (%) | Forecast sales (¥ billions) | Change (%) |
|---|---|---|---|---|
| *Lipovitan D* | *38.6* | *-3.5* | *38.6* | *-0.1* |
| *Other Lipovitan* | *21.9* | *-0.8* | *21.8* | *-0.4* |
| Total Lipovitan brand | 60.5 | -2.5 | 60.4 | -0.2 |
| Cold remedies (Pabron brand) | 24.8 | -1.5 | 25.5 | +2.9 |
| Hair treatments (RiUP brand) | 16.5 | +10.9 | 16.9 | +1.9 |
| Biofermin | 7.5 | +11.2 | 8.2 | +10.2 |
| Gastrointestinal treatments | 4.1 | +0.3 | 4.1 | +0.3 |
| Livita series | 3.9 | -2.8 | 4.0 | +2.9 |
| Analgesics (Naron brand) | 3.7 | -0.9 | 3.6 | -2.3 |
| Cold remedies (Vicks brand) | 3.6 | +3.9 | 3.7 | +3.2 |
| Laxatives (Colac brand) | 3.3 | +0.2 | 3.4 | +0.9 |
| Zena brand | 2.7 | -9.7 | 3.3 | +21.7 |
| Other Self-Medication products | 17.5 | – | 20.7 | – |
| **Total Domestic Self-Medication** | **148.1** | **+1.7** | **153.8** | **+3.8** |

**Figure 2: Breakdown of Taisho Pharmaceutical's Self-Medication sales in Japan in the year ended 31 March 2016. Forecasted sales are for the year ending 31 March 2017 compared with actual sales in the financial year ended 31 March 2016 (Source – Taisho Pharmaceutical)**

*Business Strategy/First-Quarter Results*

# Pharma changes at Hypermarcas

Brazil's Hypermarcas is reorganising the structure of its Pharma division. The firm said it would create three 'strategic business units' within the operation, including a Consumer Health segment to house its OTC medicines, along with Branded Prescription, and Branded Generics and Generics businesses.

The new business units would be "focused on the strategic and operational development of each of these segments, aiming at continuous improvement in results and value creation", Hypermarcas pointed out, and would be supported by sales, operations, and research and development areas.

"In regard to the research and development area," Hypermarcas commented, "the company has advanced in its plan for creating a new innovation centre, which should become operational by the end of 2016."

Hypermarcas made the announcement as it reported first-quarter sales up by 12.1% to BRL827 million (€207 million), thanks to successful launches of a number of OTC line extensions and higher demand for its branded prescription medicines.

The Brazilian firm said it had also during the quarter taken "important steps" in its plan to sharpen its Pharma focus, including divesting for BRL675 million its condoms and sexual-health business to Reckitt Benckiser (**OTC *bulletin***, 5 February 2016, page 7).

Hypermarcas' earnings before interest, tax, depreciation and amortisation (EBITDA) rose by just over a tenth to BRL310 million. The company's EBITDA margin dropped back from 37.8% to 37.5%.

OTC

## IN BRIEF

■ **IMS HEALTH** – the US-based market researcher – is to merge with contract developer **Quintiles** to form an "industry-leading information and technology-enabled healthcare service provider". With a proforma 2015 turnover of US$7.2 billion (€6.4 billion) and a combined market capitalisation of US$17.6 billion, the combined Quintiles IMS organisation resulting from an all-share "merger of equals" will, the partners claim, "improve clinical-trial design, recruitment and execution" and will also "create a distinctive, global real-world evidence solutions platform".

OTC

*First-Quarter Results*

# Latin American sales rise at Merck Consumer Health

A strong performance in Latin America helped drive up sales at Merck KGaA's Consumer Health business by 6.1% operationally in the first quarter of 2016.

However, negative currency effects of 13.1% had wiped out the operational gain, the German company pointed out. This left Consumer Health's first-quarter sales down by 7.0% at €215 million.

The Neurobion and Dolo-Neurobion vitamin B brands had lifted sales in Latin America in the three months, Merck noted, along with a solid showing from local brands.

During the quarter, Merck expanded its Consumer Health portfolio in Latin America with the Anemidox/Confer and Hepabionta brands, which were transferred from its Biopharma business (**OTC *bulletin***, 5 February 2016, page 15).

Anemidox/Confer was for "the treatment and prevention of iron deficiency-related anaemia at every stage of life", Merck explained, while Hepabionta was designed to support and protect the liver.

Commenting on the transfers, Uta Kemmerich-Keil, chief executive officer of Merck Consumer Health, said the brands had "great potential for consumerisation", adding that the firm planned to "further develop" them and "thereby generate future growth".

Outside Latin America, Consumer Health had "continued on its growth path" in Europe, Merck said, with sales up in a number of markets, including Germany and Poland.

"Strong demand" for the Femibion women's health supplement had driven up sales in Germany, the firm revealed, while in Poland, turnover had been boosted by the performance of the Nasivin nasal spray.

Meanwhile, in Consumer Health's Asia-Pacific region, the business had enjoyed growth in Indonesia and Thailand, Merck noted.

Indonesia's performance had been "particularly strong", the company pointed out, thanks to a strong showing from the Sangobion anaemia supplement.

During the three months, Merck expanded its portfolio in Asia-Pacific with three dietary supplements transferred from Biopharma.

The Evion vitamin E product, Livogen iron and folic acid supplement and the Polybion vitamin D brand were all marketed in India, Merck explained, and generated combined annual sales of around €45 million.

Consumer Health accounted for 5.9% of Merck's total first-quarter sales, which advanced by 20.5% to €3.67 billion.

OTC

*First-Quarter Results*

# Krka reports increase in OTC turnover

Turnover from Krka's non-prescription products – including self-medication lines and cosmetics – edged up by 1% to €27.4 million in the first quarter of 2016.

The Slovenian firm said gains in its domestic market and in its Central Europe region had been behind the single-digit rise in turnover.

Non-prescription turnover in Slovenia had advanced by 11%, Krka said, thanks to better sales of analgesics.

The company's naproxen-based product Nalgesin had been the "main growth driver" in its domestic market in the three months, the company noted, with the paracetamol brand Daleron also performing well.

Turning to Central Europe, Krka reported non-prescription turnover up by 33%, thanks to growth in Poland and Slovakia.

Better sales of ginkgo biloba brand Bilobil and Septolete throat lozenges had helped to lift turnover in Poland by 14%, the firm said.

Sales had improved by 17% in Slovakia, Krka pointed out, driven by the performance of Nalgesin.

Krka noted that non-prescription sales growth had been held back in the first quarter by the poor performance of its East Europe region. The "shrinking" of the pharmaceutical market in Ukraine and currency devaluation in Russia had negatively impacted sales in East Europe, the company explained.

Non-prescription products represented 10% of Krka's Human Health sales in the first quarter of 2016, which inched up by 0.3% to €271 million. These accounted for 90% of Krka's total group sales, which moved forward by 4.0% to €301 million.

OTC

*Business Strategy*

# Industry backs call to tackle diabetes

The OTC industry can help tackle the growing diabetes crisis that has recently been highlighted by the World Health Organization (WHO), according to two of the world's leading consumer healthcare players.

In April, the WHO revealed in its Global Report on Diabetes that the disease was on the rise across the world with over 422 million adults now suffering from either type 1, type 2 or gestational forms of diabetes (**OTC *bulletin***, 6 May 2016, page 20).

The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population, the report states, reflecting an increase in associated risk factors such as being overweight or obese.

This massive increase in diabetes plays into many of the trends that have been embraced by the OTC industry over the past decade, as consumers – especially in established markets – recognise the dangers of certain lifestyle choices, live longer and demand easier access to products that can help them prevent and manage certain conditions.

Responding to the report, two of the world's leading consumer healthcare companies – Sanofi Consumer Healthcare and Merck Consumer Health – told **OTC *bulletin*** that the industry could help tackle this growing problem.

A spokesperson for Sanofi said that while the report revealed that one person in every 11 was now living with diabetes, it had also confirmed that with the right lifelong management and regular check-ups, people with all types of diabetes could live "longer and healthier lives".

"This reflects our philosophy and vision at Sanofi Consumer Healthcare," the spokesperson pointed out, "that having diabetes should not stop people from living and enjoying their life."

"We fully agree with the WHO report's conclusions and recommendations that key gaps in the diabetes knowledge-base need to be addressed," she continued, "such as education on both the disease and the importance of a healthy and balanced lifestyle."

**Sanofi has teamed up with Diabetes Australia to install Diabetes Health Hubs in pharmacies**

"At Sanofi, we believe that consumer healthcare organisations can not only help play a vital role in providing that education and knowledge, either through online content platforms or in-store," the spokesperson explained, "but can also help pharmacists with holistic in-store solutions, such as the ones we have implemented in Australia."

As a way of raising awareness and enabling consumers easily to find the right products to manage diabetes, Sanofi had teamed up with Diabetes Australia to install Diabetes Health Hubs in some Australian pharmacies, the spokesperson pointed out.

These hubs not only included monitoring equipment and accessories, but also a 'Health & Lifestyle' section, that featured the company's supplement brands.

Consumer healthcare organisations could also develop products specifically targeted to managing the needs of people who were living with diabetes, the spokesperson said.

"Within the Sanofi portfolio we already have the Gold Bond Diabetics and Emolium Diabetix skin-care ranges, which have been specifically formulated to meet the dry skin needs of people living with diabetes," she pointed out, "and we will continue to look for more self-care solutions to better serve people living with diabetes around the world."

Echoing Sanofi's thoughts, Merck Consumer Health added that OTC companies could also "play a role in addressing the increasing global diabetes crisis, especially when it comes to early, so-called pre-diabetes stages".

"For example, within our Consumer Health business, we provide vitamin B complexes under our global, world-leading Neurobion brand," the company noted. "A B-vitamin combination is well established in the treatment of peripheral neuropathy – a common complication of diabetes – in particular in the early phases when the nerves could still regenerate from their initial damage."

While diabetes was the focus of the WHO report in April, the organisation has previously pointed out that over 36 million people a year are killed by conditions such as cardiovascular disease, chronic respiratory disorders and cancer, as well as diabetes.

Sanofi highlighted that the European Commission had also estimated that European Union (EU) member states alone spend around €700 billion annually – about 70%-80% of total healthcare costs – on these diseases.

"We know these diseases are largely preventable," the Sanofi spokesperson said, "as they are connected to behavioural risk factors like tobacco, alcohol, physical inactivity and unhealthy diets."

"Sanofi believes that self-care should play a more central role in the prevention of these diseases," she added, "especially as nine out of 10 consumers in Europe view self-care as a vital part of the management and prevention of both minor ailments and chronic conditions and diseases."

OTC

## IN BRIEF

■ **FDA** – the US Food and Drug Administration – has warned customers not to **purchase or use weight-loss product Step 2** as it contains the banned substance sibutramine. Products containing sibutramine were removed from the US market in October 2010, as the ingredient had been shown substantially to increase blood pressure and/or pulse rate in some people and might present a significant risk for those with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

OTC

*Market Research*

# Millennials in US like alternatives

A quarter of American Millennials – a group defined as having been born between 1982 and 2004 – are using alternative therapies more often than conventional options, according to a new study by Nielsen Healthcare.

In a survey of 2,252 American adults, younger people were found to have embraced alternative therapies, such as herbal remedies, massage and chiropractic therapy, more than those aged over 70, the company revealed, but generally the majority of Americans – 69% – viewed these options as safe alternatives to conventional medicines and therapies.

Almost two-thirds of those asked said such treatments were effective, Nielsen pointed out, while half thought that they were reliable.

Jennifer Colamonico, vice-president of Nielsen Healthcare, said that while many alternative treatments predated modern medicines, consumer interest had been bolstered by "two important consumer trends".

"First, consumers are looking for affordable healthcare in a high deductible world," she noted, "and second, people are seeking natural approaches to pain and disease management."

"As these trends are likely to continue for some time, we anticipate more consumers will consider and try alternative treatments, as well as other types of self-care to achieve health and wellness goals."

According to the survey, about seven in 10 Americans have used some kind of alternative therapy, with 37% stating that they have used herbal remedies and 34% chiropractic care.

Herbal remedies appealed more to a younger audience, with 40% of those under 50 having tried them, the survey revealed, while in the over-70s, chiropractic care was the most-used alternative therapy, with 45% having used it.

When it comes to how likely Americans are to use alternative options for various conditions, a majority – 64% – are likely to use them to treat physical pain.

Millennials are particularly likely to consider alternative therapies to treat things like addiction and mental health problems, the survey showed.

OTC

## IN BRIEF

■ **EMA** – the European Medicines Agency – said it had completed the assessment of **16 new herbal substances** in 2015.

OTC

*Switches*

# Poland's Adamed switches sildenafil

■ *Continued from front page*

-ucts for Human Use (CHMP) highlighted in particular a lack of medical supervision involved in Pfizer's plans to offer Viagra 50mg-strength tablets without a prescription.

New Zealand has come closest to granting OTC status, but sildenafil remains partially restricted in the country. It is still a prescription medicine "except when supplied by a pharmacist who has successfully completed the approved training programme for the treatment of erectile dysfunction in males aged 35 to 70 years" (**OTC *bulletin***, 24 October 2014, page 1).

Meanwhile, in the UK, Viagra is available direct from a certain pharmacies through a 'private-patient-group direction', which enables healthcare professionals to supply prescription-only medicines without a doctor's prescription, subject to certain conditions (**OTC *bulletin***, 30 June 2009, page 18).

Adamed said that it would be launching a television and digital marketing campaign for MaxOn Active at the end of May, along with a comprehensive pharmacist-training programme.

"We will educate pharmacists about the product and the questionnaire, so they feel comfortable explaining how to use the product safely," the spokesperson pointed out. The spokesperson added, however: "The user does not need to consult a pharmacist when buying the product. It could be sold by a pharmacy assistant."

Although the product had only just started to make its way into pharmacies, the response from pharmacists had been "really good so far", the spokesperson said.

"Pharmacists have been very positive," the spokesperson added, "especially about the questionnaire."

Adamed's successful switch of sildenafil in Poland could provide a blueprint for the product to be switched in other markets. It could also open up the OTC market to other erectile-dysfunction drugs, such as Elli Lilly's Cialis, which Sanofi is currently working on switching in a number of markets (**OTC *bulletin***, 30 May 2014, page 1).

Commenting on the potential switch of Cialis last year, Vincent Warnery, head of Sanofi's global consumer healthcare business, told **OTC *bulletin*** that the process was still at the "exploratory stage", but that initial feedback from regulators had been good (**OTC *bulletin***, 3 April 2015, page 20).

Switch expert Natalie Gauld – who was heavily involved in making sildenafil conditionally available without a prescription in New Zealand – told **OTC *bulletin*** that companies would "watch with interest" how MaxOn Active performed in the market, especially as the switch had taken place in an EU country.

"It will also be useful to see how men use the product," she added. "Will they read the questionnaire? And will they follow its advice? If they have bought the medicine and then find they are ineligible to use it, will they take it back and get a refund, give it to someone else or throw it away?"

"Regulators will be interested in understanding the outcomes for consumers in Poland and how they compare with both the experience in New Zealand and the patient-group direction in the UK," Gauld said. "However, differences in availability are likely in different countries, no matter how positive the outcome in Poland."

Gauld also hoped Poland would now look at making oral contraceptives available without a prescription, particularly given the tightened rules on abortion access in the country.

Oral contraceptives could be supplied safely by pharmacists with additional training and a screening tool similar to that approved for MaxOn Active, Gauld maintained.

### Issues with questionnaires

Including a questionnaire to help facilitate an innovative switch is not new, and indeed has caused problems elsewhere. The demands placed on such questionnaires by regulators have been blamed for the failure of two high-profile switches in the UK – Boehringer Ingelheim's Flomax Relief (tamsulosin) and Johnson & Johnson's Zocor Heart-Pro (simvastatin).

In 2013, Paul Carter, global head of development, medicine and regulatory affairs at Boehringer Ingelheim, blamed a "prohibitive" pharmacy protocol – that required a pharmacist or pharmacy assistant to ask the consumer numerous questions – for the commercial failure of the German company's Flomax Relief product in the UK (**OTC *bulletin***, 28 June 2013, page 10).

Calling the protocol a "camel's hump – a horse designed by committee", he pointed out that Flomax Relief had been switched, but made almost inaccessible. The consumer – most likely an embarrassed late middle-aged man – had had to ask, more often than not, a young female pharmacy assistant for the product from behind the counter. He would then have been questioned about his suitability to use the product.

Gauld told **OTC *bulletin***, however, that screening tools could work well if they were properly designed and, crucially, if people actually wanted to access the medicine without a prescription.

"The negativity from the UK around screening tools is possibly a greater reflection of concerns pharmacists had around simvastatin and tamsulosin," Gauld said, "when coupled with fully-subsidised doctor visits and prescriptions for many, than with the screening tools alone."

According to Carter, the pharmacy protocol – a "series of icebergs", involving 28 questions – had been designed to make it highly unlikely that the pharmacist would sell Flomax Relief to the consumer. Instead, the consumer was likely to be referred to his general practitioner (GP), who would recommend a herbal remedy or prescribe a generic version of tamsulosin.

Carter believed the complex protocol for Flomax Relief drove the consumer towards the GP, who then drove the patient away from the OTC self-care environment by issuing a prescription. The protocol, coupled with the fact that prescriptions for many men in Flomax Relief's target range were free in the UK, meant it was highly unlikely that the patient would use Flomax Relief, he said.

The switch raised many questions, such as whether men's products were the best switch candidates, and whether switches were doomed to fail while prescription and OTC versions of the same product coexisted.

Protocols, he added, were "of no use to anyone", least of all the sufferer, if they inhibited the likelihood of commercial viability. "Helping patients requires commercial success," he insisted.

## IN BRIEF

■ **SANOFI** has **recalled four batches of its Combiflam** ibuprofen and paracetamol combination painkillers in India over quality concerns. The recall was initiated after India's Central Drugs Standard Control Organisation (CDSCO) discovered that some batches of Combiflam had a delayed disintegration time, which meant it took too long a time for the tablet to break down in the human body. Despite the recall, Sanofi said that the problem did not present any safety issues or impact the efficacy of the drugs.

*Regulatory Affairs*

# Health Canada issues warning

Health Canada has warned the public over potential risks associated with the combination of methylisothiazolinone and methylchloroisothiazolinone (MI/MCI) which is used as a preservative in certain 'leave-on' non-prescription and natural health products.

For some people, the MC/MCI combination – used in numerous products including topical pain-relief products and acne creams – could lead to adverse skin reactions, the regulator warned, such as blistering, dry, cracked or scaly skin, itching, a red rash or bumps and/or swelling, burning or tenderness of the skin.

"These symptoms may occur each time someone uses a product containing MC/MCI," Health Canada said, "and may become more severe with repeated use."

Consumers have been advised to check the ingredient list of their leave-on cosmetics, non-prescription medicines and natural health products. Those that experience a reaction should avoid all products that use MC/MCI.

The regulator said that all products intended for use by children under the age of three should be removed from the market by 14 June 2016, while all other leave-on products containing MC/MCI should be no longer available after 31 December 2016.

*Regulatory Affairs*

# FDA calls for industry views on OTC monograph user fee

Industry stakeholders will get to voice their views on a proposed OTC monograph user-fee system put forward by the US Food and Drug Administration (FDA) at a meeting on 10 June 2016.

Announcing the meeting, the FDA said that it wanted to "gather input on the potential development of a user-fee programme for non-prescription monograph drugs".

"A user-fee programme would provide funding to supplement congressional non-user fee appropriations," the agency claimed, "and would support timely and efficient FDA review of the efficacy and safety of ingredients in, or proposed for inclusion in, a monograph."

The FDA has invited comments on the potential user-fee programme and suggestions for the features such a programme should include.

This latest meeting is part of a review of the OTC monograph system, which began in 2014 (**OTC *bulletin***, 30 May 2014, page 12).

Earlier this year, Patrick Lockwood-Taylor, chair of the Consumer Healthcare Products Association (CHPA) said that reform of the US OTC monograph system was a big opportunity for the industry to shape its future rather than have its future decided for it.

"Capitol Hill and the FDA want to complete the monograph system and modernise it," he pointed out, "as do we."

"But any reform needs to create value for consumers, the FDA and for the manufacturers of the medicines within this system," Lockwood-Taylor insisted, referring to the FDA's statement two years ago that it believed its OTC monograph system needed a "critical examination at this juncture to examine whether and how to modernise [the FDA's] processes and regulatory framework" (**OTC *bulletin***, 25 March 2016, page 23).

### Regulatory framework challenges

The regulatory framework faced "significant challenges" as it did not allow rapid responses to drug safety issues or scientific advances, the FDA claimed, with the agency questioning whether the challenges facing the system "necessitated a more agile and responsive process than the OTC drug review allowed".

This had presented an opportunity, Lockwood-Taylor said, to "push for a simplified, more transparent rule-making process, which offers a more effective way to address safety issues around potential OTC products".

*Regulatory Affairs*

# ASMI backs codeine monitoring system

The Australian Self Medication Industry (ASMI) has welcomed a report that supports the use of a real-time monitoring system for codeine-based OTC products as an alternative to reverse-switching them.

Published in the journal *Addiction*, the authors acknowledge that a real-time monitoring system for all codeine-based products may be an alternative to rescheduling, despite the study showing an increase in misuse and abuse of the drug.

Earlier this year, the ASMI backed a monitoring system and other risk-reduction proposals after the Therapeutic Goods Administration (TGA) launched a consultation on whether to reverse-switch OTC codeine products to prescription-only status (**OTC *bulletin***, 19 February 2016, page 11).

*Regulatory Affairs*

# Greece reveals general-sale plans

■ *Continued from front page*

-ablish and develop self-care in Greece.

The move towards general sale is one of several measures that are being introduced to liberalise the OTC market in Greece.

Free pricing of OTC medicines should be allowed for the first time from 1 January 2017, and a move towards general sale for some OTC drugs would reinforce this change.

Transition arrangements on OTC pricing, in force since March 2014, have effectively frozen OTC prices for two-and-a-half years.

In considering the move that will allow some OTC medicines to be sold through mass-market channels, Greece's Nation Organisation of Medicines (EOF) drew up the following criteria for general availability.

To be included on the list, a medicine should:

■ already have OTC status (be present on the OTC List); and not be the subject of new scientific data suggesting a possible reclassification to prescription status;

■ be suitable for treating symptoms that are obvious and easily self-diagnosed and that cannot be confused with other symptoms;

■ have dosage guidelines that are easy to understand;

■ have minimal interactions with other commonly-administered treatments; or, if they have, the interactions are of low risk;

■ not require special storage and handling conditions;

■ be in a small pack size such that the total amount of the drug cannot exceed a dose that could endanger life;

■ not present a serious risk in long-term use that has been documented in scientific journals.

*Product Recalls*

# GSK warns on kids' Panadol

GlaxoSmithKline (GSK) is recalling in Australia three batches of its Children's Panadol 5-12 Years liquid suspension due to the risk of allergic reactions caused by possible contamination of the products.

An announcement from the Australian Therapeutic Goods Administration (TGA) states that an ingredient used in the manufacture of the medicines – supplied in 200ml bottles – may have been contaminated with small particles that could contain trace minerals and inert fibres, and may not be visible in the product.

### Low risk of allergic reaction

Should contamination occur, there was a "very low risk of allergic reaction", the TGA said, adding that there was also the "potential for the medicine to be less effective over time".

Two bottles of strawberry-flavour suspension had been affected, the TGA noted, and one orange-flavoured product.

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*Legal Cases*

# ACCC appeals RB penalty for misleading consumers

The Australian Competition and Consumer Commission (ACCC) is to appeal a A$1.7 million (€1.1 million) fine handed to Reckitt Benckiser (RB) for misleading consumers over its range of Nurofen 'Specific Pain' products.

The Federal Court of Australia has ordered the UK-based firm to pay the fine after ruling late last year that RB had made "misleading representations" by claiming that each Specific Pain variant had been formulated to treat a particular type of pain, despite all products containing 342mg ibuprofen lysine (**OTC *bulletin***, 15 January 2016, page 15).

However, in April, the ACCC called for RB to be fined A$6 million for the violations (**OTC *bulletin***, 22 April 2016, page 16).

Announcing the appeal, Rob Sims, the ACCC's chairman, said that the Commission would submit to the court that the fine would not "act as an adequate deterrent and might be viewed as simply a cost of doing business".

"This is particularly the case when the judge found that RB had made many millions in profits from sales of 5.9 million units of these products at around 8,500 outlets during the relevant period," Sims argued.

In handing down the A$1.7 million fine in April – which was close to the A$1.1 million penalty proposed by RB – the Federal Court said that while consumers potentially suffered financial loss due to the price premium attached to the products, the products had still been effective in treating the pain that they represented.

In addition, although RB's conduct had been designed for profit, the profit made from the products was "unquantifiable", the court ruled.

In its earlier decision on the case brought by the ACCC last March (**OTC *bulletin***, 20 March 2015, page 10), the court ordered that the four Specific Pain products should be removed from shelves.

OTC

*Advertising Complaints*

# UK's ASA bans Omega's Urostemol spot

Omega Pharma's television advertisement for its Urostemol Men bladder- and prostate-health product has been banned by the UK's Advertising Standards Authority (ASA) for discouraging essential treatment for conditions for which medical supervision should be sought.

The advertisement featured an older man getting out of bed, while on-screen text read: "frequent urge to urinate?" and "often getting out of bed at night?"

This was reiterated by a voiceover, which also encouraged consumers to try the product if their bladders felt "constantly under pressure".

Consumers were advised to try Urostemol Men "for a good night, undisturbed by frequent urges". The voiceover added that it was used by over 10 million people to relieve urgency and frequency.

Responding to complaints that the advertisement discouraged essential treatment for more serious health conditions, Omega said the Summary of Product Characteristics (SPC) stated that Urostemol Men was a traditional herbal medicinal product used for the relief of lower urinary-tract symptoms in men related to an overactive bladder or bladder weakness, such as urgency to urinate and urinary incontinence.

Omega added that consumers were instructed in the advertisement to read the product's patient information leaflet (PIL), which was also available on the internet.

The PIL stated that medical advice should be sought if symptoms worsened after seven days or persisted for more than four weeks, Omega noted, while the product packaging also stated "clearly" that Urostemol Men was intended for the relief of symptoms of an overactive bladder.

However, the ASA pointed out that the advertisement did not state or imply how long the man in the advertisement had suffered from his symptoms, how severe or recurrent they were, or what condition was causing them.

### On-screen text insufficient

While the ASA acknowledged that there was on-screen text stating the product was intended to treat overactive bladder, the watchdog said this information was "insufficiently prominent in relation to the visual and voiceover references to frequent urination – without the context of a specific condition – to make clear to consumers that the product was intended to treat a distinct, medically-diagnosed condition".

Therefore, the ASA found that viewers suffering from the symptoms shown in the advertisement would infer that the product could be taken generally to treat them, and so those with symptoms that required medical supervision would be encouraged to self-medicate rather than seek professional advice and supervision.

The watchdog added that although the advertisement encouraged consumers always to read the leaflet, the PIL was only likely to be seen after consumers had decided to purchase and so would be insufficient to clarify the message of the advertisement.

Noting that complaints had also been made over whether the claim "used by over 10 million people" was misleading and could be substantiated, Omega argued that Urostemol product combinations were marketed – under the name Granufink – in Austria and in Germany, where the brand had been present for over 50 years.

The firm provided data from 1996 to 1997 of estimated total sales in Germany of all varieties, and also claimed that over 21 million units had been sold between 1996 and 2015.

However, the ASA pointed out that the claim appeared only when Urostemol Men was shown, while the voiceover repeated the claim immediately after making a statement about the product, so viewers would believe that 10 million related to Urostemol Men specifically and not to all Urostemol variants.

While the watchdog noted that Omega had also provided sales figures from 1964-1996 in lieu of unavailable sales data, it pointed out that these were estimated on the basis of factory production figures, and there was no indication that all the units had been sold.

As a result, the ASA said the methodology used to calculate the number of consumers who had purchased Urostemol Men was "insufficiently robust" to substantiate the claim that the product had been used by over 10 million.

The advertisement was found to be irresponsible and misleading, and must not be broadcast again in the form complained about.

### Omega must not repeat claims

Future advertisements must not discourage essential treatment for conditions for which medical supervision should be sought, the ASA ruled, adding that Omega should not repeat the claim "used by 10 million" – or any similar declaration – unless there was documentary evidence to support it.

In a statement, Omega said it aimed to "inform and educate about the variety of evidence-based self-treatment options available that can support people who suffer from an overactive bladder, while ensuring consumers are equipped with all the information they need to seek further medical advice where necessary".

*Product Launches*

# Gilbert offers French homoeopathy range

France's Laboratoires Gilbert has launched a new homoeopathy range in its domestic market under the name LG Homéo. Comprising "nine exclusive formulas", the range aims to address a variety of ailments through remedies that are each composed of three plant-based ingredients.

"With LG Homéo," the firm said, "Laboratoires Gilbert is making more widely accessible medicines that are ecological, ethical and effective through innovative, value-added formulations." Each product was made entirely from plant ingredients, the company emphasised.


**The LG Homéo range includes a HoméoTonyl product that is said to aid circulation**

HoméoNormyl is designed to treat minor sleep problems and anxiety, while HoméoQuintyl and HoméoRub are remedies for dry and irritating cough and for cough and cold respectively. HoméoTonyl aids circulation, and HoméoCyst is a cystitis treatment.

HoméoDrain facilitates urinary elimination, while HoméoRegul and HoméoDigéo are digestive aids. Meanwhile, the HoméoRyl variant is an anti-haemorrhoid treatment.

With prices that vary between €6.00 and €9.50, the LG Homéo range is available in colour-coded packs.

*Marketing Campaigns*

# Orajel wants UK to "get tough"

"Get tough with toothache" is Church & Dwight's message to UK consumers in its latest campaign for Orajel Dental Gel.

Created by advertising agency Media Therapy, the print-and-digital campaign encourages consumers to "fight toothache with a small dollop of fast and effective pain relief".

The print advertisements and online videos, which also feature the message "give toothache the finger", show how a "pea-sized amount" of the gel applied to the end of a finger turns it into a "finger fighter" – in the form of a ninja, a superheroine or a wrestler – to tackle tooth pain.

Although Orajel Dental Gel was the UK's number-one toothache gel – containing 10% w/w benzocaine – there was "relatively low awareness" of the brand, Media Therapy claimed, adding that there was also "increased competition from big-name painkillers".

**The marketing campaign for Orajel Dental Gel shows how applying a blob to a finger turns it into a 'finger fighter' – such as a superheroine – to tackle toothache**

Rather than using "standard facts and scare tactics to persuade purchase", the firm explained, the campaign – which is due to run until December – used a "bold, light-hearted approach focused on humour and standout visuals" to communicate that Orajel Dental Gel delivered "effective and rapid relief from toothache straight to the source of pain".

As part of the latest push, print advertisements would appear in "key dental titles" Media Therapy noted, while digital advertisements would feature on a range of consumer and lifestyle websites. There would also be mobile advertising, the firm pointed out.

The *orajel.co.uk* website was also due to be updated, the firm explained. Consumers would be invited on the refreshed website to "interact with the finger fighters in a fun and engaging way", Media Therapy said, adding that they would also be able to access features on toothache symptoms, causes and triggers.

Public-relations activity was also ongoing, the company noted, while content was planned for Facebook and Twitter.

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*Product Launches*

# Mission Pharmacal makes Lycelle lice kit OTC in US

US consumers can now purchase Mission Pharmacal's Lycelle Head Lice Removal Kit without a prescription.

Containing the same formulation as the original prescription product, the kit – which is registered as a 510(k) Class I medical device – comprises a 100ml bottle of Lycelle Pre-Combing Gel and a fine-toothed lice comb.

Safe for use on children aged from two years, the Lycelle Pre-Combing Gel – which includes ingredients such as citronellyl acetate, isopropanol, methyl salicylate and sodium laureth sulphate – is said typically to kill both lice and their eggs in one 10-minute application.


**The Lycelle Head Lice Removal Kit comprises Lycelle Pre-Combing Gel and a lice comb**

To support the OTC introduction of the Lycelle Head Lice Removal Kit, a new website, *lycelle.com*, had been launched, the firm explained, which highlighted that the product was pesticide-free. The website also features "competitive comparisons" with products such as Bayer's Rid – with piperonyl butoxide and pyrethrum extract – and Prestige Brands' permethrin-based Nix, which has recently been extended with a pesticide-free Ultra product (**OTC *bulletin***, 6 May 2016, page 16).

The website claims that Lycelle is a "quick, convenient choice for lice removal – approved by parents" and offers consumers a printable US$5.00 (€4.40) discount coupon redeemable against other purchases of the product.

A launch campaign geared towards nurses, paediatricians, and pharmacists would include direct mail and email promotion, Mission Pharmacal pointed out.

Meanwhile, digital support via 'mommy bloggers' – as well as Facebook, Twitter and Instagram – would form part of the campaign aimed at consumers, the company noted, in addition to public-relations activity.

All campaign activity was expected to last until February 2017, Mission Pharmacal noted.

OTC


**Spain's Isdin has extended its Velastisa women's-health range in its domestic market with capsules for urinary incontinence.**

**Claimed by the firm to be the first effective treatment for urinary incontinence based on natural ingredients, Velastisa In Control is formulated with pumpkin seed extract and soybean germ extract.**

**The product is also said to help "regain and maintain the normal functioning of the urinary system", with no side effects.**

**Clinical studies had shown that use of the product had improved the quality of life of 95% of patients, Isdin noted.**

**The Velastisa range currently includes cystitis capsules, as well as a nipple-care cream and a postpartum skin-firming cream. There is also the Intim line, with products such as a vaginal moisturising cream and an intimate hygiene gel.**

OTC


**GlaxoSmithKline (GSK) is offering two UK consumers the chance to win an all-expenses-paid trip to Ibiza by transforming their bodies using its MaxiNutrition sports-nutrition range.**

**To be in with a chance of winning the Ibiza 30-day challenge competition, consumers must upload a 'before' and 'after' photograph – from the first and last day of the challenge – to a dedicated microsite, *maxinutrition.com/ibizachallenge*, by 31 July.**

**The microsite would also provide downloadable training and nutrition plans, GSK pointed out.**

**Members of the public will be invited to vote via the MaxiNutrition Facebook page for a winning entry from two categories – 'best transformation' and 'best body' – to determine the final winners, who will each be able to take two friends with them to Ibiza.**

**In addition to online activity, the campaign will be promoted in-store and through print advertising.**

OTC

*Marketing Strategy*

# Point-of-care campaigns can drive purchase

Point-of-care (POC) marketing introduces OTC brands to consumers when they are most likely to be thinking about their health, starting them along the path to purchase, according to Shauna Garshon, president of US POC marketing firm Brandperx.

Speaking to **OTC *bulletin***, Garshon pointed out that POC marketing – targeting consumers at locations where they received medical care – meant that brand messages were delivered at a time and place where health and wellness decisions were top-of-mind.

POC marketing was a proven way to "create positive brand experiences, improve customer loyalty and increase sales", she maintained, noting that this method generated a five-times return on investment (ROI) on average.

Most POC marketing options, such as screens, posters and brochures, appeared in the waiting room, Garshon said. But her company – which claims to be the largest provider in the US of POC marketing programmes – introduced physicians and their patients to OTC brands through product detailing and education.

Controlled sampling and coupons – allowed in the US for OTC medicines – increased the impact, Garshon added, as this enabled patients to try the product for themselves and gauge its effectiveness.

The firm's POC programmes – which could be used for both OTC and prescription brands – fostered an "active discussion between healthcare providers and their patients about specific brands in a trusted space at the direct time of need", she explained, which was when they had the greatest impact on purchase behaviour.


**The Bump Bag was launched last year and contains a variety of samples, special offers and information "hyper-targeted" to pregnant women**

These programmes were more cost-effective than traditional marketing or sampling methods, Garshon claimed, and prevented "sample and/or coupon hoarding" as they were hand-delivered to consumers by healthcare providers. Greedy consumers were also prevented from taking handfuls of samples from a dispensing display, she added.

The one-to-one introduction of a brand or product by a healthcare professional resulted in an "implied endorsement" of the item that was being recommended, Garshon claimed. This was the "single most powerful driver of trial and purchase", she insisted, and the best possible way to lead consumers on the path to brand loyalty.

OTC companies such as Bayer, Combe and ProPhase Labs have benefitted from Brandperx' claims to help brands engage with more than 400 million consumers every year.

Bayer wanted to make its MiraLAX laxative the number-one recommended laxative brand to treat opioid-induced constipation.

To achieve this, 250,000 patients potentially suffering from this problem were targeted via a 'patient discharge kit' – containing educational materials and a MiraLAX sample – handed out by surgical and hospital physicians in 451 locations.

The efficacy of the programme could be measured through monitoring and analysis, Garshon noted, pointing out that the firm offered physician and consumer surveying to verify compliance and receive brand-specific feedback.

As a result of the MiraLAX programme, the brand had become the number-one recommended laxative brand among surveyed physicians, Garshon said.

Nearly all – 96% – of healthcare providers targeted for the campaign now recommended MiraLAX for patients who required an OTC constipation treatment, she maintained, adding that, due to the POC programme, recommendations for non-prescription osmatic laxatives in general had increased by 36%.

Meanwhile, Combe used POC marketing to increase the presence of its Vagisil feminine-hygiene brand in the healthcare provider channel.

The POC programme for Vagisil had seen 150,000 female patients receive product samples through a 'Scriptbag' patient-activation bag, Garshon pointed out, handed to them by their obstetrician or gynaecologist.

Patient activation bags integrated "brand messaging with patient education, coupons and product samples" in a heat-sealed bag featuring branded artwork, Garshon explained.

### Constant visual presence

These were displayed throughout offices – including exam rooms, nurses stations, and reception desks – to provide a "constant visual presence", she pointed out.

"When a patient is diagnosed with a condition related to a sponsor's product, the product is literally hanging right in the exam room – top-of-mind and ready for sampling," Garshon explained.

A follow-up survey had found that more than four-fifths – 88% – of those that received the bags tried the Vagisil sample product, and 68% of non-purchasers said they were likely to buy the product in the future.

Another advantage of POC marketing was that it could be "scaled" to "accommodate both emerging and established brands", Garshon said, allowing them to be promoted to their target audiences in a more efficient and cost-effective manner.

Clients were guaranteed "category exclusivity" for the term of the POC programme, Garshon noted. These were intended to be 'in-market' for 120 days, she pointed out, but could

*Product Launches*

# Perrigo launches Mucinex DM rival

Perrigo has started shipping in the US a store-brand rival to Reckitt Benckiser's (RB's) Maximum Strength Mucinex DM extended-release tablets.

The guaifenesin and dextromethorphan hydrobromide 1200mg/60mg tablets are said by the firm and its partner Allergan to be the first OTC generic equivalent of RB's product.

Indicated to control coughs and break up mucus, Maximum Strength Mucinex DM produced sales of about US$108 million (€95 million) through food, drug and mass merchants during the past 12 months, Perrigo pointed out.

Commenting on the launch, Robert Stewart, Allergan's vice president, said the roll-out added to the "record of success" the firm had experienced in combining its "leadership in generic product development with Perrigo's strength in marketing OTC and store-brand products, to deliver high-quality, affordable medicines".

According to Perrigo's chief executive officer, John Hendrickson, the two firms would launch the "remaining Mucinex-equivalent products" throughout the rest of the year.

OTC

be designed for up to a year or longer.

"We offer emerging brands the opportunity to make their presence known in a competitive market, allowing them quickly to gain recognition among healthcare professionals while reaching their target consumers," Garshon explained.

Meanwhile, established brands benefitted from the "ability to reach their target audience in a unique way that increases credibility while stimulating conversation about their products", Garshon added.

Brands could feature in programmes as often as they wished, Garshon noted, "as long as another competitive brand has not already committed to that space".

ProPhase Labs' Cold-Eeze brand had experienced the value of POC marketing on a number of occasions, Garshon pointed out. It had participated in several programmes, she explained, adding that the brand had seen a "sales lift for three consecutive years".

Survey data of participating physicians showed a 47% increase in recommendations of the Cold-Ezee brand, she maintained, and 98% of patients had indicated that they were "excited" to try the product.

While patient-activation bags usually contain single samples, 'Bump Bags' were introduced last year to target pregnant women through their obstetrician or gynaecologist. These bags contained a variety of samples, special offers and information "hyper-targeted" to the mother-to be, Garshon explained, to "ultimately drive them to retail to purchase the products".

"Nearly nine out of 10 participating physicians report that they now regularly recommend our clients' products as a result of the Bump Bag programme," Garshon insisted, noting that this method provided "ongoing post-programme sales lift" for the brands featured.

Both the first and second Bump Bags – which had featured products such as MedAltus' Belli Elasticity Belly Oil, Sea-Band's Mama! anti-nausea lozenges and Viactiv Lifestyle's Viactiv calcium soft chews – saw a "lift in physician recommendations for all featured products", Garshon noted.

MedAltus had enjoyed a 45% rise in recommendations for its Belli oil, she said, while Viactiv Lifestyle saw a 24% lift for its calcium soft chews. Sea-Band experienced a 15.4% increase for its ginger-based lozenges.

Products contained in the latest third bag include Premama's eponymous pre-natal vitamin drink mix, Moberg Pharma's Balmex diaper-rash cream, and Psi Health Solutions' drug-free PsiBands anti-nausea wristbands.

Plans were underway for the launch of the fourth 'Bump Bag' in the autumn, Garshon said.

OTC


**Ferrer Consumer Health is targeting Spanish holidaymakers with the launch of its its Hidrasec anti-diarrhoea capsules.**

**Containing 100mg racecadotril per hard capsule, Hidrasec is indicated for the symptomatic treatment of acute non-specific diarrhoea in adults.**

**The roll-out of the capsules had been scheduled to coincide with the summer, the Spanish firm explained, when more people were expected to go on holiday and therefore be more susceptible to traveller's diarrhoea.**

**Ferrer pointed out that the product's name referred to its mechanism of action, noting that the capsules restored the "water balance between absorption and secretion, without causing additional constipation or bacterial overgrowth".**

**One Hidrasec capsule should be taken initially, Ferrer advises. After this, one capsule should be taken three times a day before meals.**

**The company said it would provide pharmacies with a brochure containing tips and information on traveller's diarrhoea.**

**Each pack of Hidrasec contains 10 capsules.**

OTC

*Marketing Strategy*

# Consumer focus helps Similasan climb

Similasan jumped up two places in just under a year to become the third-biggest eye-care brand in the Netherlands, thanks to a consumer-centric approach, a focus on brand development, and an emphasis on retailer education and promotion, according to Harm-Jan Schuurman, head of the Swiss homoeopathic firm's Dutch subsidiary.

Speaking to **OTC *bulletin*** about a growth rate of over 70%, Schuurman claimed people were "beginning to feel more comfortable with non-chemical products", adding that this was "especially apparent when it comes to those used to treat and care for such important parts of the body as the eyes".

"Products combining efficacy, safety and ease of use, along with fast, effective relief, are the main drivers of the eye-care category," Schuurman pointed out.

Due to an ageing population, increased air pollution and increased "screen time", there was consumer demand for solutions to treat and care for specific eye problems, he said.

Similasan's range of eye drops and sprays were attractive to consumers as they met their needs, he maintained, noting that the products were "very quick in providing relief, safely and without the use of a chemical solution".

Similasan opened its Dutch subsidiary – led by Schuurman – in January 2014 to reintroduce the eponymous Similasan Oogdruppels brand to the Dutch market, where it had previously been market leader.

The firm's exit from the Dutch market came after the country's Ministry of Health in 2012 placed restrictions on homoeopathic products which meant they were no longer permitted to include any medicinal product indications or claims without supporting evidence.

In response, Similasan launched Nr.1 and Nr.2 eye drops in 2014 as medical devices with altered formulations, yet with similar claims to the originals.

As part of its relaunch plan, Similasan's new proposition had included an emphasis on the brand's history as a market leader and a more 'premium' positioning, including refreshed silver packaging and a broader product range. There had also been a price increase.

Speaking to **OTC *bulletin*** in June last year, Schuurman said that thanks to this plan – developed and executed in co-operation wth Gian Trepp of business development consultancy GBT Pharma – Similasan had re-established itself as a top-five player in the eye-care category (**OTC *bulletin***, 24 July 2015, page 16).

Nearly 12 months later, Similasan was now the third-biggest brand in the market, Schuurman noted, leapfrogging Heel and Weleda to position it under A. Vogel and Reckitt Benckiser's (RB's) Optrex, with a market share of 8.5% in the food and drugstore channels – excluding pharmacy – according to Nielsen data for April.

### Strong focus on eye-care category

Similasan's strategy had included continuing the firm's "strong focus purely on the eye-care category", Schuurman said, which differentiated Similasan from some competitors and had been "very important" to the brand's growth.

Aside from Similasan's "natural formulation" and "proven efficacy", the "breadth of the range" had been key to the brand's success, Schuurman added.

The brand had entered all the "big segments" in the eye-care market over the past 12 months to cater for the wide range of consumer eye-care requirements, Schuurman pointed out, noting that the ten-strong Similasan eye-care line now included options for red eye, itchy eye and dry eye, as well as a recently-launched Computer Ogen range.

Introducing the the Computer Ogen line had resulted from another element of Similasan's relaunch strategy, namely targeting consumers aged 25 years and over, Schuurman said, rather than its original target audience of 50 years and above.

Harm-Jan Schuurman, head of Similisan's Dutch subsidiary, says the firm has increased its focus on promoting to pharmacists and retailers

Comprising drops, single-use 'monodose' droppers and a 'two-in-one' spray, the Computer Ogen range had been "specifically developed to moisturise and quickly relieve sore, tired, strained and aching eyes as a result of intense computer or office work", Schuurman explained. The products were also for use after long periods of 'screen time', he said, as well as reading, writing and night driving.

"The younger age group is an important one to us," Schuurman maintained. "This group tend to be heavy users of modern media like television sets, games consoles and smartphones. They also spend significant amounts of time studying, so there is strong demand for products like our Computer Ogen option."

### Competition from Optrex and Opticalm

With new products entering the market – including from Optrex and Omega Pharma's Opticalm – average product prices had increased, Schuurman said, noting that the firm, like some of its rivals, had had to respond to retailer's requests for price promotions, such as buy-one-get-one free or 30% discount offers, to stay competitive.

Similasan's relaunch plan had also encompassed "smarter marketing" and a promise to retailers that the firm would "shake up" the eye-care category, including helping to grow the market by a fifth.

"Since the launch of Similasan, the category has grown from around €5 million to just over €7 million," Schuurman pointed out. "Given


Similasan reintroduced its Nr.1 and Nr.2 eye drops to the Dutch market as medical devices after earlier versions had been withdrawn in light of new regulations for homoeopathic products that many new brands and line extensions had been launched onto the market, the growth was driven collectively. However, we are very encouraged by the most recent figures from Nielsen, which show that Similasan's rate of growth is at 72% compared with the market growth rate of 30.1%."

While the firm's "smarter marketing" plan had used digital tools, with a new website and "some" social-media activity, brand promotion had generally remained more traditional, Schuurman said, through radio and email pushes as well as public relations.

More recently, there had been a "shift in tactics" to involve "more intensive work with retailers and pharmacists", he pointed out.

This was especially relevant now that the firm had increased its distribution from just having a presence solely in the drug-store channel to establishing itself in pharmacies.

The firm had entered the pharmacy channel this year, Schuurman explained, noting that it had been "successful in the independent pharmacies like Service Apotheek, with distribution in around 100 outlets".

"Our objective remains to make the Similasan brand available in every pharmacy in the Netherlands," he maintained.

The increased work with retailers and pharmacists meant that the firm was focusing more


**Computer Ogen is aimed mainly at younger people who spend extended periods in front of screens**

on in-store activity at the point-of-sale – including shelf dividers, giant packs, displays and shop-window materials – and sampling on shop floors, Schuurman said, adding that this activity was "important to support store staff in recommending Similasan products".

A "key focus" for the firm's salesforce over the past year had been the brand's "unique selling point (USP)" in the form of a "convenient" and "easy-to-use" applicator, Schuurman noted.

Similasan had developed an educational campaign for pharmacists to highlight the "new concept of the two-in-one Computer Ogen spray formulation" and on "growing this product in the market", Schuurman noted.

Meanwhile, sampling was a tried and tested – and effective – consumer-centric marketing solution, Schuurman added, and one that had had a large impact on Similasan's sales growth.

"In the eye-care category, trial is one of the key drivers not only to gain new users, but also to encourage people back to brands they have used before," Schuurman insisted.

"The feedback we hear many times is that 'you don't experiment with your eyes', Schuurman continued. "People say to us, 'once a product does what I expect it to do, I see no reason to move to another brand'."

"It comes down to the fact that, despite companies undertaking heavy television campaigns or buy-one-get-one-free offers, consumers are the judge; ultimately they make the final decision on how they treat eye ailments. People ultimately use the brands they trust, and Similasan's long history has served us well here," Schuurman maintained.

While the firm had made good progress, it was not going to become complacent, Schuurman insisted.

"Similasan's aim is to become the leading eye-care brand," Schuurman revealed. "We expect the eye-care category to keep growing, and our objective is absolutely to play a key role in the future growth and development of this category in the Netherlands."

OTC

## JUNE

*13-17 June*

■ **MedTech Summit**
*Brussels, Belgium*
A five-day summit focusing on medical device regulatory affairs in Europe and globally.
***Contact**: Informa Life Sciences.*
*Tel: +44 207 017 7481.*
*Email: registrations@informa-ls.com.*
*Website: meddevregs.com.*

*14-17 June*

■ **Fispal Technologia**
*São Paulo, Brazil*
Pharmaceuticals, personal care, dietary supplements, and sports nutrition will be covered at this four-day exhibition.
***Contact**: Informa Exhibitions.*
*Tel: +55 11 3598 7800.*
*Fax: +55 11 3598 7801.*
*Email: falecom@informa.com.*
*Website: fispaltecnologia.com.br.*

*16 June*

■ **Drug Label and Package Design**
*Bonn, Germany*
Regulatory recommendations, umbrella brands and patient-friendly design will be addressed at this one-day event run by Germany's medicines manufacturers' association, the BAH.
***Contact**: BAH.*
*Tel: +49 228 957 4556.*
*Email: abresch@bah-bonn.de.*
*Website: bah-bonn.de/widi-services/fachseminare.*

*20-22 June*

■ **Pharmacovigilance**
*London, UK*
A three-day training course covering pharmacovigilance and drug safety monitoring in Europe, Japan and the US.
***Contact**: Management Forum.*
*Tel: +44 20 7749 4730.*
*Email: info@management-forum.co.uk.*
*Website: management-forum.co.uk.*

*22-24 June*

■ **The Medical Devices Introductory Course**
*London, UK*
This three-day course is run by 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: topra.org.*

*26-30 June*

■ **52nd DIA Annual Meeting**
*Philadelphia, US*
This five-day annual meeting, organised by the Drug Information Association (DIA), will include sessions on: 'How to prepare for a Food and Drug Administration (FDA) inspection'; 'Digital Health Debate'; and 'Acquisitions and mergers, when companies' regulatory operations systems and processes converge'.
***Contact:** DIA Global.*
*Tel: +1 888 257 6457.*
*Fax: +1 215 442 6199.*
*Email: customerservice@diaglobal.org.*
*Website: diaglobal.org/en/flagship/dia-2016.*

*27-29 June*

■ **Legal, Regulatory and Compliance Forum on Dietary Supplements**
*New York, US*
Post-conference workshops will accompany this three-day event, which will look at legal and regulatory developments in the dietary supplements industry.
***Contact**: Council for Responsible Nutrition (CRN) or American Conference.*
*Tel: +1 888 224 2480.*
*Fax: +1 877 927 1563.*
*Email: gpowers@crnusa.org.*
*Website: americanconference.com/dietarysupplements.*

*31 May-2 June*

■ **52nd AESGP Annual Meeting**
*Athens, Greece*
'The future of self-care: Shaping the new environment' is the theme of this three-day event being organised by the Association of the European Self-Medication Industry, the AESGP.

The conference will include sessions on: 'The European market place: How to be successful in a competitive environment'; 'Big becoming bigger: Mergers and acquisitions in the consumer health and pharmaceutical industry'; and 'Digital strategies to make the market move'.

Speakers will include: Alexandra Nikolakopoulou of the European Commission; Jan Smits and Jurate Svarcaite of the Pharmaceutical Group of the European Union (PGEU); Michael Becker of Germany's medicines manufacturers' association, the BAH; Alfred Grün and Gerhard Lötsch of the Austrian Self-Care Association; Brian McNamara of GlaxoSmithKline (GSK); Erica Mann of Bayer Healthcare; Vincent Warnery of Sanofi; Laurent Faracci of Reckitt Benckiser; Briain de Buitleir of PGT Healthcare; Jörg-Thomas Dierks of Meda; and Francine Nieto of IMS.
***Contact**: AESGP. Tel: +32 2 735 51 30. Fax: +32 2 735 52 22.*
*Email: info@aesgp.eu. Website: aesgp.eu/events/Athens52/.*

## JULY

*5 July*

■ **Herbal Medicines**
*Bonn, Germany*
Demands on the pharmaceutical quality of herbal medicines will be covered at this one-day event run by Germany's medicines manufacturers' association, the BAH.
***Contact**: BAH.*
*Tel: +49 228 957 4556.*
*Email: abresch@bah-bonn.de.*
*Website: bah-bonn.de/widi-services/fachseminare.*

*14 July*

■ **Basics of Regulatory Affairs**
*London, UK*
A one-day seminar run by the 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: topra.org.*

## AUGUST

*26 August*

■ **Marketing Authorisation in Russia, Ukraine and the Eurasian Economic Union**
*Frankfurt, Germany*
This one-day seminar will look at changes in legislation for the registration and circulation of medicines in Russia, Ukraine and the Eurasian Economic Union.
***Contact**: Institut für Management.*
*Tel: +49 6221 500 680.*
*Fax: +49 6221 500 555.*
*Email: h.wolf-klein@forum-institut.de.*
*Website: forum-institut.com.*

## SEPTEMBER

*1-2 September*

■ **Vitafoods Asia**
*Hong Kong*
A two-day exhibition and conference focusing on nutraceuticals, as well as functional foods and drinks and dietary supplements.
***Contact**: Informa UK.*
*Tel: +44 20 7017 5803.*
*Email: maria.sidiropoulou@informa.com.*
*Website: www.vitafoodsasia.com.*

*14 September*

■ **Meet the Manufacturer**
*New Jersey, US*
This one-day meeting, run by the Consumer Healthcare Products Association (CHPA), is open to members only.
***Contact**: CHPA.*
*Tel: +1 202 429 9260.*
*Fax: +1 202 223 6835.*
*Email: ccrowell@chpa.org.*
*Website: chpa.org/MX/Register.*

*28-30 September*

■ **13th TOPRA Annual Symposium**
*Amsterdam, the Netherlands*
A three-day event run by The Organisation for Professionals in Regulatory Affairs (TOPRA.
***Contact**: TOPRA.*
*Tel: +44 20 7510 2560.*
*Email:meetings@topra.org.*
*Website: toprasymposium.org/.*

## OCTOBER

*13-14 October*

■ **WSMI/APSMI Conference**
*Nagoya City, Japam*
A two-day conference run by the World Self-Medication Industry (WSMI) and the Asia-Pacific Self-Medication Industry (APSMI).
***Contact**: Japan Federation of Self-Medication Industries (JSMI).*
*Tel: +81 3 5657 0789.*
*Email: info_apsmi2016@jfsmi.jp.*
*Website: jfsmi.jp/apsmi/index.html.*

## NOVEMBER

*21-22 November*

■ **EuroPLX 62**
*Nice, France*
This two-day meeting will provide a forum for business development decision makers for discussing and negotiating collaborative agreements in licensing, marketing, and distribution of patented medicines, generics, biosimilars, OTC products, medical devices and food supplements.
***Contact**: RauCon.*
*Tel: +49 6221 426 2960.*
*Email: meetyou@europlx.com.*
*Website: europlx.com.*

# Bayer will innovate to stay relevant

***Product innovation will be crucial in further developing Bayer's Consumer Health business, but offering consumers not just a pill to take but the support to live a healthier life will also play a key role, Natalie Bartner, president of Bayer's Consumer Health business in North America, tells Matt Stewart.***

**Natalie Bartner, president of Bayer's Consumer Health business in North America, said the firm was poised to take advantage of the positive self-care trends in the region**

The dynamics in play in the North American healthcare sphere are changing the landscape for consumer healthcare in the region, but Bayer is positioned to take full advantage, according to Natalie Bartner, president of the company's North American Consumer Health business.

"More people are embracing self-care and seeking a broader selection of items to help them stay healthy," said Bartner. "Bayer's portfolio of iconic brands helps them to do just that – with products that range from prevention to treatment and maintenance, our business is poised for growth."

"We are aiming for stable, predictable growth across the business," Bartner stated, "and we want to lead in bringing the best innovations to market – including prescription-to-OTC switches – to make it easy for consumers to get what they need."

"Convenience means looking beyond just the product," she explained, "and will require us to stay relevant across customer lifestyles. We want to communicate with consumers in engaging ways and offer the support they need to live a healthier life."

Bartner – previously head of commercial strategy and operations and deputy to the president at Sanofi's North America Pharmaceuticals business – spoke to **OTC *bulletin*** seven months after taking responsibility for Consumer Health's North American business in September (**OTC *bulletin***, 25 September 2015, page 23). She replaced Timothy Hayes, who is leading the integration of the Merck & Co Consumer Care business Bayer snapped up in 2014 (**OTC *bulletin***, 10 October 2014, page 1).

Acquiring the Merck business has significantly bolstered Bayer's North American Consumer Health business, adding brands such as Claritin, Coppertone, Dr Scholl's and MiraLAX to the company's existing portfolio in the region.

Led by a strong performance from the loratadine-based Claritin, thanks to an "extended" allergy season in the US, North America overtook Europe to become Consumer Health's biggest region in terms of sales in 2015. Turnover in the region advanced by 65.8% – 47.3% adjusted for currency effects – to €3.80 billion (see Figure 1).

Bartner brings more than 25 years of experience in the OTC and pharmaceuticals sector to her role, having spent nearly 15 years working at Wyeth and subsequently Pfizer – after the latter acquired the former in 2009 (**OTC *bulletin***, 29 January 2009, page 1) – before joining Sanofi.

Speaking at the time of Bartner's appointment, Erica Mann, member of the board of management at Bayer and president of Consumer Health, said she was "thrilled to have someone of Bartner's calibre, industry perspective and deep understanding of the OTC business to join Consumer Health" at what was an "exciting time" for the business.

***"We want to lead in bringing the best innovations to market – including prescription-to-OTC switches – to make it easy for consumers to get what they need"***

"Bartner's leadership of our North America region," Mann insisted, "will allow us to build upon the success we have achieved over many years and take our success to the next level in this critical market."

| Region | Annual sales (€ millions) | Change 2014/2015 (%) € | CER* |
|---|---|---|---|
| North America | 3,796 | +65.8 | +47.3 |
| Europe | 2,535 | +2.5 | +4.9 |
| Asia-Pacific | 1,474 | +28.3 | +19.3 |
| Latin America/Africa/Middle East | 1,324 | +19.2 | +29.8 |
| **Consumer Health total** | **9,129** | **+30.0** | **–** |

* CER is constant exchange rates

**Figure 1: Breakdown of Bayer Consumer Health's sales in 2015 by region (Source – Bayer)**

Reaching this next level, Bartner said, was possible thanks to the "high calibre organisation" Bayer had in place in the North America region, which was staffed by a "committed and experienced team".

This team, she insisted, was ready to latch on to the dynamics in play in the North American healthcare market as a whole, which in the main were positive for the consumer healthcare industry.

"Consumers are now much more informed, thanks to the adoption of digital channels," Bartner said, "and they are eager to use the knowledge that they can now access to improve their health and live a better life."

"People are living longer and want to be empowered to address their own health issues," she added, "and self-care, covering areas such as wellness, prevention and treatment, is becoming more important to help maintain the viability of our healthcare systems."

"The US is already experiencing a shortage of doctors," Bartner pointed out, "so, as an industry, we have a responsibility to help consumers embrace self-care, and empower them to lead a healthier life."

Speaking about prevention, Bartner noted that Bayer's Consumer Health division has already expanded its position in the vitamins, minerals and supplements (VMS) market with its TruBiotics daily probiotic supplement.

"This line extension, under the trusted One-A-Day name, helps support digestive and immune health, a specific health concern of consumers," Bartner said.

"Driving innovation on established brands


Launched in 2014, Aleve PM took the established pain-relief brand into the sleep-aid market


Bayer leveraged the equity of its One-a-Day supplements brand to launch the probiotic-based TruBiotics line

is a key priority for Consumer Health's growth in North America," Bartner said, noting that retailers and consumers alike expected manufacturers to meet the demands of an "evolving and dynamic marketplace".

"For example, we have seen unprecedented growth in the US allergy space recently, which has brought a host of new products to market," Bartner noted, "and while there are now many choices for consumers, Claritin remains the number-one, doctor-recommended, non-drowsy oral allergy brand."

"But we also recognise that consumers want more and different offerings. As an example, we recently built on our allergy expertise to launch ClariSpray (fluticasone propionate)," she added.

"Aleve PM is another example of leveraging brand equity in one space to enter another," Bartner said. "There is a direct link between pain and sleep quality," she pointed out, "and this innovation enables consumers to treat their pain and also get a restful night's sleep."

Launched in 2014 (**OTC *bulletin***, 10 October 2014, page 20), Aleve PM combines the non-steroidal anti-inflammatory drug (NSAID) naproxen with the sleep-aid diphenhydramine. Containing 220mg naproxen sodium and 25mg diphenhydramine hydrochloride per caplet, Aleve PM is positioned as "the first OTC night-time product that combines a safe sleep aid plus the 12-hour pain-relieving strength of Aleve".

"We intend to innovate very broadly," Bartner said, "at the brand level, ingredient level, and commercial level."

Prescription-to-OTC switches were high on the innovation agenda, Bartner added, with the company looking to take advantage of a positive switch environment in the US by seeking out switch candidates both internally and from outside the Bayer group.

"We will look at creating new OTC categories through innovative switches," Bartner explained, "while also looking at switches to grow existing categories and provide consumers in those categories with value-added benefits."

### Challenge to make switch work

However, prior to Bartner joining Bayer, the firm revealed it had discontinued Oxytrol for Women (oxybutynin) – the first OTC treatment for overactive bladder in women. This had been switched with much fanfare by Merck Consumer Care in the US (**OTC *bulletin***, 8 February 2013, page 1), immediately prior to Bayer acquiring the business.

Bartner admitted that making a switch work commercially could be "challenging" and emphasised the importance of consumers understanding the product and its benefits.

"Ensuring that the company communicates with consumers in the best possible way is also key to our overall innovation approach," Bartner said.

"Having the right conversations with consumers is critical," she explained. "We are ensuring that all our marketing and communications are relevant and engaging people in relevant ways, whether that be online or offline."

"In store, we are making sure the shopper can easily find our selection of Bayer brands and is able to easily select the right product for them," Bartner said.

"We are making sure we know who our brands speak to and are designing our communications for that audience," Bartner pointed out. "Sometimes that means different communications for different audiences who are all using the one brand."

Taking Bayer Aspirin as an example, Bartner pointed out that older customers tended to use the product for its cardiovascular benefits, whereas millennials saw it as an alternative to other pain-relief products.

This challenge was "intimately tied" to the growth of technology, Bartner claimed. "As consumers have embraced social media, mobile access to information, and the ability to track one's health and wellbeing, the industry has been slow to take notice."

To ensure Bayer stayed with consumers on this journey, the firm was on the lookout for "unique partnerships" that would accelerate its ambitions in the digital space, Bartner said.

"We aspire to lead the market in terms of innovation and go-to-market strength," Bartner insisted, "and we are set up to achieve that goal."

OTC


Faced with increased competition in the US allergy market, Bayer launched ClariSpray to take its Claritin allergy line into the nasal spray category

# Changes may soon double Greek sales

***Free pricing of OTC medicines – allied with sales outside of pharmacy and by fledgling pharmacy chains – should provide a strong impetus to growth of the Greek OTC market over the coming years ... provided reforms are properly implemented and medicines remain affordable. Mike Rice reports.***

**EFEX' official policy is that OTC medicines must be sold by pharmacists, says George Dokios, director-general of the Greek self-care industry association, EFEX, but he adds that EFEX' "primary vision" is to develop self-care in Greece**

Free pricing of OTC medicines in Greece is now about six months away from coming into effect. All the signs are that when it does, the move will play a significant role in transforming the Greek OTC market.

George Dokios, director-general of the Greek self-care industry association, EFEX, estimates that the local OTC market could double its present size within five years, given sufficient support from all of the stakeholders involved.

The market has already done remarkably well since the advent of the Greek financial crisis less than a decade ago, thanks to changes the Greek government has introduced.

"The financial crisis has dramatically affected the Greek people in terms of unemployment, lower incomes, higher tax burdens and rises in their cost of living," Dokios comments. "It has also caused delays at health centres due to understaffing, fees for outpatient visits, and health authorities to impose prescription restrictions."

"But, on the other hand, and due to Greece's commitment to promote reforms, the crisis opened up the way to solve the chronic problem of the OTC market," he adds.

Firstly, the government elected to remove OTC medicines from reimbursement in June 2010; and secondly, in March 2014, it made the "bold decision" to legalise free pricing of OTC medicines after a two-and-a-half year transition period. This comes to an end on 1 January 2017.

Greece's total non-prescription medicines market – comprising only medicines included in the official OTC List – was worth almost a third more in 2015 than it had been in 2013. Its share of the total Greek pharmaceutical market was up to 5.83% from 4.37% two years earlier, thanks also to declines in the prescription market (see Figure 1). This was under the transition arrangements that have capped prices at 2014 levels.

However, the total Greek self-care market was worth nearly €900 million if the personal care, patient care, food supplement and nutritional supplement segments are included alongside OTC medicines. Just under half of the self-care market comprised OTC products in 2015, and less than half of that OTC figure was price-controlled medicines on the official OTC List.

| Brand | Volume (units millions) | Value (€ millions) | Average price (€) |
|---|---|---|---|
| Depon | 14.0 | 9.9 | 0.7 |
| Panadol Extra | 4.5 | 8.2 | 1.8 |
| Voltaren | 1.6 | 7.9 | 4.8 |
| Depon Maximum | 6.6 | 7.5 | 1.1 |
| Panadol Cold & Flu | 1.6 | 4.6 | 2.8 |
| Otrivin | 1.3 | 4.4 | 3.4 |
| Bisolvon | 0.82 | 4.1 | 5.0 |
| Daflon | 0.67 | 3.5 | 5.2 |
| Ronal | 0.90 | 3.4 | 3.8 |
| Omacor | 0.32 | 3.1 | 9.7 |
| Mucosolvan | 1.1 | 3.1 | 2.9 |
| Regaine | 0.19 | 2.9 | 14.9 |
| Fenistil | 0.90 | 2.9 | 3.2 |
| Sinecod | 0.68 | 2.7 | 4.0 |
| Strepsils | 1.1 | 2.7 | 2.5 |
| **Total top 15** | **36.3** | **70.8** | **2.0** |
| **Total others (376)** | **37.1** | **100.5** | **2.7** |
| **Total OTC** | **73.4** | **171.4** | **2.3** |

**Figure 2: Leading brands in Greece's OTC medicines market by value and volume in the 12 months to October 2015 at wholesale prices (Source – EFEX/IMS Health)**

Great changes are anticipated by Dokios when free pricing eventually becomes a reality next year. "The market will grow," he forecasts, and will be boosted by new product introductions and switches of medicines from prescription to OTC status. "More and better communications can also be anticipated with consumers," he adds, "who will have a greater selection of OTC products from which to choose."

"Health authorities will benefit because doctors' time will be better spent on more serious cases, while consumers will take more responsibility for their own health. Pharmacists will also be able to enhance their scientific role," Dokios maintains, "and grow their businesses."

"Opportunities dominate the Greek scene and make any threats appear secondary," he states, "with the most important among the threats being any official delays in ratifying free pricing."

"A Ministerial Decree, explaining how free pricing will be implemented, is still awaited," Dokios explains. He is confident, however, that this will be forthcoming in the second half of this year. One of the challenges to be faced is integrating the changes into pharmaceutical legislation that dates back to the 1930s.

Dokios is equally confident that free pricing will not lead to a "price explosion" for OTC medicines. Most of his member companies, he believes, will adopt competitive pricing better to position themselves in the growing market.

"Don't expect dramatic price increases," he says, although he also notes that prices have effectively been frozen since March 2014, and

| Market | 2013 (€m) | 2014 (€m) | 2015 (€m) |
|---|---|---|---|
| **OTC** | **122** | **152** | **161** |
| Total (%) | 4.37 | 5.78 | 5.83 |
| Change (%) | +13.1 | +24.6 | +5.9 |
| **Total Pharma** | **2,792** | **2,628** | **2,763** |
| Change (%) | -10.3 | -5.9 | +5.1 |

**Figure 1: Greece's non-prescription medicines market, defined by the OTC List, over the past three years at wholesale prices, compared with Greece's total pharmaceutical market (Source – EFEX/IMS Health)**

that the local OTC paracetamol brand – the largest product in the Greek pharmaceutical market by volume – has a unit wholesale price of just €0.7 (see Figure 2).

Distribution of OTC medicines outside of pharmacies is another hot topic in Greece.

It is currently forbidden, but last week the Ministry of Health added a provision to a bill awaiting Parliamentary vote to allow general sale. "It is evident that the government plans to open distribution channels," remarks Dokios, adding that he expects the issue to be "decided, voted upon in Parliament and implemented" within the next year.

***"Due to Greece's commitment to promote reforms, the crisis opened up the way to solve the chronic problem of the OTC market"***

"Such a change would increase competition for the benefit of consumers," he concedes, "and reinforce the move to free pricing."

The government's provision would allow a sub-group of the OTC List to be sold in the mass market. The sub-group, called "Medicines for general availability", comprises 216 forms. Criteria for inclusion were also spelled out.

Supermarket chains and some local Greek firms, he notes, would be keen to supply the products in the sub-group.

Dokios is emphatic, however, that the official policy of EFEX is that "an OTC medicine must be sold by the hand of a pharmacist".

EFEX is concerned, he adds, that any change to the current distribution arrangements should be implemented in the safest way possible for citizens and also safeguard the role of pharmacists as health advisors.

Nevertheless, he underlines that the "primary vision" of EFEX is to establish and develop the concept of self-care in Greece.

"The concept, even as a term, is not known among consumers," he notes. "Greek citizens are doctor-dependent, but with social changes and with the difficulties the health system is facing, this dependency is decreasing. More consumers now rely on a pharmacist's advice for their minor health problems."

"Doctors should encourage their patients to consult a pharmacist for minor health problems, instead of queuing up at health centres," believes Dokios, "while health authorities should actively support the self-care concept in cooperation with industry."

"Pharmacists should believe in the role for which they were educated and embrace the opportunity to be health advisors."

"Close cooperation with industry will support pharmacists in further expanding and enriching their knowledge of communication skills," he insists. "In this way, consumers will gradually become more conscious of the benefits of self-care."

Another pillar of Greek pharmaceutical law that has recently fallen – and that awaits clarification by a Ministerial Decree – is the restrictions on multiple pharmacy ownership.

Non-pharmacists are now allowed to own a majority share in a pharmacy chain of up to four pharmacies, but it remains unclear exactly how the new rules should be interpreted. "Nothing has changed yet," Dokios remarks, "but we anticipate seeing the first examples of what to expect soon."

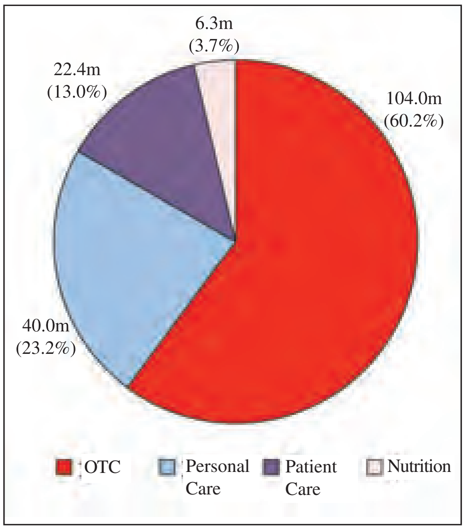
Foreshadowing how the market may function after January 2017 was the enormous increase in OTC medicines that became available after free pricing was in the offing. Dokios points out that in the five months between July and December 2014 – shortly after the free-pricing law was passed by Parliament – 139 product forms were added to the number of authorised non-prescription medicines in Greece.

Most of these came from the country's negative list, introduced in early 2011, but a few also moved from the positive list of reimbursed prescription medicines. The negative list is frequently described as the "cemetery list" because it contains prescription medicines that cannot be reimbursed, Dokios explains.

Products currently carrying a brown safety sticker – or coupon – are on the official OTC List of non-reimbursed, non-prescription medicines. Whether the brown sticker will have any role after price deregulation on 1 January 2017 is still not clear.

Medicines on the positive list carry a black safety sticker. Sales of medicines on the negative list were up by 4.5% to about €65 million in the 12 months to October 2015, making the segment worth less than 40% of the value of the OTC List. The largest negative-list category was erectile dysfunction drugs with sales of €23.2 million.

Dokios is unable to quantify the number, if any, of active substances that moved to the OTC list for the first time among the many that were transferred from the two prescription lists. Each manufacturer has to apply separately for non-prescription status; switches of status are determined by product as well as by ingredient.



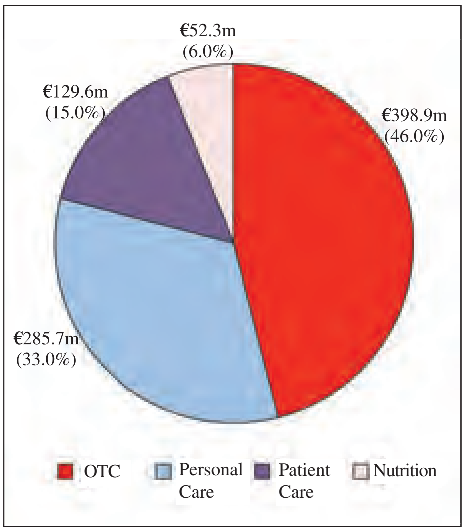




**Figure 3: Greece's total self-care market – OTC medicines, and personal care, patient care and nutrition products – by volume (top) and value (below) in the 12 months to September 2015 at wholesale prices (Source – EFEX/IMS Health)**

Switch criteria applied by Greece's National Organisation of Medicines (EOF) include OTC availability in at least three other European Union (EU) member states as well as the rules contained in its own switch guideline, revised in January 2006, that is in line with EU pharmaceutical legislation.

## Self-care Manifesto

Consumer communications are central to what Dokios describes as EFEX' "Self-care Manifesto". He says a series of articles on the benefits of self-care have started appearing in the pharmacy and lay press, and a research project is at the planning stage to explore citizens', pharmacists' and possibly doctors' attitudes to self-care, with a conference scheduled to present the findings.

EFEX has also made a strong proposal to the health authorities that a 'Directorate of Self-Care' should be created, although Dokios concedes that staffing problems within the authorities and bureaucratic delays amid the "ongoing financial crisis" will be significant obstacles.

In the meantime, EFEX wants its newly-revised and broadened code of conduct on promoting self-care products to be recognised by the authorities as an official code, and for a self-regulation system to be introduced for advertising self-care products.

***"Today there are advertisements for self-care products – particularly food supplements – which do not comply with the law"***

Pointing out that advertising regulations for OTC medicines in Greece are fully harmonised with EU rules, Dokios acknowledges that the authorities also impose mandatory extra warnings, for example on paracetamol, that are not required in other EU countries. "These are not wrong," he comments, "but are more than is needed and cause confusion among consumers."

A much more significant issue, as far as Dokios is concerned, is abuse of the rules by advertising for non-medicinal self-care products.

"Today there are advertisements for self-care products – particularly food supplements – which do not comply with the law," Dokios maintains. "They make medicinal claims, or health claims that are not allowed, and give false promises to consumers. This is having a negative impact on the OTC market."

"EOF is currently understaffed and unable effectively to control these abuses," Dokios continues. "We want to assist the health authorities in their efforts to protect the citizens from false advertising. This can be achieved by setting up, together with the health authorities, a more reliable mechanism for controlling these advertisements," he maintains.

"With a self-regulatory approach to advertising, we would expect EOF's burden of work to be reduced and far fewer unlawful claims to be made."

The wider self-care market includes an OTC segment that was worth nearly €400 million in the 12 months to September 2015. Free-priced supplements and other products outside the official OTC List contributed over €230 million to the OTC total.

OTC products represented 46% of the self-care total by value, but 60% by volume (see Figure 3 on preceding page). The leading OTC companies in the 12 months to October 2015 – with Novartis identified separately alongside its February 2015 joint-venture partner GlaxoSmithKline – are shown in Figure 4.

Dokios believes the prospects for the Greek self-care market are "favourable". Free pricing will encourage companies to increase their investment by introducing new products, switching prescription medicines to OTC status, offering new jobs, launching educational programmes and increasing their informative advertising about the benefits of self-care.

"Wider distribution channels will contribute to further penetration of the self-care messages and enlargement of the market," he notes.

But he emphasises: "This cannot happen at the expense of citizens' health. The health authorities should take into consideration every measure necessary to safeguard public health, including recognising that the presence of a pharmacist, or at least an assistant pharmacist, is vital for this to happen," Dokios insists, noting that combined support will be needed by all of the stakeholders involved.

### Responsibility rests with authorities

Responsibility to progress matters, however, rests with the authorities. "The government has to understand the benefits that self-care has to offer, not only in healthcare spending, but also to Greek citizens. Our goal is to commit health authorities to a policy embracing self-care," Dokios declares.

"In particular," he adds, "EOF should work with us to adopt a self-regulatory approach to advertising and continue working on further switches of medicines."

"The benefits of these are well documented: less of an economic burden on the state healthcare system, enhancement of the pharmacists' role, and, above all, easier access for citizens."

OTC

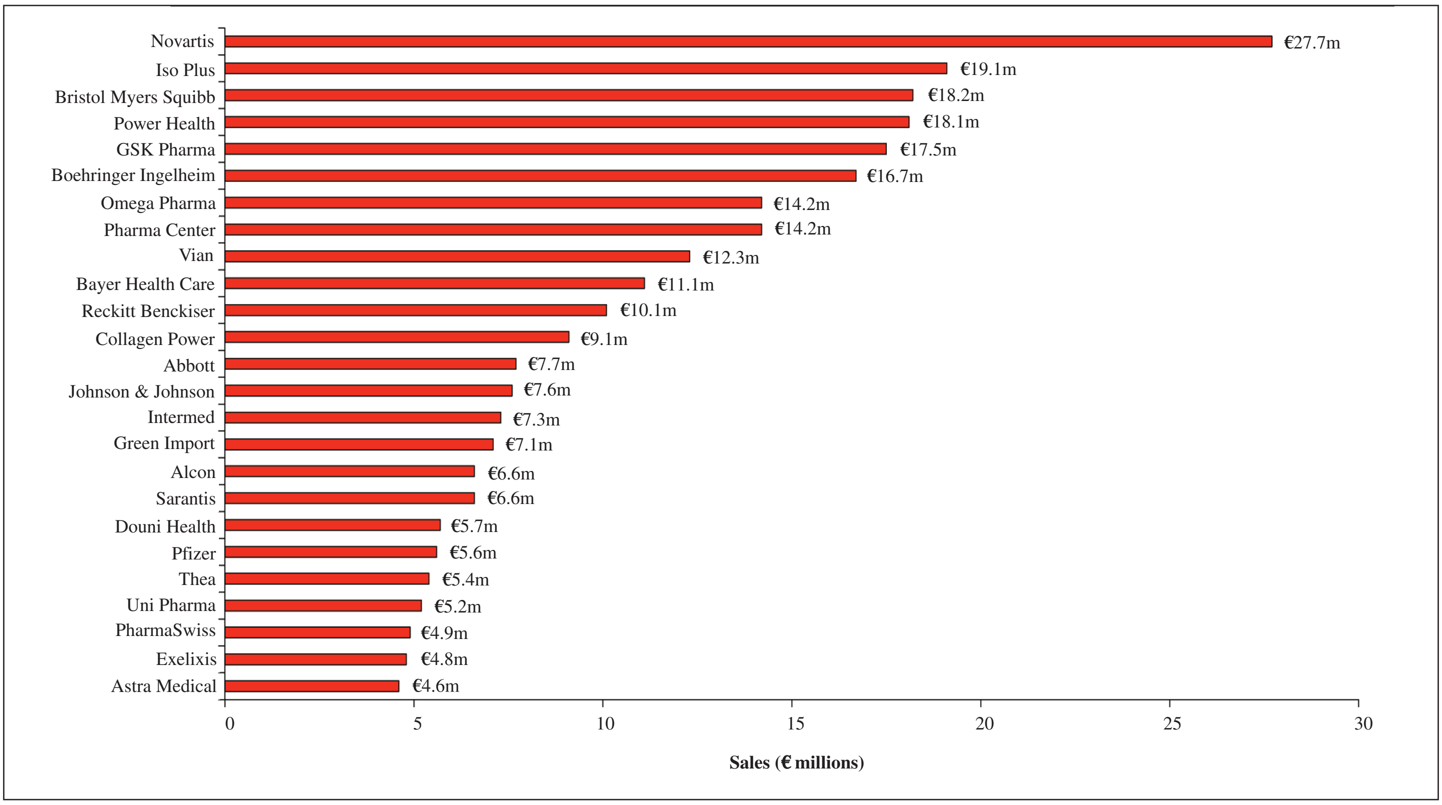



**Figure 4: Greece's leading OTC companies by sales in the 12 months to September 2015 at wholesale prices (Source – EFEX/IMS Health)**

*Manufacturers*

# Schwabe appoints CEO from within

Olaf Schwabe has taken over from **Dirk Reischig** as chief executive officer of homoeopathy specialist Dr Willmar Schwabe.

**Olaf Schwabe** has taken over from **Dirk Reischig** as chief executive officer of homoeopathy specialist Dr Willmar Schwabe.

In his 12-year tenure as head of the family-owned German firm, Reischig had doubled the company's sales from €400 million to €800 million, Schwabe pointed out, had expanded the group's international presence through a series of acquisitions and had also positioned it for further growth.

Formerly head of Schwabe's business services division, Olaf Schwabe had also led the company's Nature's Way subsidiary in the US, the company noted, and held consultancy positions in Germany and the US.

As chief executive officer he would also lead a newly-formed group executive team, Schwabe said. Along with Olaf Schwabe, the team consists of **Anke Balzer** as chief commerical officer – responsible for marketing and sales – and **Rainer Oschmann** as chief operations officer, with responsibility for production, quality, supply chain and research and development.

*Manufacturers*

# Chopra leads oral-health marketing at GSK India

GSK Consumer Healthcare (GSK) India has named Anurita Chopra as area marketing lead for its Oral Health business. She takes over from Charubala Sheshadri, who has taken on the position of global marketing director for the company's respiratory health business, based in Nyon, Switzerland.

Chopra – who was previously business head for the personal-care category at Philips India – will report to Manoj Kumar, GSK's managing director for the Indian sub-continent.

Before joining Philips, Chopra had "spent substantial time" at Nokia in India, GSK pointed out. She had also held roles within PepsiCo and Hindustan Unilever.

Commenting on the appointment, Kumar said Chopra brought with her "over 16 years of rich consumer marketing and brand management experience" and that she had an "exceptional track record of business successes".

"I am confident that under her able leadership, our Oral Health category will deliver on our aggressive growth plans," he added.

Anurita Chopra

Chopra said she was "excited" to work with the marketing team to "augment the reach and reputation of power brands like Sensodyne".

GSK has recently outlined Sensodyne as one of the brands it plans to focus on in India, with Zubair Ahmed, head of the Consumer Healthcare unit in Asia-Pacific, Middle East and Africa, saying that the firm wanted to get more out of its Oral Health portfolio (**OTC *bulletin***, 22 April 2016, page 5).

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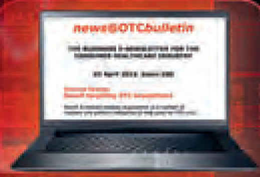

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