

German OTC Market Roundup 2018



The MedServa logo features the word 'Med' in black, a stylized 'S' in red and blue, and 'erva' in black. A small medical syringe icon is positioned above the 'S'.

MedServa



...Creating HEALTHY business

MedServa GmbH is a privately held networking company located in the center of Europe in Freiburg, South Germany, between Basle and Strasburg. The company was founded in 2001.

We support small and medium sized healthcare companies with innovative products in internationalising their business in Europe, from Lisbon to Moscow - mainly CE Medical Devices, Nutraceuticals, Dermocosmetics and OTC products.

Our aim is to reduce “go to market” time and costs for both partners in generating sales thus “Creating HEALTHY business” in true win, win mode. We are not a consulting company. Our focus is to produce sales opportunities.

Creating win, win collaborations

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- To open business opportunities by linking partners
- To offer attractive health problem solutions, e.g. for cough & cold, nail fungal, pain management, IBS, hairloss, skincare sanitizer, probiotics, home diagnostics and other innovative devices
- To offer portfolio optimization for partnering companies

About our business activities

We scout for product innovations for self-medication, which have already made some consumers and patients happy.

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Introduction

It's been another interesting year for the German OTC market. While the overall market for non-prescription drugs grew at a steady pace in 2017 – with sales increasing by roughly 3% – the difference in how this growth was distributed between bricks-and-mortar and online retail channels was once again marked, the latter growing almost ten times faster than the former in sales-value terms.

Within this channel, consolidation has accelerated in the last year. Zur Rose, now by far the largest 'pure play' online pharmacy operating in Germany, has swallowed up no less than four online competitors in the last 18 months. As well as frantically buying up the competition, Zur Rose has also acquired an online retail platform – Promofarma – which the firm hopes will potentially allow it to become the Amazon of European healthcare.

Elsewhere, after a decade that saw uneven success with prescription-to-OTC switches, Germany is finally catching up with more liberal markets like the UK. 2018 saw the release of two major switched products on the German market – GlaxoSmithKline's cold-sore treatment Zovirax Duo and Sanofi's Thomapyrin Tension Duo analgesic – with three more switches approved by the country's expert committee earlier this year.

However, the switch system in Germany could be better. The German industry association, the BAH, is calling for longer periods of data exclusivity in order to protect the significant investment made by pharmaceutical firms in the reclassification process. The BAH echoed calls from industry at the Association of the European Self-Medication Industry (AESGP) meeting earlier in the year urging for reforms to make switching more attractive for firms.

And finally, homoeopathy has recently come under fire in Germany, as it has in other European countries such as France. Joseph Hecken, a senior figure within Germany's state health insurance system, called into question the scientific basis of homoeopathy, suggesting that homoeopathic medicines were not suitable for reimbursement. Parliamentary representatives from the country's two leading political parties – the Christian Democratic Union/Christian Social Union (CDU/CSU) and the Social Democratic Party (SPD) – echoed this sentiment, despite the popularity of homoeopathy in the Germany.

Bayer's herbal gastrointestinal remedy Iberogast also came under attack during the year, after it had been reported – initially in neighbouring Switzerland – that use of the medicine had caused liver damage, and in some cases, liver failure resulting in death. Again, German politicians waded in to the debate, with Green Party *Bundestag* member Kordula Schulz-Asche calling out the German firm for not immediately responding to these reported concerns. Finally, after months of horse-trading, Bayer in September conceded to add warnings in future to the patient information leaflet of Iberogast in Germany.

The stories collected in this report represent only a fraction of the German coverage in *HBW Insight*, our new digital-first offering that brings together the legacy publication *OTC bulletin* and Informa Pharma Intelligence's *Pink Sheet* OTC drugs coverage and its food and supplements and cosmetics title *Rose Sheet*. For a full suite of health, beauty and wellness news and analysis, head over to: <https://hbw.pharmaintelligence.informa.com/>

David Ridley
Senior Editor, Europe
HBW Insight

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MARKET INTELLIGENCE ▶

Green scrips growing steadily

German doctors continued to recommend non-prescription medicines to patients using ‘green’ prescription pads in 2017, with the number of such prescriptions growing steadily according to IQVIA market data. Introduced in response to Germany’s delisting from reimbursement of most non-prescription medicines in 2004, the grüne rezept – or green prescription – scheme enabled doctors to write recommendations for non-reimbursable medicines on green notes designed to look like prescribing pads.

Green prescriptions were intended to boost consumer confidence in buying non-prescription medicines for themselves and reassure patients that the non-prescription medicines they were buying were approved and were needed.

This innovation acted to sustain the non-prescription market that had been devastated by de-reimbursement, contributing to the 38% growth recorded by the self-medication market in Germany between 2004 and 2016.

According to the latest IQVIA figures, green prescriptions as a proportion of all prescriptions issued by doctors in Germany increased from 1.2% to 6.3% during the same period.

Last year the number of green prescriptions issued in Germany continued to grow steadily, increasing by 7.7% to 47.3 million in the year ended 30 September 2017.

Just over a quarter of green prescriptions were for cough and cold medicines in the 12 months – growing by 13.5% to 12.6 million – almost five times the next category, pain-relief, which jumped by 9.8% to 2.8 million.

The strongest rise came from the throat-pain category, with doctors writing 2.2 million green prescriptions for such products, an increase of 19.6%. Vitamins and the anti-diarrhoea, oral electrolytes, digestive health categories were the next fastest growing, with both outpacing the total green prescription market rate with advances of 17.5% and 14.6% respectively.

However, not all categories improved, with the number

of green prescriptions for intimate health products dropping by 2.7% to 1 million in the 12 months, while green prescriptions for topical analgesics fell by 1.4% to 1.1 million.

Turning to the brands, IQVIA noted that the top-10 OTC brands prescribed by doctors accounted for around a fifth of all green prescriptions in the 12 months.

Bionorica’s Sinupret herbal cold remedy was the brand most prescribed using green prescription in 2017, IQVIA added, followed by Pohl-Boskamp’s GeloMyrtol sinusitis and cough product and Bayer’s Iberogast herbal gastrointestinal oral liquid.

Sinupret and Iberogast were also the second and third overall best-selling OTC medicines respectively through German pharmacy during the same period, according to Insight Health. Cough and cold remedies dominated the green prescription top 10, with six brands being either cold remedies or nasal sprays.

Commenting to HBW Insight on the “success story” of its green prescription initiative, the German manufacturers’ association, the BAH, said the move had allowed German doctors to continue to recommend OTC medicines, despite limitations imposed by de-reimbursement.

Information gathered via green prescriptions had also enabled physicians to “gain an overview” of what medicines patients were taking, the association added, preventing problems arising from “interactions with other medicines”.

Patients benefitted from the scheme, the BAH argued, as each green prescription was printed with the most important information about OTC medicines “at a glance”. Furthermore, many statutory health insurance companies were now willing to reimburse OTC medicines if prescribed via green prescriptions. “Green prescription is well established within the German health care system,” the BAH concluded. “It is accepted by patients and strengthens the role of pharmacists.”

Category	Number of green prescriptions (millions)	Change (%)
Cough and cold	12.6	+13.5
Pain-relief	2.8	+9.8
Anti-diarrhoea, oral electrolytes, digestive health	2.8	+14.6
Throat-pain remedies	2.2	+19.6
Blood-thinning agents	2.1	+2.3
Antacids, anti-flatulence and ulcer therapies	1.8	+9.3
Constipation and colonic irrigation aids	1.7	-1.3
Antifungals for dermatological use	1.6	±0.0
Vitamins	1.5	+17.5
Allergy remedies	1.2	+0.2
Topical analgesics	1.1	-1.4
Intimate health	1.0	-2.7
Total top-12	32.4	+8.8
Other	15.0	-
Total green prescriptions	47.3	+7.7

Figure 1: Number of green prescriptions issued in Germany in the year ended 30 September 2017 broken down by product category (Source – IQVIA)

German mail-order threat rises

Germany's mail-order pharmacy channel has grown significantly in recent years, and has played an important role in the recovery of the country's non-prescription market since de-reimbursement in 2004.

Online 'pure play' pharmacies selling into the country from Europe have driven this growth, with these receiving a boost in 2016 when the European Court of Justice (ECJ) ruled the discounts they offered on prescription medicines were legal.

Capitalising on this liberalisation, online pharmacies have invested heavily in marketing to attract consumers to the mail-order channel.

As a result, turnover at the German market's two leading mail-order pharmacies DocMorris – a subsidiary of Swiss supply chain disruptor Zur Rose – and Shop Apotheke increased at double-digit rates in 2017.

While the ECJ ruling has benefited these online players, German community pharmacists claim it will lead to "pharmacy death", especially in rural areas, and have turned to extreme measures to defend their interests.

Thanks to vigorous lobbying by the German pharmacists' association, ABDA, a ban on mail-order sales of prescription medicines in the country has made it onto the new coalition government's agenda for the upcoming legislative period.

While such a ban, if implemented, would not directly affect mail-order sales of OTC medicines, many people in the country stock up on these products while buying their discounted prescription drugs online. If mail-order sales of prescription medicines were lost due to a ban, it would inevitably have an effect on OTC sales.

ONLINE GROWING FAST

Following an impressive 12.9% growth in 2016, mail-order pharmacy sales of OTC medicines in Germany continued to advance quicker than the country's overall market for non-prescription drugs in 2017, according to data released this month from the German manufacturers association, the BAH.

Self-selected sales of OTC medicines through mail-order pharmacy increased by 8.9% to €904 million in the 12 months, significantly outpacing the overall market for non-prescription drugs through mail-order and community pharmacy, which moved forward by 2.4%.

Furthermore, mail-order pharmacy sales of prescribed non-prescription medicines also showed strong growth in 2017.

In Germany, OTC drugs may be prescribed to treat serious diseases where medicine is part of 'standard therapy', to treat adverse drug reactions during treatment with other medication or if their use is mandatory concomitantly with other medicines. Mail-order sales of these drugs rose by 10.8% to €12 million last year.

By contrast, self-medication sales of non-prescription medicines through community pharmacy grew by only 1.3% to €4.55 billion in 2017, while sales of prescribed non-prescription medicines through this channel edged up by just 0.8% to €1.26 billion.

In 2017, the total market for non-prescription pharmacy-only medicines – including community and mail-order pharmacy – reached €6.34 billion.

Commenting on the reasons behind the continued rapid expansion of the mail-order channel, the BAH's director general Martin Weiser told HBW Insight that "price" was the "key driving factor".

"Online pharmacies face lower costs when it comes to personnel and rent," he argued, "and this saving is usually passed on to consumers."

Furthermore, consumers could compare prices "quite easily," he insisted, meaning that competitive pressure within the online market forced individual 'pure play' pharmacies to keep their prices low.

"In the long run, lower prices are advantageous for patients, especially for patients with chronic illnesses who are in permanent need of certain medicines," Weiser added.

The price of medicines online became a contentious issue in 2016 after the ECJ ruled that Germany's price-control legislation for prescription medicines, the AMPreisV, could not be applied to Netherlands-based DocMorris, as this would constitute an unjustified restriction of the free movement of goods within the EU.

Spurred on by the ruling, DocMorris and Shop Apotheke have been actively seeking to consolidate their relative positions in Germany's booming online pharmaceuticals market.

In October last year, Shop Apotheke swallowed up smaller rival Europa Apotheek for €126 million in an all-share transaction, which the firm at the time claimed made it continental Europe's "largest and fastest growing online pharmacy".

However, in the closing months of 2017 DocMorris also snapped up – through its parent company Zur Rose – two other German online pharmacy rivals, Eurapon and Vitalsana.

This trend towards market consolidation seems set to continue, with Shop Apotheke announcing earlier this month that it had raised €75 million through a bond issue, which would be "primarily used to finance OTC acquisitions in Germany to further accelerate the company's growth in its most developed core market".

Announcing its financial results earlier this year, Zur Rose revealed that as a result of its successful initial public offering in 2017, the firm would be able to "respond quickly" and "exploit immediately" any opportunities for further acquisitions that might arise in the near future.

While the growth of mail order has ramped up the pressure on German bricks-and-mortar pharmacies, the BAH's Weiser suggested that rather than spend time focusing on their "disadvantages" – particularly on pricing – German community pharmacists should concentrate on "improving the quality of their advisory service", an area that has proven to be a point of weakness for their online competitors.

In November 2017, a "quality test" by German consumer watchdog Stiftung Warentest found that mail-order pharmacies operating in Germany were offering inadequate advice to customers.

Advice customers received regarding the side effects of OTC medicines and their contraindications with other medicines was particularly "disappointing", Stiftung concluded.

"Too many mail-order pharmacists recommended OTC products without any qualification on what the products

were for,” it added. “Ginkgo for increasing forgetfulness? Eye vitamins for loss of vision? Why not? That’s how many recommendations can be summarised.”

Responding to the test, Shop Apotheke celebrated its position as test winner, despite the bar set by mail-order customer service having been low overall. DocMorris – which came fifth overall in the test – said it would “look at the results in detail”.

The BAH’s call for community pharmacists to emphasise the value of face-to-face consultation follows the launch by ABDA last month of an image-based online and print media campaign to highlight how the country’s community pharmacies were “simply indispensable”.

“In addition to the delivery of medicines,” ABDA insisted as part of the campaign, “community pharmacies also provide many other services for patients: Individual prescriptions, personal advice, night and emergency services, monitoring and control of drug withdrawal and much more.”

Supporting the poster campaign, a series of videos on social media also showed patients “authentically telling their own personal health history and talking about the importance of their pharmacy for them”, ABDA explained. These video-based “emotional stories” had also been a “great success”, commented Reiner Kern, ABDA’s head of communications.

However, alongside this positive response to the threat of online pharmacy, German community pharmacists have since 2016 also been trying to take back control of the country’s price-controlled pharmaceuticals market by pushing for a ban on mail-order sales of prescription medicines in Germany.

Last year, as a result of extensive lobbying in the run-up to the German federal elections, ABDA managed to get the ban on the legislative agenda for the Christian Democratic Union’s (CDU’s) and Social Democratic Party’s (SDP’s) new ‘grand coalition’ German government.

Distribution channel	Annual sales (€ billions)	Change (%)
Self-medication medicines via community pharmacy	4.55	+1.3
Prescribed non-prescription medicines via community pharmacy	1.26	+0.8
Total community pharmacy	5.81	-
Self-medication medicines via mail order	0.90	+8.9
Prescribed non-prescription medicines via mail order	0.01	+10.8
Total mail-order pharmacy	0.92	-
Mass market	0.19	-5.0%
Total non-prescription medicines market	6.92	+2.0

Figure 1: Sales of self-medication and prescribed non-prescription medicines worth €6.92 billion in Germany’s total retail and mass markets in 2017 (Source – BAH)

“Alongside easily accessible doctors, local pharmacies are essential for a comprehensive healthcare service,” stated the coalition agreement, adding that in order to “strengthen local pharmacies, we are pushing forward with a ban on the mail-order sales of prescription medicines.”

Both Zur Rose and Shop Apotheke, backed by the German association of mail-order pharmacies, the BVDVA, promptly issued responses questioning the legality of the proposed ban, with Zur Rose claiming it would “in the interest of patients” take “all necessary legal and operative steps” to

“Too many mail-order pharmacists recommended OTC products without any qualification on what the products were for. Ginkgo for increasing forgetfulness? Eye vitamins for loss of vision? Why not? That’s how many recommendations can be summarised ”
–Stiftung Warentest

fight the ban both in Germany and at the European level.

By contrast, the BAH cautiously welcomed the ban, saying it was a “sensible measure” to “counteract the competitive advantage” that foreign ‘pure play’ pharmacies had over German community and mail-order pharmacies.

However, while the BAH approved of the ban, it also warned that policy decisions should not stifle innovation, and advocated “dialogue” between the various players in the country’s healthcare system going forward.

“Only in cross-party discussions can a common understanding be created as to the future of drug supply,” argued Hermann Kortland, deputy chief executive of the BAH. “This dialogue must also involve a willingness on the part of politicians to secure medicines provision on a lasting basis.”

While the development of the mail-order channel made an important contribution to the 2.4% rise in the overall non-prescription market through pharmacy in 2017, a strong cough and cold season also helped to drive up sales of OTC medicines during the year, according to the BAH.

A “huge outbreak of the common cold” and a “strong flu epidemic” had resulted in a 2.6% rise in the sale of cold remedies in 2017, the BAH noted, reaching a total of €746 million.

While cold remedies represented the largest product category by over €200 million during the period, the fastest growing category, the BAH pointed out, was respiratory medicines, sales of which increased by 7.4% to €301 million.

Gastrointestinal products was the second-fastest growing category in the twelve months at 5.9%, according to the BAH, producing total sales of €359 million. Other categories that showed strong increases were anti-fungal

medicines with 4.7% and cough medicines with 4.1%.

On a negative note, sales of minerals and analgesics fell back by 1.2% and 0.7% respectively.

Herbal medicines remained an important component of the German OTC medicines market in 2017. Self-medication sales of herbal medicines through community pharmacy came to €1.24 billion in the year, a turnover just over twice the size of that of homoeopathic medicines at €516 million. Self-medication pharmacy sales of synthetic drugs reached €3.67 billion, nearly 10-times that of self-selected free-sale medicines through pharmacy, which ended the year at €353 million.

Mass-market sales of free-sale medicines fell back by 5% to €192 million, slowing down growth to 2% in Germany's total non-prescription medicines market – both inside and outside pharmacy – valued at €6.92 billion.

The market in 2017 for unlicensed healthcare products other than medicines was worth €2.94 billion, noted the BAH. Of this total, sales of €1.98 billion were recorded by pharmacies and €967 million by other retail channels. BAH

figures, therefore, show that two-thirds of Germany's unlicensed healthcare market continued to be controlled by pharmacies last year.

By adding all of the various components of Germany's OTC market together – total sales of non-prescription medicines of €6.92 billion and total sales of unlicensed healthcare products of €2.94 billion – the grand total came to just under €10 billion, at €9.86 billion during the 12 months.

Asked by HBW Insight about what he thought the future held for the German OTC market, Weiser said he believed that self-medication would become “even more important in the future”.

“Self-medication with OTC medicines, especially in combination with professional advice from pharmacists, is very important for healthcare,” he commented.

“Taking into consideration the challenging developments of society and ageing populations, the viability of healthcare systems can only be ensured by promoting self-medication with OTC medicines,” he concluded.

Coughs and sore throats lift German cold season

Strong sales of cough and sore-throat remedies in Germany during last year's cold and flu season helped the overall category in the country grow by 5% to €1.4 billion in the six months ended March 2018, according to market researcher IQVIA.

Between October 2017 and March 2018, cough remedies grew well ahead of the country's cough and cold market as whole, with sales of these products rising by 10.4% to €332 million (see Figure 1).

Sore-throat remedies were the second-fastest growing product group within the category, also outpacing the market, posting a 6.1% increase in sales to €180 million during the period.

Representing the largest product group in the category, cold and flu products commanded about a third of the market in terms of sales value, growing by 2.4% to €523 million.

Looking at the category by retail channel, IQVIA pointed out that volume sales of cough and cold products through

mail-order pharmacy had climbed by 8.4% during the season, compared to just a 1% rise through community pharmacy. However, while mail-order sales accelerated, the channel only made up 12% of the total pharmacy market by volume during the period.

The most popular products during the season, IQVIA noted, were (in no particular order): Ratiopharm's Nasal Spray; Bionorica's Sinupret herbal cold remedy; and Aliud Pharma's xylometazoline-based Nasal Spray AL; as well as Hexal's ACC cough syrup and GlaxoSmithKline's Otriven nasal spray.

IQVIA pointed out that colds were “no joke” for people suffering from asthma, chronic obstructive pulmonary disease patients, or people whose immune systems had been compromised.

Even the healthy were affected by cold viruses “on average twice a year”, it continued, adding that children were affected “even more frequently”, suffering from up to 10 colds per year.

Product group	Sales (€ millions)	Change (%)	Proportion of total (%)
Cold and flu remedies	524	+2.4	37
Cough remedies	332	+10.4	23
Respiratory	222	+2.4	16
Sore throat remedies	180	+6.1	13
Immunostimulants	59	+5.5	4
Saltwater sprays	39	+2.9	3
Others	44	-	3
Cough and cold total	1,400	+5	100

Figure 1: Value sales for Germany's cough and cold category in the six months ended March 2018 (Source – IQVIA)

Discounts drive German online

Discounts on expensive alternative medicines such as ginkgo and probiotic supplements are driving German consumers to the country's online pharmacy channel, according to the latest research from Sempora Consulting.

Drilling down into the "average shopping basket" of German online pharmacy users in the six months ended July 2018, Sempora discovered that discounted purchases of probiotics and ginkgo brands were the "typical driving forces" for the mail-order channel in Germany, which had shown "dramatically higher" growth than that of community pharmacy during the period.

In more than 50% of visits to online pharmacies, Sempora found that discounted purchases of probiotics and ginkgo brands were the reason that consumers went online. Furthermore, while consumers spent an average €44 online per visit, when probiotics or ginkgo products were included, this average rose to €78 and over €100 respectively.

However, a "detailed analysis" of the order in which products were purchased had shown that, although consumers were driven online for the percentage discounts offered on these expensive alternative medicines, it was the "absolute savings" achieved through purchasing a variety of OTC products online at the same time that kept consumers coming back to the channel, Sempora explained.

While the first product placed in shopping baskets offered an average saving 60% higher than that of the second item in the basket, Sempora noted, online consumers came

"A shopper insights perspective offers OTC firms a way to identify the growth potential of specific brands" - Thomas Golly "

away with an absolute saving across the whole basket of between 27% and 29%.

Sempora's founder and managing partner Thomas Golly told HBW Insight that analysing online consumer habits from a "shopper insights perspective" offered OTC firms a way to "really identify the growth potential of specific brands".

While it was "obvious" that consumers were increasingly willing to buy their OTC products on the internet, Golly argued that industry needed to understand how the growth rate of online sales differed between specific categories and even from brand to brand.

Furthermore, the data generated by consumers online, could help firms to "identify and exploit the up-sell potential" of their brands, he insisted.



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ONLINE CONSOLIDATION ►

Shop Apotheke seeks further buys

German ‘pure-play’ pharmacy Shop Apotheke has raised €75 million to finance further acquisitions as it looks to stay ahead of the competition in the fast-consolidating German online pharmacy market.

Announcing its first-quarter results, Shop Apotheke revealed that proceeds from a recent €75 million bond issue – which had been “placed successfully” with institutional investors last month – would be “primarily used to finance OTC acquisitions in Germany to further accelerate the company’s growth in its most developed core market”.

The additional finance was needed, commented chief financial officer Ulrich Wandel, to enable Shop Apotheke to “play an active role” in the “ongoing consolidation” seen in the German mail-order market during the last few months.

During this period, Shop Apotheke in October swallowed up smaller rival Europa Apotheek for €126 million in an all-share transaction, which the firm at the time claimed made it continental Europe’s “largest and fastest growing online pharmacy”.

However, in the closing months of 2017, Shop Apotheke’s closest German competitor, DocMorris, also snapped up – through its parent company Zur Rose – two other German online pharmacy rivals, Eurapon and Vitalsana.

Turning to its first-quarter results, Shop Apotheke said the successful integration of Europa Apotheek had led to a “significant acceleration” in sales at its Germany segment, which reached €104 million, up from €47.5 million in the prior year.

Turnover at its International segment – which includes Austria, France, Belgium, the Netherlands, Spain and Italy – grew by 69% to €27.1 million in the three months.

The group’s first-quarter sales more than doubled to €131 million.

Separately, Zur Rose reported first-quarter sales in Germany – where it operates mainly through online pharmacy subsidiary DocMorris – up by 51% to CHF170 million (€142 million), thanks to a “surge” in the demand for OTC products.

The firm’s Germany segment contributed 57% to the firm’s total turnover, which grew by 30% to CHF298 million.

Zur Rose adds Promofarma

Pharmaceutical supply chain disruptor Zur Rose has acquired for an undisclosed sum Spanish e-commerce platform Promofarma, signalling a step change in its international expansion strategy.

Zur Rose described the purchase of Promofarma – which it expected to complete by mid-September – as a “significant move”.

“Zur Rose is not just acquiring the Spanish online leader in the consumer health category,” commented chief executive officer Walter Oberhänsli, “but also a platform technology that will enable us to pursue our international expansion and to roll out a new business model by partnering with pharmacies and health stores across Europe.”

Currently, Zur Rose sells OTC and prescription medicines in Switzerland through its own-brand online and bricks-and-mortar pharmacies, and in Germany and other German-speaking countries through its DocMorris ‘pure play’ online pharmacy.

By adding Promofarma’s “capital-efficient model” to its existing business, Zur Rose said it now had a “springboard” for international expansion “both cross-border and country-by-country”.

The firm told HBW Insight that it intended to “rapidly expand” the platform – which operates in 20 European countries and lists “50,000 consumer health products” from “more than 3,500 brands” – with Southern European countries, such as France and Italy, a “particular focus”.

Zur Rose said that no decision had yet been made whether the platform would be offered in the company’s home markets of Switzerland and Germany.

Asked whether the move would mean competing with global retail giant Amazon – which, like Promofarma, offers European manufacturers, wholesalers and pharmacies an online space for their e-commerce operations – Zur Rose insisted that it was “well-positioned” to face such competition, having already established itself as “Europe’s largest e-commerce pharmacy”.

Zur Rose’s “strong growth strategy” has seen the firm swallow up three Germany-focused online competitors in the last year: Apo-Rot, Vitalsana and Eurapon.



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Zur Rose consolidates its position in Germany

Zur Rose through its DocMorris subsidiary has acquired German rival Apo-rot, in a move that will further bolster its position in the country's online pharmacy market.

Subject to approval “by the relevant competition authorities”, the deal, Zur Rose revealed, would see it takeover Apo-rot's mail-order operations and from January 2019 distribution to Apo-rot's four wholly-owned pharmacies in Hamburg, Germany.

Both firms have agreed to maintain confidentiality about the financial aspects of the transaction.

With the acquisition of Apo-rot, Zur Rose had added “another strong brand” to its existing portfolio, the firm claimed. The deal had “consolidated” Zur Rose's position in Germany – the “largest European mail-order market” – and systematically expanded its “leading market position in Europe”, the company added.

Adding Apo-rot's turnover of about €100 million to DocMorris' sales of €370 million in 2017 would put the pro-forma sales of the two companies in the year to just under €0.5 billion, Zur Rose pointed out.

Under the terms of the deal, Apo-rot's ‘click-and-collect’ service – which extends to the 18 independent pharmacies in the Hamburg area that have co-operation agreement with the company – will be offered to DocMorris customers, enabling them to pick up online orders in the participating bricks-and-mortar pharmacies.

COMBINED STRENGTH

To get around Germany's rules against the foreign ownership of German bricks-and-mortar pharmacies, Apo-rot's founder and current owner will continue to run for the foreseeable future the firm's four bricks-and-mortar pharmacies.

“By combining the strengths of both partners,” a spokesperson for DocMorris told HBW Insight, “Apo-rot's omnichannel pharmacy model will be put on a broader footing in the future.”

DocMorris' parent company Zur Rose is no stranger to omnichannel retailing, having moved into the bricks-and-mortar pharmacy space in its home market of Switzerland.

Zur Rose opened its first ‘shop-in-shop’ pharmacy in a Migros supermarket in the Swiss capital, Bern, in August last year.

Following a “very positive reaction” from customers, Zur Rose announced it had agreed with Migros to open further outlets, beginning with Basel in mid-2018.

OMNICHANNEL STRATEGY

Speaking to **HBW Insight** last year, Zur Rose's chief executive officer Walter Oberhänsli said the shop-in-shop outlets – along with Zur Rose's ‘flagship’ bricks-and-mortar stores – were manifestations of the company's “omnichannel strategy” of combining online with bricks-and-mortar operations.

While Zur Rose had made great strides towards the “digital disruption” of Europe's pharmacy channel – par-

“The Apo-rot acquisition is part of a wider trend which has seen various players working to consolidate their market positions within the German mail-order pharmacy channel ”

ticularly since acquiring DocMorris from Celesio in 2012 – Oberhänsli explained it had been forced to employ a different strategy in Switzerland, where OTC mail-order trade is banned.

The Apo-rot deal follows the acquisition by DocMorris last year of two other German online pharmacy rivals, Eurapon and Vitalsana.

These deals are part of a wider trend which has seen various players working to consolidate their market positions within the German mail-order pharmacy channel. Doc Morris' closest competitor, Shop Apotheke, has been trying to best to keep up with its rivals' recent spending spree.

In October last year, Shop Apotheke swallowed up smaller rival Europa Apotheek for €126 million in an all-share transaction, which the firm at the time claimed made it continental Europe's “largest and fastest growing online pharmacy”.

By acquiring Europa Apotheek, Shop Apotheke said it would be able to offer its customers a “comprehensive product portfolio including OTC, prescription medicines, and pharmacy-related beauty and personal-care products”, the firm said.

“The respective business models of both companies are highly complementary,” Shop Apotheke insisted.

“While Europa Apotheek generates the lion's share of its revenues from the sale of prescription medicines,” the company pointed out.

Zur Rose swallows up another German rival

Swiss supply chain disruptor Zur Rose has swallowed up yet another competitor in its bid for German mail-order pharmacy channel domination.

Subject to approval by the relevant competition authorities, Zur Rose will acquire for approximately €170 million the e-commerce operations of German online pharmacy Medpex.

With its focus on OTC medicines and pharmacy exclusive cosmetic products, the firm said that the acquisition of Medpex – the “third-largest online pharmacy in Germany” – would “enhance” the market position of its Germany-focused DocMorris subsidiary and have a “positive impact” on Zur Rose’s growth and profitability in the country.

Financed through a capital increase, the deal was “split into three components”, Zur Rose explained: an initial cash consideration; a smaller part payable in newly-issued Zur Rose Group shares; and two subsequent earn-out components in 2019 and 2020 respectively.

Zur Rose said it would pay an initial purchase price in cash and shares equivalent to a multiple of around 0.7-times Medpex’ expected 2018 sales of €170 million.

The deal would be financed by a capital increase of approximately CHF200 million (€176 million), which Zur Rose said it would raise by issuing new shares, with subscription rights guaranteed to existing shareholders.

The share portion and of the deal – which was expected to close in the first quarter of 2019 – would be settled with existing authorised shares, the firm noted.

Initially, Medpex’s mail-order operations would remain at its headquarters in Ludwigshafen, Germany, Zur Rose told HBW Insight, and its www.medpex.de website would remain independent of the DocMorris brand.

However, in the medium- to long-term, the firm revealed that it planned to “bundle” Medpex’s logistics with that of DocMorris, which operated from the Netherlands.

Zur Rose’s chief executive officer, Walter Oberhänsli, said he was “delighted” with the acquisition. “Within a single year we will have increased our e-commerce pharmacy market share in Germany from 18% to 31%,” he added.

By acquiring Medpex – which was “oriented towards a young customer group with high purchasing power” and had a “high level of competence in digital marketing and the development of agile platforms” – Zur Rose said it would be “well positioned to capitalise on the opportunities offered by increasing digitalisation”.

“The acquisition will further strengthen the firm’s leading position in e-commerce pharmacy and increase its active customer base in Germany to over 5 million,” Zur Rose concluded.

Ulrich Spinder, representative for Medpex’s shareholders, said that with the deal, Medpex now had a “new, strong partner at our side with whom we want to continue our successful journey”.

“We will also benefit from additional economies of



Medpex' online store

***“The acquisition will further strengthen the firm’s leading position in e-commerce pharmacy and increase its active customer base in Germany to over 5 million”
– Zur Rose***

scale, for example in purchasing, and broader expertise in European regulatory affairs,” he continued. “By joining forces, we are actively contributing to the consolidation of the European e-pharmacy market.”

Turning to Zur Rose Group’s third-quarter results, German OTC sales jumped up by 63% to €74 million in the three months. OTC sales now account for the majority of group’s Germany turnover, which rose by 27.5% to €138 million. The remainder came from sales of prescription medicines.

Retail sales in Zur Rose’s home market, Switzerland, grew by 2.4% to CHF32.1 million in the period. The majority of Zur Rose’s Swiss turnover came from its wholesale operations, which posted sales up by 4.1% to CHF94.2 million.

Zur Rose’s total group sales were up by 16.6% to €287 million.

Zur Rose's European playpen



As Switzerland-based e-commerce pharmacy Zur Rose goes from strength to strength, David Ridley talks to the company's chief executive officer, Walter Oberhänsli, about his firm's latest experiments in European OTC market disruption.

Zur Rose has in the last 12 months been “investing heavily”, the firm’s chief executive officer, Walter Oberhänsli, told HBW Insight, to develop its online retail business in Germany and Switzerland, with the long-term aim of becoming the largest e-commerce pharmacy in Europe.

In Germany, Zur Rose through its DocMorris subsidiary now dominates the ‘pure play’ pharmacy market after swallowing up three major competitors: Apo-Rot, Vitalsana and Eurapon.

Zur Rose has also made investments to address the country’s rural drugs supply problem through its experimental automated pharmacy in the small town of Hüffenhardt, an initiative that was shut down by the pharmacy lobby after only a few weeks. Its fate is now the subject of several lawsuits, with decisions pending in 2019.

Meanwhile, in its home market of Switzerland, Zur Rose is pushing forward with its ‘omnichannel’ strategy, committing to opening another ‘shop-in-shop’ own-brand pharmacy in a Migros supermarket by the end of this year.

All these initiatives were united by a “common aim”, Oberhänsli noted, namely to “provide a better service for our customers and to be at the forefront of digitalisation”.

Zur Rose’s latest acquisition – Spanish e-commerce platform Promofarma – presented the firm with an opportunity to use digitalisation to realise its goal of becoming the biggest pan-European e-commerce pharmacy in a “much faster, much easier” way, he suggested.

Rather than having to establish a physical presence in a new country and deal with the complexities of national pharmacy regulations, Promofarma’s platform technology allowed Zur Rose to work with existing pharmacies in target markets, he explained, connecting them with consumers via the platform.

France and Italy were the first markets that would see the firm’s platform-led “internationalisation” strategy, he revealed, with the long-term plan to use the platform as a “complementary channel” in Germany and Switzerland.

As for the competition Zur Rose might face in France and Italy, Oberhänsli said that there were “two or three” other e-commerce operators selling from Belgium into France, but he was not aware of any significant players in Italy.

Overall, the platform model was “just starting in all these markets”, he insisted, noting that e-commerce penetration in the European pharmacy market was “generally still very low”, compared to fashion or media, for example.

“We are coming in at an early stage in these markets compared to Germany, for example, where the online market in general is already quite established,” he explained. “In France, the proportion of online pharmacy compared to bricks-and-mortar pharmacy is probably about 1% or 2% in terms of market volume.”

Zur Rose had, however, “only just acquired” Promofarma, he warned. “There are no firm plans yet,” he added, “at least not any that we are ready to announce.”

HEAD-TO-HEAD WITH AMAZON

Asked whether its bid for European e-commerce hegemony would put Zur Rose in head-to-head competition with global retail giant Amazon, Oberhänsli admitted that no one knew what Amazon intended to do in Europe.

With the threat of Amazon looming in the background, Zur Rose had to “accelerate” its strategy and “take selective opportunities” that presented themselves, he insisted.

One advantage Zur Rose had over Amazon was that it understood the complexity of the European market, particularly from a regulatory point of view, he explained, and was on the way to establishing a successful pan-European business model.

“The market in Europe is very interesting,” he commented. “The online penetration is still low because of how fragmented the regulatory landscape is.”

While this fragmentation was what “makes the European market interesting”, he insisted, it was also something that firms such as Amazon had to “deal with” if they were to take advantage of this untapped online potential.

Given Amazon’s current online pharmacy activities in the US – where it has rolled out its Perrigo-manufactured Basic Care OTC line and acquired prescription-focused online pharmacy PillPack – Oberhänsli said he did not expect the retailer to pursue a ‘greenfield’ approach of building a business from the ground up, “if and when they enter the European market”.

Zur Rose in its core markets of Switzerland and Germany

had also been exploring ways to leverage digitalisation to offer consumers the cost and convenience of an online platform while “providing at least the level of service of a brick-and-mortar pharmacy”, he explained.

In Germany, Zur Rose last year opened a DocMorris-branded ‘automated pharmacy’ in the small, rural village of Hüffenhardt, in which residents could receive consultations from qualified pharmacists in the Netherlands via a video link, and collect their recommended medications in-store, dispensed by a remotely controlled machine.

Speaking to HBW Insight last year, Oberhänsli explained that the Hüffenhardt automated pharmacy had been an “e-health solution” to address the issue of pharmacies shutting down in rural areas, and was therefore a “contribution to the political discussion” about the future of community pharmacy in Germany.

After a series of interventions by the Baden-Württemberg pharmacy association, however, the automated pharmacy was shut down by the Mosbach district court after only being open a few weeks.

“Instead of investing time and money in developing new ideas,” Oberhänsli asserted, “community pharmacists continue to defend their traditional business model.”

Oberhänsli said he couldn’t understand why the country’s pharmacy lobby maintained a defensive position towards digitalisation, pointing to the issues faced by community pharmacies in rural areas while at the same time eliminating any attempts to use technology to offer an alternative way forward.

It was “logical” for the people in Hüffenhardt to respond positively to the automated pharmacy, he said, because it was an “appropriate answer” to the problem of community pharmacies disappearing from rural areas.

EXPERIMENT NOT FINISHED

There were currently “no plans” for another automated pharmacy in Germany, Oberhänsli conceded, but he insisted that Zur Rose would keep experimenting with the Hüffenhardt model.

“At the moment work on the model has been halted, but it isn’t the end,” he insisted. “If it doesn’t work in Germany then we may try it in Switzerland.”

While Zur Rose had been thwarted for now in Hüffenhardt, Oberhänsli believed that the German pharmacy lobby’s latest attempt to shut down e-commerce pharmacy for prescription drugs in the country would not prove so successful.

Ever since the European Court of Justice (ECJ) ruled in favour of discounts offered by foreign mail-order pharmacies such as DocMorris – which it decided were not bound by the country’s AMPreisV price regulation system – the German pharmacists’ association, ABDA, has been pushing for a ban on mail-order sales of prescription medicines.

Thanks to lobbying by ABDA, the ban made it onto the legislative agenda for the Christian Democratic Union’s (CDU’s) and Social Democratic Party’s (SDP’s) new ‘grand coalition’ German government.

New German Minister for Health Jens Spahn is currently working on the issue as part of a “complete package” of healthcare reform, which will be presented to the Bundestag at some point during this Autumn’s session.

Oberhänsli reiterated his earlier position that he thought a ban would be “unconstitutional and contrary to European law”.

Meanwhile, Oberhänsli said he looked forward to the introduction in Germany of e-prescriptions, which he argued would lead to a “disruptive change” in the country’s “entire pharmaceuticals market”.

“We have been talking for years about e-prescription in Germany,” Oberhänsli explained, “making speeches everywhere to raise awareness that the inconvenience and inherent risks of paper prescription are no longer necessary.”

At the beginning of this year, the German federal parliament, the *Bundestag*, finally decided to implement its “e-health card” system after years of stalling, which will provide the necessary infrastructure for the introduction of e-prescriptions.

Spahn has now said that he wants to introduce e-prescriptions in the country, suggesting that this could be part of the comprehensive reform package to be introduced later this year.

Removing this restriction, Oberhänsli explained, would make it easier for patients to buy their OTC and prescription drugs online at the same time, making the mail-order channel more attractive. The introduction of e-prescriptions, therefore, he said would “significantly push e-commerce penetration for both OTC and prescription medications”.

Based on his experience in the Swiss market, Oberhänsli said he “strongly believed” in the convenience – and therefore the disruptive potential – of e-prescriptions.

In Switzerland, he pointed out, doctors in some cantons were sending e-prescriptions on behalf of their patients to e-pharmacies such as www.zurrose.ch, where the orders were then delivered directly to the patients through the post.

“This is really convenient, especially for chronic patients with a recurring prescription,” Oberhänsli said. “And you can get your medicines the next day or, in the future, even the same day.”

However, in Switzerland, for regulatory reasons consumers were not able to buy OTC drugs directly from e-pharmacy, in contrast to Germany, he noted. This meant that Zur Rose had had to adopt a different approach to digital supply-chain disruption in the country, he explained.

In cantons where doctors weren’t allowed to supply drugs to their patients directly, Zur Rose had been pushing forward with its ‘omnichannel’ approach, Oberhänsli continued, which involved opening bricks-and-mortar stores and offering consumers lower prices on OTC and prescription drugs.

“In Switzerland there is almost no price competition in the bricks-and-mortar field,” he continued. “Huge pharmacy chain operators like Galenica and McKesson Europe cannot compete on prices without cannibalising their wholesale businesses.”

“What we do with our Migros shop-in-shop and flagship pharmacies,” he noted, “is apply the same pricing that we offer on our website.”

“For the moment, I think the price is the most powerful differentiation tool in the Swiss pharma market,” he argued.

Furthermore, as cheaper prices attracted consumers to Zur Rose’s shop-in-shop and ‘flagship’ bricks-and-mortar pharmacies, Oberhänsli insisted that at the same time, word of the Zur Rose e-pharmacy would also spread.

“It will take some time,” he admitted, “nevertheless, I think we will see a gradual rise in the awareness of the Zur Rose brand among consumers in Switzerland.”

SWITCHING ►

German switch success rare

High hopes for prescription-to-OTC switches in Germany have not always been met, despite significant investments by manufacturers to support subsequent product launches, according to a report by IQVIA.

Over the past few years, there have been a number of high profile switches in Germany, driven to a large extent by the European Union's (EU's) centralised procedure for prescription-to-OTC switches, introduced in 2009.

GlaxoSmithKline's (GSK's) orlistat-based weight-loss medicine Alli was the first pan-EU OTC brand switched under the procedure, acquiring a non-prescription license on 21 January 2009. An OTC version of Alli was then launched in April that year in Germany.

However, despite the "enormous sums" GSK invested to launch the brand across Europe – including a media budget of more than €30 million – Alli proved to be a frustrating proposition in the German OTC market, IQVIA commented.

In the first nine months after its launch, sales of Alli fell consistently, IQVIA noted, with sales in December 2009 reaching just a third of those in May when the product was released in the German market.

GSK finally decided to withdraw Alli from Germany in 2015, although it continued to be available in other countries.

One reason that orlistat-based weight-loss products failed to gain market share, IQVIA claimed, was the unpleasant side effects associated with the drug – including greasy bowel movements and diarrhoea – which were "communicated quickly via the internet as well as in women's magazines".

While Alli was unsuccessful, German manufacturers had better luck with a series of switches in the proton-pump inhibitor (PPI) category.

Heartburn treatment pantoprazole was the second drug to be switched via the EU centralised procedure on 19 February 2009.

Nycomed – acquired by Takeda in 2011 – launched an OTC version of its pantoprazole-based Pantozol Control in Germany that year, backed by extensive pharmacy-press and television marketing campaigns.

During its first three weeks on the German OTC medicines market, Pantozol Control generated sales of 11,400 packs, realising an ex-factory value of €53,800.

But Pantozol Control met competition sooner rather than later with the introduction of another PPI heartburn treatment.

OMEPRAZOLE SWITCH

In August 2009, the German upper house of parliament, the *Bundesrat*, decided to also switch omeprazole from prescription-to-OTC status in Germany.

Companies were quick to capitalise on the switch, with Bayer's Antral, Boeringer Ingelheim's Buscogast and Hexal's Omeprazol all released within a month, supported by heavy-weight consumer advertising campaigns.

AstraZeneca's esomeprazole-based Nexium Control heartburn medicine then became the third drug to be switched across Europe by the EU-wide centralised procedure.

Already successful as a prescription-only heartburn relief brand in the US, in 2012 Pfizer acquired the global rights for OTC versions of Nexium from AstraZeneca for €250 million.

Nexium Control was subsequently launched in Germany in 2014 accompanied by a "large-scale attention-grabbing television campaign" and by print and online advertising.

Despite the initial success of Pantozol Control and the enthusiasm from manufacturers for other PPI switches, IQVIA argued that overall the switches in this category had produced mixed results.

Manufacturers of PPI drugs had hoped, IQVIA said, that a "significant percentage" of prescriptions for pantoprazole, omeprazole and esomeprazole would be replaced by self-medication purchases.

Looking at the market data, however, IQVIA argued that this hope was "only partially fulfilled".

While volume sales of these OTC heartburn products since 2007 reached 4.7 million in 2016, volume sales of prescription-only PPI medicines also rose from 23.8 million to 36.4 million packs during the same period (see Figure 1).

Despite huge marketing investments by manufacturers, people tended to "favour" the cheaper, prescription-only generic products over OTC alternatives, IQVIA noted.

Furthermore, generics manufacturers benefited from the significant investments in publicity and advertising of brand-oriented counterparts, which were at pains to point out the medicinal benefits of such products to consumers.

"With price differences of approximately €5.00 between a branded and a generic product, the decision was clearly in favour of the cheaper," IQVIA concluded.

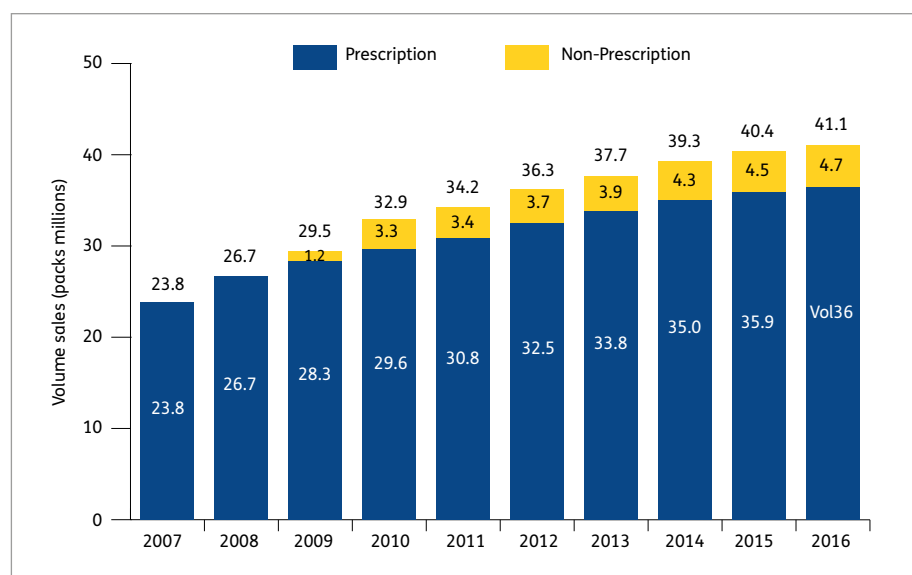


Figure 1: Volume sales of prescription and non-prescription proton pump inhibitors through community and mail-order pharmacies in Germany (Source – IQVIA)

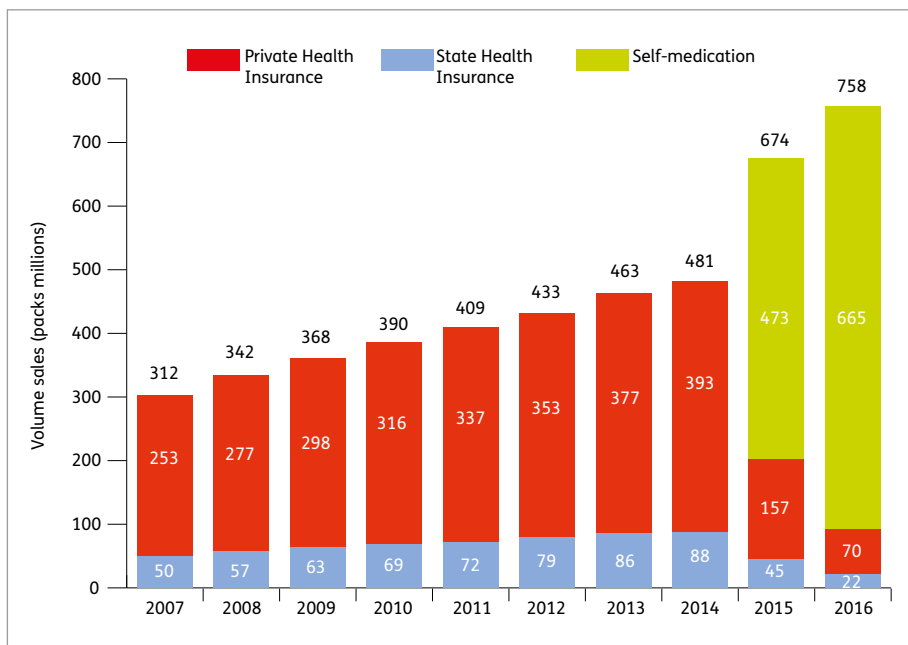


Figure 2: Volume sales of emergency contraceptives through community pharmacies in Germany by reimbursement (Source – IQVIA)

Meanwhile, perhaps the most controversial – and arguably the most successful – prescription-to-OTC switch in Germany since 2009 has been HRA Pharma’s ulipristal acetate emergency contraceptive EllaOne, which was granted non-prescription status through the EU centralised procedure in January 2015.

Until the EU-wide switch of EllaOne, attempts to make levonorgestrel-based emergency contraceptives available non-prescription had met political resistance in Germany.

Proposals to grant levonorgestrel OTC status in Germany had been languishing in the country’s national switching procedure for almost 15 years before, despite the country’s expert committee for prescription twice making recommendations to this effect.

Political controversy prevented action from being taken on these recommendations, and attempts to push a statutory order to switch levonorgestrel through the Bundesrat had proved similarly fruitless.

Having been forced into action, after years of intransigence, by the EU centralised switch of ulipristal acetate, the German government finally also extended the emergency contraceptive switch to levonorgestrel in 2015.

However, the switch of these emergency contraceptive drugs in Germany came with a series of caveats.

Firstly, German legislators prohibited mail-order purchases of both ulipristal acetate and levonorgestrel on the grounds that this would ensure the pills were “taken as quickly as possible” and would promote “face-to-face advice in a community pharmacy”.

Secondly, German legislators banned advertising of these OTC emergency contraceptive drugs in Germany.

The ruling coalition of Christian Democratic and Social Democratic parties at the time believed that advertising would “risk promoting repeated use” of the drugs, replacing other forms of contraceptives such as condoms.

SWITCH JUDGED A SUCCESS

Nevertheless, ulipristal acetate and levonorgestrel emergency contraceptives had established themselves in the

OTC market, IQVIA argued, adding that their switch from prescription to OTC status should be regarded as a “success”.

Volume sales of these drugs rose by just over 40% to 674 million packs in 2015 (see Figure 2), according to IQVIA data. As a proportion of these sales, almost three quarters were purchased as self-medication.

Despite the switch to OTC status, women aged under 21 could still claim back purchases of ulipristal acetate or levonorgestrel emergency contraceptives through the state health insurance system, the GKV, and reimbursement was also provided by some private insurance schemes.

After these drugs were switched in 2015, the number of emergency contraceptives reimbursed by private or state health insurers dropped by about half from the previous year.

Total volume sales grew again by 12% to 758 million packs in 2016, with almost 90% of these purchased as self-medication. The number reimbursed by private or state health insurance fell again by half during the period.

EllaOne is the most recent drug to be switched through the EU’s centralised procedure. However, there were two other significant switches in Germany in 2016: the corticosteroids fluticasone and mometasone.

Germany’s expert committee for prescription had advised that both fluticasone and mometasone could be sold safely without a prescription at the beginning of 2016.

In October that year the Bundesrat then passed an order allowing fluticasone and mometasone to be sold without a prescription for the treatment of allergic rhinitis in adults, provided a doctor had diagnosed the condition first.

GSK was the first company to offer a fluticasone-based OTC product in Germany with its Otri-Allergie Nasenspray in early 2017.

Extensive consumer marketing supported the launch, including a digital and internet search-engine campaign, as well as print advertising and public-relations support.

In addition, an Otri-Allergie ‘pollen radar’ app was made available for customers to download, and GSK’s brand website was updated to include information about hayfever symptoms and their causes.

Hexal’s mometasone-based MometaHexal followed swiftly on Otri-Allergie’s heels, promoted via a television advertisement showing hayfever sufferers who had used the product hugging trees and leaping through fields.

Hexal also released an app for its nasal spray, available through brand website mometahexal.de, which shows visitors a full list of different pollen types, as well as what types are present in a particular area at the time.

These prescription-to-OTC switches of nasal sprays could also be counted as successful, IQVIA argued, as they had produced a “clear shift to self-medication” in consumer behaviour.

Volume sales of beclomethasone-based OTC nasal sprays in Germany – which have been available non-prescription through pharmacies since 1997 – totaled 0.4 million packs from January to October 2016.

With the switch of fluticasone and mometasone total volume sales of OTC nasal sprays tripled to 1.2 million packs during the same period in 2017, with mometasone-based products cornering three quarters of this market at 0.9 million packs and volume sales of beclomethasone-based products halving to 0.1 million packs.

Looking at the year ahead, the market is gearing up for the launch of new and innovative products thanks to two major German prescription-to-OTC switches, which were approved in 2017.

Aciclovir and hydrocortisone combinations for the treatment of herpes labialis and ibuprofen for external use were authorised as non-prescription medicines by Germany's Bundesrat in November 2017.

GSK had received a positive recommendation for the switch of its Zovirax Duo cold-sore treatment – which combines 5% acyclovir and 1% hydrocortisone – from Germany's expert committee for prescription in early 2017.

The Bundesrat made the changes to the German prescription order, the AMVV, recommending that the combination should not contain more than 100mg aciclovir and 1% hydrocortisone.

An amendment was also made for the use of ibuprofen for external use “including patch” – in concentrations of up to 200mg – with Reckitt Benckiser (RB) rumoured to be behind the switch application.

“The launch of an ibuprofen patch is particularly exciting,” IQVIA noted, “especially as the analgesic market represents the highest-revenue OTC market after the cold segment.”

According to figures from the German manufacturers association, the BAH, analgesics accounted for 8% of the total German retail pharmacy market for OTC medicines in 2016, achieving sales of €527 million.

Ibuprofen “dominated” the analgesics segment, IQVIA pointed out, with “every second pack of tablets, capsules or oral suspensions containing ibuprofen as the active ingredient.”

As yet, however, no launches in Germany had been announced for either the OTC version of Zovirax Duo or for an ibuprofen patch, IQVIA noted.

Zovirax launched OTC in Germany

German consumers are now able to buy GlaxoSmithKline (GSK) Consumer Healthcare's Zovirax Duo cold-sore treatment without a prescription.

GSK had received a positive recommendation for the switch of its Zovirax Duo cold-sore treatment – which, by combining 5% aciclovir and 1% hydrocortisone, the firm claimed “stopped virus replication” and “could prevent blistering” – from Germany's expert committee for prescription in early 2017.

Following the recommendation, aciclovir and hydrocortisone combinations for the treatment of herpes labialis were authorised as non-prescription medicines by Germany's Bundesrat in November last year.

“While classic mono-preparations containing aciclovir and penciclovir help to prevent [cold-sore] viruses spreading and shorten healing times,” GSK explained, “Zovirax Duo goes one step further.”

“Applied early,” it added, “its unique combination of antiviral aciclovir and anti-inflammatory hydrocortisone can even prevent the ugly cold-sore blisters arising at all.”

“What many of those affected don't know is that it's not the virus that causes the swelling and blisters,” GSK continued, “but rather the inflammatory reaction of their own body.”

“Zovirax Duo is the only clinically proven cold-sore cream that not only stops viral replication,” the firm pointed out, “but also combats the annoying blisters by adding the anti-inflammatory drug hydrocortisone.”

GSK pointed to clinical trials showing that Zovirax Duo, if applied in the “tingling phase” of a cold-sore attack, raised to 46% the likelihood that crusts and blisters would not form at all.

“Applied early, blister formation can even be completely

prevented,” GSK claimed. “This not only saves the affected person from the unsightly blisters, but also the painful consequences.”

Women were especially affected by the visible symptoms of cold sores, GSK added. According to a recent study by the firm, “86% of women said their self-confidence was severely diminished when blisters appeared on the mouth”, while “74% even avoided going out in public” as a result of visible blistering.

The fact that the product was now available without a prescription, GSK pointed out, meant that consumers could “anticipate” the visible symptoms of a cold-sore outbreak, applying the treatment before blisters appeared, rather than waiting for a doctor's appointment.

Zovirax Duo is based on Swedish firm Medivir's Xerclear aciclovir and hydrocortisone topical cold-sore treatment.

GSK entered into an agreement with Medivir in June 2010 to commercialise and distribute Xerclear as a non-prescription product under the Zovirax name across multiple markets.



Zovirax Duo is now available in Germany

BAH wants exclusivity for German switches

German industry association, the BAH, has called for a three-year market exclusivity period to be awarded to successful prescription-to-OTC switches in the country.

Speaking at a BAH switch conference in Berlin earlier this month, the association's scientific director Elmar Kroth insisted that the country needed "more switches" to ensure that there was "innovation in self-medication".

"Against a background of demographic change and a shortage of doctors, self-medication with over-the-counter medicines will become more and more important," Kroth commented. "Any drug switched from prescription to OTC status means fresh blood for self-medication."

"However, this is only possible if the conditions for the drug manufacturers are favourable," he warned.

Specifically, Kroth argued, the lack of market exclusivity – the period of time after a reclassification during which no other company can sell a version of the switched ingredient – was an "obstacle" for companies looking to pursue switch applications.

LACK OF INCENTIVES TO SWITCH

Other European switch experts have recently raised similar concerns regarding the lack of incentive for OTC manufacturers to engage with often complex national-level and pan-European reclassification procedures.

In an interview with HBW Insight earlier this year, John Smith – chief executive of the Proprietary Association of Great Britain (PAGB) – challenged the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to think harder about market exclusivity.

Currently, exclusivity was rare, Smith explained, adding that sometimes companies put "huge amounts of time and money" into switch applications only to have a competitor copy the product and grab a share of the market.

"[In biotech] if you bring a totally new chemical entity to market, you get years of exclusivity," Smith explained. "I'm not saying OTC firms should be given 20 years, but 12 or 18 months must be easily attainable."

Giving companies that were first to market with a unique product a period of exclusivity as part of a successful switch application would give firms a chance to build a brand and get a return on their investment, Smith argued.

Smith's arguments echoed those made by panelists at the Association of the European Self-Medication Industry (AESGP) Conference with the Heads of European Union (EU) Medicines Agencies that took place in Lisbon, Portugal, in March.

Bayer Consumer Health's Dirk Ossenburg-Engels pointed out that reclassification was a "huge undertaking" for firms, which needed "better protection" on their investment to justify spending "all their energy" on switch applications.

Eric Teo, head of drug safety at Sanofi, agreed with Ossenburg-Engels, adding that the hurdles to reclassification for companies were "enormous".

"Giving companies that are first to market with a unique product a period of exclusivity as part of a successful switch application would give firms a chance to build a brand and get a return on their investment"

Kroth's intervention came as the BAH released the results of three surveys it had conducted recently with German consumers, pharmacists and doctors on their respective attitudes to prescription-to-OTC reclassification.

According to the surveys – which questioned 752 pharmacists, 540 physicians and readers of the *Deutsche Apotheker Zeitung* – the BAH said that approval ratings with regards to switch were "high" overall.

More than every second person saw the release of medicinal products from prescription-only status as "positive", the BAH said. Respondents cited the "greater say" that OTC status gave them in the treatment of their ailments and the time saved in not having to go and see a doctor as contributing factors, the association explained.

Approval ratings were particularly high among pharmacists, with 85% of respondents in favor of "releasing more active substances from prescription-only status", the BAH reported, in contrast to only 51% of doctors favouring more switching.

Almost all pharmacists surveyed thought that switching "strengthened their healthcare competence", the BAH noted. Doctors, on the other hand, were more likely to see a shift in roles as a result of more switches: 41% percent believed that their role as a point of contact for common health problems might diminish, while 33% thought that their competence in serious illnesses would be strengthened.

Three switches for Germany

Germany's Expert Advisory Committee for Prescription has given the green light to three new prescription-to-OTC reclassifications, following a strong show of support by consumers and pharmacists for more switches in the country.

Earlier this month, the Expert Committee – which recommends, where appropriate, prescription-to-OTC reclassifications as well as OTC-to-prescription reverse switches to the German Federal Ministry of Health, the BMG – met to consider the latest applications.

According to a short summary report of the meeting, the Committee unanimously recommended the prescription-to-OTC switch of levocetirizine for oral use and by majority the reclassifications of diclofenac for use as a patch, and preparations containing sodium bituminosulfonate and hydrocortisone acetate. However, it rejected an application for the prescription-to-OTC switch of muscle relaxant methocarbamol for oral use.

A spokesperson for the Committee told HBW Insight that

it was not appropriate to comment on the names of applicants, as this would “go beyond protocol”.

Levocetirizine is already classified as an OTC medicine in other European countries, including Switzerland, Portugal and Russia, and outside Europe in Australia, New Zealand, Columbia and the US, where it was switched only last year.

Sanofi was behind the switch application in the US with its levocetirizine-based allergy remedy Xyzal, which is currently available in Germany as the prescription-only drug Xusal.

Meanwhile, diclofenac-containing plasters are available without a prescription in the UK, France, Italy and Portugal, with GlaxoSmithKline (GSK) serving these markets with its Voltarol range of diclofenac-based pain relief products.

In Germany, Voltarol – marketed in the country as Voltaren – has been very successful, having outsold all other OTC brands through community and mail-order pharmacy in the year ended September 2017, according to Insight Health.

The Expert Committee's switch recommendations will now be passed on to the BMG for final approval.

Sanofi readies Thomapyrin Tension Duo

German consumers will soon be able to buy Sanofi's long-awaited Thomapyrin Tension Duo analgesic in pharmacies after the country's federal parliament, the *Bundestag*, approved the prescription-to-OTC switch of combinations of ibuprofen and caffeine.

Earlier this year, Germany's expert committee on prescription medicines recommended that single doses of up to 400mg of ibuprofen with up to 100mg of caffeine should be switched to OTC status for treating acute, moderate pain in adults.

Following the decision by the *Bundestag* to accept this recommendation, Sanofi predicted that it would be “about eight weeks” until Thomapyrin Tension Duo would be launched in German pharmacies.

Sanofi pointed out that the analgesic's “innovative combination” of ibuprofen and caffeine had so far only been approved OTC in Germany, Austria and France. Therefore, its new pain relief product represented a “unique development” in the European consumer healthcare market, the firm claimed.

Furthermore, Thomapyrin Tension Duo was the latest contribution to a “tradition” of evidence-based self-medication within the firm, Sanofi insisted, adding that Thomapyrin caffeine-containing analgesics had “been in the portfolio for a very long time”.

“We have presented recent clinical trials of the combination and have shown that ibuprofen plus caffeine is clearly superior to ibuprofen in terms of analgesic efficacy, with comparable tolerability,” commented Thomas Weiser, Sanofi's head of pain for its Consumer Healthcare division.



Sanofi's Thomapyrin Intensiv line

Sanofi failed at its first attempt to switch Thomapyrin Tension Duo. In January 2017, a majority of the members of the German expert committee on prescription medicines voted against allowing ibuprofen and caffeine combinations as an OTC analgesic for adults.

At that time, Germany's federal institute for drugs and medical devices, BfArM, observed that only one medicine combining ibuprofen and caffeine – Boehringer Ingelheim's ThomaProfen Plus 400g/100mg film-coated tablets – had been authorised through Europe's decentralised procedure.

Committee members were concerned by a lack of clinical experience with – as well as long-term safety data for – the newly authorised combination that had not yet been launched into the German market. Thomapyrin Tension Duo is the latest addition to Sanofi's Thomapyrin OTC line in Germany which also includes the Intensiv and Classic variants.

HOMOEOPATHY ▶

DHU launches effort to defend homoeopathy

“Homoeopathy. Naturally. My decision!” is the motto of a new campaign from the German Homeopathy Union, the DHU, designed to fight back against criticism of the increasingly controversial treatment method.

Defending the practice against growing and concerted criticism online, especially via social media, the campaign was built around a website ‘hub’ – homöopathie-natürlich.de, which translates as ‘homoeopathy of course’ – where users of homoeopathy in Germany could exchange experiences and information, the DHU pointed out.

Furthermore, a hashtag – #MachAuchDuMit (#DoYouToo) – had been created, the association pointed out, which people could use to show their support for homoeopathy on social media platforms such as Twitter.

The aim of the campaign, the DHU insisted, was not to sell homoeopathy as an alternative to other medicines, but as something which could be used in conjunction with conventional treatments.

“There should never be an either/or choice between mainstream medicines and other therapies”
– Peter Braun

HOMOEOPATHY POPULAR

Over half of Germans used homoeopathy, the association pointed out, and over 7,000 doctors were trained to practise the treatment.

Thus the need for reliable information was great, the DHU said, and so the campaign had been designed to underline the importance of homoeopathy as an “established and successful therapy” and also to protect the public’s right to choose whichever method of treatment they felt was right for them.

Peter Braun, the DHU’s chief executive officer, said that as more than 30 million people relied on homoeopathy for their health, it was incumbent on his organisation to

“strengthen the self-confidence of people to opt for homoeopathy or at least stand for their right to choose”.

“There should never be an either/or choice between mainstream medicines and other therapies,” Braun insisted, “and a decision to use homoeopathy should not be seen as a decision against conventional medicines.”

“Both have their benefits,” he added, “and complement each other in many cases.”

In August last year, homoeopathy’s availability in Germany as pharmacy products came under attack from a member of the Bundestag representing the Christian Democratic Party (CDU) and a leading consumer protection commissioner.

Mechthild Heil insisted that for most homoeopathic remedies there was “no evidence of efficacy” and no clinical trials backing their registrations.

“Their exclusive sale in pharmacies makes it look like they are scientifically-recognised alternatives to orthodox medicines,” she claimed.

Heil’s claims drew an angry response from German industry and homoeopathy practitioners, who said that removing homoeopathy’s exclusivity in pharmacy would weaken rather than strengthen consumer protection.

“Homoeopathic medicines are usually pharmacy-only – and rightly so,” maintained the German medicines manufacturers’ association, the BAH. “Pharmacy-only status ensures the correct use of homoeopathic medicines within the framework of a pharmacist’s medical advice, which is important for patient safety.”

Cornelia Bajic, chair of the German association of homoeopathic physicians, the DZVhÄ, agreed. “The abolition of the pharmacy obligation would not strengthen consumer safety, but rather significantly weaken it.”

NEED EXPERT ADVICE

Expert advice from pharmacists was important as most homoeopathic medicines were sold without a prescription, she added. Noting that 65% of Germans would like to use more homoeopathic remedies, Bajic labelled the call to remove such products from pharmacy-only status as “grossly negligent”.

Homoeopathic medicines account for a tenth of the German OTC market through pharmacies, including self-medication and prescribed non-prescription categories. This segment grew by 4.3% to €622 million in 2016, according to BAH data.

The majority of these sales were of pharmacy-only homoeopathic medicines. Despite having been taken out of the reimbursement system along with most other OTC drugs in 2004, sales of prescribed non-prescription homoeopathic medicines through pharmacies still accounted for over €100 million last year.

“Homoeopathic medicines have been used without problems for decades,” added pharmaceutical industry association, the BPI.

Homoeopathy blasted by legislators in Germany

Germany should revoke the ‘medicinal’ status it applies to homoeopathic products so they no longer qualify for reimbursement by the country’s statutory health insurance system, leading representatives of Germany’s legislature have argued.

Speaking to the *Stuttgarter Zeitung* earlier this month, Joseph Hecken – chair of the German federal joint committee, the G-BA, which issues directives on which medicines should be covered by state health insurance funds – insisted that citizens must be able to “trust” that such funds “only pay for what has been scientifically proven to work”.

As the medical evidence of the efficacy of homoeopathic medicines was “comparable to that of effervescent vitamins and food supplements”, Hecken argued, these drugs should not be reimbursed by statutory insurance funds.

Furthermore, homoeopathic products should not be granted medicinal status and therefore be subject to pharmacy-only restrictions, he continued, as this restriction should only be applied to medicines “with proven efficacy that require professional advice”.

Hecken’s comments were echoed in the article by members of the German federal parliament, the *Bundestag*, representing the ruling ‘coalition’ parties, the Christian Democratic Union (CDU) and the Social-Democratic Party, the SPD.

Mechthild Heil, parliamentary chair of the *Bundestag* Committee for Building, Housing, Urban Development and Local Government, agreed that homoeopathic medicines should be removed from pharmacy-only status, while deputy chair of the SPD, Karl Lauterbach, claimed that these drugs were “completely ineffective”.

Homoeopathic industry representatives, however, argue that the German public is happy for homeopathic medicines to be reimbursed.

According to the German Homoeopathy Union, the DHU, the “majority” of Germans – based on a recent survey of over 1,000 men and women aged of 16 to 64 – “reject restrictions on the reimbursement of homoeopathic medicines by health insurance funds”.

With regard to a possible change of status from ‘medicines’ to ‘non-medicines’ for natural remedies, including homoeopathy, – and therefore a removal from pharmacy-only status – the “resistance” was “even greater”, the DHU reported, with 72% of respondents against such a move.

Homoeopathy was generally very popular with German people, the DHU argued. Two-thirds of respondents supported ‘integrated medicine’ – in which alternative and natural medicines, such as homoeopathy, are used in conjunction with mainstream medical care – and for the “vast majority”, having the power to choose between mainstream and alternative types of therapy and medicines was considered “important”.

The DHU’s survey was the latest intervention as part of its campaign #MachAuchDuMit – which translates as #JoinInToo – to defend homoeopathy against growing and concerted criticism online, especially via social media.

**“People must be able to trust that state health insurance funds only pay out for medicines for which proof of efficacy has been demonstrated”
– Joseph Hecken**

The campaign was built around a website ‘hub’ – www.homöopathienatürlich.de, which translates as ‘homoeopathy of course’ – where users of homoeopathy in Germany could exchange experiences and information.

“Homoeopathy. Naturally. My decision!” was the motto of the campaign, the DHU explained, and the #MachAuchDuMit hashtag could be used by members of the German public to show their support for homoeopathy on social media platforms such as Twitter.

The aim of the campaign, the DHU insisted, was not to sell homoeopathy as an alternative to other medicines, but as something which could be used in conjunction with conventional treatments.

The need for reliable information was great, the DHU said, and so the campaign had been designed to underline the importance of homoeopathy as an “established and successful therapy” and also to protect the public’s right to choose whichever method of treatment they felt was right for them.

Homoeopathic medicines were taken out of the German reimbursement system along with most other OTC drugs in 2004. However, since 2012, statutory insurance funds have been able to choose whether to fund certain non-prescription medicines, such as homoeopathy, as an optional service.

Bayer backs Iberogast against safety attacks

Bayer Consumer Health has defended its decision not to include warnings about possible liver-damage when taking its herbal gastrointestinal product Iberogast, after harsh criticism from German Member of Parliament (MP) Kordula Schulz-Asche.

A spokesperson from Bayer Consumer Health told **HBW Insight** that the firm continued to “review and assess the medical risks and benefits of Iberogast on an ongoing basis”.

ISOLATED REPORTS

Iberogast included a “low dose of greater celandine extract”, Bayer explained, adding that “while there have been isolated reports of liver damage associated with celandine in high doses of 8mg and above per day, the recommended daily dose of Iberogast contains only 0.3mg of the substance”.

The health and safety of its consumers were Bayer’s “top priorities”, the firm insisted. “Bayer is taking all necessary measures to ensure that the medical benefit-risk ratio of its products is continually assessed,” the company pointed out.

NO INFORMATION CHANGE

Bayer remained “committed to a dialogue with health authorities around the world”, the company confirmed, but as the “facts” remained “unchanged”, it was not “currently planning” to change Iberogast’s patient information.

Bayer’s comments came after German MP Schulz-Asche slammed the company on her website, writing that it had a “moral obligation” to be “fully transparent about the benefits and dangers” of its products.

“Bayer’s behaviour fosters mistrust of the entire pharmaceutical industry,” she claimed. “Especially when risk information is knowingly concealed.”

Schulz-Asche’s aggressive post came after the Swiss medicines agency, SwissMedic, in January, recommended changes to Iberogast’s patient information in Switzerland.

“Due to recent reports of very rare but sometimes serious liver damage”, SwissMedic said it had decided to adjust the suggested text for Iberogast in the country. This revision, however, was subject to “final judicial review” by the Swiss Federal Administrative Court, it explained.

Asked by **HBW Insight** to what ‘recent reports’ it was referring, SwissMedic pointed to two scientific papers published in 2015 and 2016 respectively that claimed to show the liver-damaging side effects of Iberogast use.

While admitting liver damage as a side effect was “very rare”, SwissMedic argued that as the effect was “not predictable” and could be “serious, even life-threatening in the long run”. Therefore, it had decided to recommend an adjustment to the patient information for the product.

Schulz-Asche also blasted *Bundestag* colleagues for not responding to the concerns raised by SwissMedic, accusing the federal government of “trying to escape its responsibility with convoluted justifications”.

In response to a letter submitted by Schulz-Asche to the *Bundestag*, German secretary of state Ingrid Fischbach pointed to a ‘graduated plan notification’ that BfArM had released last year, which recommended the inclusion of warnings about liver-damaging side effects in the patient information of celandine-containing products.

Bayer, however, had appealed against BfArM’s notification, Fischbach pointed out, resulting in a suspension of its legal force while the case was under “judicial review”. As a result, the firm was currently under “no obligation” to implement the text changes ordered by the German medicines agency, Fischbach added.

*“Bayer’s behaviour fosters mistrust of the entire pharmaceutical industry”
– Kordula Schulz-Asche*

PREVIOUS REGULATORY ISSUES

This is not the first time that Iberogast has been hit by regulatory concerns.

BfArM first tried through a graduated plan notification to get the risk of liver damage added to the patient information of Iberogast in 2008.

But former Iberogast owner Steigerwald Arzneimittel – which was acquired by Bayer in 2013 – filed an objection against the notification. As there were hardly any studies on the risk of celandine at that time, BfArM decided not to follow up the case.

Since then, as more studies have been released pointing to the liver damaging side effects of Iberogast, BfArM has renewed its efforts to get Bayer to revise the product’s patient information in Germany.

Iberogast gets warnings after Bayer concession

Bayer Consumer Health has after a decade long stalemate with the German Federal Institute for Drugs and Medical Devices, BfArM, conceded to add warnings regarding possible liver damage to the patient information leaflet of its Iberogast gastrointestinal herbal medicine.

After new reports of liver damage associated with the use of the drug – including a death BfArM said had been linked by medical experts to Iberogast, specifically its herbal ingredient celandine – Bayer dropped its legal case against the agency’s order to update the patient leaflet.

Iberogast’s leaflet will from now on note that “cases of liver damage have occurred with products containing celandine” and include the warning that the drug “should not be taken if you have or have had a history of liver disease or if you are taking medicines with liver damaging properties at the same time”.

The leaflet will also warn that “if signs of liver damage (yellowing of the skin or eyes, dark urine, discoloured stools, abdominal pain, nausea, loss of appetite, tiredness) occur, you should stop taking Iberogast immediately and see a doctor”. In the sub-section relating to ‘pregnancy and breast-feeding’, the leaflet will also state that Iberogast “must not be taken by pregnant women and nursing mothers”.

In 2008, BfArM first issued a notification that the patient information leaflets of medicines containing celandine, such as Iberogast, should contain warnings about liver-damaging side-effects.

However, former Iberogast owner Steigerwald Arzneimittel – which was acquired by Bayer in 2013 – filed an objection against the notification, which had the effect of suspending its legal force. As there were hardly any studies on the risk of celandine at that time, BfArM decided not to follow up the case.

BfArM renewed its efforts to force Bayer to respond to the notification earlier this year, as more studies had been released pointing to the liver damaging side effects of Iberogast.

Nevertheless, Bayer decided not to submit to BfArM’s request, launching instead a brochure aimed at pharmacists

“Consumer health and safety is always our top priority and we act accordingly”

– Bayer Consumer Health

and consumers that defended the brand and answered questions in relation to its safety.

Commenting on its decision to include a liver-damage warning, Bayer once again defended the safety of Iberogast, pointing out that, like all of the firm’s products, it was “subject to constant routine safety monitoring”. “Consumer health and safety is a top priority for Bayer,” the firm added. “The medical benefit-risk balance of our drugs and medical devices is continuously evaluated throughout the product life cycle.”

Bayer also responded to renewed criticisms from German Member of Parliament (MP) Kordula Schultz-Asche, who on her website said that “the events paint a devastatingly poor picture of the pharmaceutical company Bayer” and accused the company of waiting until someone died before acting on BfArM’s notification.

Bayer said that the death linked to Iberogast had “not yet been conclusively assessed by the company”, and that the patient may have had “pre-existing conditions” that may have contributed to liver failure.

“We disagree with the accusation that we have a devastating attitude towards the welfare of the patient,” Bayer added. “Consumer health and safety is always our top priority and we act accordingly. We prefer a factually based discussion that is in the interests of everyone.”

Schultz-Asche also claimed that BfArM had been cast in a “bad light” for “not being able or unwilling to enforce its own orders against Bayer”.



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