



Last year's ECJ ruling on Germany's price-control mechanism could see a ban for online prescription sales. With German elections looming, David Ridley examines the implications for the country's burgeoning online OTC market.

Germany debates online future

German industry executives believe that the online pharmacy market will not be significantly affected by the recent European Court of Justice (ECJ) ruling, which found that Germany's internal price-control regulations for prescription drugs, the AMPPreisV, did not apply to non-German mail-order firms selling into Germany.

However, the German pharmacy lobby claims that the ECJ ruling will lead to "pharmacy death". German community pharmacies – as well as German-based mail-order operations – will not be able to compete with discounts offered by foreign firms like DocMorris and Europa Apotheek on online sales of mail-order prescription

medicines to German customers.

Pharmacists have been lobbying politicians in the run-up to the German federal elections in September, with the main parties now taking positions on a possible blanket ban for all mail-order sales of prescription medicines. This would effectively turn the clock back to 2004.

But industry consultant Sempora does not think "pharmacy death" is on the horizon. It points out that mail-order sales of prescription medicines make up only a tiny proportion of the overall medicines market in Germany compared to community pharmacy (see Figure 1).

And in a recent survey of industry executives and pharmacy representatives, Sempora found that just under half expected no change in the mail-order segment of the German pre-

scription medicines market, while most of the others thought it would grow. Only 8% believed it would shrink.

Sempora adds that German community pharmacies are gradually declining in number, but the turnover of the remaining pharmacies is increasing, not least because of the rising German prescription market as a whole.

Mail order may be relatively insignificant in the prescription sector, but it is far more important for OTC sales, not only in size but also in terms of growth. Indeed, online OTC sales have played a part in the recovery of the OTC market, which has taken more than 10 years to get over the shock of de-reimbursement in 2004 (*OTC bulletin*, 26 May 2017, page 24).

Although online OTC sales will not be directly affected by a ban on mail-order prescription sales, many consumers will buy their OTC medicines at the same time as their prescription drugs while shopping online. If mail-order sales of prescription medicines were lost due to a ban, it would inevitably have an effect on OTC sales.

Meanwhile, in election year, Germany's main political parties have adopted positions on the ECJ ruling and the future of online prescription sales.

Germany is now faced with four scenarios as a result of the ECJ judgement in 2016, according to Uwe May and colleagues, in a report commissioned by German wholesaler Noweda and German pharmacy publisher, the Deutscher Apotheker Verlag:

- Status quo – the German government does nothing in response to the ECJ ruling
- Margin competition – Germany abandons

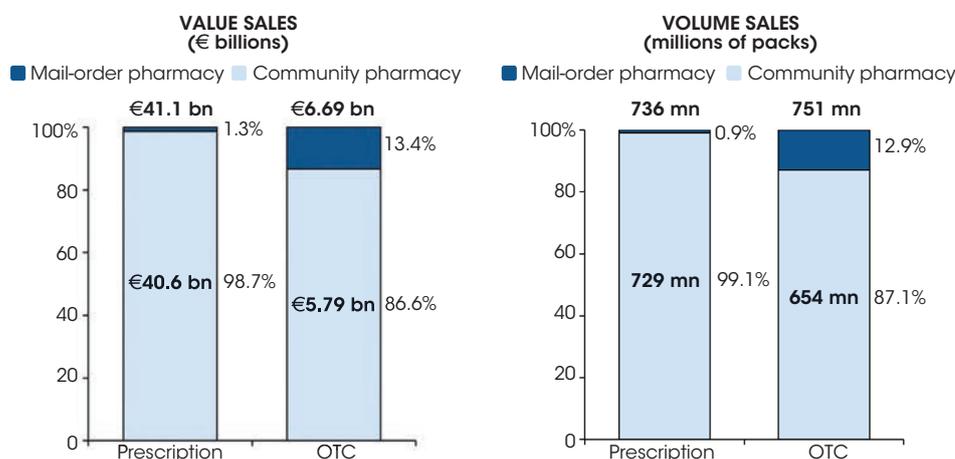


Figure 1: Germany's pharmaceutical market through pharmacy in 2016, showing the relative proportions of mail-order and 'bricks-and-mortar' sales of both prescription medicines and OTC medicines by value and volume. OTC sales are of non-prescription medicines excluding complementary medicines, supplements and veterinary medicines (Source – DAV)

its price-control mechanism altogether

- Gentle competition – German pharmacists are allowed to offer limited discounts on prescription drugs

- Prohibition – an overall ban on sales of prescription drugs by mail order

In the first scenario, the German government considers that change is unnecessary. “Unfair competition” from non-German online pharmacy retailers would then potentially result in a collapse of community pharmacy in Germany, according to the report’s authors.

They believe that allowing firms like DocMorris to undercut community pharmacies would bring the sector to its knees.

In their report, they claim that discounts on prescription drugs offered by foreign online companies like DocMorris would successfully attract consumers away from German pharmacies, which are limited by the domestic price-control system. This imposes a series of fixed mark-ups for each element of the supply chain.

About a quarter of prescriptions in Germany are “non-urgent”, they point out, which means that mail-order delivery times for these medicines are less of a factor for patients. Many people are already getting their OTC products online, and if this proportion of prescriptions were to move to this channel along with OTC medicines, the resulting loss of business would jeopardise the financial viability of German pharmacies, especially in rural areas.

Customer safety undermined

Furthermore, customer safety would also be undermined, as decisions would be made based purely on price, which May and colleagues consider to be an “improper standard” compared to expert medical advice from pharmacists.

“Recent studies confirm that pharmacists have contact with prescribing physicians several times a day to clarify prescription questions,” the authors point out, “but many of the doctors have never had any professional contact with a mail-order pharmacy in other European Union (EU) countries.”

The ECJ ruling in 2016 was the culmination of a legal battle that began when the German Association for the Protection Against Unfair Competition – with the support of the German pharmacy lobby – brought a case against DocMorris and Germany’s Parkinson’s Association for offering discounts on prescription drugs (*OTC bulletin*, 4 November 2016, page 15).

The case was referred to the ECJ, which ruled that the German price-control legislation could not be applied to DocMorris, as this would constitute an unjustified restriction of the free movement of goods within the EU.

This was not the first time that DocMorris had attempted to “disrupt” the German medi-

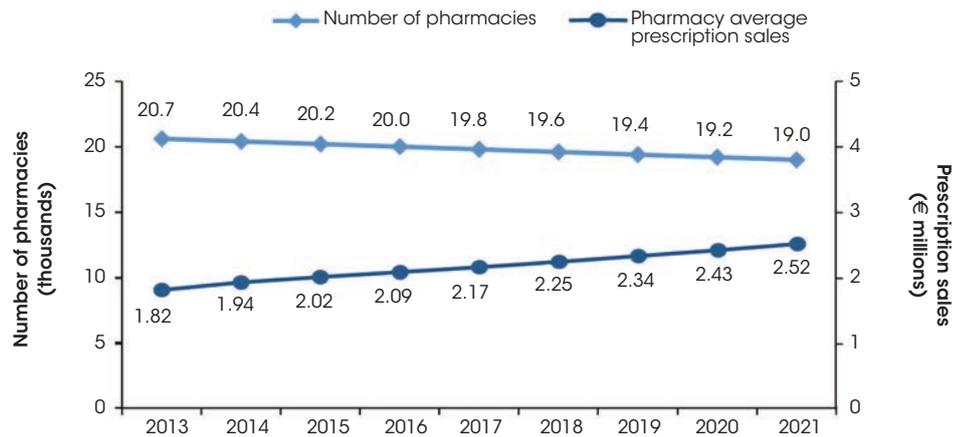


Figure 2: Germany’s declining number of community pharmacies, projected to 2021, compared with the rising average turnover of each individual pharmacy (Source – Sempora)

cine market. In 2003, the ECJ ruled against the German pharmacy association, the DAV, which had taken DocMorris to court for selling OTC drugs into Germany via mail order. Up until this point, distance selling of medicines had been illegal in Germany, according to the German law on medicinal products, the AMG.

Although the 2003 ECJ ruling said that a ban on OTC mail-order sales was not justified, a prohibition on mail-order sales of prescription drugs on the grounds of public health was left open as a possibility.

Germany decided in its 2004 healthcare reforms to allow not only the distance selling of OTC medicines, but also mail-order sales of prescription medicines, as long as operations were based in a community pharmacy in Germany and met German safety standards.

DocMorris began selling prescription medicines into Germany by mail order, but this resulted in a German Federal Court of Justice case in 2007. The German Association for Social Competition, which brought the case against DocMorris on behalf of the German pharmacy lobby, pointed out that the company was based in the Netherlands, and therefore breaking the rule that mail-order companies had to be based in a German community pharmacy.

The Court of Justice in Frankfurt, however, established that the Dutch company met the required safety standards and was thus allowed to sell prescription medicines into Germany through mail order.

DocMorris’ popularity has grown significantly in recent years. Last year it increased its turnover by about 10% to €331 million, according to the end of year accounts of its parent company, Zur Rose. OTC sales – which grew by 50% – and “intensified marketing measures” in Germany, were cited as contributing factors.

Capitalising on its victory in the 2016 ECJ case, DocMorris has continued to disrupt the German medicines market, most recently by developing a “video consultation with medicinal delivery” service in Hüffenhardt coupled

with a pharmacist in the Netherlands.

However, the Dutch mail-order company was not successful, and the outlet was closed last month after a series of legal battles.

Sempora disagrees with May and colleagues that the “status quo” scenario would lead to the end of community pharmacy in Germany.

Extrapolating from Insight Health historical market data, it predicts a compound annual growth rate (CAGR) of 2.9% for the prescription medicines market as a whole in Germany for the next five years. This would mean an increase of 15.2% from €42.4 billion in 2016 to €48.8 billion in 2021.

Although it is true that the number of community pharmacies in Germany has been slipping back by approximately 200 a year to just over 20,000 in 2016, this drop was happening before DocMorris began offering discounts, Sempora points out.

Furthermore, a decreasing number of pharmacies – combined with a steadily growing market – would mean an increase in average turnover for the remaining community pharmacies of 20.6%, from €2.09 million in 2016 to €2.52 million per pharmacy by 2021 (see Figure 2).

“With its low market share, even in a very optimistic scenario, it cannot be said that the mail-order trade with prescription medicines would be a major threat to the continued existence of German community pharmacies,” Tobias Brodtkorb, managing partner of Sempora, told *OTC bulletin*.

By opening the “video consultation with medicinal delivery” in Hüffenhardt, a small town in rural Germany with just over 2,000 residents, DocMorris believes it has shown that online pharmacies can offer both convenience and care, especially for customers in remote places.

Customers in Hüffenhardt were advised by DocMorris staff based in the Netherlands via a video interface. Medicines were then released and handed over immediately in-store.

Although DocMorris was initially stopped only from selling prescription drugs through

the Hüffenhardt outlet, the Mosbach district court has now closed it down entirely, after a series of interventions by the Baden-Württemberg pharmacy association.

SWR Fernsehen, a German regional television channel covering the Baden-Württemberg and Rhineland-Palatinate regions, found that when interviewed, customers said they had enjoyed using the Hüffenhardt video pharmacy.

Residents of the rural town also pointed out that the nearest community pharmacy was 5km away, as the local pharmacy had closed. There was no interest, they claimed, from German pharmacists in opening a new outlet.

“Many Hüffenhardters have now tested the new offer and see the video consultation with medicinal delivery as a good alternative,” DocMorris commented.

“We have always stood for more competition and innovative solutions in the pharmacy market, as our video advice with drug delivery shows,” Olaf Heinrich, chief executive officer of DocMorris, pointed out. “The judgment makes it more difficult to improve the situation in rural regions and to explore the opportunities of digitalisation for pharmacists.”

May and colleagues’ scenario two warns of the dangers of allowing margins to be fixed freely by wholesalers and pharmacists, imagining what would happen if the German price-control system were abandoned altogether.

The report contends that price control is an integral part of reimbursement in Germany. Abolishing the AMPPreisV mechanism would remove price certainty from the authorities and place the onus for prescription payments fully on patients. Instead of a co-payment of a few euros, they would be responsible for paying – and claiming back – the full prescription cost.

May and colleagues claim that German consumers, if faced with the full cost of medicines, would be focused on price rather than health and safety considerations. Many rural pharmacies would close, unable to compete with both mail order and other community pharmacies.

The authors also explore the possibility of modifying the AMPPreisV system by introducing “gentle competition”. In scenario three, German pharmacists are allowed to offer limited discounts of €1.00 or €2.00 per pack to compete with non-German mail-order companies.

However, firms like DocMorris would still be able to offer higher discounts on prescription medicines, as the ECJ ruling determined that price control was not applicable to non-German retailers. May and colleagues argue that, in this scenario, German pharmacies would remain victims of “unfair competition”, but with “additional uncertainties and disadvantages”.

The final scenario is the one May and colleagues recommend: a ban on mail-order sales

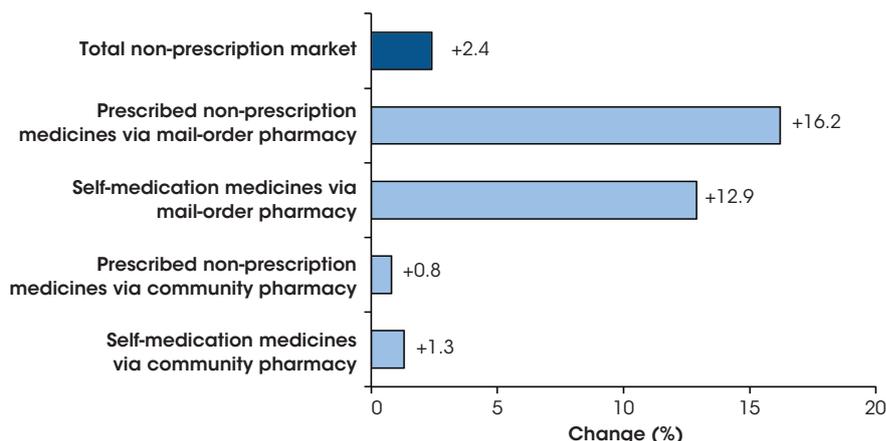


Figure 3: Growth of self-medication and prescribed non-prescription medicines - worth €6.78 billion - in Germany's total retail pharmacy and mass markets. Mass-market sales of non-prescription medicines, worth €0.2 billion, declined by 1.4% (Source - BAH)

of prescription medicines in Germany. Even though the Federal Court of Justice established that DocMorris should be allowed to sell prescription drugs into Germany through mail order, the ECJ ruling in 2003 left open the possibility of a national ban on mail-order prescription sales on the grounds of customer safety.

In all three previous scenarios, May and colleagues essentially argue that “unfair competition” undermines not just the viability of German community pharmacies, but also consumer safety. Comprehensive coverage and patient safety are “public goods” that cannot be provided by a free market, they claim.

Provision organised by state

“Public goods are not provided in a market economy system because they are not financed by private individuals,” the authors point out. “If they are socially desired, their provision must be organised by the state.”

Compared to state intervention, price control is a “comparatively market-based” alternative, the authors claim. This is because manufacturers are free to set their prices; only mark ups from factory to patient are set in law.

“The prohibition of mail-order prescription sales is an indispensable prerequisite for safeguarding price control and thus for maintaining the nationwide pharmacy supply in Germany.”

But banning online prescription sales could damage Germany’s burgeoning online OTC market. In 2016, the value of OTC mail-order sales accounted for 13.4% of the overall OTC market at €896 million, with a sales volume of 12.9% at 97 million packs.

Mail order was the fastest-growing segment of the German OTC market last year, with both prescribed and self-medication sales showing double-digit increases (see Figure 3).

According to the German medicines manufacturers’ association, the BAH, community pharmacies were responsible for nearly 85% of Germany’s non-prescription medicines mar-

ket – inside and outside pharmacy – worth €6.78 billion in 2016. The mail-order pharmacy segment amounted to €840 million and grew 10-times faster than self-medication sales through community pharmacies.

Despite mail order as a proportion of sales being large in some product categories, the value of these sales is mostly small in terms of the OTC market as a whole. For example, 40.9% of weight-loss products were sold through mail order in the first quarter of 2017, but claimed a market share of only 0.7% (*OTC bulletin*, 30 June 2017, page 11). Respiratory was the largest category at 28.4% of the OTC market, however, only 9.4% of sales were conducted online (see Figures 4 and 5 on page 23).

Sempora’s Brodtkorb told *OTC bulletin* that the possibility of a ban actually happening was “currently low”. If a ban did happen, “only DocMorris and Europa Apotheek would lose customers”. According to Brodtkorb, German pharmacies would take over the estimated €140 million of annual mail-order prescription turnover of these two firms in the event of a ban.

Commenting on behalf of the the BAH, Johannes Koch, head of European policy and international affairs, agreed: “We do not expect any effects of a possible mail-order ban for the OTC segment.”

But banning mail-order prescription sales is now on the agenda for the coming German federal elections in September. The Federal Union of German Associations of Pharmacists, ABDA, has successfully lobbied the ruling joint union party of the Christian Democratic Union in Germany (CDU) and Christian Social Union in Bavaria (CSU) to include a ban in their election manifesto.

Earlier this year, Herman Gröhe (CDU), Germany’s federal minister for health, attempted to get the mail-order ban through the German parliament, but the CDU/CSU’s coalition partners, the Social Democratic Party of Germany (SPD), rejected an early draft.

Manufacturers

Stada's top team resigns

Stada Arzneimittel has unveiled a new chief executive officer and chief financial officer, following the sudden simultaneous resignations of **Matthias Wiedenfels** and **Helmut Kraft** "for personal reasons".

With immediate effect, former Boehringer Ingelheim executive **Engelbert Coster Tjeenk Willink** has taken over from Wiedenfels as chief executive officer and assumed responsibilities for marketing and operations. Wiedenfels led Stada for just under year having taken over from **Hartmut Retzlaff**, who resigned last August "due to personal circumstances" (*OTC bulletin*, 9 September 2016, page 1).

Meanwhile, Kraft has been replaced as chief financial officer by **Bernhard Düttmann**, a former finance head at local chemical firm Lanxess.

Both have been appointed on an interim basis until the end of this year.

Supervisory board chairman Ferdinand Oetker insisted that Stada's operational business was unaffected by the management overhaul, "and we do not deviate from our operating and financial targets".

The reshuffle came just a week after Stada announced a €5.32 billion takeover bid by Bain Capital and Cinven had failed after the private-equity firms were unable to garner the requisite shareholder support for their offer (*OTC bulletin*, 30 June 2017, page 1).

Bain Capital and Cinven have since submitted a renewed improved takeover offer for Stada which has gained the support of the German company's management (see front page).



Engelbert Coster Tjeenk Willink

Commenting on the increased offer, Willink said it reflected Stada's growth potential and a commitment to the company's corporate growth strategy. **OTC**

The SPD's Brigitte Zypries, federal minister for economics and technology, claimed that rather than protecting German pharmacies, a mail-order ban could undermine pharmacy supply in Germany.

"As German mail-order pharmacies are always also community pharmacies, the existence of these pharmacies would also be jeopardised," Zypries pointed out. "State intervention could lead to a restriction and endangering of comprehensive coverage."

In their election manifesto, the SPD says nothing about a ban, asserting only that "the competence of pharmacists must be integrated efficiently into the care structure".

Currently, the Greens (die Grünen) and the Left (die Linke) are the main opposition parties in the Bundestag, although this may change after federal elections on 24 September. Although opposed to the CDU/CSU on many other policies, the Left supports a ban, commenting in its election programme that it would "aim to limit mail-order sales of medicinal products as far as possible" with the intention of "strengthening" the role of professional advice from pharmacists and ensuring "the provision of services close to the place of residence".

However, the Green party does not agree that a mail-order ban is the best way to secure comprehensive coverage. The party thinks that mail order is essential for the supply of medicines for complex and chronic diseases.

By far the most detailed proposals come from the Free Democratic Party (FDP), which failed to get any seats in the last election. The FDP rejects a ban, calling for even further liber-

alisation by lifting restrictions on the foreign ownership of German pharmacies.

While mail order may not be contributing a great deal to the German prescription market, it has played an important role in the recovery

of the OTC segment since de-reimbursement. If a prescription ban were to go ahead, patients who have turned to online retailers to fulfill their prescriptions may no longer stock up their medicine cabinets online with OTC drugs. **OTC**

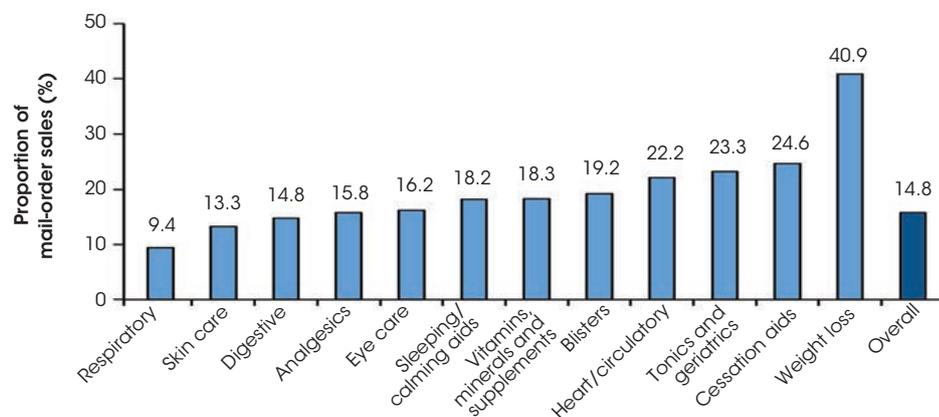


Figure 4: Proportion of pharmacy sales in the major OTC categories of licensed medicines and selected unlicensed healthcare products that were sold by mail order in the first quarter of 2017 (Source - QuintilesIMS)

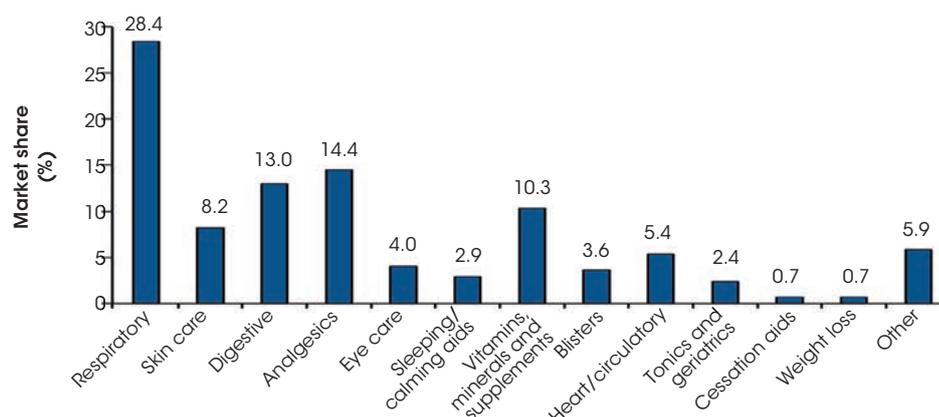


Figure 5: Proportion of the total pharmacy market of licensed medicines and selected unlicensed healthcare products represented by the major OTC categories in the first quarter of 2017 (Source - QuintilesIMS)