In focus: the speciality pharma market

Not a pharmacy, not a pharma, but an enabler

Pretty much everyone knows the names of the seven largest German pharmaceutical companies: Bayer (47.5 billion euros in sales in 2023), Boehringer Ingelheim (25.6), Fresenius (22.3), Merck (21), B. Braun (8.8), Biontech (3.8), Stada (3.7). However, companies such as PharmaMed (0.5), Chelapharm (1.49) and Medios AG, Germany's first listed specialty pharma company with a turnover of 1.8 billion euros in 2023, are still relatively unknown. In view of the planned pharmacy reform, Medios AG is now concerned about the 'security of care for seriously ill people' and has organised its own symposium on this topic at the Berlin Capital Congress - an opportunity for 'Monitor Versorgungsforschung' to shed light on the background.

>> In recent years, specialty pharmaceutical manufacturers have benefited considerably from the growing demand for personalised medicine, which is primarily used to combat genetic diseases. The US Drug Channels Institute estimates that speciality pharmaceuticals were prescribed for 243 billion US dollars in the USA last year , accounting for almost 40 per cent of prescription revenues in the pharmacy sector and an even higher proportion of net expenditure by payers.

The market for speciality pharmaceuticals has also reached considerable dimensions in Germany. In 2015, pharmacies generated sales of almost ten billion euros, which, according to the Federal Union of German Pharmacists' Associations, corresponds to almost a quarter of total sales of prescription medicines. It is therefore hardly surprising that Federal Health Minister Prof. Dr Karl Lauterbach is planning to gradually reduce the percentage remuneration from the current 3 per cent to 2.5 per cent and then to 2 per cent with his 'Act for a Pharmacy Fee and Pharmacy Structure Reform' (ApoRG), which will have a particular impact on high-priced innovative original medicines and speciality pharmaceuticals.

Dirk Düvel, who has been a self-employed pharmacist at Deich-Apotheke in Marschach for almost 30 years and also co-owner of a local pharmacy with its own mail-order business 'Wir leben Apotheken', explained at the HSK symposium that around ten per cent of German pharmacies have a particular focus on chronic care. And according to Düvel, around 1,000 pharmacies are active in the supply of sterile prescriptions, i.e. customised prescriptions for individual patients. Of these, around 200 pharmacies with sterile manufacturing laboratories produce their own and around 800 cooperate with specialised pharmaceutical companies.

One of these companies is Medios AG, which produces customised batches on a contract manufacturing basis for pharmacies and hospital pharmacies, which then supply them to their patients. 'We fulfil these orders in Germany in our six GMP clean room laboratories, which are subject to the same regulatory requirements as the laboratories of research-based pharmaceutical manufacturers such as Bayer or Boehringer Ingelheim,' explains Christoph Prußeit, pharmacist and Chief Innovation Officer at Medios. In order for pharmacies to be able to dispense special preparations for cancer or haemophilia patients, they sometimes also need specialised wholesalers - the company also has this task in its service portfolio. Prußeit: 'Medios now supports around 850 German partner pharmacies by sparing them the need to set up their own manufacturing infrastructures, which can quickly run into the millions.'



Matthias Gärtner, Chief Executive Officer of Medios.

'We enable every pharmacy andhospital pharmacy to offer patient-specific and complex medicines for their patients,' continues Prußeit, Chief Innovation Officer at Medios. Only the personalised medicine approach with individual dosages, tailored to specific patient parameters, makes effective and efficient therapy possible.

Specialised formulations for serious illnesses (3)

According to ABDA, oncologicals (against cancer) and immunosuppressants (against the body's own rejection reactions and for inflammatory diseases) have played a particularly important role in innovative finished medicinal products in the recent past. The costs are offset by the respective therapeutic benefit. In addition to finished medicinal products, individually produced special formulations (cytostatics) are also used in oncological therapy. There are also parenteral solutions for intravenous administration with monoclonal antibodies, for example. The production of these special formulations is subject to special technical requirements, which are met by around 300 pharmacies nationwide with a special clean room laboratory in accordance with Section 35a of the German Pharmacy Operating Regulations.

Zytostatika-Verordnungen und -Umsatz

Zytostatika	Verordnungen Mio.			Umsatz Mio. Euro		
	2021	2022	2023	2021	2023	2023
Zytostatika-Zubereitungen	2,1	2,0	2,0	929	849	912
Parenterale Lösungen	1,7	1,7	1,7	4.246	4.497	4.832
darunter mit monoklonalen Antikörpern	1,3	1,3	1,3	4.053	4.295	4.602

This will become even more important in the future with personalised medicines. Prußeit: 'By having highly qualified manufacturing staff and a sophisticated manufacturing infrastructure, we are the preferred partner not only for many service providers, but also for pharmaceutical companies, because we manufacture the individualised infusions from their products with a non-individual sales volume.'"

The Medios Group is made up of several subsidiaries. In the 'Patient-specific therapies' segment, these include manufacturing plants at six locations in Germany, which produce infusions for oncology, parenterally applicable antivirals, antibiotics and cytostatics as well as products for parenteral nutrition in response to direct demand from pharmacies, Medios Digital GmbH with the 'mediosconnect' platform, which enables pharmacies to order and invoice patient-specific therapies directly and easily, and Medios Pharma GmbH as a wholesale company for pharmaceutical products in the Pharmaceutical Supply segment. Prußeit, whose company covers the indication areas of oncology, neurology, autoimmunology, ophthalmology, haemophilia and infectiology: 'We are therefore not a representative of Big Pharma, but also not a pharmacy. We are a company that serves all needs in the speciality pharma sector.'

Nevertheless, Medios does have a trace of 'pharmacy DNA': Manfred Schneider, who was CEO of Medios until the end of 2020, not only founded the first BerlinApotheke, which he managed for over 20 years and expanded to a group of four specialised pharmacies, but also the current subsidiaries, after studying pharmacy at the Free University in Berlin and obtaining his licence to practice pharmacy.

In the meantime, Medios AG is no longer only active in Germany. After analysing the European market, the Benelux countries emerged as particularly interesting. Following the takeover of Ceban Pharmaceuticals B.V., the company now has its own pharmacy chain in the Netherlands, including a GMP manufacturing infrastructure that can prepare gene therapies ready for application.

If you add up what Medios produces in Germany and in the Netherlands, this amounts to almost one million customised products per year - around 400,000 of which are produced in Germany. Matthias Gärtner, CEO of Medios, comments: 'The acquisition of Ceban is an important milestone in our European expansion strategy. With its market-leading position in the Netherlands and growing market positions in Belgium and Spain, Ceban is excellently positioned for further growth and extremely profitable. Through our established speciality pharma platform in Germany, we are also creating cross-selling opportunities and synergies in purchasing.'

When CEO Gärtner talks about a 'platform', we should not imagine a digital platform à la Amazon, but rather a 'highly specialised service and infrastructure platform' that makes specialty preparations available to patients via pharmacies, but also enables companies to introduce their innovative products.

In this context, Prußeit addressed a rare and serious disease during the HSK symposium: Rett syndromeaffects around 50 girls in early childhood every year. So far, however, there is only one authorised drug in America, with several other gene therapy candidates in the pipeline. Making these drugs, including innovative gene therapy technology, available to patients in Europe is anything but trivial due to the different healthcare and billing systems and local regulations. This is where Medios sees potential for action: 'If research-based pharmaceutical companies with innovative products could approach a platform company like us that can both take over direct patient care and manufacture highly complex gene therapies, market entry and thus availability could potentially be achieved much faster,' says CEO Gärtner. <<

by:
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'Standardisable supply channels with greater efficiency'

How do you envisage the supply of medicines in ten years' time? What contribution can your company make to this?

We assume that even more patients will need to be treated due to demographic developments. Improved diagnostics may also make it possible to treat even more diseases. This means that the need for the supply of medicines will increase. We can assume that not everyone will do everything, but that there will be more focus and specialisation among service providers. I can well imagine that there will be standardisable supply channels for the provision of medicines, which will result in greater efficiency. At the same time, the individualisation of pharmaceuticals will lead to more precise drug therapy. Patients should not be subjected to a complicated care process, but a simpler one. This in turn requires the players to work together in a more networked way and to enable the most efficient care in a collaborative manner. We want to help to think progressively and meet the foreseeable challenges with proposed solutions - and not remain stuck in the status quo.



Christoph Prußeit, Chief Innovation Officer at Medios.

Literature

1: https://www.drugchannels.net/2024/04/the-top-15-specialty-pharmacies-of-2023.html
2: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/A/ApoRG-Apotheken-Reformgesetz_RefE.pdf
3: https://www.abda.de/fileadmin/user_upload/assets/ZDF/Zahlen-Daten-Fakten-24/ZDF_2024_88_89_Arzneimittel_fuer_schwere_Erkrankungen.pdf

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