# "At some point, we have to decide what we want"

Dorothee Brakmann, Chief Executive Officer of the German Pharmaceutical Industry Association since 1 April 2024, talks about the importance of the pharmaceutical industry in preventing supply bottlenecks. She is focussing on a holistic data ecosystem for the healthcare system, better structural efficiency, stable framework conditions and a rather old topic: self-medication. This is not altruistic, as her association represents over 400 pharmaceutical manufacturers, many of whom are active in the OTC business. Brakmann: "Self-medication is not only able to take pressure off the reimbursement system, but also reduce the overburdening of outpatient medical care."



In the cover interview: Dorothee Brakmann, Managing Director of Pharma Deutschland

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**>> In April of this year, Pharma Deutschland published its own digital strategy with the aim of providing intensive and structured support for future digital developments in the healthcare sector. At the presentation, Ms Brakmann, you said the following: "The pharmaceutical industry has long since grown beyond the mere supply of medicines. However, the digitalisation of the industry is far more than just an additional aspect. Today, it affects the entire value chain and is no longer just an "add-on", but an integral part of modern healthcare." Where should your digital strategy start?**

The most important thing is to think about the digital strategy along the entire value chain. For the pharmaceutical industry, it starts with raw material logistics, drug design, production and study planning and execution. However, the strategy also encompasses the pharmaceutical trade and diagnostics through to what is normally the focus of many digital approaches: supply and data management. Our digital strategy is therefore not intended as a stand-alone solution, but is always integrative.

**That is why your association is also one of the founding members of SphinX.**

Exactly. This is an association of different players in the digital healthcare sector. They are concerned with how the entire healthcare system can be digitalised: from production and supply chains to the necessary standardisation, from data flows between individual countries to a harmonised European data space.

**There are various pilot projects in this area, some of which we have already discussed in "Monitor Versorgungsforschung" (03/25) in an interview with Maro Bader, Excellence Lead Digital Transformation at Roche Pharma, and Michael Hübner, Manager Innovation and Digitalisation, Corporate Development at Sana Kliniken.**

However, I would like to mention an approach that is particularly close to our hearts as a pharmaceutical industry because it helps to solve the current discussions about supply problems for medicines, which we will certainly come back to. The SphinX model project "HealthTrack-X" is attempting to create a holistic data ecosystem for the healthcare sector, starting by digitising the basic production and supply chains. This will allow the most important data to be recorded in a structured manner well in advance of actual on-site care, for example to avoid supply bottlenecks later on. Another working group called "EHR2EDC" - an acronym for the transfer of health data between the electronic health record (EHR) of a practice management system and a study database (EDC) - is working on how ePA health data can be transferred directly into study databases in order to make clinical research easier and faster. This will accelerate the value chain - naturally also to the benefit of patients, as innovative medicines can be made available more quickly than before.

***"Above all, it is important that the data hosted in the various silos is structured and made generally accessible to everyone."***

**Unfortunately, we are still at the very beginning of the electronic patient record or Electronic Health Record (EHR). Health professionals**

**have only been obliged to fill the ePA with data since 1 October this year. This means that as things stand today, the record is practically empty! If you had to give marks from 1 very poor to 10 super-optimal: where do we stand in terms of digitalisation in Germany?**

On a scale of 1 to 10, I would give us a 4. But what's the point? At some point, we have to start collecting the data that we can all use to improve our healthcare system so that we can utilise it. Of course, not everyone is aware of the ePA and not all healthcare professionals are using it yet, but since 1 October they have to do so. This will hopefully take us a long way forward. Above all, it is important that the data hosted in the various silos is structured and made generally accessible to everyone so that a standardised data structure is finally created.

**You have just mentioned supply shortages caused by bottlenecks in the supply of medicines. There is currently talk of around 500 medicines that are officially reported as being difficult to obtain. Would your digital strategy help to avoid supply bottlenecks by reducing inefficiencies in the healthcare system?**

That is our hope. Above all, we need better structural efficiency because we have very tight budgets at the moment. If we digitalise consistently, we will certainly be able to become more efficient and free up funds where we can use them better. Digitalisation is just one tool that we could use. There are others, but unfortunately they are not at the centre of political attention.

**What would they be?**

First and foremost, there is a well-known and at the same time very topical issue: self-medication.

**Your statement as Managing Director of Pharma Deutschland is not really surprising.After all,your association -known as the Federal Association of Pharmaceutical Manufacturers, or BAH for short,until it was renamed inMarch 2024 - is the largest pharmaceutical industry association in Germany, which also represents most manufacturers of prescription and over-the-counter medicines.**

That's true. But it is also true that self-medication is not only able to take pressure off the reimbursement system, but also to reduce the overburdening of outpatient medical care. If, like other European countries, we finally managed to switch more prescription drugs to self-medication, patients with minor illnesses would be able to obtain their medication more quickly and easily because they would go straight to the pharmacy instead of the doctor's

surgery. On the one hand, this would relieve the burden on surgeries, as millions of unnecessary visits to the doctor could be avoided, as the extremely well-trained pharmacists in this country could just as easily provide the necessary advice for minor illnesses. This in turn creates efficiency reserves in the medical profession for serious cases and reduces the pressure on the financial reserves of the health insurance funds. Of course, we need to talk about hardship clauses for the socially disadvantaged, although it is important to realise that most of the drugs in question are below the co-payment threshold anyway.

***"We need stable framework conditions in Germany and Europe more urgently than ever before, which will lead to our pharmaceutical industry investing in Germany and Europe again!"***

**Trump's tariff policy is nothing more than an extortionist settlement tactic.**

We need stable framework conditions in Germany and Europe more urgently than ever before, which will lead to our pharmaceutical industry investing in Germany and Europe again! For me, the BMG's expert commission and the Chancellery's pharmaceutical dialogue are the acid test of whether we really want resilient drug development and production again. Or whether we will continue to act from year to year according to the Rhenish motto "Et hätt noch emmer joot jejange" and end up with a shambles at some point.

**How would you use part of the budget that would be freed up as a result?**

Among other things, I would use it to make the supply chains in the pharmaceutical sector safer and more resilient. In Germany, generics make up a large part of the pharmaceutical supply - the basic supply. However, these generic active ingredients often no longer come from Germany and Europe, but from China and India. Enormous, politically motivated cost pressure has ensured that usually only one or a few participants in the health insurance companies' generics tenders are awarded the contract: precisely those who offer the most favourable price. However, in terms of security of supply, even in times of crisis, it is in everyone's interest to make funds and resources available in order to strengthen resilience by making it possible again to obtain active ingredients from different sources and to diversify supply chains through adequate pricing.

**Don't you fear that the pharmaceutical industry will come under even more pressure? On the one hand, there is US President Donald Trump, who seems to be throwing around tariffs in an aleatory manner - but probably not quite - and, on the other hand, the recently appointed "Healthcare Finance Commission", which is expected to present initial proposals for measures to stabilise contribution rates from 2027 by March 2026. Who will be the first to be burdened with further special levies?**

The latter would not be the smartest decision. As a society, we have to decide at some point what we want. We have all seen in the generic sector that the cheapest solution is probably not the best, because it has led us into really massive supply problems for years. In addition, there are currently global crises such as the war in Ukraine and the Middle East conflict and, on top of that, US President Trump with his threatened tariffs on medicines. All of this is putting increasing pressure on the supply of medicines. Now we have to think about it: Do we want to continue like this? Do we also want to be completely dependent on innovations such as generics, this time not on the Asian and Indian markets, but on the American market?

**Do you recognise any positive signs that politicians are really rethinking and want a long-term strategy to secure the future of the industry instead of repeatedly plugging the financial holes of the health insurance funds in the short term?**

I do indeed see a rethink in Europe.

**You are probably thinking of the "Critical Medicines Act", or CMA for short, with which the European Commission introduced a proposed regulation in March 2025 to counter recurring drug shortages and ensure the availability and supply of critical medicines within the EU. The most important objectives include the promotion of pharmaceutical production and the necessary supply chains.**

That's right: the European Commission has recognised that we have a problem here.

**Based on the famous radio message from the Apollo 13 crew to NASA in 1970, which read: "Houston, we've had a problem" after the truly critical explosion of an oxygen tank on board the spacecraft.**

They had a life-threatening problem. And we also face the same threat, albeit in the longer term and on several levels. Firstly, there are the aforementioned generics tenders, where the focus is always on the lowest

price, regardless of where and how production takes place. It would be important here not to look at the cheapest price, but to include other factors, such as the stability of the supply chains, consideration of the production location and compliance with sustainability standards. That would be a good first step that politicians could take very quickly if they wanted to. But there would also be the realisation that it really is time to finally identify and exploit all efficiency reserves. These are not being discussed at all in the urgently needed hospital reform, for example.

**A major hospital reform worthy of the name would be able to release massive efficiency reserves in the system. Instead, there will probably be a new manufacturer discount in the short term instead of focussing much more on efficiencies through significant structural changes.**

Let's hope not. I am counting on the general understanding that short-term hole plugging is not a strategy and will lead nowhere in the long term. Incidentally, this would be a great topic for healthcare research: "What economic impact do reforms in the healthcare system have on security of supply?"

**This is a nice transition to the Innovation Fund, which tests and evaluates new models. Do you have any possible project ideas in your digital strategy that the innovation fund could support?**

I strongly fear that the fund is far too slow due to its regulatory nature to play a major role in the very fast-moving digitalisation process. It takes far too many years for a project to be set up, applied for, funded, implemented, evaluated and finalised. Real-world laboratories - regulatory sandboxes - as envisaged in the AI Regulation would make more sense here. This approach would certainly make it possible to test innovations for a limited period of time under conditions that are as real as possible. I am really curious to see whether this can be implemented in this country. I have my doubts as to whether we are fast and unbureaucratic enough.

**Which brings us to data protection.**

We shouldn't just talk about data protection, which is of course important. However, the issue of health protection is just as important. Let's think about diseases such as endometriosis. If we had the data that will be available in the future with the research dataset, we would certainly have recognised the pattern that many women suffer from unspecific symptoms but similar complaints much earlier. And many women could have been helped earlier.



**Dorothee Brakmann** *has been Managing Director of the German Pharmaceutical Industry Association since 1 April 2024. She comes from the manufacturer Jansen, where she was Head of Health Economics, Market Access and Reimbursement and was most recently commercially responsible for the Oncology/Haematology division. She was already elected to the board of the BAH (the predecessor association of PharmaD) in September 2021 and held the role of treasurer.*

*Before joining Janssen, she worked as a hospital pharmacist in the UK and for healthcare payers. There she developed pharmacoeconomic software solutions for pharmacies.*

**All the more so when AI is also used.**

If all the data available in the research data centre as a result of the Health Data Utilisation Act were to be searched for anomalies using AI, it would certainly be possible to identify rare diseases more quickly. This would have enormous benefits for all patients affected by rare diseases. Well-trained artificial intelligence in combination with a large amount of data would have great benefits and added value for society. Incidentally, this is also an interesting field for healthcare research.

**Where do you see the role of the pharmaceutical industry? We can all remember quite well that the pharmaceutical industry had to fight hard to even be a participant in both the German and European data space.**

We are at least envisaged as participants in the law. In this respect, we assume that we will have access to data. I can still see some of the old

reservations from 30 or 40 years ago, but we should finally put these aside in the interests of patients.

**Now you have mentioned health services research twice. Does your association have a healthcare research strategy?**

Recently, we have indeed been active in an area that we have already mentioned. I'm referring to the topic of personal responsibility and self-medication. Here, we have looked very closely at whether it makes sense to relieve the burden on our healthcare system through OTC switches, in which many things that are currently done in doctors' surgeries can be increasingly managed by pharmacies in future. This would strengthen pharmacies as part of a primary care system.

**Can efficiency reserves really be realised in this way?**

Of course. If only 13 of the best-selling substances were to be removed from the prescription requirement, 1.4 billion euros could be saved in health insurance expenditure. We could really think about this unutilised efficiency reserve in Germany!

**The roadmap for "reforms in the pharmacy sector" presented by Federal Health Minister Nina Warken at the 75th Pharmacists' Day in Düsseldorf in September of this year will certainly lead to a more important role for pharmacists once it comes into force, because, among other things, the competences of pharmacies are to be better utilised for the provision of care. For example, vaccination options in pharmacies are to be expanded and it will be possible to carry out rapid tests close to the patient in pharmacies.**

This would also be an important relief for the medical profession. The relief provided by the elimination of prescriptions for OTC switches and vaccinations with inactivated vaccines, which can also be carried out in pharmacies at a low threshold - because they do not require an appointment - will lead to a reduction in system costs - while maintaining the same level of quality.

***"If we had ensured earlier on that the medicines available for simpler entities were released from the prescription requirement, pharmacists would have had the tools and the corresponding influx long ago."***

**What plans do you have for the future?**

Take the package leaflets, for example, which must be included with every medicine but are not always read from start to finish - in fact, they are rarely

read. In addition, the formats are unwieldy and updates can only be made in the form of a reprint. However, the changes are not easily recognisable for patients. This could be remedied by thinking more digitally here too. For example, package leaflets could be available digitally in the health insurance companies' apps. To this end, we, the diGItal pilot project, are currently entering into cooperation with some health insurance companies. Package leaflets could also be made available via the electronic patient file. Because we also see the advantages of structured information in this area, we are politically active, as we are with the so-called electronic green prescription. This type of recommendation from the treating doctor to the patient has now been implemented. Even such small and often unnoticed steps ensure progress in digitalisation, so that in the grading from 1 to 10 that you mentioned, we can perhaps achieve a 5.

**Let's think ten years ahead. Where do you think the German healthcare system should be in terms of digitalisation?**

My vision would actually be for us to have a genuine, networked and fully digitalised healthcare system. But one thing will always remain important: Patients must retain sovereignty over their data. Data protection is hugely important for broad acceptance. However, despite all the necessary cyber security, it must be possible for every patient and - with the appropriate consent - every treating doctor or pharmacist to have access to the current status of their medication and other care. This also includes an electronic package leaflet that is as easy to understand as possible, as well as information on co-medication or nutrition. I also consider a vaccination calendar with a reminder function to be useful. If all of this is available to patients as easily as possible, they will be better able to take responsibility for their own health.

**The current coalition agreement calls for the introduction of a nationwide and mandatory primary doctor system. But how can we achieve an interprofessional primary care system - including the involvement of nursing, pharmacies and possibly level 1i hospitals?**

The former Federal Minister of Health, Prof Dr Karl Lauterbach, tried something similar with his 1,000 health kiosks. Unfortunately, he wanted to set up a secondary structure instead of using the existing one where it still exists - that of pharmacies or care centres. We therefore think the "Pharmacy First" concept presented by the pharmacists is very smart. It envisages pharmacies becoming the first point of contact in the healthcare system to provide patients with urgently needed medication for relatively simple or chronic illnesses,

something that has long been implemented in the UK, for example. If we had ensured earlier on that the medicines available for simpler entities were released from the prescription requirement, pharmacies would have had the tools and the corresponding influx long ago. Germany simply missed this step. It is obvious that this is extremely frustrating.

**Because the medical profession is not at all happy about being released from the prescription obligation.**

This attitude dates back to a time when there were still enough practices with sufficient appointment times. Today, things are very different. On the contrary, the two professions can work together extremely well to ensure the provision of care in the future. And they must do so if they put the well-being of their patients first.

**Where the pharmacy and medical professions meet, it's always primarily about money. We have seen this all too often at our vaccination congresses.**

Nevertheless, I believe that this conflict can be defused. And it must be, because it's about the health of patients and not about maximising the size of the budget pie.

**That's what a representative of the pharmaceutical industry of all people says.**

That's right. But one that represents the interests of around 400 member companies, which in turn produce almost 80 per cent of over-the-counter medicines sold in pharmacies and almost two thirds of prescription medicines. It doesn't matter whether we're talking about steel, the automotive industry or pharmaceuticals: "Economic recovery is the best social policy". That's my opinion too. However, it wasn't me who said it, but Jens Spahn, the head of the CDU/CSU parliamentary group, who was also once the Federal Minister of Health. We need to give our important industries - and this clearly includes pharmaceuticals with around 132,000 employees - room to breathe again and thus to do business. This is the only way we will achieve the necessary upturn. This is the only way that the health insurance funds will finally get their revenues back on track.

**And we will then have to worry much less about the expenditure side.**

We have to do this anyway, because we all have to be concerned about a healthcare system that can continue to be financed in the future. Of course, this also includes adequate, but also fair pricing for all sides.

**Isn't it part of your members' business model to want to sell as many and as expensive drugs as possible?**

Above all, the pharmaceutical industry has a vested interest in ensuring that the medicines it develops and produces are taken correctly. Correct means: not too much and not too little and certainly not according to the scattergun principle. Ultimately, since the introduction of the early benefit assessment - which we cannot discuss here due to its inherent complexity - we are measured by how our medicines work in the real world of healthcare. Incidentally, this data is collected almost regularly on an annual or at least biennial basis, as there are always renegotiations. This is another reason why we in the pharmaceutical industry really care a lot about adherence and compliance.

**Are there corresponding concepts for adherence and compliance?**

There have already been many. But they will only be really successful once the electronic patient file is functional and filled with the necessary medication data. Then it will be possible to analyse very precisely whether a patient has picked up the prescribed medication and, at least depending on the pack size, obtained it again within the relevant period. Whether he or she has actually taken the medication is another matter, of course. But with this knowledge alone, the topic of adherence can be addressed much better. And in a fully digital world, if the patient cooperates, you can ensure that he or she is reminded to take their medication: via the ePA, apps or smartwatches or whatever wearable.

**Of course, this always involves respecting the patient's wishes: Anyone who doesn't want to be reminded can decide that for themselves.**

Most people will want to play an active role in their health. We should therefore move away from the paternalistic view of wanting to determine and remember everything and everyone. It would make more sense to involve many more patients in PROM and PREM projects. This would enormously enhance the role of patients, because their experiences could be taken into account more and possibly in all aspects.

**This brings us back to reality: Most real-world data that is not collected in RCT studies is not recognised at all because it will never have the same quality as data from a randomised controlled trial.**

It is of course true that only a very small proportion of such data has so far been recognised in the early benefit assessment. Nevertheless, we must continue to expand patient involvement by collecting PROM and PREM data as

consistently as possible. And, of course, we must work harder to ensure that such data is also recognised. If we fail to achieve this in the foreseeable future, the motivation of companies to collect such data will wane at some point. Yet data collected in this way is highly relevant: What really matters is what the patient really feels and how the clinical effect turns out for them and not in some cohort. That is why recognising this data as valid evidence is of the utmost importance. But I think we are actually on a very positive path, even if we are still a long way from reaching our goal.

Mrs Brakmann, thank you for talking to us. <<

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