

## **Drug shortages may compromise patient safety – Results of a survey of the reference pharmacies of the Drug Commission of German Pharmacists<sup>1</sup>**

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### **Summary**

Drug shortages can compromise patient care and adversely affect their safety, as shown by the findings of the 41st Survey of Reference Pharmacies conducted by the Drug Commission of German Pharmacists (Arzneimittelkommission der Deutschen Apotheker, AMK). However, survey findings also revealed that pharmacists in Germany go to great lengths to ensure that patients continue to receive adequate medication.

### **Methods**

The 41st AMK Survey of their Reference Pharmacies was conducted in October 2016 on the topic of drug shortages (1-3). At the time of the survey, the AMK's two nationwide networks of reference pharmacies included 865 community pharmacies and 54 hospital pharmacies.

The aim of the survey was to shed light on the current implications of drug shortages in terms of outpatient and inpatient safety from the perspective of pharmacies (4, 5). Reference pharmacies were sent an email link and asked to complete a six-question online survey. A total of 482 community pharmacies and 36 hospital pharmacies participated in the survey, meaning a response rate of 56% for community pharmacies and 67% for hospital pharmacies.

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## Results

### *Drug shortages in everyday pharmacy practice*

Nearly 90% of the community pharmacies and over 80% of the hospital pharmacies surveyed confirmed that they had experienced drug shortages at least once in the last three months which had (or could have had) health consequences for the patients. Over 20% even stated that this had happened more than 15 times during that period.

Obviously, not every drug shortage has critical implications for patient care; pharmacists were therefore initially asked about what they viewed as direct consequences of drug shortages. Possible answers included safety-related observations, such as medication errors or discontinuations (multiple answers possible); however, individual free text answers were also possible.

Typical consequences for the patients depended on whether drug shortages occurred in community or hospital pharmacies. Most pharmacists (over 50% of community pharmacies and over 60% of hospital pharmacies) admitted to having given patients inferior drugs or less suitable dosage forms as a result of shortages. While at 20% and 21%, the incidence of medication errors reported by community and hospital pharmacies, respectively, was near-identical, 39% of hospital pharmacists believed that the shortage either denied patients a life-saving treatment or at least delayed it, compared to 15% of community pharmacists. In contrast, at 26%, the rate of discontinuation reported by community pharmacies was far higher than the 6% described by hospital pharmacies. Sixty per cent of community pharmacists vs. 18% of hospital pharmacists asserted that the use of substitute drugs had adverse effects on adherence to treatment.

Differences in the incidence of life-threatening drug shortages and in patient medication adherence attributed to the use of substitutes may be explained by the characteristics of hospital and community settings. The illnesses of inpatients tend to be more serious and associated with a higher likelihood of complications. However, the hospital setting also means that the use of drug substitutes can be supervised by qualified healthcare personnel.

An increased risk of documentation errors was reported in isolated cases, as was a significant increase in the time and cost expenditure associated with obtaining medications. Some pharmacists also lamented the increase in patient anxiety associated with supply shortages, which could in some cases lead to complete loss of confidence in the supplying pharmacy despite the increased time and effort expended by pharmacists. In total, only ten pharmacies reported having observed no negative consequences.

The results clearly show that drug shortages can adversely affect patient safety. Medication errors, decreased patient compliance, or even discontinuation, or delaying of vital treatments are no longer the exception.

*Do delivery shortages equal supply shortages?*

According to the definition of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), the term “delivery shortage” refers to an interruption in the normal volume of supply lasting more than two weeks, or a significant increase in demand which cannot be adequately met (6). Any additional adjustments made to a drug treatment as a result of delivery shortages entails significant time and cost expenditures, especially for pharmacists (7). Drug substitution, usually with alternative therapeutics made by other manufacturers, requires a high level of professional expertise, interprofessional cooperation and intensive patient counselling (Table 1).

**Table 1.** Measures which pharmacies may resort to in the event of a drug shortage in partnership with prescribers; selection, based on (28)

Action step	Measure
Identify and report	Check details of shortage (duration, cause) Try alternative sources, e.g. individual import Carry out inventory and determine how long stocks will last Information and consultation with prescriber(s): Identify affected patients Determine medical need Estimate costs Check production for defects and compliance
Act and inform	Identify therapeutic alternatives: Take into account legal and contractual provisions (e.g. § 4 Framework contract pursuant to § 129 para. 2 of the SGB V ( <i>Sozialgesetzbuch V</i> [German Social Code, Book V]) as as well as pharmaceutical concerns (§ 17 para. 5 ApBetrO ( <i>Apothekenbetriebsordnung</i> [Ordinance on the Operation of a Pharmacy]) approved indications, pharmaceutical form, dosing regimen and storage Pharmacology, including mechanism of action, pharmacokinetics Use in special patient populations Use during pregnancy and breastfeeding Comparison of efficacy Comparison of drug safety Comparison of user-friendliness Definition of delivery terms  Provide users and patients with information and training on therapeutic alternatives
Support and follow-up	Evaluation of strategies for the prevention of medication errors related to the use of alternative therapeutics Development of (temporary) measures for consumption control and patient prioritisation, e.g. special requirements, quotas Adverse event reports due to treatment delays or -prioritisation, intolerances or medication errors submitted to the AMK

Things get particularly problematic when delivery shortages translate to treatment shortages. Appropriate drug treatment is compromised due to the non-availability of therapeutic alternatives. Indeed, the vast majority of community pharmacists (80%) and hospital pharmacists (90%) view up to 25% of drug shortages as treatment shortages. Fifteen per cent of community pharmacies and 6% of hospital pharmacies

estimated that the proportion of treatment shortages was even higher. Only 3% of pharmacists surveyed did not yet see adequate drug supply as under threat.

### *Countermeasures*

Drug shortages often pose major challenges for pharmacists, who resort to different measures to counteract imminent or current shortages and ensure that patients continue to receive drug treatment. This was clearly reflected by the findings of this AMK Survey of Reference Pharmacies. Pharmacists were asked to specify how often in the past three months (never, <5 times, 5-10 times, 11-15 times, >15 times) they had resorted to a selection of logistic, galenic and medical-pharmaceutical solutions listed in the survey (multiple answers possible).

Approximately half of the reference pharmacies stated that they had contacted other pharmacies (including subsidiaries) to enquire about the availability of medicines due to shortages up to 10 times in the last three months. Sixty per cent of community pharmacies and 45% of hospital pharmacies had dispensed a substitute for the originally prescribed drug (covered by a rebate contract) in the last three months more than 15 times in order to remedy a drug shortage. Forty-three per cent of community and hospital pharmacies alike consulted the prescribing physician for advice on alternative prescriptions. In addition, dispensing pharmacies tried to counteract supply shortages by preparing prescription drugs on site (“compounding”). Forty-eight per cent of hospital pharmacies, but only 17% of community pharmacies reported having prepared up to four prescriptions during the specified period.

Logistical measures play an important role for pharmacies. Nearly all community pharmacies (98.5%) stated that they had occasionally obtained drugs from pharmaceutical companies instead of their wholesaler. All hospital pharmacies also confirmed that they had made direct purchases from alternative pharmaceutical companies in order to remedy a shortage.

Approximately 90% of hospital pharmacies and 48% of community pharmacies also imported medicinal products on at least one occasion within the last three months in

accordance with § 73 (3) of the AMG (*Arzneimittelgesetz* [German Medicinal Products Act]). Nearly all community pharmacies (95%) and all hospital pharmacies stated that they had increased their stockpiles of the relevant drugs to prevent shortages at least once during the specified period.

*Pharmacies keep up to date*

In order to ensure that patients receive comprehensive counselling and appropriate care, it is essential for pharmacies to remain up-to-date on the availability of drugs and their alternatives. Pharmacies were asked to name their sources of information (multiple answers possible).

The Federal Institute for Drugs and Medical Devices (BfArM) has published reports on its website on current shortages of medicines for human use in Germany since 2013 (Table 2) (6). However, at the time of the survey, these reports relied solely on information voluntarily submitted by marketing authorization holders. The federal authority had no further information regarding the supply status of the listed drugs, and no way of verifying the accuracy of the data. In addition, the only drug shortages recorded at the time were those for which information was specifically requested by the healthcare community. These included prescription drugs predominantly used for the treatment of severe to life-threatening diseases, and for which no alternative therapeutics are available.

**Table 2.** Sources of information on drug shortages (6, 8, 9)

Website	Path
www.bfarm.de	→ Medicinal Products → Licensing → Information on Medicinal Products → Shortages
www.pei.de	→ Medicinal Products → Vaccines → Shortages
www.ema.europa.eu	→ Human regulatory → Post-authorisation → Medicine shortages

The Paul-Ehrlich Institute (PEI) issues reports on shortages of human vaccines (8). Alternative therapeutics are listed when available and otherwise, recommendations are issued by the Standing Committee on Vaccination (Ständige Impfkommission, STIKO) at the Robert Koch Institute (RKI).

More than 60% of community and hospital pharmacies use reports issued by the federal authorities (BfArM and PEI). The website of the European Medicines Agency (EMA) seems far less well-known or relevant (9). Only about 5% of community pharmacies and 15% of hospital pharmacies resort to the latter when searching for information on drug shortages. The vast majority of community pharmacists use information from pharmaceutical wholesalers (94%), pharmaceutical companies (85%), or the trade press (54%). For hospital pharmacies, information from wholesalers (24%) and the pharmaceutical trade press (33%) plays a less prominent role than that supplied by pharmaceutical companies. All hospital pharmacies stated that they obtained information on drug shortages directly from manufacturers.

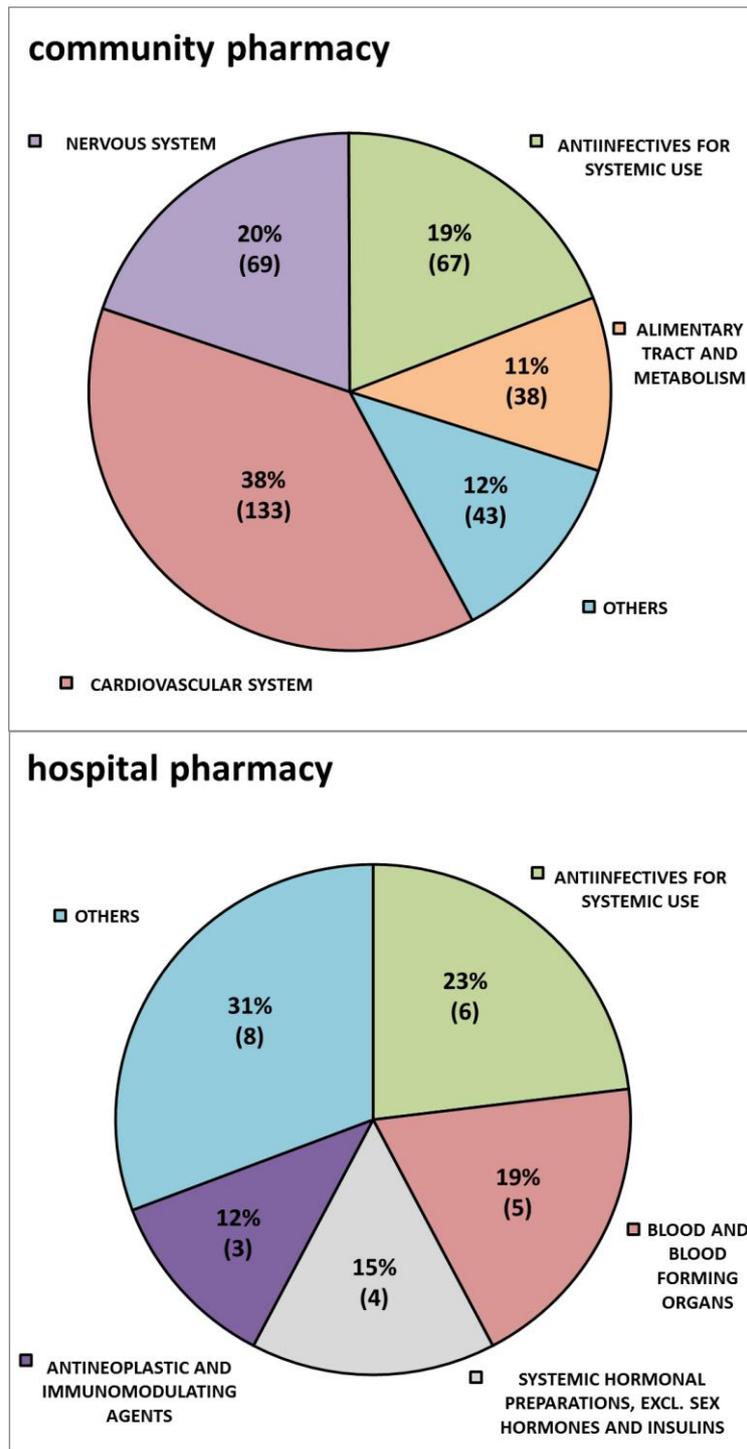
Further sources of information cited included colleagues from other pharmacies (including subsidiaries), medical sales representatives, purchasing communities, and even social media.

#### *Anti-infectives are often affected by shortages*

Pharmacies which stated that they had been affected by drug shortages in the last three months were asked to provide specific examples. Seventy-five per cent of community pharmacies and 72% of hospital pharmacies complied (Figure).

A number of drug classes are known to be prone to shortages (10). As expected, there were differences between community and hospital pharmacies in the therapeutic indications (ATC code) of the drugs concerned. Only systemic anti-infectives accounted for a significant proportion of drug shortages in both cases (11). However, drugs prone to shortages in community pharmacies were less likely to be traditional antibiotics, with human vaccines against infectious diseases accounting for 85% of the total.

**Figure.** Drugs listed as prone to supply shortages by community pharmacies (top) and hospital pharmacies (bottom) according to the 1<sup>st</sup> ATC level. Ten of the names given by community pharmacies were not taken into consideration on account of the impossibility to conclusively assign the active substance to a ATC category.



The shortages most commonly reported by community pharmacies were beta-blockers (metoprolol), with a total of 130 mentions. In addition, there were 35 reports of shortages of metamizole (dipyrone), which made it the most commonly cited analgesic, and, together with fluspirilene, quetiapine and St. John's Wort, formed the bulk of CNS active substances. Community pharmacies also mentioned 28 cases of shortages of anti-diabetic drugs, especially liraglutide, empagliflozin and dapagliflozin. Other drug classes included chemotherapy drugs such as melphalan, thyroid hormones (levothyroxine), platelet aggregation inhibitors such as ticagrelor, urological drugs (solifenacin) or drugs for obstructive airway diseases (salmeterol/fluticasone, salbutamol (albuterol), and vilanterol).

Beside systemic anti-infectives such as piperacillin/tazobactam, hospital pharmacies mainly mentioned shortages of electrolyte solutions (potassium chloride), haematological agents, chemotherapy drugs such as melphalan or oxaliplatin, and thyroid hormones (levothyroxine). Other drug classes included gynaecological drugs, neuromuscular blocking agents, opioid anaesthetics (remifentanyl), antiparasitic drugs (metronidazole) and antidotes such as 4-dimethyl-aminophenol (4-DMAP) or calcium folinate.

It cannot be said with certainty whether the above examples of supply shortages met the criteria of BfArM. As of May 2017, only six of all the active substances mentioned by pharmacies were explicitly listed in the BfArM report on current supply shortages: 4-DMAP, calcium folinate, levothyroxine, melphalan, piperacillin/tazobactam and remifentanyl. In contrast, 49 of the 57 vaccines mentioned in the survey were also listed in the current April 2017 and past drug shortage reports of the PEI.

## **Discussion**

This AMK survey shows that medication errors, treatment discontinuations or delaying of vital treatments due to drug delivery or supply shortages are far from uncommon. Survey participants thus confirmed that drug shortages can have a negative impact on patient safety (12), making it all the more important to report potential and actual risks to the AMK. The AMK records and processes each individual case report and forwards it to the competent authorities so that early action

can be taken. In the first quarter of 2017, only three cases explicitly due to supply shortages were reported to the AMK. Given the high incidence of indication- and medication errors recorded in relation to alternative therapeutics in this survey, their documentation and reports detailing their specific negative consequences for patients in terms of medication safety to the AMK remain too rare. The AMK recommends using the adverse event report forms due to the specific reference to the patient. These are online forms which can thus be submitted directly to the AMK ([www.arzneimittelkommission.de](http://www.arzneimittelkommission.de)).

The reasons for drug shortages are manifold and usually due to manufacturing problems, pricing or recalls; they can also be demand-related (13, 14). Processes such as drug development, approval, production and distribution are all subject to high quality standards. Shortages often result from quality deficiencies or (serious) industrial accidents in production facilities. Where product recalls mandated by the authorities come into play, e.g. due to deficiencies in the above-mentioned processes, it also becomes necessary to assess the potential impact of these measures on patient care. In the absence of alternative therapeutics and as long as there are no immediate risks to patients, abrupt market withdrawals should be avoided in some cases in order to prevent supply shortages (15).

Drug shortages are especially noticeable when only a few manufacturers are in charge of the global supply of the agents concerned (16). The pricing of new and older drugs is also held responsible. When early benefit assessments fail to reveal an additional benefit, marketing authorization holders have sometimes been known to take new drugs off the German market (“opt-out”). In contrast, older drugs (no longer under patent protection) are subject to constant pricing pressures. As a result, production and sales in Germany are no longer attractive for the manufacturer, which can give rise to new monopoly situations resulting from license sales worldwide. Problems with manufacturers who have a monopoly are thus quick to impact the care of patients in Germany.

We have pharmacies to thank for the fact that frequent supply shortages rarely have a significant impact on patient safety. While measures such as drug imports, direct purchase, phone calls to prescribers, compounding or larger stockpiles can ensure

drug supply for individual patients, they involve considerable time and effort (17). Higher financial costs, e.g. for individual imports or alternative therapeutics should also be taken into account.

This calls for sustainable solutions, particularly to relieve pharmacies. In order to prevent drug shortages and ensure a consistent supply of medicines in Germany, current measures should be expanded and adapted, and controls integrated into the processes involved. This requires the cooperation of the full spectrum of professionals, institutions, organisations and agencies involved in the healthcare system both at the national and international levels (18).

On the occasion of the German Pharma Dialogue, it was therefore agreed to dedicate a “Jour Fixe” (regular meeting) to drug delivery and supply shortages attended by the federal authorities and healthcare professionals, with the participation of the AMK on behalf of pharmacists (19). This “Jour Fixe” has been monitoring and assessing the supply situation in Germany since the third quarter of 2016.

A list of relevant drugs potentially sensitive to shortages would be helpful in ensuring their specific and continued supply. These include prescription drugs or drug combinations whose supply is relevant to the entire population (usually no orphan drugs), as well as active substances at high risk of shortage. The latter are supply-relevant medicinal products for which only one marketing authorization holder, only one manufacturer with final clearance or only one active substance manufacturer is available (20). In the future, drugs at high risk of shortage will be subject to particularly close regulatory monitoring.

The current lists of supply-relevant active substances and those at high risk of shortage have been available on the homepage of the BfArM website since early May 2017, marking the first time that the recommendations of the “Jour Fixe” on delivery and supply shortages were implemented (21). Both lists are subject to monitoring, regular updates and further development by the Federal Authorities with respect to the supply situation in Germany. Improvements in the framework conditions for the deliverability of currently very inexpensive drugs, especially

antibiotics will be considered during price-fixing negotiations, although the relevant criteria are still being drawn up (22).

### *New reporting obligations*

The AMK is not alone in viewing the current system, whereby shortage reports by the pharmaceutical industry are voluntary, as a failure. This system must be supplemented by mandatory reporting obligations, as confirmed by the outcomes of the survey. Pursuant to the Care Provision Strengthening Act (Arzneimittelversorgungsstärkungsgesetz, AMVSG), in future, both federal authorities will be given the opportunity to request information on sales and prescription volumes straight from pharmaceutical manufacturers (23). Hospital pharmacies will be able to order appropriate quantities of imported drugs in order to improve acute patient care. Pharmaceutical companies are required to inform hospitals as soon as they become aware of shortages of prescription drugs intended for inpatient care (commitment to report pursuant to § 52b No. 3a of the AMG).

Since early May 2017 and regardless of mandatory drug shortage reporting in hospitals, as recommended by the “Jour Fixe”, the BfArM now requires marketing authorization holders to report supply shortages involving active substances whose supply has been subject to shortages in the past. This obligation likewise applies to supply-relevant drugs for which three or fewer marketing authorization holders, manufacturers with final clearance or active substance manufacturers are registered in the German Federal Drug Information system. Holders of marketing authorisations for unlisted active substances are asked to report shortages to BfArM from a 25% market share (24).

The extent to which the new reporting requirements will achieve timely reporting of delivery and supply shortages or even prevent them remains to be seen. While the AMK welcomes the obligation to report, it also encourages the prompt, comprehensive and transparent notification of community pharmacies with regard to foreseeable short- and longer-term supply shortages (25). The AMK has already included information on developments and regulatory measures on selected drug shortages under the headings “Information from institutions and authorities” and

“Information from manufacturers”. Pharmacies can receive this information directly by subscribing to an RSS feed (26, 27).

### **Limitations**

The results of the 41st Survey of Reference Pharmacies conducted by the AMK provides important insights into the manner in which drug shortages were being handled by German pharmacies at the time of the survey. However, the response rates of 56% and 67% increase the possible risk of bias, here: Overestimation of the relevance of drug shortages to patient safety. Some answers such as the estimated number of supply shortages may be subject to distortion, as they were mostly based on subjective impressions. Therefore, scientific caution is advised when interpreting the results.

The AMK network of reference pharmacies comprises, however, a large number of pharmacies of various sizes (in terms of both staff and turnover) and geographical locations (urban, rural, peripheral and border regions). In addition, compared to other surveys of this kind, the response rate and the number of participating pharmacies were high (482 community pharmacies and 36 hospital pharmacies) (12).

### **Conclusions**

This study is the first to provide robust and comprehensive figures on the effects of potential supply disruptions from German pharmacies. The AMK survey showed that pharmacists in Germany are aware of their responsibilities and dedicate a great deal of time and effort to preventing drug shortages and ensuring patient safety. /

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