

Recommendations of the *Jour Fixe on Delivery and Supply Shortages* for drafting contracts between operators of hospital pharmacies / pharmacies supplying hospitals¹ and pharmaceutical companies with the aim of improving the delivery excellence of relevant medicinal products in hospitals

A reliable and continuous supply of sufficient quantities of medicinal products to hospitals is an essential prerequisite for ensuring the supply of medicinal products to patients.

Medicinal products in hospitals are usually supplied within the framework of contracts with pharmaceutical companies. These recommendations present options as to how the robustness of the supply of medicinal products to hospitals can be considered when drawing up contracts between pharmaceutical companies and pharmacy operators.

In the pharmaceutical market for generics, the production of active ingredients is concentrated on a few manufacturers. Loss of production at these active ingredient manufacturers can result in delivery or supply shortages for medicinal products. Delivery or supply shortages for medicinal products mean increased expenses for hospitals. The consequences are that hospitals have to assign personnel to "supply shortages management" and, if necessary, switch to more expensive or less suitable alternative preparations.

Both pharmacy operators and pharmaceutical entrepreneurs can contribute to the improvement in the supply of medicinal products by agreeing upon suitable contractual conditions. This includes, among other things, reliable purchase forecasts and pricing, taking into account the guaranteed supply capability of the products, transparency with regard to production conditions and storage capacities as well as binding commitments, e.g. for production and stockpiling.

Affected products:

The necessity of a medicinal product's availability increases with the importance of that medicinal product for patients' wellbeing. Medicinal products are particularly important for the provision of care if no therapeutic alternatives are available or if such alternatives can only be obtained at great expense.

Clinically relevant supply shortages occur predominantly in the case of anti-infective and antineoplastic medicinal products, especially those for parenteral use.

The following criteria for identifying supply-relevant medicinal products form the basis of these considerations:

- There is currently no equivalent alternative for the medicinal product.
- In the event of unavailability of the medicinal product, the prognosis of the patients affected worsens.
- The medicinal product must be taken within a short period of time (within 24 hours).
- The medicinal product is recommended in current guidelines of the professional associations or it corresponds to the current therapeutic standard.

¹ hereinafter referred to as pharmacy operator

Contract duration:

The duration of the contract is a decisive element for planning security. The shorter the terms of a contract, the more susceptible is the supply system for active ingredients and thus for medicinal products.

Contracts should therefore have a duration of at least 12 months with a lead time of at least 6 months.

Robustness of delivery capability:

The assurance of supply capability should be plausibly demonstrated by the pharmaceutical entrepreneur during the contract negotiations (e.g. by disclosing manufacturers of intermediates and active ingredients) and taken into account during the design of offers in order to offer pharmacy operators an objective basis for decision-making.

The most frequent causes of supply shortages are quality defects in manufacturing and problems in production (loss of production, inadequate production capacities, production and delivery delays for raw materials, limited availability of the active substance or production stoppages for medicinal products).

Therefore, the contract negotiations should include the agreement of conditions that ensure the provision of care.

The following requirements should be considered when designing a contract for supply-relevant medicinal products as they represent an essential contribution to ensuring supply security:

1. contractually agreed and correspondingly remunerated additional stockholding for the contractual partner on the part of the pharmaceutical companies for the short-term improvement of supply security,
2. parallel and correspondingly remunerated use of several production lines by the pharmaceutical entrepreneur, including the active ingredient and intermediate sources, with the possibility of compensating for fluctuations in individual production lines,
3. for medicinal products that are produced intermittently, a reliable proof that and how fluctuations in demand are cushioned,
4. if there is a high demand for the medicine, pharmacy operators should conclude contracts with several marketing authorization holders, who in turn obtain their intermediates and active ingredients from different sources,
5. in order to provide pharmacy operators with a secure basis for their decisions the pharmaceutical entrepreneur should supply proof of the ability to supply the medicinal product/the active ingredient when designing the offer. Pharmacy operators are thus given the opportunity to select contract offers with a demonstrably higher supply security,

6. additional costs arising from the establishment of more robust supply chains, which are documented accordingly by the pharmaceutical entrepreneur, should be adequately taken into account in pricing and contract terms,

7. volumes will be accepted in accordance with the contractual agreement.

Both the acceptance and the criteria of these recommendations are regularly reviewed in the *Jour Fixe on Delivery and Supply Shortages* to determine whether they contribute to an improvement of the situation or whether they should be adapted if necessary.

The *Jour Fixe on Delivery and Supply Shortages* was established as a result of the 2016 Pharma Dialogue. The purpose of this *Jour Fixe* is to monitor and evaluate the supply situation. Further information on the work of the *Jour Fixe* can be found on the homepage of the Federal Institute for Drugs and Medical Devices (BfArM) at www.bfarm.de/lieferengpaesse