

Role of the Paul-Ehrlich-Institut in Vaccine Supply Shortages

A supply shortage exists when a manufacturer does not have sufficient supplies to deliver orders for more than two weeks or cannot meet an unexpected increase in demand with increased delivery quantities.

The Paul-Ehrlich-Institut provides information about which human vaccine products or packaging sizes are not available or not available in sufficient quantities for delivery from the manufacturer and how long the supply shortage could potentially last.

Publication of instructions for action and vaccine alternatives

Receipt of notifications and categorisation of supply shortages

Communication with manufacturers, BMG, RKI, EMA office

Vials (source: Momentum studio/shutterstock.com)

3 Categories of Supply Shortages and Corresponding Measures

Category 1

Shortage: individual packaging sizes not available, one or more other packaging sizes available

Publication of information on missing or available packaging

Category 2

Product supply shortage affects all packaging sizes
Equivalent alternative vaccine product is available

Publication of the reported supply shortages of affected human vaccine products
plus:
List of alternative vaccine products

Category 3

Product supply shortage: Alternative vaccine product is not available
Supply shortage concerns one vaccine product and all equivalent alternative vaccine products

Publication of the reported supply shortages of affected human vaccine products
plus:
Link to recommendations for action by RKI/STIKO: e.g. prioritisation of a risk group with regard to a specific vaccination and additional flexibility of vaccination intervals

Countering Supply Shortages Through Redistribution

In the event of supply shortages, the Paul-Ehrlich-Institut enables manufacturers in individual cases to make vaccine products from other regions of the EU or the world available on the German market in order to meet demand.



Preventing Supply Shortages Through Planning

As an example of vaccine planning, reports on the demand for seasonal influenza vaccines are submitted to the Paul-Ehrlich-Institut by the German National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) and the leading organisation of pharmacists, which was formed for the protection of economic interests.

The Paul-Ehrlich-Institut assesses the reported demand by comparing the expected orders from pharmacies and medical practices with the delivery quantities of seasonal influenza vaccines planned by the marketing authorisation holders, taking into account an additional reserve of 10 percent. **The Institute reports any increase or decrease in demand to the marketing authorisation holders, who adjust their delivery schedule accordingly.**