

Novartis Position on Security of Supply

Novartis has a mission to prevent shortages and supply the market in order to satisfy all patients with timely access to high quality medicines. To fulfill this mission, we keep our commitment to our global, strong and resilient supply chain.

A harmonized definition of a shortage as a cornerstone for the security of supply

To fulfill our commitment and deliver on time high quality medicines, we at Novartis believe in the central role of the patient. Therefore, a harmonized definition of a shortage within the European Union that takes into account the **patient's need at national level** is key. An **increase in transparency of the correct data** combined with **regulatory flexibility** can and should enhance allocation of the products, securing the supply for a larger patient population.

A risk-based approach focusing on shortage of critical products

Novartis supports the differentiation between non-critical and **critical products** in the supply chain. Critical products have a high risk of shortage and/or are products where shortage has a high potential negative impact for patients. The **qualification** of critical products should be done **based on clear and harmonized criteria defined by the EU. No additional amendments by national competent authorities** should be allowed in order to avoid additional complexity and ensure operational excellence in the supply chain.

We believe that qualification of critical products is **the responsibility of the marketing authorization holder**. At Novartis, we have a chain of mitigation processes in place, starting at manufacturing site level where industrial best practices is guaranteed through our supply chain excellence model. Besides this process, we have our business continuity management and on top of that we have also specific **supply risk management strategies** covering the entire supply chain adjusted to our critical products. This consecutive sequence of complex processes illustrates our commitment to our mission of delivering medicines and treatments on time with high quality to patients worldwide.

Safety stocks for critical products

Novartis acknowledges the importance of **safety stocks for critical products** as a preventive action against shortages. Due to evident reasons, products as immunotherapeutics and personalized medicines should be kept out of scope.

We believe the safety stocks for critical products should be **managed at EU level**, where a distinction is made between what needs to be available in the companies' supply chain cycle and what needs to constitute a potential strategic reserve owned by the authorities.

The management at EU level should imply **no additional requirements by national authorities on the EU criteria**. The proliferation of national requirements can have a very harmful impact on the availability of medicines for patients in other countries. **Regulatory flexibility** is therefore needed to allocate supplies to the countries that need medicine to prevent or reduce shortages.

Maintain resilient global supply chains

To secure the supply of medicines to our patients, resilient supply chains are a prerequisite. As a global company, Novartis has a global supply chain which has a **lower dependency on one specific country or continent**. A lower dependency acts as an additional **resilience** factor, allowing Novartis to maintain production and timely supply of high quality medicines to our patients regardless of localized issues and conflicts.