

Global Position Statement on Drug Shortages

Key Takeaway Messages

- BMS is committed to minimizing the impact of drug shortages on patients and supports ongoing and balanced discussions with regulatory authorities and policymakers to address both anticipated and unanticipated drug shortfalls. To help ensure that patients have access to the medicines they need, BMS invests systematically in policies and processes to reduce the risk of product shortages. Since drug shortages usually result from complex interactions among many stakeholders, we believe careful consideration should be given to new regulations in this area to ensure a balanced and appropriate approach.
- BMS is committed to timely notification of drug shortfalls and working with regulatory authorities to maintain treatment options and limit shortages. In deciding what should be reported, we believe balance needs to be achieved in terms of an appropriate notification process. We support the appropriate use of national data repositories for monitoring inventory levels and identifying potential and actual shortages, as understanding the root cause of shortages is critical to addressing them.
- BMS supports efforts by regulatory authorities to look for ways to help reduce drug shortages by expediting re-inspections of plants, shortening the process for approving modified product specifications that can address shortage issues, and working through various raw material issues that could impact the industry.
- BMS encourages governments and payers to ensure appropriate reimbursement for essential medicines. This includes supporting market stability and sustainability, and implementing predictable and sustainable reimbursement and demand estimation policies that facilitate production planning. This also includes implementing tendering regulations that avoid extreme single-winner, price-only situations that create supply risk in the medium-term.

Bristol Myers Squibb Position

A drug shortage occurs when the demand or projected demand for a medicine exceeds the supply of the medicine at the national level.

- Product shortages present a serious concern for patients—and the potential clinical and economic effects may be substantial. The impact of a drug shortage may include inferior or delayed treatment, higher costs to purchase products from the non-legitimate drug supply chains (e.g., the “gray market”), prolonged hospitalization due to lack of a recommended treatment, or delays in clinical trials.

BMS is committed to minimizing the impact of drug shortages on patients.

- We support ongoing and balanced discussions with regulatory authorities and policymakers to address both anticipated and unanticipated drug shortages.
- BMS continues to engage with our peer companies and regulatory partners on issues related to drug shortages and the supply chain.
- BMS is committed to **timely notification of drug shortfalls** and working with regulatory authorities to maintain treatment options and limit shortages. In deciding what should be reported, we believe balance needs to be achieved in terms of an appropriate notification process. We support the appropriate use of national data repositories for monitoring inventory levels and identifying potential and actual shortages, as understanding the root cause of shortages is critical to addressing them.
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- BMS encourages governments and payers to **ensure appropriate reimbursement for essential medicines**. This includes supporting market stability and sustainability, and implementing predictable and sustainable reimbursement and demand estimation policies that facilitate production planning. This also includes implementing tendering regulations that avoid extreme single-winner, price-only situations that create supply risk in the medium-term.

To help ensure that patients have access to the medicines they need, BMS invests systematically in internal policies and processes to reduce the risk of product shortages.

- BMS is committed to systematic investment to reduce the chance of product shortages.
 - This includes investing in good manufacturing practices and quality manufacturing; procedures and processes to continually monitor the inventory status of our products; business continuity planning to identify and mitigate potential manufacturing interruptions; and notifying regulatory authorities of a potential disruption in supply.
 - BMS also vets and seeks to work with reputable supply chain partners who are committed to quality operations and processes.
 - Open trade and globally integrated and diversified supply chains are a strong guarantee against shortages, in addition to other precautionary measures as outlined here.
- BMS has risk management systems in place that enable ongoing identification, assessment, and prioritization of the major risks associated with product shortages. This includes a significant focus on resiliency in global supply chains to ensure a continuous supply of brand medicines to meet patient needs. Furthermore, BMS is committed to diversified supply chain partners to ensure continuous supply and redundancies.

Since drug shortages usually result from complex interactions among many stakeholders, we believe careful consideration should be given to new regulations in this area to ensure a balanced approach.

- BMS believes that the causes of drug shortages are complex and multi-factorial. Regulatory solutions must be proportionate and aligned with the root causes of the shortage. For example, BMS believes extending the expiration date of a drug if a manufacturer has data to support safely doing so may help mitigate the risk associated with drug shortages.
- **While BMS manages inventory levels to minimize the risk of drug shortages, BMS does not support mandatory minimum inventory levels** as this limits our ability to optimize our supply chain operations to keep costs low and enable access for patients.
- We encourage governments to cascade adequate information to stakeholders about shortages in a manner that allows for preparation but discourages unnecessary mandatory stockpiling that can aggravate a situation of limited supply. Emergency intervention from governments should be the last resort.
- BMS believes careful consideration should be given to any new regulations in this area to ensure a balanced approach to addressing drug shortages for all stakeholders involved. Drug shortages usually result from complex interactions among many stakeholders involved in the supply, manufacture, and delivery of medicines to patients, including global regulatory authorities and healthcare providers.
- In keeping with our goal of helping to ensure that patients have access to the medicines they need, we are committed to continuing to actively engage and coordinate with industry associations, regulators, advocacy organizations, legislators, and policymakers to develop constructive recommendations that address the drug shortage issue in the most effective and efficient way possible for all concerned.