

## Global Position Statement on Counterfeit Medicines

### Key Takeaway Messages

- Counterfeit medicines are produced and sold with the intent to deceptively represent their origin, effectiveness or authenticity – a serious global health issue. Counterfeit healthcare products place people at risk of adverse events, which include serious health problems and potentially death.
- At BMS, we aim to protect those who use our products by maintaining our products’ integrity, and we believe the trade in counterfeit healthcare products should be eliminated. BMS remains highly committed to preserving product integrity and patient safety as part of our mission to help patients prevail over serious diseases. Counterfeit drugs, theft and diversion represent serious threats to patients and can interfere with our ability to provide customers with effective and high-quality products.
- BMS believes that only a multi-faceted and multi-stakeholder approach can effectively combat counterfeit and falsified medicines and protect patients. This includes governments passing laws, law enforcement agencies applying them, all actors in the supply chain working hard to ensure its integrity, consumers sourcing medicines from the approved channels and the public generally being aware of the risks.
- BMS has a role to play in ensuring the integrity of its supply chain and providing effective mitigation against its being penetrated by falsified medicines. To that end, BMS employs a number of tools such as unique packaging features and serialization, as well as proactive monitoring and the professional investigation of incidents. All of these efforts are managed in a way that supports and exchanges information with regulatory agencies, law enforcement and the public. Moreover, these efforts are constantly being reviewed and improved to take advantage of innovative practices and to address the increasing complexity of the threat.

### Background

Counterfeit medicines—products designed, dressed, branded, and/or packaged in a manner intended to be indistinguishable from that of the genuine original and not manufactured and/or distributed with the authorization of the legal brand owner—are a serious threat to global health.

Counterfeit healthcare products are designed, dressed, branded, and/or packaged in a manner intended to be indistinguishable from that of the genuine original product, and they are not manufactured and/or distributed with the authorization of the legal brand owner. They are sold with the intent to deceptively represent their origin, effectiveness or authenticity. These counterfeit products pose serious patient and consumer safety risks and are a global health issue. Counterfeit healthcare products place people at risk of adverse events, which include serious health problems and potentially death. At BMS, we aim to protect our patient and consumer population by maintaining product integrity, and we believe the trade in counterfeit healthcare products should be eliminated.

### Bristol Myers Squibb Position

- Bristol Myers Squibb (BMS) remains steadfast in our efforts to preserve product integrity and patient safety as part of our mission to help patients prevail against serious diseases. Counterfeit drugs, theft and diversion represent serious threats to patients and our ability to provide customers with effective and high-quality products. BMS is committed to preventing the associated harm of counterfeit products through the following:
  - Implementing product and packaging security measures that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering.

- Improving controls in our supply chain—from sourcing of ingredients and manufacturing through distribution—to help minimize the risk of counterfeit products entering the system.
- Monitoring markets and investigating counterfeiting activities.
- Working with regulatory and law enforcement authorities worldwide to remove counterfeits from the market and support the prosecution of the criminals involved in their manufacture and supply.
- Coordinate with governments and regulators to identify opportunities to strengthen laws and enforcement efforts to ensure the integrity of distribution channels.
- In tandem with support given to the public sector, BMS shares information and collaborates with other pharmaceutical companies and supply chain actors. This is often done under the auspices of the Pharmaceutical Security Institute, a not-for-profit institution that BMS currently chairs. BMS is also an active participant in public/private sector awareness initiatives such as the ‘Fight the Fakes’ program and the Partnership for Safe Medicines.
- BMS believes that only a multi-faceted and multi-stakeholder approach can effectively combat counterfeit and falsified medicines and protect patients. This includes governments passing laws, law enforcement agencies applying them, all actors in the supply chain working hard to ensure its integrity, consumers sourcing medicines from the approved channels and the public generally being aware of the risks.
- Industry, and therefore BMS, has a role to play in ensuring the integrity of the pharmaceutical supply chain and providing effective mitigation against its being penetrated by falsified medicines. To that end, BMS employs a number of tools such as unique packaging features and serialization, as well as proactive monitoring and the professional investigation of incidents. All of these efforts are managed in a way that supports and exchanges information with regulatory agencies, law enforcement and the public. Moreover, these efforts are constantly being reviewed and improved to take advantage of innovative practices and to address the increasing complexity of the threat.
- BMS believes that it is critical that serialization systems be implemented in a stepwise, scalable manner, in realistic timelines and with suitable consultation with stakeholders.