Since 2009, we have invested in a rigorous, intelligence-led anti-counterfeiting strategy. The program today is recognized as an industry-leading effort.

Producing, distributing, marketing and/or selling counterfeit pharmaceutical products are serious criminal offenses, and the threat of these actions has become a real and significant risk to global public health. Counterfeit pharmaceuticals can include the wrong doses of an active ingredient, no active ingredient or, in some cases, harmful or poisonous ingredients.

We define a counterfeit medicine as a product that exhibits an unauthorized use of trademark, trade name, other identifying mark, imprint or device, or any likeness thereof, to adulterate, falsely purport or falsely represent a product's or material's identity, source or history. As counterfeiters have become more sophisticated, counterfeit products have become so similar in appearance to authentic products that, without laboratory testing, it is often difficult to tell the authentic from the counterfeit medicines.

The threat to patient safety from counterfeit medicines is not specific to our company. Consequently, we work with industry peers and proactively share anti-counterfeiting intelligence with other pharmaceutical companies as a way of protecting the public and raising awareness.

**COMMITMENTS**

- Continue in the execution of a proactive, worldwide corporate anti-counterfeiting strategy focused on securing the supply chain, detecting and responding to counterfeit events, and raising awareness of the risks of counterfeit pharmaceutical products
- Take proactive measures to identify, assess and mitigate threats to our patients associated with counterfeit and other fraudulent products
- Take actions to raise public awareness of the risks posed by counterfeiters and advocate for increased enforcement to shape relevant regulatory requirements
- Train key stakeholders and business partners in the identification of suspicious activities and/or suspected counterfeit products
- Continue to partner with industry groups to provide advocacy on high-priority anti-counterfeiting policy initiatives, and explore new partnership opportunities with patients and other external stakeholders
- Develop metrics to gauge the impact of specific actions to ensure that resources remain focused on the areas that can have the greatest benefit
- Continue advocacy efforts to support the development of a standardized system to identify and code medical products, following the passage of the Drug Quality and Security Act (DQSA) in the U.S.
- Develop data analytics and intelligence management capabilities to enhance threat detection and mitigation activities associated with counterfeit and other illicit events, including increased levels of intelligence-sharing within the Pharmaceutical Security Institute (PSI) and other public and private partnerships
- Comply with all DQSA reporting requirements and associated actions regarding suspect and illegitimate products impacting the U.S. patient population, as set forth in the regulation

ANTI-COUNTERFEITING STRATEGY

Ensuring product efficacy and patient safety and protecting our reputation are paramount. We maintain a comprehensive, worldwide anti-counterfeiting strategy and operational program that has three primary strategic deliverables:

- **Product & Supply Chain Security**: Enable product protection through the use of sophisticated product-security features and supply chain security measures.
- **Investigations & Enforcement**: Deter, detect and respond to suspected and/or confirmed counterfeit activity in ways that mitigate risks to patient safety.
- **Advocacy, Engagement & Awareness**: Raise public and stakeholder awareness of the risks posed by counterfeits, and advocate for increased enforcement to shape relevant regulatory requirements.

To focus our work in this area, our Anti-Counterfeiting Steering Committee oversees our global anti-counterfeiting strategy to ensure that our goals are reached.

The cross-functional team is led by senior leaders from Global Human Health, Quality, Manufacturing, and Global Security. These areas are responsible for marketing and selling our products worldwide, investigating suspected counterfeit events, testing suspected counterfeit products, implementing innovative security measures, and preparing investigative reports.

Other functional areas involved in our anti-counterfeiting efforts include Legal, which manages trademarks and other forms of intellectual property and provides Global Security with information necessary to assist law enforcement and regulators in enforcement efforts; Global Public Policy, which coordinates our advocacy activities to support stronger anti-counterfeiting laws; and Compliance, which liaises with federal regulators in relation to the management of controlled substances.

ANTI-COUNTERFEITING OPERATIONS

In keeping with our long-standing commitment to providing high-quality, safe and effective medicines and vaccines to patients who need them, we have executed a comprehensive Anti-Counterfeiting Operations Program that delivers on our three primary strategic deliverables.

**Product & Supply Chain Security**

We carefully manage our supply chain through strict policies and procedures designed to keep the legitimate drug distribution system safe and secure. In the U.S., for example, we require customers to purchase our products directly from our company or from distributors authorized by our company. In addition, we publish the names of authorized distributors on our corporate website. We conduct risk-based audits of our distributors to ensure compliance with our policies and procedures. Proactive threat assessments are also completed for facilities and supply routes identified to be at risk of cargo thefts and other illicit activity.

Product-security features deployed on our products are a key measure taken to protect patients who use our products. Our pharmaceutical products are protected with best-in-class product-security features, uniquely applied on the basis of a global, risk-based assessment methodology. Our key focus in this assessment is the patient-safety threat should a counterfeit or illegally diverted product of our company be introduced into the supply chain.

Each of our new medicines and vaccines is assessed for risk using this methodology prior to regulatory approval. The risk level assigned to a new product is used to determine which product-security features will be included on the product and packaging prior to the product’s market release. A complementary threat assessment is also performed on marketed products for which a credible counterfeit threat has been identified and for which updates to packaging security features may be required.

These product-security features, along with our advanced forensic detection capabilities, enable us to accurately
authenticate all finished products in our portfolio.

Serialization—or putting a unique identification number on each package that goes to market—is one of the tools we are investing in to secure our supply chain and prevent counterfeiting. A serial number on individual packages enables anyone along the supply chain—from a distributor to a pharmacist to a patient—to scan the code and authenticate it as a genuine product of our company.

Serialization adds a robust layer to the company’s product-security platform. It provides the ability to uniquely identify and rapidly authenticate individual packs. When associated with a regulatory mandate that specifies effective implementation, this method of product tracking can become a more meaningful product-security tool.

Many jurisdictions around the world are requiring serialization on pharmaceutical packages or are considering such mandates. Serialization is required today in China, Turkey, Argentina, South Korea, Nigeria and India, and will soon be required in Saudi Arabia, Brazil, the U.S. and Europe. Unfortunately, each country’s regulations are different, making it very challenging for our packaging sites and distribution networks to meet these diverse and complex requirements.

We responded by launching the Global Product Serialization Initiative in 2012, with the goal of meeting these varying requirements in a robust, standardized and effective way. We are working with industry associations and regulatory authorities to help shape these new requirements, and advocate for simple, standardized and common-sense regulations that can be effective at protecting against counterfeit medicines.

**Investigation & Enforcement**

Our company’s anti-counterfeiting operations are driven by intelligence-led decisions to identify, prioritize and aggressively pursue criminal enterprises responsible for the manufacture and distribution of counterfeit and other illicit medications, and to identify and enable meaningful enforcement actions against those offenders.

We respond to every notification of suspected counterfeit or illicit medicine, in alignment with local regulatory requirements and in support of our global patient-safety mission. We also proactively conduct threat assessments and other risk-based operations to identify offenses that threaten the health and safety of patients. These proactive activities are intended to identify, assess and develop effective enforcement actions for high-value targets engaged in illegal activities involving our products that have the potential for negative patient-safety impact.

In 2015, the biggest risks to patient safety involved counterfeit versions of our company’s products sold in multiple countries, some involving the legitimate supply chain. Several incidents of both inter-market and intra-market diversion of our pharmaceutical products, and multiple cargo thefts and product thefts from MSD or third-party facilities, are also a concern.

Global Security addressed 673 events in 60 countries in 2015 involving counterfeiting, diversion, product theft/loss (including cargo theft), tampering and brand security (non-company, unapproved generic products), which led to 228 arrests and the seizure of more than 500,000 dosages of counterfeit products.

Another key aspect of investigations is the forensic analysis of suspect products. This forensic testing is aimed at concluding whether a suspect product is counterfeit, diverted, or otherwise illicit. Counterfeit products are characterized in order to gain further intelligence and understanding of the counterfeiters and the threats to public health. Our company also has forensic detection devices in the field to analyze and detect counterfeits in regions around the world. As counterfeiters improve their skills and techniques, our forensic scientists have pioneered the use of several analytical tools for pharmaceutical-counterfeits detection, and continue to explore new analytical tools that would increase their forensic-testing capabilities. Lab findings are shared with regulatory and/or law enforcement agencies, and may be used to support subsequent enforcement actions and legal proceedings. There were 1,022 unique suspect samples received as evidence and prepared for forensic testing in relation to active events in 2015.

To support and enable enforcement actions, we partner with law enforcement agencies to detect and respond to threats from counterfeit products. This includes working with U.S. authorities on the importation of counterfeit pharmaceuticals and with EU authorities on the importation and/or transshipment of counterfeit pharmaceuticals through the EU. Working with customs authorities, we have helped identify high-risk ports, borders and postal depots, and have provided a framework of action for use by customs authorities to detect and respond to counterfeit activities. This training enables customs agents to identify suspicious pharmaceutical shipments and take appropriate actions to detain suspicious shipments and/or have suspect products analyzed.

**Advocacy, Engagement & Awareness**
We are committed to cooperating with relevant government agencies, other pharmaceutical manufacturers, wholesalers, distributors, health professionals, consumer groups and key related organizations in fighting the problem of counterfeit pharmaceutical products and in educating the public about the risks of counterfeit products and how to protect against them.

This effort includes a multi-pronged approach to communicating the threat that counterfeit medicines pose and to mitigating this threat as effectively as possible, while recognizing that it cannot be entirely eliminated.

Collaboration and information-sharing in order to raise public and stakeholder awareness of the issue and risks are a crucial focus of our anti-counterfeiting program. Through active partnerships with other pharmaceutical companies, and with organizations focused on security, patient safety and public health, we provide effective advocacy on high-priority anti-counterfeiting policy initiatives.

Highlights of our 2015 activities include:

- We assisted in the creation of an Asia-Pacific Economic Cooperation (APEC) Online Pharmacy Best Practices Toolkit and Internet Pharmacy Survey for APEC health regulators and law enforcement, educating and engaging 19 APEC economies in the process.
- In the U.S., we established strong relationships with key U.S. Government officials such as the U.S.T.R., U.S. Intellectual Property Enforcement Coordinator (IPEC) in an effort to promote intra- and intergovernmental action.
- We contributed to an educational campaign that reached more than 70 million consumers in 2015, including coverage by major media outlets and scientific journals.
- We supported independent academic research on how Twitter is being used by illegal online drug sellers to peddle drugs of abuse.
- Our Global Security staff trained more than 4,300 law enforcement and customs officials worldwide.

In keeping with our mission to protect global public health, we actively collaborate with international law enforcement agencies that prioritize the investigation, prosecution and disruption of counterfeit medicines and associated criminal enterprises.

We further support efforts to educate the public about the risks of counterfeit drugs and how to protect against them, as well as efforts to develop industry collaborations to support a unified response to the threat of counterfeit medicines. We have deep partnerships and/or leadership positions with the following organizations:

- Pharmaceutical Security Institute (PSI)
- Alliance for Safe Online Pharmacies—Global (ASOP Global)
- International Anti-Counterfeiting Coalition (IACC)
- International Trademark Association Anti-Counterfeiting Committee (INTA ACC)
- International Federation of Pharmaceutical Manufacturer (IFPMA) Fight the Fakes partnership
- US Chamber of Commerce’s Global Intellectual Property Center (GIPC)
- Partnership for Safe Medicines (PSM)
- Quality Brands Protection Committee of China Association of Enterprises with Foreign Investment (QBPC)
- Rx360 Consortium.

These collaborative efforts support the production of reports, white papers and data-circulation initiatives, as well as promoting the intelligence-sharing necessary to combat threats from counterfeit medicines.

**PUBLIC POLICY**

We support the increased enforcement of existing anti-counterfeiting laws and the adoption of new public policies to strengthen existing laws and enforcement programs,
including increased criminal and civil penalties for counterfeiters.

We advocate for such change in a number of ways:

- As a member of the Alliance for Safe Online Pharmacies – Global and ASOP-EU we support initiatives and advocacy in the U.S., Europe and Asia to raise awareness about the dangers of illegal online drug sellers and to steer patients to safe sources of medicines.
- As a member of the Global Intellectual Property Center, we support the White House’s Intellectual Property Enforcement Coordinator as well as policy matters related to anti-counterfeiting and enforcement on the Hill and with Federal Agencies.
- As a member of the Pharmaceutical Distribution Security Alliance (PDSA), our company supported the passage of the Drug Quality and Security Act (DQSA), U.S. legislation that creates a national system and uniform standards for tracking products across the pharmaceutical supply chain. PDSA includes over 20 partners in the domestic pharmaceutical distribution supply chain working to achieve a national solution toward product tracking.
- We support the Anti-Counterfeiting Trade Agreement, which increases protection against a wide range of intellectual property infringements.
- In 1997, our company and other pharmaceutical companies created the Pharmaceutical Security Institute (PSI) to develop global security strategies focused on both prevention and enforcement in order to ensure public safety and product integrity. We continue to be an active participant in this organization, and are pushing for increased levels of intelligence-sharing among the members.
- Our company supported the SAFE DOSES Act, which was signed into law in the U.S. in October 2012. The bipartisan legislation modernizes the U.S. Criminal Code to increase criminal penalties for medical-product cargo theft and provides law enforcement tools to deter this criminal behavior and take down the organizations that are perpetrating it.
- Our company supported the Trade Facilitation and Enforcement Act, which was signed into law in the U.S. in February 2016. Known as the Customs Reauthorization Act, this bill provides additional resources to Customs and Border Protection (CBP), and formalizes the capacity for public-private partnership to strengthen Intellectual Property enforcement.

**PERFORMANCE**

In 2015 our company addressed 673 active product-integrity events. Approximately 60 percent of these events have been proactively investigated by Global Security to identify new or emerging product-integrity threats, or to further characterize and mitigate known product-integrity threats.

When a new product-integrity event is initially reviewed, it is assigned to one of five categories:

- Product Theft/Loss
- Brand Security
- Diversion
- Tampering
- Counterfeiting

The following table details the number of Suspected and Substantiated Counterfeit events handled in 2015. The category
for any event can change as the event develops and further information is collected, typically as a result of forensic testing or other review of associated samples.

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