We invest in an industry-leading, rigorous, intelligence-led anti-counterfeiting strategy that is solely focused on protecting patients from the harm associated with counterfeit, diverted and other illicit medicines.

RESOURCES

Public Policy Position Statement: Counterfeiting of Medical Products

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.

We have launched a global Forensic Services program that significantly enhances our capacity and capability for the robust forensic analysis of suspect counterfeit, diverted and illicit medicines. The Forensic Services program focuses on both the identification and characterization of illicit medicines, and will further support our efforts in the detection, characterization, and enforcement of criminal enterprises engaged in the manufacture and distribution of illicit medicines. The global Forensics Services capacity will be supported by three laboratories, the first of which became operational in 2017, with the remaining two set to be operational in 2018. These labs follow international standards and best practices for forensic testing, including the WHO Guidance on Testing of Suspect Falsified Medicines and ISO 17025.

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

- Execute 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 counterfeits and advocate for increased enforcement
shape relevant regulatory requirements

- Maintain the capability and capacity to provide robust forensic analysis of suspect counterfeit, diverted, and illicit medicines. To this end, we have invested in a global forensic laboratory capability that facilitates more innovation and significantly increases our capacity to identify and characterize suspect products and support enforcement actions.
- Train key stakeholders and business partners in the identification of suspicious activities and/or suspected counterfeit products
- 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
- Advance 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

Our company’s Global Security Group oversees the global anti-counterfeiting strategy, and leads its execution. The overall strategy is supported by a cross-functional team comprised of 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 the Office of General Counsel, 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 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**

Our Product & Supply Chain Security strategy enables product protection through the use of sophisticated product-security features and supply chain security measures. In 2016, we expanded our capacity to provide product protection services with additional resources dedicated to this area of focus, and have continued to build this strategy out in 2017.

**Investigations & Enforcement**

The Investigations & Enforcement pillar of our strategy is focused on deterring, detecting and responding to suspected and/or confirmed counterfeit activity in ways that mitigate risks to patient safety. While we support the entire company product portfolio, in 2016, we chose certain products for increased focus, specifically: BELSOMRA® (suvorexant), GARDASIL® [Human Papillomavirus Quadrivalent [Types 6, 11, 16, and 18] Vaccine, Recombinant], JANUVIA® (sitagliptin), KEYTRUDA® (pembrolizumab), and ZEPATIER® (elbasvir and grazoprevir).

These products were chosen due to threat to patients if counterfeited or sold outside of the regulated supply chain. We continued to focus on these products for proactive investigative work throughout 2017.

**Advocacy, Engagement & Awareness**

Our efforts in the area of Advocacy, Engagement & Awareness involve raising public and stakeholder awareness of the risks posed by counterfeits, and advocate for increased enforcement to shape relevant regulatory requirements. In 2017, we continued our commitment to increasing our focus in this area and have strategically enhanced our ability to make a
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

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.

Suspected counterfeit products are reported to our company by patients, providers and from internal and other healthcare stakeholders. 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 2017, 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, were also a concern.

Global Security addressed approximately 1,000 events in a total of 79 countries in 2017 involving counterfeiting, diversion, product theft/loss (including cargo theft), tampering and brand security (non-company, unapproved generic products), which led to 108 arrests and the seizure of more than 25,000 units of counterfeit or illicit versions of company 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 counterfeiters 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 approximately 1,425 unique suspect samples received as evidence and prepared for forensic testing in relation to active events in 2017, which represents almost a 300 percent increase in samples from 2016.

To support and enable enforcement actions, we partner with law enforcement agencies to detect and respond to threats due to counterfeit products. This includes working with U.S. authorities on the importation of counterfeit pharmaceuticals and with EU authorities on the importation and/or trans-shipment 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 AND 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 2017 activities include:

- Assisted in the development and distribution of the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC) "Roadmap to Promote Global Medical Product Quality and Supply Chain Security" with direct engagement on the Online Pharmacy Best Practices Toolkit and Internet Pharmacy Survey, the Center of Excellence Pilot Program for Global Medical Product Quality and Supply Chain Security, and the Center of Excellence for Product Quality & Supply Chain Pilot Program: Securing Medical Product Quality Through the Supply Chain
- Contributed to multiple educational campaigns regarding the dangers of imported and counterfeit medicine sold through online pharmacies that reached thousands of health care providers, caregivers and older Americans in 2017, including coverage by major media outlets
- Supported a global Best Practices Guide for IP Enforcement that was distributed to thousands of stakeholders
- Sponsored a joint program focused on improvement of policy and enforcement of pharmaceutical crime in Latin America
- Launched an educational program focused on the link between importation and counterfeit medicine
- Our Global Security staff trained more than 4,000 law enforcement and customs officials worldwide
- Launched internal Company trainings focused on Supply Chain Security and Reporting of Counterfeit, Diversion and Tampering Events

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)
- Association of Industrial Manufacturers Anti-Counterfeit Workstream (ANDI)
- Alliance for Safe Online Pharmacies—Global (ASOP Global)
- International Chamber of Commerce’s Business Action to Stop Counterfeiting and Piracy (BASCAP)
- International Anti-Counterfeiting Coalition (IACC)
- International Trademark Association Anti-Counterfeiting Committee (INTA ACC)
- International Federation of Pharmaceutical Manufacturers (IFPMA) Fight the Fakes partnership
- U.S. 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 board members 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 in Congress and with federal agencies.
- As a member of the Pharmaceutical Distribution Security Alliance (PDSA), we 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.
- Together with other pharmaceutical companies we 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 advocating 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 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 2017 our company addressed approximately 1,000 active product-integrity events.

More than 40 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 new Suspected and Substantiated Counterfeit events in 2017, as well as the number of events introduced in previous years and the subsequent outcome for these events. 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: the data below reflects the current status of each event as of May 2018.
<table>
<thead>
<tr>
<th>ANTI-COUNTERFEITING¹</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigations of suspected counterfeit products</td>
<td>182</td>
<td>326</td>
<td>146</td>
<td>210</td>
<td>247</td>
</tr>
<tr>
<td>Substantiated cases of counterfeit products</td>
<td>48</td>
<td>172</td>
<td>71</td>
<td>92</td>
<td>91</td>
</tr>
</tbody>
</table>

1. Prior-year data have been adjusted to reflect the current status of each event as of May 2018.