FDA says industry must take responsibility for supply chain security

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The US Food and Drug Administration has called on lawmakers to grant the agency more regulatory powers so that it can place the onus on industry to tighten pharmaceutical supply chain security.

In testimony before the Senate Committee on Health, Education, Labor and Pensions (HELP), FDA Deputy Commissioner for Global Regulatory Operations and Policy Deborah Autor described a raft of new authorities the agency would like to see written into the law to level the playing field between US and foreign manufacturers, increase drug safety and improve the flow of information. If Congress accepts the proposals, the provisions would be introduced as part of the legislation to re-authorise the Prescription Drug User Fee Act (PDUFA V) next year.

Among other things, the FDA wants Congress to update the law so the agency has explicit authority to refuse admission of a product into the US if the foreign manufacturer delays, limits or denies inspection of its facilities. Currently, the agency only has this authority for food imports.

Unlike many other countries, Autor said, the FDA also lacks the authority to require importers or product owners to certify that an imported drug is compliant with US standards and requirements as a condition of importation. If the law were to make importation conditional on such certification, then foreign drugs would be subject to the same standards and requirements as the domestic drug supply, she said.

As for quality management systems, the FDA believes that additional statutory authority could place greater responsibility on manufacturers to account for the quality and provenance of the materials that go into their products. At present, some companies work diligently on their quality management systems to provide high quality products, whereas others do not - but the FDA's hands are tied.

Autor acknowledged that the current law also falls short on drug safety provisions. Most notably, the FDA has no mandatory recall authority for drugs, which could leave the public exposed to potentially serious health risks.

Furthermore, the agency lacks the administrative authority to destroy violative products at the border. The existing process for destruction requires a hearing, which is time-consuming and costly. As a result, the FDA often has no choice but to return these products to their senders, only to find the products reappearing at other US ports later. Likewise, the agency cannot administratively detain illegal drugs in US commerce, though the FDA has this authority for other products it regulates.

Autor added that strengthening criminal and civil penalties for foreign and domestic suppliers could deter would-be criminals from targeting drug products and bring the FDA's penalties into line with those for other serious federal health and safety violations.

The FDA would also benefit from statutory changes relating to the information it receives.

Specifically, Autor called for modernisation of drug registration and listing information to ensure the agency has accurate and timely details about foreign and domestic parties involved in medical product manufacture. In addition, the FDA could more easily spot emerging risks if it had the authority to require foreign and domestic companies to provide complete information on threats to the security of the supply chain such as counterfeiting, theft, non-compliance with regulatory standards, mislabelling or misbranding.

She said that the absence of a system of unique drug facility identifiers submitted to the FDA both as a condition of registration and importation makes it difficult for the agency to follow threats up the supply chain effectively. Cross-referencing is also difficult under these circumstances, especially if different agencies are involved.

Track-and-trace

The FDA regulator further pointed out that a mandatory track-and-trace system for all drug products throughout the supply chain would improve the security and integrity of the drug supply and ensure transparency and accountability of product manufacturing and distribution, regardless of where the product is manufactured.

Finally, if the agency had authority to share certain non-public information with other regulatory agencies and foreign governments, it could lead to timely identification, prevention and resolution of emerging threats.

Marcia Crosse of the Government Accountability Office echoed some of Autor's concerns about the agency's ability to secure the drug supply chain. The GAO's Health Care Director said that the agency "is far from achieving foreign drug inspection rates comparable to domestic inspection rates" and pointed out that the types of inspections the agency conducts "generally do not include all parts of the drug supply chain."

Some particular hurdles include the agency's limited ability to require foreign establishments to allow it to inspect their facilities and logistical issues that preclude the agency from conducting unannounced inspections.

Crosse concluded by saying that the FDA needs to act quickly to implement changes across a range of activities in order to better assure the safety and availability of drugs for the US market.