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FDA: drug safety benefits of import inspection system easy to Predict

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The US FDA says its new screening system will expedite the importation of genuine drugs and help inspectors focus their efforts on "high risk" products.
At present, customs officials only examine a fraction of the 20m shipments that reach US ports each year, with products being selected in what is essentially a random fashion, albeit one based on officer expertise and experience.
The new web-based system, called Predict (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting), assigns drug, food and cosmetics imports a risk rating based on contents, supplier and point of origin.

High risk imports are flagged for inspection, enabling customs officials to focus their investigations on imports that have been problematic in the past such as, for example, heparin or those that contain melamine.

Food and Drug Administration (FDA) Commissioner Margaret Hamburg set out the scale of the challenge facing customs inspectors in relation to pharmaceuticals which, increasingly are, coming sources outside the country.
Dr Hamburg explained that: "*Up to 40 per cent of the drugs [US citizens] take are imported*" and that "*up to 80 per cent of the active pharmaceutical ingredients in those drugs come from foreign sources*."

She went on to say that while systems are in place to try and ensure the safety of imports "*clearly our nations' traditional approach – relying on FDA inspections to catch problems at the border or in foreign facilities – needs a significant overhaul*."

Global collaboration on inspection
While the launch of Predict was the focus of Hamburg's address at the Center for Strategic and International Studies (CSIS) last week, she also touched on the new collaborative approach the FDA and other drug regulatory agencies are adopting .
She explained that, in addition to setting up offices new offices worldwide over the last 12 months, the FDA now has agreements with more than 30 agreements with counterparts worldwide to share data on facility inspections

"If our British counterparts share with us critical information about inspections… we can use that information and not re-inspect," said Hamburg, citing the FDA's work with the EC and the TGA on API plant inspection as a further example of the approach .

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