Closer scrutiny of foreign API sites on the horizon

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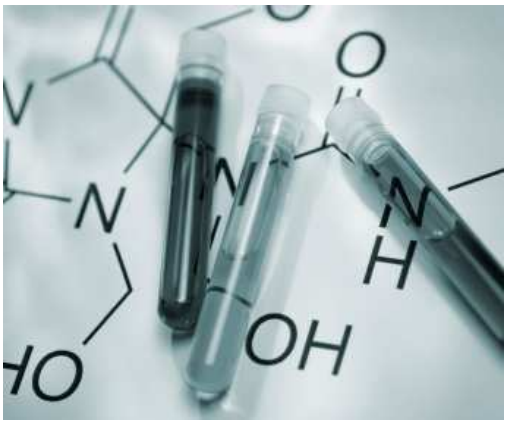

Active pharmaceutical ingredient (API) manufacturers in the USA and Europe are a step closer to ensuring that the Food and Drug Administration (FDA) monitors facilities in high-risk regions such as China and India with the same degree of stringency as it does for domestic sites.

Following months of negotiations, the FDA and three industry associations - the Bulk Pharmaceuticals Task Force (BPTF) of the USA-based Society of Chemical Manufacturers and Affiliates (SOCMA), the European Fine Chemicals Group (EFCG) and the Generic Pharmaceutical Association (GPhA) - have reached an agreement on the terms and proposed legislative language to authorise the Generic Drug User Fee Act (GDUFA).

Under the agreement, which all of the parties ratified earlier this month, industry is expected to pay the FDA about $299m for each of the five years of the user fee programme; in exchange, the agency will commit to various measures that are set out in a confidential "performance goals letter."

One of GDUFA's main aims is to secure the global generic drug supply chain. The legislation will achieve this in part by ensuring that companies participating in the USA's generic drug system "are held to consistent high quality standards and are inspected biennially, using a risk-based approach," according to a letter from GPhA Board of Directors Chairman Paul Bisaro to the association's members. The objective is to achieve parity of inspection frequency between foreign and domestic firms by fiscal year 2017.

The legislation will also enhance the FDA's ability to protect the global supply environment by increasing transparency, the GPhA says. It will require the identification of facilities involved in the manufacture of generic drugs and associated APIs, and improve the agency's communications and feedback with industry in order to expedite product access.

BPTF Chair Patty Benson welcomed the agreement, saying: "US manufacturers are in an unfair situation seeing strong FDA oversight and enforcement, where some foreign sites have little or no oversight. This agreement will lead to parity and will go a long way in preventing deaths and illness associated with contaminated or counterfeit drugs."

The Department of Health and Human Services (DHHS) and the Office of Management and Budget (OMB) will now review the goals letter and the proposed legislative language. Most of the details will not be available to the public until after OMB clearance, when the FDA submits the

package to Congress. This is expected to take place in January 2012.