HHS Announces “Safe Importation Action Plan”

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Today the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) released a Safe Importation Action Plan that outlines two pathways for the importation of some foreign versions of FDA-approved drugs.

In 2003, the Medicare Modernization Act gave HHS and FDA the authority, under certain circumstances, to permit the importation of non-FDA approved prescription drugs from Canada. This provision, which is Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA), required the Secretary of HHS to certify that imports would pose no additional risk to public health and safety and would lead to reduced costs for American patients and consumers. To this point, HHS has not made this certification and FDA has not implemented Section 804.

Under the administration’s new policy, HHS will issue a Notice of Proposed Rulemaking (NPRM) that would create a pathway for states, wholesalers and pharmacists to submit plans for time-limited pilot projects to import drugs that are approved by HHS. The NPRM, which will be released in the coming months, will set forth conditions regarding drug quality, record keeping, testing and protections against counterfeiting. The program would be limited to drugs that “contain only active pharmaceutical ingredients (API) manufactured at facilities that also manufacture API for the FDA-approved version, and if they are formulated using processes, specifications, and facilities that are used in accordance with the approved new drug application for the FDA-approved version.” Controlled substances and biologics would likely be excluded from this program. The NPRM will also require applicants to comply with labeling, registration, importation entry, and track and trace requirements.

This proposal will take some time to implement. The final regulation would likely be complex and technical, and will have many interested stakeholders, some of whom have opposed programs of this nature in the past. A contentious issue will likely be whether proposed provisions or the program in general could guarantee the safety and efficacy of drugs. Complex rulemakings, like this one, often take two years or more.

Implementation on a large scale may also prove challenging. The Canadian drug market is much smaller than the United States market. In the past, stakeholders have raised concerns that a widespread program could lead to drug shortages in Canada, which would then lead to a Canadian legislative response. A smaller program would
be less likely to disrupt the Canadian market, but would also provide fewer drugs to the U.S. market.

One safety concern relates to the fact that FDA does not have a Mutual Recognition Agreement (MRA) with Canada, as it does with the European Union. Under the U.S.-Europe MRA, FDA has evaluated European Member State inspectorates and found them to be capable of overseeing pharmaceutical manufacturing. Because of this capability assessment, the U.S. and Europe recognize each other’s inspections, which reduces the need for each regulator to oversee products made in the other jurisdiction. The development of an importation program with Canada may well lead FDA and Health Canada to explore an MRA and to conduct assessments of each other’s inspectorates.

The administration also outlined a plan to allow manufacturers of FDA-approved drugs “to import versions of these FDA-approved drugs that they sell in foreign countries into the U.S.”2 The manufacturer would have to establish that the foreign version of the drug is identical to the U.S. version and that it is appropriately labeled. FDA will soon issue a draft guidance providing more details on this program, which it believes could offer cost savings.

The Safe Importation Action Plan has the potential to create a large shift in HHS and FDA policy toward the U.S. drug supply chain and importation. However, the scope will depend on the details in the final rule and guidance that would implement the new proposals. There will be notice and comment periods and opportunities for interested parties to provide input. In addition, there are proposals in Congress to amend the FDCA and expand drug importation.

We urge interested stakeholders to engage in the rulemaking and guidance process and with Congress. In this area, which is both highly technical and touches on an important area of public policy, thoughtful input can have a significant effect on the final policy.


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