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Importation of Prescription Drugs from Canada for use within State Healthcare Systems

FDAImports.com, LLC reviewed and evaluated a proposed program whereby prescription drugs can be legally imported from Canada under section 804 of the Federal Food Drug and Cosmetic Act ("FFDCA") exclusively by or under the direct control of a State authority. The U.S. Food and Drug Administration ("FDA") regulates and enforces the provisions of the FFDCA including the importation of all prescription drugs from Canada. We provided our initial assessment regarding the legality and of feasibility the proposed program. The following outlines our review and evaluation and summarizes our opinions based upon the preceding.

The Applicable Law

Under FFDCA Section 804, Congress directed FDA to establish and implement by regulation a drug importation program whereby a "pharmacist" or a "wholesaler" can legally import drugs from Canada provided that certain safeguards are in place to ensure that each prescription drug imported under this regulation complies with FFDCA sections 505 (including with respect to the drug's safety and efficacy for its intended use), section 501 (adulteration) and section 502 (misbranding), and with other applicable sections. Section 804 includes "poison-pill" language, which has left the authority dormant since its enactment. Specifically, section 804(l)(1) states that the provision shall become effective only if the Secretary of the U.S. Department of Health and Human Services ("HHS") certifies to the Congress that its implementation will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. After this certification to the Congress, the Secretary of HHS may promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada after consultation with the United States Trade Representative and the Commissioner or Customs (CBP).

Section 804(k) expressly limits the authority of the Secretary regarding application of section 801(d)(1), which otherwise expressly prohibits the re-importation of prescription drugs and inulin. Therefore, prescription drugs and insulin products that were manufactured in and exported from the United States can be re-imported from Canada under this program. Because of the required

prerequisite conditions in the section, no HHS Secretary has made the required certification to the Congress – thus, the Canadian drug importation (and re-importation) provisions have never gone into effect.

The Proposal

NASHP has proposed, in short form, to initiate a regime established and maintained by various States under their own authorities (1) permitting and regulating the importation from Canada of qualified prescription drugs and insulin into the State under the section 804 protocol, and (2) restricting distribution of such drugs to qualified facilities within the state.

In our view, there is no legal impediment to such a program. We discuss specific questions posed by stakeholders below, along with some additional commentary that may prove helpful in developing a program that the current Secretary of HHS can certify that it meets the statutory limitations criteria.

A. What would the Supply and Distribution Chains look like under such a program?

The Supply and Distribution Chains under such a program would look much like every other drug supply chain. Wholesale distribution of prescription drugs is governed now by the Drug Supply Chain Security Act of 2013 ("DSCSA"), which supplemented the Prescription Drug Marketing Act ("PDMA") and amended the FFDCA. The DSCSA states that all parties in the prescription drug distribution chain, including drug manufacturers, wholesale distributors, repackers/relabelers, and pharmacies, which do business in the State are required to hold various registrations, licenses or permits from each State authority and maintain certain records establishing a pedigree for each lot of drug received, stored and distributed. As an initial caveat, under section 804 the first foreign recipient of a qualifying drug to be imported under the program must be able to document having purchased the drug from an FDA-authorized manufacturer and that the drug was lawful in the first purchaser's foreign country. Further, under the DSCSA, the foreign (Canadian) seller of qualifying drugs imported to the States under this program is required to register with FDA as such and to appoint a U.S. Agent for FDA purposes.

Where the first foreign purchaser and the foreign seller are the same entity (in Canada), importation of the qualifying drug would follow the same basic supply chain as other prescription drugs imported into the USA, except, there will need to be a repacking and/or relabeling step prior to export from Canada.[1] Plainly, for Congress to require that the first foreign purchaser receive the drug in compliance with the local laws applicable to foreign purchaser, Congress intended qualifying drugs to undergo a repackaging and/or relabeling step prior to being exported to the U.S. Under existing FDA regulations, the repacker/relabeler must also be an FDA-registered entity.

[1] FDA regulations permit prescription drug repacking and relabeling after a drug has left the manufacturer. The agency designates drug repackers/relabelers as a type of "manufacturer" and requires the facility performing the activity to be registered as a drug establishment. Repacking or relabeling of a new drug subject to an FDA approved new drug application does not render the resulting drug a new drug or an adulterated or misbranded drug under FFDCA sections 505, 501 or 502.

The foreign seller and foreign repacker/relabeler do not have to be the same entity (that is, the repacker/relabeler can operate under contract); however, the foreign seller to the U.S. must act as the Canadian exporter. The qualified drugs would then pass through the border via international carrier/courier to the U.S. Distributor/Wholesaler or Pharmacist. Section 804 contemplates the importer of a qualified drug will be a wholesaler or pharmacist. Under the current provision, there is nothing in the federal law that prevents the State from requiring participating importers to be partly or wholly owned by the State, which would thereby increase the chance of satisfying FDA and HHS that the State can maintain secure distribution of the imported drugs.

In situations where the first foreign purchaser is not the same entity as the Canadian foreign seller to the US, additional steps are necessary to ensure the authenticity and integrity of the qualifying drug, but the supply chain will be similar. We recommend considering restricting the number of commercial entities between the manufacturer and the Canadian foreign seller and requiring documentation from the Canadian foreign seller demonstrating the purchased drug can be traced back to the FDA-recognized manufacturer of the FDA-approved drug.

Under the DSCSA, all prescription drug wholesalers are already required to be licensed or permitted in the states in which they operate. Some states require non-US wholesalers, repackers/relabelers and manufacturers to hold certain licenses or permits to allow for distribution of prescription drugs into their jurisdictions. In some cases, the applicable state law may require some modification before qualified drugs may be legally imported into the state from a Canadian foreign seller.

The critical element for monitoring and maintaining the integrity of the program's supply chain is governed primarily by the track and trace methods used for the drugs within a supply chain. Through the DSCSA pedigree requirements and the advancement of Block Chain technology, we see no significant hurdle to presenting adequate evidence to FDA that a State program is as secure as the supply chain of the manufacturer.

B. How/When/Where in the Supply Chain can imported or reimported drugs be relabeled for the U.S. market?

As intimated in the answer to Question A, the imported or reimported drugs must be relabeled and, as needed, repackaged, prior to importation into the USA. This reduces the likelihood that FDA will successfully refuse admission to an entry of drugs imported under the program. FDA has the authority to detain and refuse admission to imported drugs that merely "appear" to be violative under applicable provisions of the FFDCA. In the case of a section 804 program, the importer is already required to certify to the Secretary of HHS that the drugs are FDA-approved, are not adulterated, and/or misbranded. We contemplate use of an FDA Code to be transmitted to FDA during importation informing the agency whether a specific imported drug shipment qualifies for admission under the section 804 program. This will reduce unnecessary delays during the importation process and provide a mechanism for aligning specific import transactions with identified supply chains participating in the program. It also affords FDA with the opportunity to examine any shipment or documents associated with any shipment of prescription drugs under the program.

C. How can the FDA National Drug Code (NDC) number be placed on the product to allow billing of U.S. payers?

Solution to this question remains open for several reasons, though we expect it can be answered during the proposal and review process.

Under current law, the initial five digits of the NDC code are the "labeler code" and represent the specific drug establishment that labeled the finished drug product. Consequently, using the drug manufacturer's NDC code is not an option because in most instances the qualifying drug will have to go through a repackaging/relabeling step.

Implementation of a section 804 program requires review and acceptance by the Secretary of HHS. The Secretary is also obligated to establish by regulation those provisions dictated by law. The statute clarifies that these regulations must:

> (1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with [FFDCA] section [505] . . . (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502 . . ., and with other applicable requirements of [the FFDCA];
>
> (2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and
>
> (3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health *or as a means to facilitate the importation of prescription drugs*.

See FFDCA § 804(c) (*emphasis added*).

Among the regulations to facilitate importation of qualifying drugs would be those ensuring that section 804 wholesalers, pharmacies or foreign sellers (whether or not repackers/relabelers) could list the drugs with FDA and obtain NDC numbers for exportation to the USA under the approved program. Because FDA and Centers for Medicare and Medicaid Services ("CMS") are sister agencies within HHS, the Secretary clearly has the authority to ensure successful third-party billing for qualified drugs.

Second, we anticipate ensuring through the section 804 proposal process that importers or foreign sellers can obtain NDC numbers for repacked/relabeled drugs. The NDC numbers for such qualifying drugs could be cross-linked to existing NDC numbers for the FDA-approved manufacturers' products for the purposes of third-party billing.

In our opinion, answers to this question should be an essential part of a section 804 program proposed by a State. Because the lot numbers for qualified drugs imported under the program must

already be tracked, it should be relatively simple to incorporate into the billing systems the appropriate NDC numbers to enable third-party billing. However, we expect there to be technical gaps that would need to be filled to implement the program.

D. How can an imported drug be identified for tracking for safety and U.S. billing purposes?

The existing supply chain track-and-trace technology, pedigree requirements under DSCSA and state laws, and the power of the evolving Block Chain technology are fully capable of reducing the risk of an unqualified drug slipping into the pipeline and ensuring the imported prescription drug was handled to ensure its safety and efficacy. U.S. billing questions primarily revolve around the approval status of a prescription drug, and compliance with that requirement is already a prerequisite of an adequate section 804 proposal.

E. Any recommendations for Canadian suppliers to approach for this program?

We have not contacted any potential suppliers at this point because the details of the program are still too vague. As part of any discussion with Canadian companies, the matter of drug shortages and price increases for Canadian citizens will surely become part of the discussion. We have spoken with various companies interested in similar arrangements, without having a State filing the proposal with HHS. The combination of the two elements (State support and action and the commercial interest of international companies) is likely to produce powerful alliances. At this stage, the States must consider the roles they will play in the process (whether regulatory oversight only, as partner-participant, or as the importer/distributor). The suppliers' interest levels will change depending upon the role the State decides to ultimately pursue.

Conclusion

We have attempted to provide enough detail to provide an appropriate level of confidence that a State-sponsored program could obtain the HHS Secretary's certification. In our view, importation and re-importation of qualified prescription drugs exported from Canada could be accomplished in a manner and with adequate safeguards to ensure at least the same level of safety, efficacy, authenticity and integrity contemplated by section 804. In our opinion, the existing federal and state regulatory structures and the supply chain technologies already exist to implement the program, though certain modifications would be required. The question of U.S. billing will likely require some rule making by CMS.

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