

Importation of Pharmaceuticals

OPR and some of the members have recently received communication from the company, Gallant Pharma International (also known as Harmanda Medical Supply, LLC) represented by Mr. Harvey Whitehead. This company is soliciting the membership regarding their lower prices on oncology pharmaceuticals and has asserted that our distributor Oncology Supply/ION has VERY HIGH pricing while calling into question our price matching policy. After research, OPR has learned that Gallant is offering foreign sourced (Canada, and Europe) product imported into this country. Other countries do not require the same FDA scrutiny and regulations that are required by the FDA. While this can result in cheaper prices, it also increases risk for counterfeit product. While Gallant claims to have never had any problems with reimbursement or auditing and no litigation acquisitions, this does not mean that the importation is legal or appropriate. In response to these actions OPR and Oncology Supply would like to remind members of the following:

- OPR has the right of first refusal provision in our contract with Oncology Supply. If Oncology Supply is unable to obtain a price match then we share the competing offer to our members.
- To continue to provide a competitive price book we must continue to abide by our pricing confidentiality policy, and NOT share the OPR pricing with other distributors.
- Most importantly, importation of drugs from outside the country is not legal. Please review the letter from our legal counsel below:

Attorney Response:

This letter responds to your request for information regarding the importation of drugs from the U.K. As we understand it, a member physician has asked if importing drugs from the U.K. is legal. The drugs are less expensive than their U.S. equivalents and are functionally identical.

In general, the importation of drugs from outside the country is not legal. The Federal Food, Drug, and Cosmetic Act explicitly prohibits the sale of food, drug, devices, or cosmetics that are misbranded. (21 USCA 331(a)). It is also explicitly prohibited to import a drug when that drug is misbranded. (21 USCA 331(t)). In general, drugs or devices will be deemed "misbranded" if they are manufactured, prepared, propagated, compounded or processed in a location not duly registered with the FDA. (21 USCA 352(o)).

Based on the above information, the question, therefore, is whether the drugs to be imported are registered for distribution in the U.S. By your physician's own statement, this is not the case. Therefore, importing the drugs for sale will be a violation of the Act. Initial violations of the act will result in imprisonment for not more than one (1) year or a fine of not more than \$1,000 or both. Subsequent violations or violations with the intent to defraud or mislead will result in three (3) years imprisonment, a fine of not more than \$10,000, or both. (21 USC 333(a)).

The FDA further explains on its website that drugs from outside the country are often not approved by the FDA for distribution in the U.S.. Even though the active components may be

identical, because the foreign-made drugs are not formally approved by the FDA, it is illegal to import them. As part of the FDA's approval process, a drug manufacturer may be permitted to make a particular drug only at a specific facility in the U.S. even though the drug is functionally identical to one made in a foreign facility. The FDA explains that drugs produced overseas may not have been packaged or stored under approved conditions to prevent degradation, and may not have been manufactured in accordance with current good manufacturing practice standards.

We hope this letter is useful to you. Because the FDA position precludes the importing of foreign drugs, there is no reason to look at Medicare or counterfeiting issues. To have and sell these drugs will almost surely violate the law, subject to extreme narrow exceptions. In the meantime, if you or your members have additional questions or concerns, please do not hesitate to get in touch.

Oncology Supply Response:

Oncology Supply encourages our customers to only purchase products from approved distribution channels and should actively verify the licensure of any entity that is attempting to sell products to them. Specifically, we encourage them to actively verify if this entity is licensed to distribute products in Michigan by the Michigan Department of Licensing and Regulatory Affairs. To make it easy for the customers they can go to this website:

<http://www7.dleg.state.mi.us/free/default.asp?Facility=Yes>