BAKER & McKENZIE

Client Alert

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New Circular from The Ministry of Health Regarding The Export and Import of Drugs and of Primary Packaging

On 29 December 2010, the Ministry of Health ("MOH") published Circular No. 47/2010/TT-BYT to provide guidelines for the export and import of drugs and primary packaging ("Circular No. 47"). This Circular came into effect on 12 February 2011, and supersedes (i) Circular No. 06/2006/TT-BYT regarding the export/import of drugs and cosmetics, (ii) Circular No. 13/1998/TT-BY regarding the receipt, management and use of drug donations from abroad in Vietnam, and (iii) only the regulations on vaccines and biological products in Circular 08/2006/TT-BYT stipulating the importation of vaccines and biological products, chemical, insecticidal or germicidal preparations for household and medical use, and medical equipment.

Issued together with Circular No. 47, there is a list of 178 raw materials and finished products which are banned from import into Vietnam.

1. Right to import drugs by foreign-invested companies – market barriers remain

Under Article 3.2 of Circular No. 47, a foreign-invested company ("FIC") in Vietnam that has a certificate of satisfaction of drug business conditions (CSC) with the scope of activity in manufacturing can directly import raw materials for the company's own drug manufacturing. Apart from importing raw material for the purpose of drug manufacturing, FIC must wait for the new MOH guidelines related to the export/import of finished products.

This stipulation is not new when compared to Circular No. 06. The question here is when will the MOH provide detailed drug import guidelines for FIC. It is also worth noting that the MOH started drafting a Circular regarding the rights of FIC to import drugs ("Pending Circular") in 2008, but development on this Circular appears to be very slow.

Under Vietnam's WTO Commitments, since 1 January 2009, certain types of drugs are allowed for import by FIC. However, due to the MOH's lack of guidance, there remains a market barrier for FICs to-date.

The Pending Circular, once passed, will work in tandem with Circular No. 47 and should provide a more comprehensive basis to understand the policy and design of the MOH's drug import regulatory framework.

Baker & McKenzie (Vietnam) Ltd.
12th Floor, Saigon Tower
29 Le Duan Blvd
District 1
Ho Chi Minh City
Socialist Republic of Vietnam
Tel: +84 8 3829 5585
Fax: +84 8 3829 5618

Baker & McKenzie (Vietnam) Ltd.
Hanoi Branch Office
13th Floor, Vietcombank Tower
198 Tran Quang Khai Street
Hoan Kiem District, Hanoi
Socialist Republic of Vietnam
Tel: +84 4 3825 1428
Fax: +84 4 3825 1432

www.bakermckenzie.com

For further information:

Vu Minh Ha
+84 8 3520 2664
MinhHa.Vu@bakermckenzie.com

Seck Yee Chung
+84 8 3520 2633
YeeChung.Seck@bakermckenzie.com

2. Import of drugs without registration numbers in Vietnam

Currently, principles on managing imports of drugs without registration numbers, conditions on foreign traders supplying drugs without registration numbers, as well as other specific conditions on the import of drugs without registration numbers into Vietnam, are provided under Decision No. 151/2007/QD-TTg. However, in this Decision, there are no detailed guidelines for the dossiers and procedures necessary for the MOH's approval.

Circular No. 47 covers this gap, in which dossier requirements for each case of import and the timeline for the regulatory authorities' approval are provided. In case of refusal to grant import permits, the regulatory authorities will give written replies to enterprises, clearly stating the reasons.

We believe that this represents progress arising from the Prime Minister's administrative procedures simplification project—Project 30.

3. Forms of drug import management

Drugs with valid registration numbers (except addictive drugs, psychotropics and precursors for use as medicines) are allowed to be imported on demand and are not required to have the import permits or certifications of import orders.

The following cases require import permits from the MOH:

(i) Addictive drugs, psychotropics and precursors for use as medicines in single or in combination form with valid registration numbers;

(ii) Finished products, raw materials, vaccines, biological products without registration numbers;

(iii) Primary packaging.