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Vietnam Pharma Update

Foreign Drug Company and Local Distributor Relationships in Vietnamese Public Drug Procurement

Vietnam's Drug Distribution Policy

Under its WTO commitments, Vietnam agreed to allow foreign-invested entities (FIEs) to conduct distribution services (i.e., commission agent, wholesale, and retail services) for most types of products, but it specifically excluded "pharmaceutical products and drugs." Consequently, foreign pharmaceutical producers typically establish legal presence in Vietnam by way of representative offices through which they can conduct marketing activities, and use local drug distributors to conduct sales and delivery of their products.

Drugs in state-owned hospitals are provided through either "internal pharmacy departments" or "hospital pharmacies." The internal pharmacy departments supply drugs to doctors for treatment of patients and not directly to patients. Furthermore, the departments only provide drugs which have been paid for by the health insurance body through the public drug procurement process. In contrast, hospital pharmacies provide drugs directly to patients and at the patients' own expense. These pharmacies may provide, along with other types of drugs, the same drugs that are on the list of drugs paid for by the health insurance body, but the patients will pay for them directly.

As of January 1, 2015, participation in health insurance became compulsory for all Vietnamese nationals working in Vietnam. Therefore, winning public drug tenders will play a key role in increasing sales for foreign pharmaceutical companies doing business in Vietnam.

Drug Tenders

There are two ways of conducting public drug procurement in Vietnam: (i) tenders by individual state-owned hospitals and (ii) centralized tenders. Currently, centralized tenders are only conducted at the provincial level, where the provincial Department of Health (DOH) is responsible for organizing the tenders and choosing the winning bids. All hospitals under a provincial DOH are required to use the tender results from the DOH to purchase drugs used in their establishments. Individual state-owned hospitals under the Ministry of Health (MOH) organize tenders and choose winning bids by themselves. However, according to the defined roadmap, centralized drug tenders will be held at the national level starting in 2016 and the MOH, not the DOH, will be responsible for organizing them. There are still no detailed guidelines for centralized tenders at the national level. A possible scenario is that hospitals under the MOH will use the tender results from centralized tenders at the national level, while hospitals under the DOH will continue to use the tender results from tenders at the provincial level.

There are three main tender packages: innovator drugs; generics; and traditional and herbal medicines. The generics package is divided into five sub-packages. Each package/sub-package has only one winning drug. This limits the number of chemical drugs with the same active ingredient which can win tenders to a maximum of six. However, bidders also face the challenges of ensuring adequate supply if they win. Therefore, it is difficult for a bidder with limited capacity to join a drug tender, especially a centralized tender.

The table below provides more details for each tender package:

Package of generics	**Package No. 1**	Drugs manufactured at EU-GMP or PIC/S-GMP facilities in ICH countries ***or*** Drugs manufactured at WHO-GMP facilities certified by the MOH and having marketing authorizations from ICH countries.
	Package No. 2	Drugs manufactured at EU-GMP or PIC/S-GMP facilities not in ICH countries ***or*** Drugs franchised from EU-GMP or PIC/S-GMP facilities in ICH countries and manufactured at facilities certified as WHO-GMP by the MOH.
	Package No. 3	Drugs manufactured at WHO-GMP facilities certified by the MOH.
	Package No. 4	Drugs having evidence of bioequivalence as announced by the MOH.
	Package No. 5	Other drugs
Package of innovator drugs		Innovator drugs or therapy equivalent to innovator drugs or rare drugs, issued by the MOH.
Package of traditional and herbal medicines		

Relationship Between Local Distributors and Foreign Drug Companies

Role of local distributors in winning the tender

As FIEs are prohibited from distributing drugs in Vietnam, they cannot be the bidders in drug tenders but must assign local distributors to be the bidders instead. Such appointments are normally governed under distribution agreements. In most cases, this is a mutually beneficial relationship.

The local distributor plays an important role in determining the success of a drug tender. There are three groups of criteria used to select the winning bid, including: (i) price; (ii) technical criteria of the drug (scored on a 100-point scale); and (iii) capacity and experience of the bidder. Although, technically, the capacity and experience of the bidder is evaluated on a pass/fail basis and most bidders can "pass," in reality, the capacity of the bidder also carries over to the technical criteria group, where 70% of the score is for drug quality and the remaining 30% is ostensibly for "packaging, preservation, and delivery," but is in fact used to evaluate the capacity of the bidder.

Therefore, foreign drug companies should carefully evaluate the capacity of their distributors to make sure they meet conditions that tenders would require, such as experience in providing drugs to hospitals or the ability to meet required conditions in goods delivery stated in the tender dossier, while also making sure the local distributor has other desired qualities such as the ability to meet the requirements set out in the distribution agreement. In practice, it is often difficult to balance the two factors.

Termination of the distribution agreement prior to fulfillment of tender obligations

After a public tender has been won, the most critical problems arise when there is a termination of the distribution agreement or other breakdown in the relationship between the foreign drug company and its local distributor prior to the fulfillment of each party's obligations under the tender. When such events occur, the distributor is often unable to supply the products as committed in the tender contract and would be liable to pay compensation under the terms of tender contracts as well as become subject to administrative penalties under the tender laws. The bid solicitors (the bid solicitor in a centralized tender is the DOH, while in a hospital tender it is the hospital) can terminate the tender contract. In theory, they can choose another bidder to replace the previous bidder. However, in practice, bid solicitors generally do not choose this course of action. They simply terminate the tender contract because they have a maximum of five other products with the same active ingredients to use. For the foreign drug company, beyond its loss of profits, if the drugs earmarked for the tender have not been paid for but are in the possession of the distributor, the foreign drug company is likely to have trouble receiving payment and/or getting its drugs back from the distributor.

Therefore, terminating the distribution agreement prior to the completion of performance of a tender contract will cause losses for both the distributors and the foreign drug company. In most cases, the foreign drug companies would have sent at least some of their drugs to their distributor on credit terms, and therefore are likely to suffer more losses than the distributors.

Possibility of switching distributors while the tender contract is active

Under the Law on Bidding, in some circumstances, it is possible for a bidder to transfer a portion of a package to another bidder while the tender contract is still active, provided it is less than 10% of the total tender contract value, and the transferred portion is valued at below VND 50 billion. Thus, in theory, a foreign drug company could switch distributors for a portion of the tender, though it would require the approval of the distributor, as only the distributor (the bidder) is party to the tender contract under the law, and the hospital (the bid solicitor) would also have to approve. However, in practice, with drug tenders, it is nearly impossible to transfer to another bidder, largely because there is no regime governing such transfers in the pharmaceutical area and because hospitals/bid solicitors, as mentioned above, are usually content to rely on their remaining generic product options.

Protective measures for foreign drug companies

Measures that a foreign drug company can take in the context of drug tenders are: (1) carefully selecting its distributors by conducting proper due diligence on their capability to meet tender requirements as well as commercial and compliance requirements (such as FCPA); and, (2) carefully drafting distribution agreements.

At minimum, the distribution agreements should include the right to conduct inspections, allow termination on clearly enumerated grounds, and have a carefully considered damages and arbitration clause. Also, if the distributors also hold the market authorizations for the drugs, there should be a provision in the distribution agreement requiring them to either cancel or transfer the authorizations to another distributor of the foreign drug company's choosing. However, practical enforcement of this provision is difficult because sign-off from the distributor is required at the time of cancellation or transfer. As a best practice, the foreign company should hold the marketing authorization in their own name, not in the name of the distributor. ■

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