



Pharmaceuticals

I. Introduction

EuroCham welcomes the government's initiatives, in particular from the Ministry of Health (MoH), to increase the quality of pharmaceutical products, patient safety and the efficient circulation of pharmaceutical and biological products in Vietnam. Despite those positive developments, there are still some areas where progress is needed and where there is significant advancement to be made. EuroCham's sector committee for pharmaceuticals (PharmaGroup) has identified the following main areas which still need progress in order to benefit patients and healthcare professionals: (i) Requirements for new and innovative medicines, (ii) the possibility for foreign pharmaceutical companies to directly import products in Vietnam, (iii) the printing of expiry date (for both drug and vaccine) and compulsory information on small label in the primary packaging (for vaccine) and (iv) intellectual property protection.

II. Requirements for new and innovative medicines

The Vietnamese government maintains several barriers to market access that, taken together, significantly impede the import of innovative pharmaceutical and biological products. This appears to be contrasted with the relatively modest requirements for locally manufactured products and imported generic by local Vietnamese companies.

1. Certificate of Pharmaceutical Product: A "Certificate of Pharmaceutical Product" (CPP) or a "Free Sales Certificate (FSC)" and "Good Manufacturing Practices" (GMP) certification from the country of manufacturing or packaging is mandatory as part of the marketing authorization process for all imported pharmaceutical products. These documents are issued by each health authority to confirm that a product has been licensed for sale within their country. However, the country of manufacturing and/or packaging may not always be the country where the product is marketed. In that case, according to the current regulation, for the registration of a new imported product, the authorities would not accept the CPP from those countries. These requirements often result in a significant hurdle in applying for registration, which has an administrative and commercial impact on pharmaceutical companies and delays the availability of innovative medicines in Vietnam. Currently, a new regulation is being discussed for these cases (manufacturing and/or packaging but not marketed), and CPP from members of the G7, United States and Japan are likely to be accepted for the submission to the marketing authorization.

Recommendation: EuroCham recommends that the Drug Administration Vietnam (DAV) and the MoH finalize the new regulation first. A CPP from any country should be sufficient acceptable to comply with the Vietnamese import regulations.

2. Quality tests of vaccines and biological products: The Vietnamese Government requires systematic quality tests for all new batches of vaccines and biological products before they are imported into the country. The Vietnamese authority requires from the importing countries the certificate of batches release delivered by the importing countries authorities with samples attached in order to test the safety of each imported products. These "batch tests" are scientifically unnecessary and time consuming, resulting in an undue burden on manufacturers and delaying the availability of vaccines to Vietnamese citizens. In addition, biological products are not manufactured in batches but must nevertheless comply with testing requirements.

Recommendation: EuroCham recommends that the requirement for quality tests be removed.

3. Requirement of remaining shelf-life (at least 2/3 of total shelf-life) upon arrival to Vietnam: According to Circular N.08/2006/TT-BYT, vaccines imported to Viet Nam need to have a remaining shelf life at least 2/3 of their total shelf life. However, under the current regulations, manufacturers must present a "National Batch Release" of the origin country. This certificate is often time consuming to obtain, and therefore remaining shelf life is becoming shorter whilst companies are waiting for importation.

Recommendation: EuroCham recommends that the requirement on remaining shelf-life (at least 2/3 of total shelf-life) upon arrival to Vietnam be removed.

4. Lack of bioequivalence study requirements: Generic medicines are exempted from clinical trials, including the bioequivalence studies before applying for their market authorization. Bioequivalence studies are designed to ensure that the generic product has the same therapeutic and chemical equivalence as the original medicine. Vietnam's policy exempts generic manufacturers from this important testing requirement fulfilled by research-based manufacturers. It is critical that these studies are conducted for all products to ensure that patients are receiving safe, effective and high-quality medicines. These low requirements for registration of generic products cannot be compared with the very strict requirements for registration of new products and can hardly be said to be in the interest of patient safety.

Recommendation: EuroCham recommends that the registration requirements for generic products are increased to a level similar to the requirements to original products.

5. Requirement that clinical trials be conducted in Vietnam: For the registration of new products, multinational companies are required to conduct local clinical trials if the product has been available in their countries of origin for less than five years. This requirement is unnecessary, as PharmaGroup member companies have developed and manufactured medicines under stringent rules and rigorous protocols in order to be in line with the regulation required by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other internationally recognized regulatory agencies such as the International Conference on Harmonization (ICH). The duplication of clinical trials already conducted outside Vietnam would

result in a significant cost for the manufacturer and would unnecessarily delay the access to medicines for Vietnamese physicians and patients.

Recommendation: EuroCham recommends that manufacturers conducting clinical trials outside of Vietnam in accordance with FDA, EMEA or other ICH standards should be exempt from this requirement.

III. Trading rights: Possibility for foreign pharmaceutical companies to directly import products in Vietnam.

1. Establishment of foreign invested import companies: Vietnam agreed, as part of its WTO accession commitments, to extend trading rights (the right to import and export independent of government-approved channels) to pharmaceuticals, effective January 1, 2009. These trading rights have further legal foundation in regulations relating to import and export rights such as Decree 23/2007/ND-CP (12/02/07) and decision 10/2007 /QD-BTM (21/05/07) issued by the Ministry of Industry and Trade. Pharmaceuticals products are subject to additional and specific regulations from the Ministry of Health and the Drug Administration of Vietnam. The Ministry of Health offered to release guidelines, which specify the operational requirements of entities intending to import pharmaceutical products into Vietnam. These guidelines would replace the current circular 06/2006/TT-BYT of the Ministry of Health regulating the exportation/ importation of pharmaceutical and cosmetic products. This current circular does not allow foreign invested companies to import finished pharmaceutical products into Vietnam. Guidance to replace Circular 06, however, has still to be released. Eurocham member companies are highly motivated to utilize the opportunity to establish legal entities in Vietnam and ask that requirements be clarified through the release of this guidance.

Recommendation: EuroCham recommends swift transparency and clarity in the requirements and processes for these investment options.

2. Reference Pricing to be based on “Price To Trade”: Under the pharmaceutical pricing Circular 11/2007/TTLT-BYT-BTC-BCT, Vietnam has chosen to use cost, insurance, and freight (CIF) prices as a benchmark to compare prices for pharmaceuticals products within neighboring countries. EuroCham’s view is that this creates unequal opportunities and restrictions for imported and locally produced pharmaceuticals. Firstly we believe Vietnam’s unique import regime, which at the moment must rely on third party arrangements due to the lack of trading rights in the sector, results in inflated CIF prices within Vietnam as compared to other countries in the region, which do not impose similar restrictions. Secondly this pricing circular per definition only applies to imported products and no similar restrictions or requirements are subject to locally manufactured products. EuroCham understands the Vietnamese authorities’ desire to compare prices with neighboring markets. However, when considering pharmaceutical pricing in neighboring markets, it is important to choose the price that determines the price to the consumer, for which the pharmaceutical company is responsible. This would be the price to the distributor (as foreign-invested companies are obliged to sell to a local Vietnamese company with distribution rights).

Recommendation: EuroCham recommends that until pharmaceutical companies are effectively and practically given the trading rights consistent with Vietnam's WTO obligations, this CIF-based pricing system should be deferred. Moreover, EuroCham suggests a reference pricing system to be based on Price to Trade (PTT), which will allow inclusion of locally manufactured products as well as imported products.

3. "Parallel Importation": On May 28th 2004, the MoH issued Decision 1906/2004/QD-BYT, authorizing the parallel importation of medicines for the prevention and treatment of human disease. In the case of patented pharmaceutical products, importation by non-patent holder from a third country violates the rights of the patent holder as well as impedes the investment of research-based pharmaceutical companies that maintain a high level of quality by strict application of "Good Practices" to each stage of the pharmaceutical chain (Good Clinical Practice, Good Laboratory Practice, Good Manufacturing Practice and Good Distribution Practice). EuroCham is concerned that parallel traders may not be complying with similar supply-chain parameters to be respected in the distribution system. This is of particular concern as re-packaging of parallel import products is often carried out by a third party, and there is no guarantee that this is performed in the right environment – generating the risk that the medicine may become ineffective. In addition, companies are increasingly faced with complaints about the lack of service provided by parallel importers and the complex issue of responsibility in the case of product defects. The repackaging of medicines, necessitated by parallel trade, has often resulted in human error, including incorrect labeling, wrong patient information leaflets, inaccurate batch numbers and expiry dates that not be complying with MOH's regulations. Such errors can sometimes result in actual danger to safety, health and even lives of patients. EuroCham is finally concerned about the lack of traceability of parallel imported products, which raises serious health concerns. In some countries, traders and wholesalers with parallel trading licenses have been found with counterfeits and sub-standard medicines in their possession.

Recommendation: EuroCham recommends that parallel traders be required to maintain and authorities to enforce compliance with "Good Practices" to each stage of the pharmaceutical chain.

IV. Printing of expiry date (for both drug and vaccine) and compulsory information on small label in the primary packaging (for vaccine).

1. Printing of expiry date (for both drug and vaccine): Internationally, the product's shelf life is calculated by month, thus the expiry date format is written as mm/yy (month / year). In the current regulation, the requested expiry date format is dd/mm/yy (Day / Month / Year). This may bring confusion to the consumer and is not GMP compliant.

Recommendation: EuroCham recommends removing the requirement on completion of the format dd/mm/yy for expiry date in the Circular 04-2008/TT-BYT.

2. Compulsory information on small label in the primary packaging (for vaccine): According to Circular N.04 the small label must content at least all information about drug name,

dosage, active ingredient, and route of administration etc. However, vaccines are usually presented in a pre-filled syringe/ ampoule with very small label correlatively and packed in a sterilized blister. Adding this information on the primary packaging is impossible and will discontinue the cold chain.

Recommendation: EuroCham recommends removing the requirement on completion of compulsory information on primary packaging.

V. Intellectual Property Protection

1. Data Exclusivity: Vietnam has to prevent unfair commercial use of confidential tests and other data developed by research-based pharmaceutical companies in order to obtain marketing authorization for new medicines. Despite the requirement under TRIPS Article 39.3 and paragraphs 5 and 6 of Article 9 of Chapter II of the U.S.-Vietnam Agreement on Trade Relations, Vietnam has implemented Data Exclusivity (DE) differently to international standards. The result is unfortunately that the implementation is administratively burdensome and the value of DE is significantly less than expected. Data exclusivity is a simple mechanism for providing the desired protection. Whilst Vietnam's Law on Intellectual Property Protection provides for a period of five years of data exclusivity, it is our understanding that no company has been granted this protection to date. In addition, the Vietnamese authorities require pharmaceutical companies to specifically request data exclusivity as part of the application for approval process. Protection of the data, however, is an explicit obligation of the government under both of the cited agreements. To impose "procedures and formalities" as a condition of extending a period of data exclusivity is not consistent with Vietnam's obligations under either TRIPS or the Bilateral Trade Agreement, nor is it consistent with international norms.

Recommendation: EuroCham believes that strict implementation of Data Exclusivity (defined and understood as by US and EU regulators (FDA and EMEA)) offers an unique opportunity to initiate effective and valuable IP protection as the process will be under complete control of the DAV under the MoH. EuroCham recommends that Vietnam makes explicit its timetable for fully implementing data exclusive in line with international norms. Data exclusivity should be automatic and comprehensive and not subject to any conditions.

2. Patent Linkage: Vietnam does currently not have a system in place for "linking" the drug registration system with the patent system. Vietnam argues that it is not appropriate to inject patent enforcement procedures into regulatory procedures, and that it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents. Vietnam suggests that the owner of the patent is responsible for re-enforcing his patent protection. EuroCham believes that the adoption of patent linkage is good public policy and the experience of countries that have adopted such a linkage is that it is relatively easy to implement. As for data exclusivity, EuroCham believes that Patent Linkage offers a unique opportunity to initiate effective and valuable IP protection as the process will be under complete control of the DAV and NOIP.

Recommendation: EuroCham recommends that the Government of Vietnam adopts a patent linkage system as one step in improving Vietnam’s developing IP protection regime.