



Pharmaceuticals

I. Introduction

EuroCham's Sector Committee for pharmaceuticals (PharmaGroup) 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. In particular, EuroCham's PharmaGroup strongly recognizes the recent improvements in the implementation of a better alignment with the ACTD registration process, as well as a new Circular on Data Exclusivity, and the progressive implementation of better enforcement of GPP and GMP standards across Vietnam. EuroCham see these improvements as important steps towards even better protection of patient safety. In addition the EuroCham PharmaGroup has been actively engaged in the Project 30 initiative aiming at reducing unnecessary administrative burden at all levels. Despite those positive developments, there are still some areas where improvement is needed. The Eurocham PharmaGroup has identified the following main areas: (i) Requirements for new and innovative medicines, (ii) the possibility for foreign pharmaceutical companies to directly import products in Vietnam, (iii) Product security and IP protection (iv) the printing of precise expiry date (for both drug and vaccine) and compulsory information on small labels in the primary packaging (for vaccines).

II. Requirements for new and innovative medicines

The Vietnamese government maintains several barriers to market access of imported innovative drugs that, taken together, significantly slowdown the access of patient to innovative pharmaceutical and biological treatments for important diseases in Vietnam. This appears to be contrasted with the relatively modest requirements for locally manufactured products and imported generic by local Vietnamese companies. Whilst recognizing the important step forward made with the implementation of the ACTD based registration process, in particular in recognizing the reference CPP of "G7"-countries, the Eurocham PharmaGroup has identified further opportunities that could benefit to the Vietnamese patient health.

1. Quality tests of vaccines and biological products:

The Vietnamese Government requires systematic quality tests for all 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 Pharmagroup recommends that the requirement for quality tests for vaccines and biological products are removed.

2. Requirement of remaining shelf-life (at least 2/3 of total shelf-life) upon arrival to Vietnam:

According to Circular No. 08/2006/TT-BYT, vaccines imported to Vietnam 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 Pharmagroup recommends that the requirement on remaining shelf-life (at least 2/3 of total shelf-life) upon arrival to Vietnam be removed.

3. Bioequivalence study requirements for protecting patient safety and ensuring product effectiveness:

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 in order to ensure good treatment of the pathology and protect patient health. Vietnam’s policy largely 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 are not in the interest of patient safety. To this end, we welcome the introduction of “Circular 8”, effective since October 2010, and generally requiring 12 active ingredients to be supported by bioequivalence studies for registration submission

Recommendation: The EuroCham PharmaGroup recommends that the registration requirements for generic products are increased to a level similar to the requirements to original products and specifically include BE/BA studies, and that Circular 8, already covering 12 molecules, is extended to all molecules of generic and bio-similar drugs.

4. Requirement that clinical trials are conducted in Vietnam for NCE registration:

For the registration of new products, multinational companies are still required to conduct local clinical trials if the product has been available in their countries of origin for less than five years. This requirement appears to overlap with already existing clinical trials, as EuroCham’s pharmaceutical companies have developed and manufactured medicines under stringent rules and



rigorous protocols in line with the requirements of 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 results in a significant cost for the manufacturer, increased administrative burdens and unnecessarily delays the access to medicines for Vietnamese physicians and patients. In fact, it is leading to social inequality: Whilst richer Vietnamese can receive these drugs and treatment outside of Vietnam, the ones who cannot afford travelling abroad are denied access.

Recommendation: The EuroCham PharmaGroup recommends the local clinical trial requirement is waived for products for which clinical trials have been conducted already outside Vietnam under FDA/EMA or other ICH standards.

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

1. Establishment of 100% foreign invested import companies:

Under WTO-rules, Vietnam has extended trading rights (the right to import and export drugs) to pharmaceuticals, effective January 1st, 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 (MOIT). Pharmaceutical products are subject to additional and specific regulations from the Ministry of Health (MOH) and the Drug Administration of Vietnam (DAV). The MoH has 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 MOH 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.

Recommendation: Eurocham member companies are highly motivated to utilize the opportunity to establish legal entities in Vietnam, and increase their investment in the Vietnamese Pharmaceutical sector. Therefore, the EuroCham PharmaGroup recommends introducing specific guidance so that pharmaceutical companies can establish fully foreign owned subsidiaries in Vietnam as per WTO-commitments.

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 PharmaGroup's view is that this creates unequal opportunities and restrictions for imported and locally produced pharmaceuticals: Firstly, Vietnam's unique import regime currently relies on third party arrangements (due to the lack of trading rights in the sector), resulting in non comparable CIF prices within Vietnam as compared to other ASEAN countries (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: The EuroCham PharmaGroup 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 PharmaGroup 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 a 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 and potentially threatening patient safety. 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. The EuroCham PharmaGroup 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: The EuroCham PharmaGroup recommends that parallel traders be required to maintain and authorities to enforce compliance with “Good Practices” at each stage of the pharmaceutical chain.

IV. Product Security and Intellectual Property Protection

1. Data Exclusivity:

The Eurocham PharmaGroup welcomes the new circular on Data Exclusivity implemented in May 2010 which is considered a good start to ensure reasonable protection of the high research and development efforts of the multinational pharmaceuticals companies. However, the Vietnamese authorities still 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. In addition the protection of the confidentiality of these data and the possible resulting unfair use are still not ensured and therefore represent a risk for multinational pharmaceutical companies.

Recommendation: The EuroCham PharmaGroup believes that strict implementation of Data Exclusivity (defined and understood as by US and EU regulators (FDA and EMEA)) offers a unique opportunity to initiate effective and valuable IP protection. The EuroCham PharmaGroup recommends that Vietnam proposes a plan to improve the existing data exclusivity system to be 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. The EuroCham PharmaGroup believes that the adoption of patent linkage is important to ensure product security for better patient protection and 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: The EuroCham PharmaGroup recommends that the government of Vietnam adopts a patent linkage system as one step in improving Vietnam's developing product security and IP protection regime.

V. Printing of precise expiry date and information on small labels for vaccine.

1. Printing of precise 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 as well as increase unnecessary administrative burdens.

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