



## POSITION PAPER OF INDIAN BUSINESS CHAMBER IN HANOI AT THE ANNUAL VIETNAM BUSINESS FORUM 2018

In order to improve the investment and trade environment, we would like to highlight key measures and few issues faced by our member businesses wishing the Government of Vietnam to take efforts on implementation.

### **I. Pharmaceutical Sector**

With the population of over 90 million, fast-paced economic growth and an increasing standard of living, Vietnam has become a market with great potential for healthcare services. Indeed, Vietnam's healthcare expenditure was estimated at \$16.1 billion in 2017, which represented 7.5 percent of the country's GDP. The healthcare spending is expected to grow to \$22.7 billion in 2021, recording a compound annual growth rate of approximately 12.5% from 2017 to 2021. We thank you the Government for its ceaseless efforts in general and of the Ministry of Health (MoH) and the Drug Administration of Vietnam (DAV) in particular, especially with the Draft amending the Decree No. 38 on reducing 50% of administrative procedures and business investment conditions submitted by the DAV.

The drug procurement has always been of high importance for the MoH that ensures the selection of qualified drugs with reasonable prices. The related circular issued by the MoH indeed shows the close attention and guidance of the MoH by covering all the contents regarding the regulation of drug procurement at medical facilities. However, there remain a number of difficulties and inadequacies in the bidding and procurement of drugs that not only Indian but many foreign pharmaceutical companies are facing.

In order to assist the MoH in amending the Circular regulating the bidding of drugs in public health facilities and also to help Indian companies overcome the said difficulties, INCHAM Hanoi would like to propose few suggestions as follows:

#### **1. With respect to the Circular No. 11/2016 TT/BYT dated May 11, 2016:**

- *Including EU-GMP certified drugs produced outside of ICH countries or Australia in Group-1 of bidding*

The proposed circular - Article 5.1 (a) prohibits drugs having EU-GMP accreditation but not produced in ICH countries or Australia from participating in Group-1 of bidding. It is in contrast with the existing international practice as drugs with similar quality accreditation are treated equally across the world. Therefore, we request MoH of Vietnam to allow drugs of the companies having EU-GMP accreditation and produced outside of ICH countries or Australia to participate in Group-1, which in turn will avoid the monopolization of drugs from ICH countries or Australia and will help the Government of Vietnam in reducing costs of treatment. The new initiative will definitely increase the access of high quality affordable medicines to the people of Vietnam and bring more people under universal social healthcare.

- *Removal of PICS from Group-2 by Article 5.1 (a) of the Draft Circular*

PICS is one of the most recognized quality accreditations worldwide, whose members comprise in majority from the ICH countries such as France and the UK. It also shares the same platform with EU-GMP as most of the ICH countries hold key positions within PICS and play an important role in formulating policies for PICS.

We seek your kind attention and request the Government of Vietnam to include PICS-GMP as qualifying criteria in Group-2. By including PICS-GMP as qualifying criteria for Group-2, not only it will also provide quality & affordable alternative to Group-1 products but also encourage more and more companies to upgrade their facilities to meet PICS-GMP standard, which in turn will benefit people of Vietnam in receiving good quality products at an affordable price and reduce cost of healthcare for MOH of Vietnam.

- *Recognition to local brands in Group-2 upon approval by the DAV as Bioequivalent*

Sole discretion is provided to DAV for recognizing any local brand from any local company as bioequivalent whose drugs meet the criteria of any Group despite there being Group-4 exclusively for Bioequivalent (BE) products.

BE products are allowed to participate in Group-2 and not Group-1. BE products are equivalent to the originator and should be allowed in Group-1 instead of Group-2 as it is where the products are most expensive and also contribute significant share to the Social Insurance Budget of Vietnam.

We as business chamber are of the opinion that Geography based categorization of the companies in spite of similar quality accreditation is unjust. Such a provision is unfair and restricts equal trade opportunity to the foreign companies.

## **2. With respect to the Decree No. 54/2017/ND-CP**

This Decree provides guidelines for implementation of the Law on Pharmacy: the additional condition is imposed for obtaining special import permit, i.e. “product needs to be licensed in ICH / Australia” for applying special import permit (in 4 out of 5 types) by Articles 65.1(a), 66.1(b), 68.1(a), 71.1(b), 72.1(a) of the Decree 54. Such additional requirement on special import permit would cause undue delay for entry of generic versions of advance molecules by companies who are not licensed in ICH/Australia which will lead to higher cost of treatment due to monopoly of off patent innovators and generics coming from ICH members. We kindly request that the mandatory condition for obtaining a special import permit be removed.

## **3. VAT Refund**

As per Vietnam government latest amendment related to VAT Refund: Article 1. Amendments to certain articles of the Government's Decree No. 209/2013/ND-CP dated December 18, 2013 providing guidelines for certain articles of Law on value added tax and is amended by the Government's Decree No. 100/2016/ND-CP dated July 01, 2016: *Exports that are produced from natural resources and minerals bought and processed into other products which are then used for producing the exports by traders or other facilities hired by the traders (through self-contained processing or establishment of workshops and processing plants in each stage) will be entitled to 0% VAT if the conditions prescribed in Point c Clause 2 Article 12 of Law on value added tax are satisfied.*”

Companies explained the situation as it buys natural resources as raw material Quartz (kind of stone) and Coal (Anthracite Coal) two different natural resources and then convert the same material into Silicon Carbide with use of Power. The first stage of product is called Silicon Carbide

Crude, hence, the 2nd stage is crushing and grading into various sizes for exporting. Its impact is still outstanding for many Indian companies not being able to get the refund during the time. On all the Indian companies' behalf, we would like to request the Ministry of Finance (MOF) to consider this issue and would like to state as follows:

- a. According to Article 3.11 of Decree 209/2013/ND-CP (“**Decree 209**”) and 1.1 of Decree 146/2017/ND-CP (“**Decree 146**”), the exports of products mainly derived from natural resources and/or minerals whose total value plus energy cost makes up at least 51% of the prime cost are subject to goods that are exempted from VAT and the Company could not claim VAT refund for these products.
- b. However, the exports that are produced from natural resources and minerals bought and processed into other products which are then used for producing the exports by traders or other facilities hired by the traders (through self-contained processing or establishment of workshops and processing plants in each stage) will be entitled to 0% VAT, if they satisfy the conditions as follows:
  - i. Having an added-value invoice on goods or service purchase or a document proving the payment of value-added tax at the stage of importation;
  - ii. Having a via-bank payment document of purchased goods or services upon each time of purchase;
  - iii. The business establishment must also have a contract signed with a foreign party on goods sale or processing or service provision, a goods or service sale invoice, a via-bank payment document and a customs declaration.

Lastly, we hope to play a more active role in supporting the investment and trade between Vietnam and India in various fields by utilizing India's past experience and expertise in several sectors.