

**EUROPEAN CHAMBER OF COMMERCE IN VIETNAM (EUROCHAM)**

**POSITION PAPER AT ANNUAL VIETNAM BUSINESS FORUM 2017**

**I. INCREASING THE LIVELIHOOD OF THE PEOPLE**

**1. Healthcare as one of the Government’s priorities - EuroCham Healthcare Forum[[1]](#footnote-1)**

**a. International Quality Generics (IQGx)**

The IQGx recognizes the efforts of the Ministry of Health and its Drug Administration Vietnam in providing guidance on the interpretation and implementation of certain provisions of Decree No. 54/2017/ND-CP detailing a number of articles and measures for the implementation of Law on Pharmaceutical (“Decree 54”).

In connection with Decree 54, we would like to request clarification from MOH/DAV regarding the rights of representative offices in Vietnam to organise pharmaceutical conferences or drug information seminars. This is in relation to the interpretation of Clause 2, Article 2 and Clause 1, Article 106 of Decree 54 provided in Section IV of the Summary of Questions and Answers at 02 Conferences of Decree 54 dated 8 May 2017 (“MOH’s Q&A”) (No. 22). The MOH’s Q&A states that *“[…] pharmaceutical business establishments are allowed to organize seminars, conferences and invite doctors to report at seminars, conferences and distribute certified drug information*”. However, under Article 16.1 of Circular No. 13/2009/TT-BYT of September 01, 2009, guiding drug information provision and advertising, drug traders and representative offices with registered pharmaceutical activities in Vietnam may organise seminars to introduce drugs which have been licensed for manufacture and circulation in other countries to medical workers.

In addition, drug introduction seminars have shown their importance as a means for (a) pharmaceutical companies to provide accurate and up-to-date information on disease treatment and education about their products to healthcare professionals to establish a clear understanding of the appropriate use of medicines; and (b) full and proper exchange of scientific information concerning a pharmaceutical product or medical condition among healthcare professionals, and between healthcare professionals and pharmaceutical companies. Therefore, considering the current inconsistency between MOH’s Q&A and MOH’s Circular 13, as well as the vital role of pharmaceutical conferences in bringing quality-assured, effective and safe pharmaceutical products to Vietnamese patients, we would respectively seek clarification from MOH to support the implementation of Decree 54/2017.

The IQGx is prepared to engage and participate with the MOH/DAV in order to address in detail these issues and other matters in the future.

**b. Pharma Group**

Firstly, Pharma Group congratulates Vietnam on its good performance in international comparisons. For instance, on health outcomes relative to healthcare spending, and on Universal Healthcare Coverage which, at an impressive 81% of the population, is one of the highest in the region. Furthermore, Vietnam is **one of the most genericised countries in the world**: **97% generic penetration** in tendering and ex-manufacturer **prices** of originator drugs and generics are among the **lowest in ASEAN. However,** patient speed of access is slow, leading to significant outbound medical tourism. Today, only **6% of new molecules** launched globally are available in Vietnam within 3-7 years. Hence, the **value** (22%) and **volume** (4%) **share of Originators** is among the **lowest across APAC,** partly leading to an estimated annual **USD2 billion** in outbound medical tourism.

Building on this analysis, we would like to bring two EVFTA-specific issues to the attention of the Government.

First, the ability of foreign companies to operate. The rights of foreign investors are already set out under the WTO, and reconfirmed in the EVFTA, but have yet to be fully implemented. This includes the right to establish a viable Foreign Invested Enterprise (FIE) which can carry out, or contract to a third party, all activities granted under international commitments, including importation. The newly-issued Pharma Decree (effective 1st July 2017) finally allows importation, but also introduces a long list of restricted activities that render an import FIE dysfunctional. If a viable FIE was offered, the time needed to shift operating model is estimated at around 2 years for most companies. Therefore, it is important to retain current operations of Representative Offices (in particular drug information activities).

The role of FIEs is critical in bringing investments and partnerships that transfer knowledge into Vietnam. To facilitate this, and to stimulate on-shoring while ensuring high compliance requirements, new investors in the Pharmaceutical sector require feasibility and predictability in the regulatory environment.

We acknowledge Vietnam’s reservation of distribution rights for 100% Vietnamese-owned companies, within the limits of the definitions in the WTO and relevant FTAs. However, by expanding the definition of “distribution”, FIEs providing warehousing and transportation services that have been operating in Vietnam for over 20 years may be forced out of business. As a result, it would be challenging for pharmaceutical MNCs to identify partners that meet international quality and compliance requirements, and so supply continuity and product quality may be at risk.

Consequently, we recommend creating a **viable FIE model** and clear legal framework for MNC pharmaceutical companies to establish a legal entity in Vietnam with associated rights that make business sense and maximise economic resources. **Representative Offices** (RO) should retain current rights to carry out drug information activities and directly hire medical representatives (drug introducers) for these activities, and there should be continued rights for **existing foreign investors** licensed to provide warehousing and transportation and related services in Vietnam.

In the past, patient access to innovative products has been artificially delayed for various reasons. These include administrative requirements for new pharmaceuticals, local clinical trial requirements, initial visa durations of 2 years before being eligible for reimbursement and lengthy administrative processes (2 to 3-year registration timelines).

The EVFTA has lifted any extra requirements relating to clinical studies going beyond ICH guidelines for all pharmaceuticals including drugs, vaccines and biologics. The Pharma Law removes the local clinical trial requirement, which is a major improvement in accelerating patient access. However, this exemption is currently not yet extended to include vaccines. Furthermore, the implementing Circular(s) should avoid introducing new technical barriers, which are misaligned with the EVFTA and international guidelines (ICH and WHO).

Therefore, we recommend a complete removal of the Local Clinical Trial requirement at all stages for chemical drugs, vaccines and biologics for registration in Vietnam, by not introducing any extra, Vietnam-specific requirements going beyond ICH guidelines (in line with EVFTA commitments) and further optimisation of the registration process and frequent review of the reimbursement list.

**3. Social Insurance - Human Resource & Training Sector Committee**

From 1st January 2018, monthly salary used as the basis for social insurance contributions includes base salary, allowances and other supplemental payments. Other supplemental payments are defined as payment in addition to salary and allowances agreed in the labour contracts and associated with the working process, position and performance of the employee.

Other supplemental payments do not include bonuses regulated in Article 103 of the Labour Code, such as mid-shift meals, petrol, telephone, travel, housing or child care. Nor does it include support for employees whose relatives have died, whose relatives get married, birthdays of employees, allowances for employees with work accidents or occupational diseases, or other allowances and subsidies.

This point of regulation may not be in line with the negotiation process for the conclusion of the bilateral Agreement of Social Security between Vietnam and other countries, because the concept of other supplemental payments does not conform to wage and salary schemes in foreign countries. For example, in Singapore, employees contribute to the Central Provident Fund (CPF) on salaries, allowances and bonuses. The concept of "other supplemental payments" is, in fact, uncommon and difficult to define. Moreover, the regulation of compulsory social insurance contribution on other supplemental payments increases the costs for employers and employees. Furthermore, the increase or decrease of social insurance contributions when there are fluctuations in income also increases the administrative procedures for enterprises participating in compulsory social insurance when they have to pay social insurance on other supplemental payments.

**II. CONSUMER CHOICE AND PROTECTION**

**1. Mobility – Motorcycles**

**a. VAT rate of vehicles, spare parts and accessories should not be increased from 10% to 12%**

Through public communication, we understand that the Ministry of Finance (MOF) has announced a proposal for a increase of Value Added Tax (VAT) from the current 10% to 12% which will be applied to most of the goods and services including vehicles, spare parts and accessories. If the proposal is passed through the National Assembly in 2018, such new tax rate will take effect from early 2019.

In the context of the current economic situation that the income and the living standard of the people and the business performance are still low, the increase of VAT rate may have further negative impacts and burden on the Vietnam’s economy and society in general (such as Impact on enterprise’s business activities and living standard of the people) and automotive industry in particular.

We recommend that the Government considers thoroughly about the proposal for increase of VAT rate for vehicles, spare parts and accessories and should have a longer roadmap to increase

the VAT rate in a harmonization with the economy of the country and income rate of the people.

**b. Ban on motorcycles circulation in big cities by 2030**

On 4th July 2017, Hanoi People Committee officially approved Resolution on strengthening transportation management to reduce congestion and pollution in Hanoi from 2017 to 2020 and vision 2030. The Resolution also provides a roadmap of banning motorcycle circulation in inner-city districts in Hanoi in order to strengthen the management of UIO and reduce congestion, traffic jam and pollution. Particularly, motorcycles will be banned in 12 inner-city-districts in Hanoi from 2030. On 7th July 2017, Da Nang city approved the proposal “improvement of public transportation, management of individual vehicles in circulation, control and management of traffic flows in the city”. The proposal provides many strict methods to manage and limit individual vehicles and traffic in city centre. For Ho Chi Minh City, in 2017, the authorities have discussed on the proposal on motorcycle limitation and ban in order to solve the traffic congestion and pollution. So far there has been no further official decision on this issue.

Motorcycles have played vital role in daily commute of mass population and has become the most economic option, convenient and flexible of transportation especially in big cities like Hanoi and HCMC which have typical architecture infrastructure of narrow streets and lines, and poor alternative mobility solutions. Current and perhaps 10 years later infrastructure and public transportation in big cities do not meet people demand on transportation. As a result of that, banning motorcycle may **create big difficulty and inconvenience for the transportation of people living in big cities.** In Jakarta, Indonesia, motorcycle banning policy was objected by people living in Jakarta and then was canceled by government due to the reason that the infrastructure and public transportation means have not met people’s demand**. Further,** banning motorcycles is **not the effective way to resolve** the **traffic jam**, **pollution** and **traffic accidents in big cities.** But may cause **great challenge to motorcycle manufacturing industry** since over 10 years, this industry has established our long-term investment **in Vietnam** for both domestic and exporting markets and made great contribution and value added to economic and social development of the country through tax contribution, local job creation.

To effectively solve the **traffic jam**, **pollution** and **traffic accidents in big cities**, instead of banning motorcycles, we recommend the Government to consider carrying out research, referring to and adopt the successful lessons from other motorized countries as seen in the case of Taiwan, where public transport and traffic infrastructure are already advanced and motorcycles is used in harmony.

Moreover, there should be a consideration of comprehensive aspects incl. actual needs of people in order to propose feasible master plan, minimize disturbances to people's daily life and work, as well as avoid negative economic consequences. The Government shall manage or ban only out-of-date motorcycles which are main cause of air pollution like in India, government ban only over- 20-year motorcycles and increase the raising of people’s awareness about and compliance with traffic regulation and traffic safety.

**c. Intellectual Property Rights (IPR) Protection in Mobility Sector**

The infringement of IPRs in Vietnam is still a serious problem in term of quantities and quality. Since infringement activities become more and more complicated and difficult to discover and control, a strong protection and enforcement of Intellectual Property Rights (“IPRs”) is essential to encourage foreign investment in Vietnam, especially at a time where Vietnam is part of major trade deals such as the European Union-Vietnam Free Trade Agreement (EVFTA).

In line with our IPRs position, we note that high-profile motorcycles manufactured by our companies are copied. Preferring to ‘imitate rather than innovate’, some companies are plainly trying to trade on the goodwill associated with the appearance of our products and confuse the public with the original products. This activity not only violates the provision on IPR relating to industrial design but also causes an unfair competition. At the same time, we note that infringement of online IPRs is becoming more important with the growth of internet users. Enforcement is particularly difficult, when it comes to illegal trading in IPR infringing goods but also with regards to infringement on websites and abusive domain name registration and maintenance.

We would like to recommend the Vietnamese Government should provide in detail the implementing legislation on IPRs enforcement, strengthen the protection and enforcement of industrial designs and product designs such as design infringement should be prosecuted by criminal laws and the penalty for IP infringement (including counterfeit and fake products) under administrative procedures should be increased. Moreover, there should be promotion of an active attitude at competent authority to proactively prevent IP violations and strengthening of the market survey activities, establish a mechanism to contact, exchange information quickly and effectively between the enforcement agencies and the IP holders to prevent timely from handling of infringing acts. We also see that it is necessary to improve the cooperation between enforcement bodies and relevant agencies, especially Market Control Department and Economic Police, the National Office of Intellectual Property (NOIP) and the Motorcycle Registration Agency to further monitor the registration of products (such as motorcycles, electric cars, cars). Specifically, it is necessary to continue implementing effective the inter-sectorial cooperation projects such as Project 168 to share information and handle specific tasks as well as promote, improve the IPR enforcement activities. Maintain and enhance the operation, authorization of the National Committee 389 to fight against smuggling, trade fraud and counterfeit products. Extend the scope of activities of the Committee to handle also IP infringement activities as well. The competent department managing domain name registration such as the Vietnam National Internet Centre (VNNIC) should have mechanisms to prevent/discourage the filing of ‘vn’ domain names in ‘bad faith’ in order to deal with domain name disputes which are on the rise and finally, the Vietnamese Government should consider establishing specialised tribunals to handle IPR violations.

**2. Wines and Spirits Sector - Draft Law on Prevention and Fighting against Harmful Use of Alcoholic Beverage**

Ministry of Health will be working on a Draft Alcohol Law which is put for discussion in the 6th session of National Assembly XIV. We noted that there is a proposal on the establishment of a Public Health Improvement Fund and imposition of a compulsory contribution (equivalent to 1-2% of SCT taxable price) on alcoholic beverages (including beer, wine and spirits). Experience from other countries tells us that similar earmarked fund has not been effective. It lacks public scrutiny and accountability as it is not part of the government budget, hence may result in misallocation and misuse. In Vietnam, the efficiency of tobacco fund is under discussions as it lacks a comprehensive assessment and audit. We would therefore recommend the Government to reconsider the setting up of alcoholic beverages earmarked fund based on a comprehensive assessment of the effectiveness of the tobacco fund. We propose the drafting committee to call for public consultation with relevant stakeholders. EuroCham Wines & Spirits Sector Committee is prepared to work with the MOH and the drafting Committee, share concerns and recommendations based on international experience on the policy options, and identify practical and enforceable regulations to effectively manage the alcohol market and mitigate harmful use of alcohol.

**III. REGULATORY & TAXATION FRAMEWORK AND ADMINISTRATIVE REFORMS**

**1. Reviewing Law on Investment 2014**

Regarding the business and investment conditions provided by the Law on Investment, Condition No. 59 on franchise should be removed from the list because the current conditions such as registration or notification to the MOIT (in case of foreign franchisor) or DOIT (in case of domestic franchisor) or the requirement that the business system has been in operation for one year does not serve to protect any public interest and restrict the market economy rules.

In nature, debt trading services is a normal civil transaction which is governed by the regulations on civil transactions. It is not convinced to consider that debt trading will create risk to public order or social ethics or the health of the community.

For the export of rice, according to Article 4 of Decree No. 109/2010/ND-CP on rice export business, in order to export rice, a trader must fully satisfy the following conditions: (i) Having at least 1 (one) warehouse which can store at least 5,000 (five thousand) tons of paddies, (ii) having at least 1 (one) rice mill with an hourly capacity of at least 10 tons of paddies. The rice warehouse and mill must be owned by the trader and located in a province or centrally run city which has export commodity rice or an international seaport with rice export activities at the time the trader applies for a certificate.

It is not clear why a trader conducting export of rice must satisfy the above technical conditions. Meanwhile, the export of rice is now an important sector in order to support rice farmers in the scenario that the rice price is lower than that of the countries in the same region.

The trading goods and activities directly relating to trading goods [distribution] by foreign investors and economic organizations with foreign invested capital are still regulated by Decree No. 23/2007/ND-CP dated 12 February 2007 which providing implementation of the old Law on Enterprises and old Law on Investment. Under the Decree 23, the Investment Certificate shall be concurrently business license. However, the Investment Certificate is no longer existed under the new Law on Investment. In addition, the term of foreign invested enterprise is no longer valid under the new Law on Investment.

Regarding automobile warranty and maintenance services, this is a normal business activity similar to other machine warranty and maintenance services. It is not appropriate to include this business activity in the List of Business Conditions.

Trading foods should be under the management of the Ministry of Agriculture and Rural Development. This provision is too broad to determine which foods trading shall be conditional.

**2. Draft decree controlling regulations on business conditions**

For the business conditions, we welcome the efforts of Government in continuing eliminating the business conditions causing the difficulties to the enterprises and we fully support the good steps taken by Government, as far as they are in line with the Law on Investment and its guiding Decree 118/2015/ND-CP.

The term of “business conditions” currently stated in the Draft Decree may give opportunities to the relevant authorities to provide business conditions which are not allowed under the Law on Investment. We recommend that in order to prevent the relevant authorities to providing for sub-licenses or business conditions as noted, the term of “business conditions” should be modified as follow: “1. Business conditions means requirements, conditions are expressly provided in laws, ordinances, decrees and international treaties in which Vietnam is a member….”

The term of “business lines in which investment is conditional” currently stated in the Draft Decree may give opportunities to the relevant authorities to provide sub-licenses or business conditions which are not allowed under the Law on Investment. In order to prevent the relevant authorities to providing for sub-licenses or business conditions as noted, it is recommended to modify the term of “business sectors in which investment is conditional” as follow: “3. Business lines in which investment is conditional means business lines expressly provided in Law on Investment in which conduct of business investment activities must satisfy requirements or conditions ….”

The term of “Law on Investment” should be re-defined to cover Law No. 67/2014/QH13, Law No. 03/2016/QH14 and subsequent laws on amendment or supplement to this Law on Investment. It is recommended to revise the definition of “Law on Investment” as follows: “7. Law on Investment means Law No. 67/2014/QH13, Law No. 03/2016/QH14 and subsequent laws on amendment to, supplement of this Law on Investment”. All references to “and laws on amendment to supplement of Law on Investment” in Article 7 and Article 8.1(b) of the Draft Decree should be removed. The content of Article is identical to Article 4.3 of the Draft Decree and it is suggested that this Article 7 should be removed from Draft Decree.

It is difficult to determine “other forms of requirement, conditions” as provided in Article 8.2(i) of the Draft Decree. This provision will create difficulties for enterprises when they conduct business activities in practice. It is recommended that the scope and forms of business requirements, conditions must be clearly stated in this Draft Decree. Otherwise, the form of business requirements, conditions which are not provided in this Draft Decree shall not be valid. Therefore, Article 8.2(i) should be removed.

Article 10 of the Decree lists out the criteria for creating a condition, including necessity, reasonableness, efficiency, clarity and legality. However, there is no information on who will decide if these criteria are met to pass a condition. What are the responsibilities of the proposers of the criteria satisfaction report and those of the condition passers? It is not clear if some criteria are not met but the condition is still passed, the affected parties can lodge a claim against the legislator? We recommend that the Draft Decree should clearly state the responsibilities of the proposers and provide for a mechanism allowing the affected parties to claim removal of conditions which do not comply with the criteria.

Article 17 requires the drafting authority to prepare the "prospective impact assessment report" when a new condition is supplemented or a current condition is amended. However, there is no mechanism for an independent review of the report to confirm whether the report is satisfactory or not and whether the legislators can rely on the report to pass the condition. In addition, there is no requirement to publish the report, either before or after the passing of the condition. We recommend that Article 17 should be amended to provide for (i) an independent review of the report and (ii) to make the report public.

In order to ensure that the relevant Ministries, branches shall strictly and promptly modify or amend the requirements or conditions on business lines which are not consistent with the criteria or conditions as provided in the Draft Decree, Article 29 should expressly provide that if the Ministries, branches fails to modify or supplement the current business conditions under its authorities within 120 days from effective date of this Decree, such business conditions shall be automatically null and void. It is recommended to modify Article 29 of the draft Decree as follows: “… If the Ministries, branches fail to modify or supplement the current business conditions under its authorities within 120 days from effective date of this Decree, such business conditions shall be automatically null and void”.

Finally, the draft Decree already provides for periodical and extraordinary assessment of business conditions based on the above criteria. However, there is no responsibility mechanism for the drafters of the report if the report was fundamentally wrong (except change in circumstances). The draft should supplement a provision specifying that if the criteria satisfaction reports prepared for the legislators to pass the conditions were fundamentally wrong not due to change of circumstances, the drafters of the reports should be subject to a certain type of sanctions (for example, in terms of promotion or pay-rise policy, etc.). This is to increase the responsibility of the drafters of the reports and conditions.

**3. Removing barriers to administrative barriers related to taxation – Tax and Transfer Pricing Sector Committee**

**Improving quality of responses from the tax authorities for concerns of tax policies**

Based on feedback from many enterprises, the responses from tax authorities (both local and central tax offices) to written requests for clarification have been recently very general and do not provide specific guidance to enterprises’ concerns/ clarifications of tax policies. Accordingly, after receiving the responses from the tax authorities, the enterprises have continued to be confused and not sure how to apply the regulations correctly e.g. VAT refund, tax incentives, etc.

This situation is creating concerns/ disappointment amongst enterprises in in transparency of applications of the current tax regulations in practice and behaviors of tax authorities.

It is recommended that, the tax authorities should improve the quality of responses to address and provide guidance to specifically address enterprises’ concerns for proper application/compliance of tax regulations as well as enhance enterprises’ confidence in the Vietnamese tax system.

**4. Transport and logistics online fees payments - Transportation & Logistics Sector Committee**

**a. Withholding taxes in the transportation fees involving international routes**

We also request the MOJ and MOT, MOF to work together to regulate what is included in the transportation fees and what is not included from transportation costs so that the MOT shall decide on the withholding taxes to be applied consistently for convenience of businesses operating in the logistics sector.

**b. Implementation of National Single Window**

Regarding the implementation of National Single Window, we recommend all Ministries to accelerate the progress to join and all requirements for documentation to be presented as originals or original copies should be removed, allowing the full use of electronic copies, so that whole process could be migrated onto a fast and efficient digital platform with minimal need for human intervention. This would help to save time and unnecessary paper works not only for enterprises but also for authorities.

**5. Unofficial costs and fees**

In September 2016 we have attended 12th Anti-corruption Dialogue held by VCCI, the General

Inspectorate and the British Embassy in Hanoi where there was a survey presented on corruption. It has showed that around 70% of enterprises voluntarily offer bribes to “lubricate” their work. The remaining 30% were cases where the government officials gave implicit suggestions for bribes including intended delays in procedures, no clear guidance, etc.

We are of opinion that with such approach, the draft will not have efficient impacts has they should focus on the current actual problems that businesses are facing with- the challenges created by the authorities. Therefore, it is important to include a provision the draft law that the public officials and servants cannot overuse the authority to create difficulties, restrict the organizations and individuals. We also would like to request that the publishing and announcing results/information to the public should be immediate and in a timely manner to meet the responsiveness demand from the requesting individuals and companies. Finally, at EuroCham, we highly recommend and support in enhancing the awareness on this topic; continue to encourage our members to build up and execute the integrity and anti-bribery culture and to fight against corruption.

EuroCham would like to thank You for the opportunity to address our key sectorial recommendations. We invite and encourage the Vietnamese Government to address the issues outlined in this Position Paper and to comfort the expectations of the European business community in Vietnam and partner with us to promote the European values for **win-win solutions.**

Please note that our suggestions in this Position Paper are made on behalf, and in the interest of the European business community in Vietnam. However, it is clear that in the vast majority of cases these suggestions are clearly in the long-term interest of the Vietnamese Government and the Vietnamese people.

We sincerely hope that our suggestions in this Position Paper will help the Vietnamese Government to reach its goals. We look forward to support the Government of Vietnam and all our Members and partners, both Vietnamese and European, to improve the business environment and enhance Vietnam's competitiveness and contribute to develop Vietnam into an attractive investment destination in ASEAN for European businesses. Thank you.

1. *EuroCham’s Healthcare Forum is a coordination platform for Sector Committees operating in the Healthcare industry– at present International Quality Generics (IQGx), Medical Devices and Diagnostics (MDD SC) and Pharmaceuticals (Pharma Group). The Healthcare Forum enables industry representatives to discuss, share and advocate on common interests and topics. Given its inherently diverse nature, it also covers different interests of those industry representatives. All Sector Committees are equally supported by EuroCham.* [↑](#footnote-ref-1)