DELEGATION OF THE EUROPEAN UNION TO VIETNAM

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To: Mr. Gunnar WIEGAND, Managing Director ASIAPAC, EEAS
Ms. Maria MARTIN-PRAT, Deputy Director General, DG TRADE
Mr. Denis REDONNET, Chief Trade Enforcement Officer, DDG, DG TRADE

Subject: Vietnam – Positive solution of Priority Enforcement Issues on MS Discrimination for Pharmaceuticals (Circular 08/2022/TT-BYT replacing Circular 32)

Summary

The priority enforcement issue on pharmaceuticals with Vietnam monitored actively by the Trade Implementation and Enforcement Board on the discrimination of EU Member States regulatory authorities was definitely solved on 5 September 2022. Circular 08/2022/TT-BYT that replaces the notorious Circular 32 was finally published.

All EU regulatory authorities, including the European Medicines Agency (EMA) and all regulatory authorities of the EU Member States, are categorised as Stringent Regulatory Authorities (SRA). This ends MS discrimination and also guarantees privileged participation in tenders by Vietnamese public hospitals which purchase at least 65% of the drugs used in Vietnam as foreseen in the EVFTA.

In addition, the new Circular promotes alignment with international practice. Certain procedural simplifications in dossier submission are also introduced. The Certificate of Pharmaceutical Product (CPP) now follows the international WHO guideline removing Vietnam's specific requirements. Whilst the Vietnamese regulatory system is far from business friendly yet, all specific issues raised by the European Union were successfully addressed. EuroCham sees a clear improvement of procedures.

However, Market Authorisations (not initially raised) remains a point of attention despite assurances.

Assessment

This new Circular 8 addresses all of the issues that the EU Delegation first transmitted in my Note Verbal in October 2019. This first NV was followed up, over the last three years, with numerous highest level meetings (meetings with two Prime Ministers, and one dedicated meeting with the responsible Deputy Prime Minister earlier this year),

letters and countless technical and informal meetings by the Trade section, DVCs with HQ including with EMA and MS regulatory authorities, MS Commercial Counsellor meetings (every month and also dedicated meetings), discussions at HOMS, several meetings with EuroCham and with the two pharmaceutical committees of EuroCham.

In HQ, PCOM Von der Leyen raised the issue with the PM, EVP Dombrovskis raised the importance of the issue during the EVFTA Trade Committee. Several Commissioners and EP INT Chair Lange raised the issue. Two dedicated discussions with the CTEO and one discussion with the Implementation and Enforcement Board at Director General level. Discussions in the Market Access Advisory Committee with MS and industry. Continuous and regular informal EVFTA implementation DVCs between TRADE/C/2 and the VN Ministry of Industry and Trade, assisted by the Ministry of Health are at the heart of this success.

Whilst the efforts were huge, the result is also unexpectedly satisfying. Moreover, the whole process of solving this priority trade enforcement issue has shown the strength of the exceptional cooperation of all parties of the European Union concerned. A success of the whole Team Europe.

Details:

1. The new Circular 08/2022/TT-BYT of 5 September 2022 is comprised of 7 chapters and 48 articles together with 6 annexes of more than 400-page long (main text herewith attached, annexes still under translation). Circular 8 regulates the registration, renewal, amendment, supplement and revoke of drugs and drug raw materials in circulation of Vietnamese market. It specifies criteria in details for clinical trials and some exemption cases from requirement of clinical trials. ***Circular 8 is entering into force on 20 October 2022, revoking the entire Circular 32 and amending in parts the Circular 23/2021/TT-BYT, the Circular 29/2020/TT-BYT, and the Circular 01/2018/TT-BYT***.

2. **Article 2, paragraph 9 (a) and (b) of the new Circular 8 stipulates that the European Medicines Agency (EMA) and all the "medicines competent authorities of the European Union countries", are in the same group of Stringent Regulatory Authorities, together with other third country partners**. The differentiation that implied less favourable participation in tenders of public hospitals (accounting for 65 per cent of the purchases in Vietnam) is eliminated. **All EU MS producers are now treated at the same level.** There are no more Reference Regulatory Authorities.

3. In addition, **Circular 8 simplifies many of the technical requirements for registration and renewal of drugs and drug precursors**, which are imported into Vietnam. Circular 8 also provides guidance on the establishment and functioning of drugs assessing experts and medicines review committee, where for the first time independent leading professors and researchers from universities can participate.

4. According to the Pharma Group of the EuroCham Vietnam, the **Circular 8 is friendlier to business and less cumbersome** in the following aspects:

- **Harmonisation with the international practices**: ***Certificate of Pharmaceutical Product (CPP) under the new Circular 8 follows WHO-CPP template and removes all the Vietnam's specific requirements.*** The previous Circular 32 used to require the authorities of EU to certify that CPP to be "licensed and (effectively) marketed". It also used Vietnam's concept of "manufacturing country" which require CPP from two SRAs if drugs are manufactured with inputs from more than one country. The previous regulation makes it almost impossible to obtain the CPP verification from the national authorities. Circular 8 requires the CPP only from one "manufacturing country".

- **Simplification of administrative procedures**: The ***CPP consular authentication verification is no longer a blanket requirement for all dossiers,*** and a risk-based approach is now applied. There are several options for verification with an aim of speeding up the process. The Articles 6 and 9 of the new Circular specify in detail the format of registration as well as designation and declaration of brand name drugs and reference biologics. ***Article 22 of the Circular also introduces simplified procedures and papers for new drugs and vaccines from the countries whose competent authorities are categorised to be SRA*** This applies therefore to all EU countries.

- **The same simplification is to be applied for vaccines** as regards minor changes (as specified also in Annex 2, page 56) which requires only notifications. In particular, the Circular 8 does not require vaccines registrants to submit Certificate of Analysis, Product Specification, Analytical Procedures (CoA) at the time of dossiers submission. This used to be a burdensome and time-consuming requirement under the Circular 32.

- **Minor implementation issues addressed:** According to the EuroCham Pharma Group, several implementation issues of the previous Circular 32 are equally addressed. This includes:

  - *Acceptance of colour print for package inserts;*
  - *Offer of flexibility in language of submission (English or Vietnamese) for package inserts;*
  - *Understanding of definition of manufacturing sites (addressing customs authorities' questions);*
  - *Removal of incorrect definition of product owner;*
  - *Offer of different options to facilitate businesses' operations;*
  - *Allows for e-labelling and e-registration. Bar code, QR code and Data Matrix Code (DMC) are accepted.*

5. The validity of Market Authorisations remains unchanged at this moment, since it requires a change of the underlying Law on Medicines: The new circular confirms that the validity period of certificate of marketing registration of drugs, drug raw materials, is 5 years from issue date or renewal date. New drugs and vaccines for the first time issued with certificate of registration for marketing in Vietnam have only a validity period of 3 years. MOH promises considering a 10-year validity for renewed market authorisations in a revision of the Law on Medicines. The amendment of the Law of Medicines, planned to be submitted to the National Assembly for the first round of discussion in October 2022, appears to be delayed. If such first submission cannot be made, the government agencies and the National Assembly cannot endorse the new Law of Medicines in May 2023***. However, both the Vice-Minister of MOIT and the Prime Minister assured EP INTA Chair Lange at the occasion of his visit on 8-9 September that Vietnam is working on a prolongation of expiring Market Authorisations for pharmaceuticals.***

Signed off: Giorgio Aliberti, Head of Delegation

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