CHAPTER 12C **PHARMACEUTICALS**

OVERVIEW

Introductions

Pharma Group (PG) represents the voice of the innovative pharmaceutical industry in Vietnam. PG and our 25 members all share the same mission: To ensure Vietnamese patients have fast and sustainable access to safe, high-quality and innovative medicines.

PG strongly appreciates the ongoing dialogue with the Ministry of Health (MOH), in particular during the recent development of key legislation in the pharmaceutical sector. We applaud MOH's efforts in drafting regulations that enhance patient access, and welcome the fact that key recommendations towards this objective raised by PG in previous editions of the Whitebook were taken into account during the legislative development process.

With the growing demand for high-quality healthcare products and services, the Government's objectives to modernise the healthcare system, targeting Universal Healthcare Coverage and development of local capabilities, PG sees the role of the innovative pharmaceutical industry in not only providing inputs to the Government during the development of patient-centric legislation, but also supporting the development of a sustainable healthcare ecosystem. PG believes that the recommendations outlined in this chapter[1] will assist the Government in enhancing the quality of care for patients, innovative industrial development and sustainable State financing that are in line with the 2030 healthcare objectives of Vietnam.

Summary of Pharma Group recommendations

1. **Fast and sustainable patient access to innovative medicines through effective implementation of key legislations**

   An optimised drug registration process that harmonises regulatory requirements with international guidelines (ICH[2], WHO) and regional practices, and a frequent review mechanism of the reimbursement list, will accelerate access to new innovative medicines for Vietnamese patients. Given the sizable role that Government procurement plays in Vietnam, the price negotiation mechanism identified for off-patent brand name medicines with multiple generics from group 1 (or from ICH countries) will help to ensure their continued availability in the hospital channel, secure doctors' choice and medicine availability for patients, and also help incentivise companies to come onshore and invest in localised manufacturing (whether through tech transfers, toll manufacturing, building local know-how and capabilities or through manufacturing essential drugs in Vietnam). PG commits to support the effective implementation of the new Registration, Reimbursement, Tender and Toll Manufacturing Circulars.

2. **Role and contributions of the innovative pharmaceutical industry to the development of a vibrant and innovative healthcare sector**

   Further to the innovative pharmaceutical industry's mission to bring high quality medicines to Vietnam, the industry has a role to play in the development of a modernised healthcare system and healthcare sector, which also includes realising the vision of Vietnam as a regional hub for innovative pharmaceutical manufacturing.

   The support of the Government and relevant Ministries in facilitating a smooth transition, without disruption, from the current Representative Office operating model to the establishment of Foreign Invested Enterprises (FIEs), i.e. legal entities, will enable and – likely – be a condition for companies to extend and expand investments. Such investments include, but are not limited to, investments in patient assistance programs, medical education, clinical trials etc. Over and above a smooth transition, further incentives in legislation

1 Some of the contents of this chapter are Pharma Group recommendations based on the draft legislations which are not yet issued at the time of writing, and are not considered Pharma Group's legal analysis and interpretation.

2 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

relating to market access and Government procurement will attract further investments, including the enhancement of Vietnamese manufacturing and export capabilities.

The study, "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam", which is being conducted by KPMG and which is expected to be completed in 2019 will support the Government in informed policy-making towards the above vision.

3. **Working together for an inclusive, forward-looking and sustainable healthcare financing system for Vietnam**

In the mid- to long-term, a sustainable environment that encourages investment and sector development while addressing short-term State budget concerns is needed and can be achieved through continuous Government-industry dialogue. PG looks forward to exploring policy solutions to balance the budget realities and long-term sector development objectives in the upcoming Health Insurance Law revision. PG also believes future discussions to enable a legal framework for innovative (Service-Based) Public-Private Partnership in healthcare can support such solutions and contribute to solving State budget concerns.

I. FAST AND SUSTAINABLE PATIENT ACCESS TO INNOVATIVE MEDICINES THROUGH EFFECTIVE IMPLEMENTATION OF KEY LEGISLATION

Relevant Government authorities: Ministry of Health (MOH), Ministry of Finance (MOF), Vietnam Social Security (VSS)

Description

Vietnam has managed to reach 87.2 per cent Universal Healthcare Coverage in 2018, with an ambitious target for 90 per cent coverage by 2020. In terms of pharmaceuticals, Government procurement has reached 96 per cent generic penetration (locally produced and imported medicines), while brand-name medicines represent the remaining 4 per cent of volume in public hospitals.[3] Although Vietnam has a fast-growing middle class with increased income and a rising need for high-quality healthcare, Vietnam is also facing a challenge of a rapidly aging population.

In order to meet the demands of a modern universal healthcare system and achieve the Government's objectives, ensuring a holistic approach across regulations for the registration, procurement and reimbursement of pharmaceutical products is key. The patient-centric Pharma Law[4] provides a strong foundation and an opportunity to streamline these regulations. PG supports the issuance of guiding Circulars that ensure: (i) quality assurance for patient safety, (ii) harmonisation of regulatory requirements, (iii) reduction of unnecessary administrative burdens, and (iv) fair and equal access to the market.

PG appreciates the opportunity to provide inputs and work in tandem with MOH on the development of the Registration, Reimbursement[5] and Tender Circulars.[6] We have seen concrete and positive signals during the consultation process that would bring great benefits to patients, most notably:

› **Requirements for the registration of new drugs, vaccines and biologics are heading in the same direction as the EVFTA.** In particular, the removal of previous requirements for local clinical trials or 5-year existing authorisation outside of Vietnam, coupled with a shorter timeline for Marketing Authorisation approval, would enable innovative medicines to become available for patients significantly faster, bringing

3 "Improving Patient Access to Innovative and High-Quality Medicines in Vietnam", *Quintiles IMS*, updated January 2018.
4 Law 105/2016/QH13 dated 6 April 2016 of the National Assembly on Pharmacy
5 Circular 30/2018/TT-BYT dated 30 October 2018 of the Ministry of Health promulgating the List of Drugs subject to reimbursement, ratios and conditions required for reimbursement for health insurance participants
6 The Circular guiding Drug Registration and Circular guiding Tender in public healthcare establishments (guiding the implementation of the Pharma Law and Decree 54) are not yet issued at the time of writing this chapter.

the country closer to parity with leading countries in the region;

- **A further optimised process for the brand-name list**. The draft Registration Circular enables the review of innovative medicines' eligibility for inclusion in the brand-name list to be conducted in parallel with the registration process, as well as recognises the continued status of current products on the list;
- **The addition of new medicines in the recently updated National Reimbursement List (NRL) through Circular 30/2018/TT-BYT,** which represents significant progress in ensuring patients will have access to new medicines through the public hospital channel; and
- **The identification of a price negotiation mechanism for Government procurement of off-patent brand name medicines with multiple generics from group 1** is a 'win-win-win' policy for patient health outcomes, Government budget objectives and a sustainable investment environment for industry.

Potential gains/concerns for Vietnam

An optimised drug registration and reimbursement process will accelerate Vietnamese patient access to new molecules, bringing the country closer to parity with leading countries in the region, and reduce incidences of existing pharmaceuticals being out of stock. To effectively benefit from this, it is important to ensure the administrative process for dossier submission in the Registration Circular is harmonised with international guidelines (ICH, WHO) and improve capacity in dossier review and management.

In particular, for brand name drugs, with the already low volume in the public hospital channel, enabling price negotiation while keeping brand names in a separate Government procurement package will help to ensure continued availability of brand name medicines, preserving doctors' choice for patient treatment. As a result, this will counteract the overcrowding in central hospitals, contribute to the overall effectiveness of treatment, and improve the efficiency of State budget and health insurance fund spending. When combined with upcoming regulations that enable faster patient access to new innovative medicines, it will create a sustainable and predictable business environment. It will also incentivise companies to continue investing in bringing new medicines to Vietnam and strengthen local capabilities through technology transfer and technical know-how.

Finally, the harmonisation of Vietnam's regulations with international guidelines and practices in the region will reduce administrative burdens for MOH, companies and other health authorities (from specific and uncommon requests), in line with the Government's objectives for administrative reform.

Recommendations:

1. **Registration:**

- Ensure the harmonisation of administrative requirements in the Registration Circular with international guidelines (ICH, WHO) and regional practices to reduce unnecessary administrative burdens;
- In terms of practical implementation, propose to improve capacity in dossier review and management, such as organising more frequent dossier review sessions and improving the e-submission system. PG is willing to support MOH and looks forward to discussions on initiatives to further optimise the registration process.

2. **Reimbursement and Health Technology Assessment:**

- More frequent review of the National Reimbursement List (for example, every 12 months or on a rolling basis);
- Introduce a clear, centralised, and seamless process based on Health Technology Assessment best practice to support the decision of new additions / withdrawals.

3. **Government Procurement:**

- Ensure fair and transparent principles for effective implementation of price negotiations;
- Build a predictable and favourable investment environment by ensuring sustainability and stability of the brand name bidding package, whilst incentivising locally-manufactured originator brands and tech transfers.

PG is committed to support MOH towards effective implementation of the above-mentioned Circulars.

II. ROLE AND CONTRIBUTION OF THE INNOVATIVE PHARMACEUTICAL INDUSTRY IN THE DEVELOPMENT OF A VIBRANT AND INNOVATIVE HEALTHCARE SECTOR

Relevant Government authorities: Office of Government (OOG), Ministry of Health (MOH), Ministry of Industry and Trade (MOIT), Ministry of Planning and Investment (MPI), Ministry of Finance (MOF) Ministry of Science and Technology (MOST)

Description

Vietnam has experienced rapid economic progress and significant social transformation over the past few years, alongside integration into the global economy. As a rapidly developing and fast-growing ASEAN economy, the demand for quality health products and services, particularly innovative medicines, will see robust growth in the next few years. Furthermore, with the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) taking effect from the 14th of January 2019, and the expected ratification of the EVFTA – which will send positive signals to attract further investment from foreign companies – there is an opportunity for Vietnam to develop a high-value, modern and self-sustaining pharmaceutical sector.

To make such vision a reality, a predictable and outward-looking legal framework that enables and encourages FDI and partnership between foreign industry and local actors is required. The innovative pharmaceutical industry sees its role in supporting the Government on this journey. We are encouraged by the recent progress to introduce policies that enables further contributions from the pharmaceutical sector, in particular:

- **Patient Assistance Programs:** the issuance of Circular 31[7] now provides a legal framework for pharmaceutical companies to implement patient assistance programs which sponsor drugs to medical service establishments for the treatment of patients, which were only possible in the past via a foreign non-governmental aid scheme;
- **Incentives for local manufacturing and technology transfer drugs:** a number of incentives, such as fast-track registration, are seen in recent draft Circulars, providing foreign companies with a positive outlook for future investment. This, in turn, will help to develop local capabilities and export capacity for Vietnam's pharmaceutical sector.

With these opportunities, the establishment of FIE legal entities will be a key enabler for foreign pharmaceutical companies to further invest and become long-term partners in Vietnam. There is strong interest from the industry, and in order to facilitate the smooth establishment of FIEs while ensuring continued safety and quality of medicines, the attention and support from Government, MOH and relevant Ministries is needed.

In addition to legal presence, effective IPR protection will give innovative pharmaceutical companies the confidence to bring new medicines to Vietnam, and encourage investment in local manufacturing and technology transfer. Furthermore, with the economy moving more toward research and innovation, IPR becomes more relevant and a strong enforcement framework will also benefit the emerging local industry, in the pharmaceutical sector as well as others.

Anticipating the rapid changes in the pharmaceutical sector in the coming years, and with the opportunities provided for foreign companies to come on-shore, further invest in technology transfer, value and local know-how, and produce essential drugs at the highest quality in Vietnam, PG is collaborating with KPMG to conduct an independent study on the "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam" which is expected to be completed and presented to the Government in 2019. The study will measure and quantify the impact and value that the innovative sector can bring to healthcare in Vietnam in terms of health, economic and social outcomes, and aims to provide concrete data to support the Government in designing holistic policies benefiting patients, Government and industry development.

7 Circular 31/2018/TT-BYT dated 30 October 2018 of the Ministry of Health regulating the implementation of patient assistant programs for drugs sponsored by pharmaceutical business establishments to medical service establishments for the treatment of patients

Potential gains/concerns for Vietnam

Taking a sectoral approach to pharmaceuticals with incentives for foreign pharmaceutical companies to further invest will stimulate the development of a healthcare eco-system in Vietnam consisting of not only manufacturing, but also of service providers, clinical research organisations, entrepreneurs in (digital) healthcare and others, thus creating a spill-over effect, benefitting local companies and strengthening an entire sector. This will attract sustainable FDI and PPPs which, over time, will enable exports and create a self-sustainable healthcare sector.

Recommendations:

1. **Foreign Invested Enterprises, i.e the establishment of a pharmaceutical legal entity**: Support from the Government, MOH and relevant Ministries for pharmaceutical companies will help to ensure the smooth establishment of FIEs, while fulfilling obligations on safety, quality and pharmacovigilance.

2. **Enablers and incentives in legislation relating to market access, Government procurement and others**: Commitments should be provided on toll manufacturing, technology transfer, investments in facilities and capability development, in patient education etc. This would facilitate long-term commitments from MNCs, leading to an enhancement of Vietnamese manufacturing capabilities and eventually export.

3. **Effective implementation and enforcement mechanisms for Intellectual Property (IP) and data protection rights**: As Vietnam is revising legislation relating to IP, it would be important to ensure commitments in the EVFTA are honoured, including but not limited to the adoption of patent protection, a strong enforcement system, automatic Regulatory Data Protection (RDP), patent term adjustment for Marketing Approval delays, and other IP protections that conform to international standards, in order to create a more predictable environment for investment, promote innovation, and help address the critical health issue of counterfeit medicines.

4. **An inter-ministerial task-force to form and implement the sector development strategy**: This should include not only MOH but also other relevant Ministries such as Ministry of Planning and Investment (MPI), Ministry of Industry and Trade (MOIT), Ministry of Science and Technology (MOST), Office of Government (OOG) and Ministry of Finance (MOF) as well representatives from industry stakeholders.

III. WORKING TOGETHER FOR AN INCLUSIVE, FORWARD-LOOKING AND SUSTAINABLE HEALTHCARE FINANCING SYSTEM FOR VIETNAM

Relevant Government authorities: Ministry of Health (MOH), Ministry of Planning and Investment (MPI), Vietnam Social Security (VSS), Ministry of Finance (MOF)

Description

The healthcare sector in Vietnam is at an inflection point: As incomes rise, access to Universal Healthcare Coverage (UHC) continues to expand, infrastructure investments by the Government increase, and demand for quality health products and services – particularly innovative medicines – will continue to grow. At the same time, debt load is high and the State budget is becoming more of a concern. This creates an increasing need for a more active private sector and for Public-Private Partnerships (PPPs) to develop the healthcare sector in general, and a sustainable healthcare financing model in particular, which is not an easy transition to make. Meanwhile, this provides the industry with an excellent opportunity to further strengthen partnership with the Government of Vietnam.

The dialogue between MOH and the industry at a workshop, "Public-Private Partnership for a Prosperous Vietnam" on 31 May 2018, followed by the drafting of a Circular guiding PPP in healthcare, present opportunities for all stakeholders from the public and private sector to work on a modern PPP framework for Vietnam, which includes service-based PPPs that focus on (i) capability building, (ii) capacity building and (iii) healthcare delivery.

A sustainable environment that encourages investment and sector development while addressing short-term

State budget concerns can be achieved through continuous Government-industry dialogue. The upcoming revision of the Health Insurance Law represents an opportunity for Government-industry dialogue to identify practical policy solutions to balance the budget realities and long-term sector development objectives.

Potential gains/concerns for Vietnam

- Sustainable service-based PPPs can unlock the total value (social and economic) that the innovative pharmaceutical industry can further contribute to Vietnam's healthcare system.
- Identification of the role of Private Health Insurance (PHI) – in the form of providing Complementary (CompHI) and Supplementary Health Insurance (SuppHI) in addition to the public health insurance scheme – will support UHC implementation by improving financial protection, access to quality health services and satisfaction of key stakeholder groups.

Recommendations:

We recommend a continuous open dialogue and consultation to:

- Enable a legal framework (guiding Circular) for innovative (service-based) PPPs in healthcare and integration into the National Healthcare Financing Strategy;
- Integrate in the upcoming revision of the Health Insurance Law a framework to adjust and determine the role of private health insurance to UHC via political, direct and indirect financial objectives. Meanwhile, pilot disease and therapeutic areas providing CompHI and SuppHI should be selected to facilitate alignment in the short run.

PG looks forward to continuing the dialogue with the Government of Vietnam on the development and implementation of a patient-centric regulatory framework, taking the country's healthcare system to the next level of development.

ACKNOWLEDGEMENTS

EuroCham Pharma Group Sector Committee