

CHAPTER 15C PHARMACEUTICALS

OVERVIEW

Introduction

Pharma Group (PG)¹ represents the voice of the innovative pharmaceutical industry in Vietnam. PG and our 22 members all share the same mission: to ensure Vietnamese patients have fast and sustainable access to safe, high-quality and innovative medicines, whilst fostering a top-tier healthcare system in partnership with the Vietnamese Government.

The Vietnamese Government has made impressive progress over the last two decades in improving the health of its citizens. As the Government's healthcare goals expand to address not only peoples' basic and complex needs for quality services and products, but also to strengthen the economic value generated by the sector, Vietnam's healthcare sector has a unique opportunity to leapfrog development stages and transform itself into a leading country in ASEAN for high-quality healthcare in the next decade.

Pharma Group and our members are grateful for the opportunity to be a part of the journey for Vietnam to realise its full potential, together with the Government, the Ministry of Health and all key stakeholders. We are excited to remain long-term partners to:

- Contribute to Vietnam's healthcare goals of increasing the health, wellbeing, longevity, and quality of life of citizens
- Develop and embrace the digital transformation of the sector through FDI in order to be on a par with regional and global peers, especially in terms of manufacturing high-quality drugs and enhancing research capability.

The year 2020 will be a significant milestone for the pharmaceutical sector, not only with the anticipation of the new National Pharmaceutical Sector Development Strategy ("National Strategy") but also the ratification of the EVFTA, which further positions Vietnam as an attractive gateway into ASEAN.

PG believes that the recommendations outlined in this chapter will assist the Government in the journey of improving health outcomes, fostering innovative industrial development and developing a predictable, sustainable environment for further investment in Vietnamese healthcare.

I. EXPLORING THE UNTAPPED POTENTIAL OF THE INNOVATIVE PHARMACEUTICAL SECTOR

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

Vietnam has been steadily expanding Universal Healthcare Coverage (UHC), reaching 90 per cent at the end of 2019. The Government continues to target 90.7 per cent coverage by 2020 and 95 per cent by 2025.² Together with this development, Vietnam is a rapidly developing ASEAN economy with a fast-growing middle class and an aging population. Therefore, the demand for quality health products and services in Vietnam, including innovative

¹ EuroCham's Healthcare Forum is a coordination platform for Sector Committees operating in the Healthcare industry – at present International Quality Medicines – Generic & Biosimilar (IQMED Generic and Biosimilar), 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.

² In 2019, the coverage of health insurance has exceeded the target assigned by the Government, Hanoi Department of Health, 2020. Available at: <https://soyte.hanoi.gov.vn/chuong-trinh-y-te/-/asset_publisher/4IVkx5Jltnbg/content/nam-2019-ty-le-bao-phu-bao-hiem-y-te-a-vuot-chi-tieu-chinh-phu-giao?_101_INSTANCE_4IVkx5Jltnbg_viewMode=view>, last accessed on May 26 2020.

medicines, is expected to see robust growth in the coming years.

For the innovative pharmaceutical industry, Vietnam is attractive in many ways. Today, the pharmaceutical market in Vietnam is growing at a rapid pace. It has increased from US\$2.7 billion in 2015 to US\$3.6 billion in 2018, and the market is attractive to and appealing for new investment.³ Together with a stable political landscape, an educated workforce and a strategic geographical location, Vietnam can further attract investment, with the potential to take a leading position in ASEAN as a provider for quality healthcare.

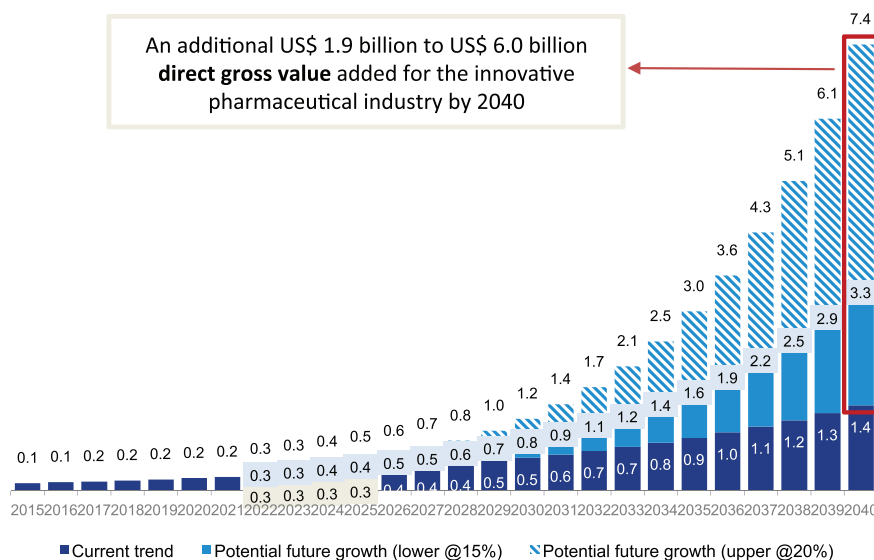
As a key driver in continuous research and development of new treatment solutions globally, the innovative pharmaceutical industry plays an important role in improving health outcomes. It contributes to economic growth, develops the local sector and spearheads the creation of a vibrant healthcare eco-system. Many countries in the world, especially those in ASEAN in recent years, also realise such potentially valuable contributions and have been putting in place a series of incentives to attract investment from the innovative pharmaceutical industry.

Vietnam has a unique and timely opportunity, through the development of the new National Strategy, to build a favourable environment with attractive incentives, in order to become the destination of choice in ASEAN for further investment and long-term commitments from innovative pharmaceutical companies.

In KPMG's recent report "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam", given an attractive and predictable investment environment, the potential value that can be generated from the industry is evident:

- **Health outcomes:** high quality medicines, including new treatment solutions, will be more accessible at a faster speed; while disease awareness and preventive healthcare practices will be enhanced. This will, in turn, support the Government in achieving the national goals of providing a sustainable healthcare system for citizens, increasing patients' satisfaction levels and improving health outcomes.
- **Enhance local capabilities:** the know-how and investment from the innovative pharmaceutical industry will accelerate the development of local industry capabilities to produce essential drugs at the highest quality, meeting domestic demand and, over time, enable those manufacturers to export.
- **Foster a vibrant healthcare eco-system:** Further investment in clinical research, public private partnership (PPP), collaborations between world-leading research-based companies with universities and local partners, attract funding for connected health, biotechnology etc., encourage entrepreneurship and start-ups who can play a significant role in developing Vietnam's next generation in healthcare, will generate additional value in terms of economic contribution and human capital.
- **Economic contribution:** the innovative pharmaceutical industry would contribute an additional US\$ 6.1 to US\$ 19.6 billion in total by 2040 (compared to the projected addition of US\$ 4.7 billion, if the current environment is unchanged), in which:
 - Direct gross value added: an addition of US\$ 1.9 to US\$ 6.0 billion
 - Indirect value added via domestic purchases from the innovative pharmaceutical companies: an additional US\$ 4.3 to US\$ 13.6 billion

³ "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam" Report, KPMG, October 2019.

Figure 6: GDP contribution from the innovative pharmaceutical industry

Note: GDP contribution is calculated based on the market value projection and economic multiplier derived from Input-Output table from the OECD. Similar to the market value project, the current trend of GDP contribution is the lower bound of the business-as-usual growth which is projected at 10% based on stakeholder feedback. Potential future growth is projected based on the growth rate of 15% and 20% from stakeholder interviews and benchmarking for the lower and upper bound respectively. Potential growth is assumed to start in 2022.

Source: "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam" report, KPMG, October 2019

Recommendations

Vietnam is well positioned to join the value chain in life-sciences ahead of several other ASEAN countries, and the time to consider the value this can bring to Vietnam is now. To create a breakthrough towards this vision, a decisive direction from the Government is strongly sought after, to prioritise pharmaceuticals as one of the key sectors to develop in the next decade. The innovative pharmaceutical industry is honoured to be the advisor for the Government to develop long-term strategy towards this vision, across the following key focus areas:

- To promote innovation and enable Vietnam to be a leading Research & Development hub in the region, through attracting investment in clinical trial activities as the first step to develop R&D capabilities;
- To enable Vietnam to become the destination of choice for investment in brand name manufacturing and technology transfer activities in the region;
- To develop and embed leading digital healthcare infrastructure.

The first and most prominent success factor is the establishment of an inter-Ministerial agency to oversee the development of long-term strategy, and subsequent implementation of relevant policies. This agency will play a key role in ensuring smooth coordination at all levels – national, regional and local.

The upcoming National Strategy 2020-2030, vision 2045 is the opportune moment to develop a holistic action plan, the basis for all policies in the pharmaceutical sector, where the following key factors should be considered:

- Put in place attractive incentives for further investment in the three specific focus areas listed above

- › Ensure predictability and consistency of the regulatory environment to provide the confidence for companies' long-term investment. Maintain quality and innovation at the forefront of policy development
- › Develop sustainable health financing solutions, taking into account the value/outcome delivery and not only cost-saving objectives
- › Enhance harmonisation and efficiency of administrative procedures

PG is honoured to continue our role as advisor and work closely with the Government, Ministry of Health and all relevant stakeholders towards the development and implementation of the National Strategy.

II. IMMEDIATE ENABLERS TO ACCELERATE PATIENT ACCESS AND PAVE THE WAY FOR FURTHER INVESTMENT

Relevant authorities: Office of Government (OOG), Ministry of Health (MOH), Ministry of Industry and Trade (MOIT), Ministry of Planning and Investment (MPI), Vietnam Social Security (VSS), Ministry of Science and Technology (MOST)

The innovative pharmaceutical industry has been and continues to pursue our primary mission of ensuring Vietnamese patients have fast and sustainable access to innovative medicines. Thanks to the continued efforts of the Government, the industry has seen impressive progress in regulations that aim to enable new treatment solutions to reach patients significantly faster, with wider coverage across public healthcare establishments nationwide. To fully realise this ambitious goal, especially during the transition period to implement new regulations, close collaboration is key to address the remaining hurdles, and enable Vietnamese patient access to be closer to parity with leading countries in the region.

Further to the above mission, the innovative pharmaceutical industry, with our long-term commitment to Vietnam, is actively exploring areas to further contribute our global expertise, expand investment and support the Government in bringing the country's healthcare system to the next level of development.

We would like to present the below recommendations, which in our view are enablers that can be unlocked immediately, to create a strong starting point towards the journey of improving citizens' health outcomes.

Recommendations

1. Fast and sustainable patient access to innovative medicines

1.1. Drug registration process:

- › Harmonise administrative requirements, such as Certificate of Pharmaceutical Product, with international guidelines and practices;
- › Ensure the dossier review and marketing authorisation issuance (new registration, registration extension, supplementation, drug information registration) adhere to the timelines stipulated in the Pharmaceutical Law 2016 and guiding regulations, through strengthening capacity, resources and building effective Standard Operating Procedures;
- › Successful implementation of the online registration system.
- › Put in place the mechanism of 01 Marketing Authorisation number throughout the product life cycle, and to only require MA maintenance fee, rather than 5-year MA extension application. This practice is also applied in many countries around the world, including those in the region such as Singapore, Thailand and Malaysia.
- › Provide a fast-track mechanism for Marketing Authorisation issuance in Vietnam for new medicines approved

by Reference Authorities⁴ or Stringent Regulatory Authorities⁵ and allow these medicines to be automatically:

- Eligible for inclusion in the Brand name drug list
- Eligible for inclusion in the National Reimbursement Drug List, in order to speed up patient access to new treatments.

1.2. National Reimbursement Drug List (NRDL):

- Ensure the NRDL is reviewed and updated frequently, either through continuous inclusion or at least every six months.
- For innovative medicines approved by Reference/Stringent Regulatory Authorities, they will be automatically eligible for inclusion in the National Reimbursement Drug List upon receiving Marketing Authorisation in Vietnam.

1.3. Government Procurement:

- We would like to emphasize again the importance of very careful consideration and consultation before implementing important policy changes on the topic of drug tendering based on the unique context of Vietnam. Three particular specificities stand out:
 - The public hospital drug tender channel currently contributes more than two-third value of the total prescription drug market for treatment, an exceptional large number and unique compare to other countries in the world. For this reason, in Vietnam, abrupt changes to tender policies will cause extensive impact to all actors in the market, and create a serious risk that patient and doctors will no longer be able to access innovative medicines, whether under reimbursement or self-pay;
 - Implementation of price negotiation as based on existing regulations will not only ensure patient access and treatment optionality for doctors, but will also provide and maintain a predictable investment environment. Reversing the course on price negotiation policy will jeopardise past, ongoing, and future investments of foreign and domestic companies;
 - Whereas in many markets access to innovative medicines is fast, Vietnamese patients, whether in self pay or under reimbursement, still have to wait many years for access. An unpredictable investment climate coupled with the existing challenges and uncommonly long timelines to bring innovative medicines to Vietnam will undoubtedly further reduce access to valuable treatment options for Vietnamese people.

Therefore, noting the Government healthcare budget objectives, we strongly urge to implement the Price Negotiation mechanism, which is already in regulations and has been identified as an optimal solution for the procurement of all originator medicines, including off-patented medicines.

- We recommend the timely appraisal, publishing and update of the brand name drug list for patient access.

1.4 Patient Support Programs (PSPs):

- Ensure clarity in the process to facilitate smooth implementation of PSPs for companies (including FIE Importers), associations and hospitals;
- Enable medicines donated through PSPs, medicines donated in aid, under sponsorship, for humanitarian purposes, etc. to be tax exempted.

2. Enablers for further investment

2.1 Legal entity:

- We appreciate and seek the continued support from the Government, the MOH and relevant Ministries for foreign pharmaceutical companies to establish pharmaceutical business establishment (FIE Importers) and effectively operationalize their legal entities. This is the first investment that unlocks further investment.

⁴ Reference Authorities: Clause 9, Article 2, Circular 32/2018/TT-BYT dated 12 November 2018 of the Ministry of Health regulating the registration of drugs, drug raw materials.

⁵ Stringent Regulatory Authorities: Clause 10, Article 2, Circular 32/2018/TT-BYT dated 12 November 2018 of the Ministry of Health regulating the registration of drugs, drug raw materials.

- The industry would like to seek further dialogue with the Government to explore how to enable optionality (scope of activities), and incentives to attract further investments. As a first step, we would like to discuss:
 - Contract manufacturing: enable FIE Importers' right to sign contract manufacturing agreements with domestic manufacturers and provide incentives together with predictability in the legal framework to attract brand name manufacturing in Vietnam.
 - Clinical trial activities: clarify the rights and scope of activities of FIEs in regard to providing support to local research studies, clinical trials.
 - Clarify the scope of activities of FIE Importers, in regard to the collaboration with partners in Vietnam (e.g., in quality management, in ensuring continued supply of drug based on actual demand for patient treatment, etc.), in accordance with regulations.
 - Among others.

2.2 Intellectual Property Rights (IPRs): In order to create a more predictable environment for investment and promote innovation, it is key to ensure effective implementation and enforcement mechanisms for IPRs and data protection rights.

Pharma Group strongly believes that unlocking the above enablers will not only accelerate patient access, but also position Vietnam as a more predictable and sustainable environment in which to invest. Over and beyond this, we look forward to having continued dialogues with the Government to identify favourable incentives that enhance Vietnam's competitiveness compared to others in the region, to attract further investment from innovative pharmaceutical companies.

III. ACHIEVING A SUSTAINABLE HEALTHCARE FINANCING SYSTEM TO FUND SECTOR DEVELOPMENT THROUGH DIGITAL TRANSFORMATION

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

Similar to other developing countries, Vietnam is facing the key challenge: 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 continue to rise. The innovative industry fully understands the Government budget concerns and appreciates on-going efforts to identify and develop comprehensive solutions towards a sustainable health financing system, while meeting key mid- to long-term objectives as identified by the National Pharmaceutical Sector Development Strategy.

We believe that this can be achieved through dialogues and collaborative actions among all partners in healthcare. The innovative industry, with our global expertise in funding mechanisms, is eager to contribute to these discussions and be a valued partner to the Government towards the shared goals of continuously improving health outcomes, while maintaining a good funding balance and fostering sector development. Furthermore, with global experience, the innovative industry can spearhead and generate spill-over effects to support the drive of the Government to move towards a knowledge-based economy.

Having assessed the current climate in Vietnam, Pharma Group would like to highlight the following key factors to enable a sustainable health financing system:

- Predictability and stability of the legal framework will need to be improved to enable the innovative pharmaceutical industry to lead and create the required momentum towards a sustainable healthcare financing system;

- › Strong support, commitment and incentives for effective implementation of programs that will reduce the financial burden to patients, while ensuring fast access to high quality and innovative treatments (through the Patient Support Program) is required.
- › Identification of digital transformation of the healthcare system (starting with primary care) as the first critical step towards realising the goal of achieving Universal Health Coverage.

Recommendations

We recommend and commit to support the following efforts towards a sustainable healthcare financing system:

- › **Cross-Ministerial agency:** Key positive legislation is already in place (such as the Pharmaceutical Law 2016) in order to attract investment and enable further contribution of the innovative pharmaceutical industry to Vietnam. The promulgation process of the guiding Circulars would need to be overseen by a cross-Ministerial agency to ensure a holistic approach for effective and predictable implementation, achieving not only short-term but also mid- to long-term cross-sector objectives.
- › **Value-based:** Leverage Real World Evidence (RWE) and other value-based models to ensure that the value of new innovative medicine and/or new disease management solution, in particular through pricing, is based on value delivery and not on cost.
- › **Encourage partnerships and enable a more active role of the private sector:** through more diversified health insurance packages, to increase the optionality and accessibility for patients with diverse needs, address growing middle class demand.
- › **Develop and implement a National Digital Health Strategy:** as a corner stone for the transformation of the Vietnamese healthcare system. The identification of digital solutions as part of this strategy will not only improve access, quality and affordability of healthcare, but also generate competitive advantages that enable Vietnam to create a breakthrough.
 - The value that the innovative industry can contribute towards this breakthrough is evident through the 2019 report by KPMG “Evaluating the Social and Economic impact of the Innovative Pharmaceutical Industry to Vietnam”, and should be taken into account.
 - Furthermore, specific recommendations and focus areas to enable this breakthrough have also been identified in the 2020 KPMG report providing input towards the new National Strategy for approval of the Prime Minister.
 - The 2019 White Paper published by Access Health International and Cisco “Reaching 650 Million: How digital technology is key to achieving Universal Health Coverage in ASEAN”⁶ also provides a concise analysis with a clear and practical framework via a recommended 10-point action plan.

Vietnam is well positioned to join the value chain in life-sciences ahead of several other ASEAN countries, and the time to consider the value this can bring to Vietnam is now. Pharma Group is honoured and committed to be a trusted partner of the Government on this journey, striving towards the vision for Vietnam to succeed in being an ASEAN hub for high quality healthcare and at the same time improving the health of its citizens.

ACKNOWLEDGEMENTS

EuroCham Pharma Group

⁶ “Reaching 650 Million: How digital technology is key to achieving Universal Health Coverage in ASEAN”, CISCO, 2018. Available at: < https://www.cisco.com/c/dam/global/en_sg/assets/pdfs/healthcare.pdf> last accessed on 8 December 2019.