CHAPTER 21 PHARMACEUTICALS

OVERVIEW

Introductions

Over the last two decades, the Vietnamese Government has continued to improve healthcare provision for its citizens. The Government's healthcare goals have expanded to address peoples' basic and complex needs for quality services and products and to strengthen the economic value generated by the sector as outlined in Decision 376 of the Prime Minister.[1] We believe that Vietnam has opportunities to transform the sector and become a leading country in ASEAN for high-quality healthcare in the next decade. Policy development and effective, efficient implementation play a crucial role in achieving this vision. In recent years, the innovative pharmaceutical industry continues to experience policy and implementation challenges which may hinder current and future investment. We would like to present these challenges and proposals for solutions in this chapter.

As the impact of COVID-19 on health, society and the economy continues to be felt across the world, treating and protecting citizens' health becomes more important than ever, especially with Vietnam's dual goal of combating the pandemic while boosting socio-economic development. The innovative pharmaceutical industry reaffirms our commitment to support the Government in efforts to prevent, diagnose and treat COVID-19, and position the healthcare system to counter future health challenges.

In parallel, patient access to medicines and vaccines for treatment and prevention of other conditions must continue. The pandemic has impacted and continues to pose challenges for the global supply chain, and the operations of regulators and companies. In these exceptional circumstances, in the best interest of patients, we respectfully call for more simplified and accelerated policy procedures while still ensuring the quality and safety of medicines.

In our view, objectives from patient access to attracting investment and administrative reform can only be achieved through (i) multi-stakeholder consultation dialogue in developing regulations, (ii) cross-ministerial collaboration in implementing regulations, and (iii) accountability and commitment to regulated timelines from all parties.

EuroCham Pharma Group (PG) believes that the recommendations outlined in this chapter will assist the Government in addressing the current critical issues and make positive progress in improving health outcomes, reducing administrative burdens, and fostering the development of a predictable, sustainable environment for quality investment in the pharmaceutical industry.

---

1 Decision 376/QD-TTg of the Prime Minister dated 17 March 2021 approving the program on developing pharmaceutical industry and domestic manufacture of herbal ingredients to 2030, vision towards 2045.

I. A PREDICTABLE AND SUSTAINABLE INVESTMENT ENVIRONMENT IS NEEDED TO ACHIEVE VIETNAM'S VISION

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), Vietnam Social Security (VSS), Ministry of Science and Technology (MOST)

Issue description

As a key driver in the continuous research and development of new treatment solutions globally, the innovative pharmaceutical industry plays an essential role in improving health outcomes and economic growth. In recent years, many countries, especially those in ASEAN, have realised this and have put in place a series of incentives to attract investment from the innovative pharmaceutical industry.

Today, Vietnam has a unique and timely opportunity to build a favourable environment with attractive incentives to become the destination of choice in ASEAN for further investment and long-term commitments from innovative pharmaceutical companies. If there is an attractive environment, the value that can be generated by the innovative industry is evident[2]:

- Economic contribution: an additional US$ 6.1 to US$19.6 billion in total by 2040.
- Health outcomes: new treatment solutions would be accessible more quickly while disease awareness and preventive healthcare practices will be enhanced.
- Local capability development to produce high-quality essential drugs, meeting domestic demand and, over time, enable export.
- Contribute to a vibrant and innovative healthcare eco-system through further investment in clinical research, public-private collaboration, etc.

We appreciate the continued efforts of the Government in the past years to attract high-quality, high-value investment through numerous policy initiatives. However, a concerted effort and efficient implementation of policies will be required to enhance the business environment and increase Vietnam's competitiveness following global key indexes.[3] As a committed partner, the role of the innovative pharmaceutical industry in Vietnam as a key contributor to the sector development has been recognised and clearly stated in Decision 376.

Potential gains/concerns for Vietnam

Concerns about the business environment and policy developments can hinder the industry development vision:

2 "Social and Economic Impact Assessment of Innovative Pharmaceutical Industry in Vietnam" Report, KPMG, October 2019.
3 As reflected in Resolution 19/NQ-CP of the Government dated 18 March 2014 on key tasks and solutions to improve the business environment, enhance national competitiveness and Resolution 02/NQ-CP dated 1 January 2019 on continuing to implement the main tasks and solutions to improve the business environment, enhance national competitiveness in 2019 and orientation to 2021.

To unlock the industry's potential, it is critical to realise that, today, companies still have significant concerns regarding the predictability and sustainability of the business environment. The industry continues to face challenges in market entry, maintenance of product circulation, and sustaining product presence in Vietnam. These factors all significantly impact the viability of the innovative pharmaceutical industry and our ability to invest.

- For drug registration, companies continue to experience significant delays and regulatory hurdles to obtain and maintain Marketing Authorisation. If not addressed, this can directly impact the introduction of new medicines to the market, and the supply of existing medicines, posing risks to patients who are being treated and affecting the entire healthcare system.
- Abrupt changes to tender regulations, as well as uncertainty in the implementation of Price Negotiation for originator medicines, present challenges to the sustainability and predictability of processes for drug procurement. As a result, these challenges can impact the supply and patient access to medicines, while reducing the investment of the innovative industry in Vietnam.
- Delays in the inclusion of new medicines to the National Reimbursement Drug List are limiting patient access through the public health insurance scheme.

These challenges will not only impact patients and industry development, but can also have unintended spillover effects such as the impact on employment, reduction of current investments, and showing the efficiency level of the Government's administrative procedures reform efforts.

A predictable, sustainable environment with attractive incentives will need to be in place:

As mentioned before, Vietnam has a unique and timely opportunity provided by Decision 376 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. Policy and smooth implementation of policy are key enablers for MNCs to consider expanding their investment in Vietnam in the long term.

We applaud the Government's dual efforts to improve the investment environment by not only reducing the conditions for business, but also implementing quantitative measures to enable evidence-based policy decisions, such as the annual Administrative Procedure Compliance Cost Index ("APCI") led by the Office of Government. [4]

To attract further investments from the innovative industry, attractive and sustainable incentives in policy should be developed with a focus on three key pillars:

1. Attract investment in clinical trial activities as an enabler to further develop Vietnam's R&D capabilities;

4 OECD Regulatory Compliance Cost Assessment Guidance, OECD. Available at: <https://www.oecd.org/gov/regulatory-policy/compliance-costs.htm>, last accessed on 4 May 2021.

2. Enable Vietnam to become the destination of choice for investment in brand-name manufacturing and technology transfer activities in the region; and
3. Develop and embed leading digital healthcare infrastructure.

Pharma Group is eager to contribute to the development of these incentives. Thus, we would like to participate and provide our support to the Program Steering Committee chaired by the Minister of Health to implement Decision 376.

Recommendations

We would like to make the following recommendations:

> Address immediate hurdles in policy and implementation, by focusing on the three key pillars: Drug registration, procurement and reimbursement.
> Implement quantitative measures in the development and assessment of policy by further improving APCI towards OECD best practices based on EuroCham Pharma Group's global experience and information resources.
> Provide an enabling business environment for innovative companies through effective enforcement of Intellectual Property Rights (in line with the EVFTA and other free trade agreements) and support for companies to establish FIE importers, effectively operationalise their legal entities and import medicines to Vietnam.
> Develop attractive and sustainable incentives in policy to attract further investments from the innovative industry, with a focus on three key pillars: (i) Clinical trials to develop R&D capabilities, (ii) manufacturing of innovative medicines through technology transfer, and (iii) digital health.

II. IMMEDIATE CHALLENGES LIMITING SUSTAINABLE PATIENT ACCESS AND FURTHER INVESTMENT

Relevant Government 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 continues to pursue our primary mission of ensuring Vietnamese patients have fast and sustainable access to innovative medicines. Challenges in recent years, mostly due to changes in regulations and implementation issues during the transition period, are bringing increasing concerns for the industry.

To address these hurdles, we would like to present the below recommendations which, in our view, are enablers that can be unlocked immediately to enable Vietnamese patient access to be closer to parity with leading countries in the region and create a strong foundation for sector development. Our recommendations focus on three goals:

- Registration: Ensure timely registration of innovative medicines through a clear, simplified and harmonised regulatory process.
- Procurement: Unlock the value of innovative medicines by ensuring a sustainable and predictable process for tender and price negotiation of originator products.
- Reimbursement: Achieve timely, value-based market access for innovative medicines to ensure equitable and sustainable availability of medicines to patients.

1. Drug registration

Issue description

Vietnam currently falls behind ASEAN markets as it has the lowest innovative pharmaceutical share across the region. Innovative pharmaceutical represents 20 per cent by value and approximately 4 per cent by volume. Innovative pharmaceutical registration timelines are ~4-5 years which is among the slowest in the world.

Today, our members are facing delays bringing new medicines to market, constant risks of supply shortages and continued challenges in operation (from the need to build significant inventories to bridge gaps if possible) because of complex regulations and delays in registration dossier review.

In practice, multinational pharmaceutical companies need 3-6 months to plan, manufacture, and import medicines to Vietnam, after receiving Marketing Authorisation (MA) approvals from the Ministry of Health. Therefore, the predictable and timely review and approval of MAs is crucial for companies to make appropriate preparations. Especially, in the present context where global supply chains are already stretched due to the complicated developments of COVID-19, the planning for the Vietnamese market needs to be more thorough and urgent.

"Today, it can take 4-5 years for a new medicine approved in the EU/US to be available in Vietnam."

Potential gains/concerns for Vietnam

The industry remains very concerned and would like to alert the Government to the potential risks to the supply of new and existing medicines, mostly due to the fact that: *Regulations for drug registration* are very complex with specific requirements for documents and processes that are different compared to requirements in ASEAN countries and globally (e.g. Certificate of Pharmaceutical Product requirements). Furthermore, there is a lack of practical transitional measures between old and new regulations, and a lack of measures to synchronize approved administrative contents (e.g. variations, updates) to relevant lists (e.g. Brand name list).

Implementation, both in terms of process and resource, is not yet fully efficient. There is a significant number of backlogged dossiers. DAV is in the process of building an e-registration system, which aims to reduce the administrative burden on the management of drugs circulating in the market, and speed up the dossier review progress. Following global experience, we understand that the effective implementation of this system requires time and resources. At the

same time, there remain critical challenges such as inconsistencies in dossier reviews (leading to delays and administrative burdens), infrequent Drug Committee meetings, lack of expert reviews and registration fees are not yet adjusted to be more appropriate and on a par with regional countries.

We would like to propose the following solutions to regulations and implementation, to 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.

Recommendations

We would like to make the following recommendations:

Regulations solutions

> Establish a mechanism for Marketing Authorisation (MA) to remain valid throughout the product lifecycle, similar to the practice in other countries, instead of being subject to renewal every 5 years.
> Harmonise administrative requirements with international guidelines and practices (most notably for the Certificate of Pharmaceutical Product).
> Remove administrative requirements that are challenging to implement while not adding to the assurance of product safety, quality and efficacy
> Enable automatic synchronisation of approved updates/variations across different lists to ensure drug information is always up to date while reducing workload for the authorities.
> Apply more appropriate drug registration fees to be on a par with other countries in the region, especially since the review of clinical dossiers requires expertise and additional resources.

Implementation solutions

> Optimise the dossier review and appraisal process with clear accountability and commitment to regulated timelines including organising fixed, preferably monthly, Drug Committee meetings to ensure shared understanding and consistent feedback from dossier review experts. Ensure an effective and efficient online registration system that is implementable for both regulator and industry, and can truly speed-up the dossier review timeline.

2. Procurement

Issue description

In recent years, there has been increased pressure on cost-containment to effectively manage the sustainability of the healthcare budget in Vietnam. For the innovative industry, we would like to highlight the importance of careful consideration before introducing and implementing important policy changes for cost-containment objectives, noting the unique context of Vietnam[5]:

5 Quintiles IMS data analysis 2020.

1. Vietnam has achieved good health outcomes, while there is an inherent need to ensure equitable and sustainable access to medicines and healthcare services for patients, without compromising on quality:
    a. From a payer perspective, Vietnam has the lowest price level in ASEAN, on par with Malaysia (better than Thailand, Indonesia, and the Philippines) when looking at the average price across five key therapeutic areas.
    b. Vietnam's use of originator products (Value/Volume) is already amongst the lowest in the world (much lower than countries such as EU5 and ASEAN+5, in 2019:
        - Vietnam (26% Value / 4% Volume);
        - In ASEAN+5 (40.4% Value / 7.4% Volume)
        - In EU5 (64.86% Value / 30.32% Volume)
2. Vietnam's procurement channels are unique. The public hospital drug tender channel currently contributes more than two-thirds of the value of the total prescription drug market for treatment, an exceptionally large number, and unique compared to other countries in the world. As a specific example, for Diabetes, the hospital channel in Vietnam contributes up to 85 per cent volume whereas the corresponding volume in Germany is 1.2 per cent, France 1.1 per cent, Korea 2.6 per cent, and Singapore 16.9 per cent.[6]

*"Drug prices in Vietnam are well-controlled and **among the lowest in ASEAN.***

*Vietnam also has one of the **highest usages of generic medicines** in public hospitals."*

For this reason, in Vietnam, if not carefully considered and managed, any change in procurement regulations will have a systemic, harsh effect, and impact all aspects and actors in the healthcare system – from hospitals, healthcare professionals, industry and, most importantly, patients – suddenly and significantly.

Potential gains/concerns for Vietnam

Today, the innovative industry is particularly concerned about the lack of clarity, predictability and sustainability for the implementation of the Price Negotiation mechanism**.** While it is agreed that Price Negotiation is an effective mechanism to help manage the healthcare budget ensuring patient access to innovative medicines, this mechanism needs to consider multiple factors to ensure the avoidance of unintended and adverse consequences. This includes sustainability in terms of price reduction magnitude and frequency, predictability of the criteria applied, and clarity of the timing and process for implementation. Without the assurance of these principles, it is estimated[7] that at least 143 out of 701 products will face possible supply disruptions, impacting

6 Ibid.
7 Impact Assessment of the new price negotiation implementation, PwC, 2021.

over 25 million patients and a reduction of 58 per cent in planned industry investment and significant job losses.

Furthermore, with the implementation of Price Negotiation, it is important to ensure clear guidance for how originators will be procured during the transition time is widely communicated. Otherwise, patient access will be put at risk and the situation will further jeopardize the value and potential investment that the industry can contribute to Vietnam.

Also, frequent considerations to revise the Tender Circular (on average every two years) presents uncertainty and challenges for both industry and hospitals in planning and ensuring an adequate supply of medicines for treatment. Most recently, in anticipating changes to the current Tender Circular 15[8]/2019 and coupled with the lack of guidance on how originator products subject to Price Negotiation are to be procured, many hospitals have delayed or put on hold the procurement for originators. This poses significant risks for patient treatment.

Besides, whereas in many other markets, access to innovative medicines is fast, Vietnamese patients - whether in self-paid or under reimbursement - still have to wait many years. An unpredictable investment climate, coupled with the existing challenges and uncommonly long timelines to bring innovative medicines to Vietnam, will risk further reducing access to valuable treatment options for Vietnamese citizens.

Therefore, procurement regulations should not be looked at separately. A holistic approach across policies for faster registration, value-based procurement and faster reimbursement decisions will need to be in place to ensure a viable environment for the innovative industry to operate, bring new medicines to market and further invest in Vietnam for the long term.

Recommendations

We would like to make the following recommendations:

- Assure that the implementation of Price Negotiation adheres to the principles set out (i) sustainability in price reduction magnitude and frequency, (ii) predictability of the criteria applied and clarity in the implementation schedule for all parties, and (iii) a transparent and meaningful process, to increase access instead of eliminating products from the market.
- Improve the predictability in the development of regulations to avoid sudden changes in procurement mechanism for originators, as transparency, consistency and predictability are critical to ensure sustainable patient access.
- Amend relevant legislation to enable patient/doctors' access to originators outside the current public hospital procurement system.

3. National Reimbursement Drug List

8 Circular 15/2019/TT-BYT dated 11 July 2019 of the Ministry of Health regulating drug tendering at public health establishments.

Issue description

Once a pharmaceutical product receives its MA for circulation in Vietnam, it is still not eligible for inclusion in the National Reimbursement Drug List (NRDL). The long and complicated process to review and update the NRDL leads to delays in patients' access to new treatments.

In practice, the NRDL is updated only every three to four years and the MOH would need to issue Circulars for such updates, which is a lengthy process. Currently, patient associations and industry stakeholders are not able to propose inclusion/removal/amendment of medicines to the NRDL, nor participate in consultation sessions.

Potential gains/concerns for Vietnam

With the significant delays in registration and reimbursement timelines in Vietnam, we have seen - compared to other ASEAN countries - only a limited number of innovative molecules approved by EU and US authorities being made available in recent years in Vietnam. This results in a significant shortage in the delivery of innovative pharmaceuticals to Vietnam, and an inefficient process where many medicines – although MAs are granted at different points in time – will need to wait for one additional round of NRDL review.

Recommendations

We would like to make the following recommendations:

> Revise and update the NRDL regularly, either on a rolling basis, or with an increased cycle frequency (at least on an annual basis), with appropriate measures to ensure implementation**.**
> Allow for simultaneous review of the registration for Marketing Authorisation and NRDL submission and innovative medicines approved by reference/stringent regulatory authorities should be eligible for inclusion in the NRDL upon MA approval, to enable fast patient access.
> Allow for fast-track review and/or NRDL updates supplemented through a decision issued by the MOH.
> Allow experts from patient associations and the pharmaceutical industry to be part of the consultation sessions with MOH and VSS to ensure that decisions to update and supplement the NRDL are made based on complete data and references from global experience.

ACKNOWLEDGEMENTS

EuroCham Pharma Group

EuroCham Pharma Group (PG)[9] 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.

9 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.