CHAPTER 21 **PHARMACEUTICALS**

OVERVIEW

Pharma Group represents the voice of the innovative pharmaceutical industry in Vietnam, with 22 member companies who all share the same mission: to ensure patients in Vietnam have fast and sustainable access to safe, high-quality, and innovative medicines.

The COVID-19 pandemic has tested the resilience and agility of health systems, including Vietnam's, in an unprecedented way. The crisis has not only cast light on the strengths and weaknesses of the current system but also has highlighted the great solidarity of all actors, from both the public and private sectors, and the importance of innovation and health security.

Pharma Group members have had a paramount role in combatting the pandemic through leveraging years of investment in vaccine and therapeutic technology platforms, the immediate initiation of clinical development programmes building on our long experience and established networks, and rapid investments in scaling up manufacturing capabilities across the world. More than ever, we believe that the innovative pharmaceutical industry can play an important role in rebuilding and improving Vietnam's healthcare system to better address tomorrow's challenges.

Beyond that, we also share the vision with the government that Vietnam can become a leading country in ASEAN for high-quality healthcare in the next decade, and a destination of choice for high-value investment in clinical research, technology transfer, and digital infrastructure.

We affirm our commitment to supporting Vietnam's efforts to address current and future healthcare challenges, and wish to contribute our proposals in this chapter to:

- Speed up the availability of new and innovative medicines, by reducing the time for Marketing Authorization approval and Reimbursement listing;
- Improve accessibility for patients: by ensuring these medicines are available via different channels, both public and private, as well as facilitating patient support programs;
- Prevent shortages of medicines by removing the administrative barriers for supply chain continuity, and providing predictability for procurement;
- Strengthen the regulatory system by adapting global best practices to improve regulatory processes and optimize resources, while maintaining oversight of the quality, safety and efficacy of medicines;
- Attain sustainable health financing via applying a value-based approach to public procurement and healthcare financing policies for the benefit of patients, government and industry; and
- Create an enabling and attractive environment for pharmaceutical companies to operate and further invest, which in turn will foster the development of the pharmaceutical sector and increase Vietnam's competitiveness in ASEAN.

As evidenced during the pandemic, with frequent dialogue and close collaboration at all levels, we can effectively combat an unprecedented crisis. We believe now is the time to use the lessons learned from the pandemic period, and the renewed economic goals and public prioritization for health, to put in place ambitious and sustainable policies for a more resilient and prosperous future.

Pharma Group and our members look forward to continuing this partnership with the government and all actors in the healthcare system to achieve the above goals toward a healthier Vietnam.

I. PATIENT ACCESS TO INNOVATIVE MEDICINES

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

Issue description

The unprecedented speed of innovation exhibited over the last few years and the health outcomes it brings provide an important opportunity for countries to look at the current innovation pipeline, access timeline, and availability of innovative medicines.

Over the last 5 years, the number of new chemical and biological entities that have been made available in Europe, the U.S., and Japan is 72, 159, and 41 respectively.[1] As a key driver in the continuous research and development of new treatment solutions globally, our members strive to bring the latest medicines to Vietnam as fast as possible. However, innovation only matters if it reaches patients when and where they need them.

At this point in time, in Vietnam, regarding availability:

- It can take 4-5 years for a new medicine approved in Europe, the US or Japan to be available in Vietnam.
- Inclusion of new medicines to the National Reimbursement Drug List is only done every 3-4 years, so there is a significant gap from the time it takes to obtain medicine marketing authorisations, to the time it is listed in the National Reimbursement Drug List (NRDL), which allows patients to gain access through the public health insurance scheme.
- This represents a significant shortcoming in the delivery of innovative pharmaceuticals to Vietnam and an inefficient process where many medicines will need to wait for the same round of NRDL review.

It is critical to note that availability is not accessible:

- Even when a medicine is on the NRDL, this does not mean that patients have access to it. In Vietnam, the public hospital drug tender channel currently contributes more than two-thirds of the value of the total prescription drug market for treatments, which is an exceptionally large number when compared with other countries. Therefore, any change in policy or implementation of public procurement will have a great impact on patient access. In the past year, shortages of medicines have affected the continuous treatment for patients, and the healthcare system as a whole. Therefore it is critical to address not only delays in drug registration and NRDL listing, but also to ensure the predictability and sustainability of procurement policies and implementation.

In terms of progress, the industry appreciates the ongoing efforts of the Ministry of Health to improve the regulatory framework for faster patient access to quality medicines. Most notably, we welcome the recent issuance of Circular 08[2] to address the technical barrier of Certificate of Pharmaceutical Product (CPP) requirements raised in previous Whitebook editions and to harmonize many regulatory requirements with international best practices. Furthermore, we appreciate the pragmatic solutions to speed up the dossier review progress via establishing new dossier review agencies, digitalising the MAs application process and improving the online submission portal.

However, it is clear from the above challenges that there is a need for a wider dialogue on holistic solutions to improve access and availability of innovative medicines. From the industry's perspective, many of the challenges today can be resolved through policies and implementation commitments from all stakeholders.

Recommendations

We would like to make the following recommendations:

› Drug Registration:

a. **Reliance**: adopt the Regulatory Reliance mechanism as recommended by the World Health Organisation for drug registration that is suitable for the Vietnam context, to optimise resources and enable faster patient access to quality medicines including new medicines and orphan drugs.

1 "The Pharmaceutical Industry in Figures", EFIPIA, Available at: https://www.efpia.eu/media/637143/the-pharmaceutical-industry-in-figures-2022.pdf, last accessed on 1st December 2022

2 Circular 08/2022/TT-BYT dated 5 September 2022 of the Ministry of Health on Registration of drug, drug raw materials

b. **Renewal**: urgently enable the MA renewal procedure to be conducted automatically, to implement the Prime Minister's Decision 1661[3] and minimise risks of supply disruption.

c. **Revise the drug registration fee** currently specified in Circular 277[4] by 2023 to respond to the current needs and with reference to practices in other countries, to enable efficient management of resources for dossier review and achieve management objectives of the authority.

› National Reimbursement Drug List:

d. Revise Circular 30[5] within 2023 to enable the NRDL to update at least on an annual basis as per the government's direction.[6]

e. Allow for simultaneous reviews of registrations for MA and NRDL submission. Innovative medicines approved by reference stringent regulatory authorities (SRA) should be eligible for inclusion in the NRDL upon MA approval to enable fast patient access.

› Public Procurement:

f. Ensure the stability of procurement policies by maintaining the brand name bidding package for on-patent and off-patent originators and by effectively implementing the price negotiation mechanism to ensure continued patient access to the highest quality treatments and a predictable, sustainable investment environment.

II. SECTOR DEVELOPMENT

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

Issue description

The global life sciences sector will be one of the key drivers of the 21st-century economy because of great scientific advances in biotechnology and related fields, and because of the growing social need to address healthcare issues.

It is, therefore, strategically important that Vietnam works to become a more significant participant and partner in the global life sciences sector, both to advance its technological and economic development, and for the health benefits it would bring the Vietnamese people. It is clear from the Resolution 29/NQ-TW by the Central Committee of the Communist Party of Vietnam and Decision 376 of the Prime Minister[7] that innovation plays a crucial role in this.

It is more important than ever to attract investment from the innovative industry to achieve the country's ambition of becoming an ASEAN hub for pharmaceutical manufacturing capable of producing innovative medicines by 2030, to have patented medicines by 2045, and have a pharmaceutical industry contributing more than US$20 billion to the country's GDP.

The innovative pharmaceutical industry has a large appetite to invest in R&D, tech transfer and digital healthcare infrastructure, in line with the government's strategic goals. The future of the innovative pharmaceutical is bright: it is projected to contribute an additional US$26.8 billion to US$99.3 billion to Vietnam's GDP by 2045 It is important to note that this promising scenario cannot be achieved unless there is an enabling investment environment with attractive policy incentives.

3 Decision 1661/QD-TTg dated 4 October 2021 by the Prime Minister approving the Plan to reduce and simplify regulations related to business activities under the management function of the Ministry of Health

4 Circular 277/2016/TT-BTC dated 14 November 2016 bythe Ministry of Finance on amounts, collection, payment, management and use of fees in the fields of pharmacy and cosmetics.

5 Circular 30/2018/TT-BYT dated 30 October 2018 by the Ministry of Health on promulgation of list of modern medicines, biologicals, radiopharmaceuticals and tracers covered by health insurance, insurance coverage ratio and payment conditions thereof.

6 Official Letter 294/TB-VPCP of the Office of Government dated 23 September 2022.

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

It is critical to realise that today, policy barriers and delays in market access, coupled with frequent disruptions in procurement policies, are significant deterrents, undermining the predictability and sustainability required to support such investment.

Therefore,

- Changes to reduce administrative burden and enable a more predictable and sustainable environment need to happen now;
- Incentives and plans to attract investment need to be integrated into a concrete roadmap towards 2045; and
- It is critical to ensure the innovative industry is a key partner in the National Steering Committee for sector development.

Potential gains/concerns for Vietnam:

Given an attractive environment, the social and economic value that can be generated from such investment is significant.

Figure 7: The prospect of success

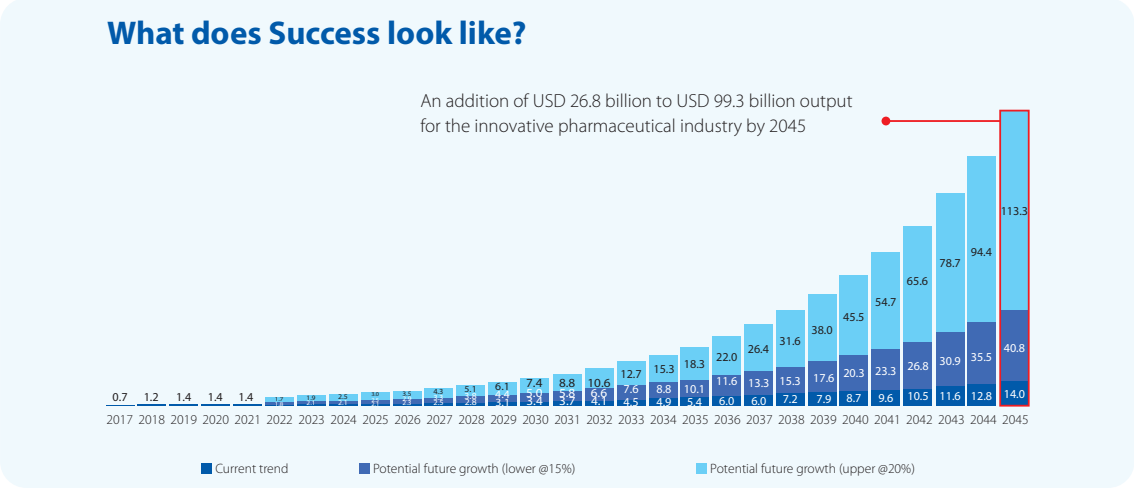

Figure 8: The Value of an Innovative Pharmaceutical Industry

Recommendations

We would like to make the following recommendations:

- Provide an enabling business environment for innovative companies through revising regulations, including the Pharma Law[8] and Decree 54,[9] to enable companies to effectively and meaningfully operationalise their legal entities.
- The National Steering Committee should develop and oversee the implementation of national strategies, including Decision 376 of the Prime Minister, and should include representatives of the innovative pharmaceutical industry. This committee is recommended to direct the development of policy incentives to attract further investments from innovative industry, with a focus on three key pillars:
    i. Attracting investment in clinical trial activities as an enabler to further develop Vietnam's R&D capabilities;
    ii. Enable Vietnam to become the destination of choice for investment in brand name manufacturing and technology transfer activities in the region; and
    iii. Develop and embed leading digital healthcare infrastructure.

The effective enforcement of intellectual property rights (IPR) in accordance with the EVFTA (EU Vietnam Free Trade Agreement) and other FTAs, particularly the introduction of patent term adjustments for MA delays, will encourage innovative pharmaceutical companies to invest in technology transfer and bring new medicines to Vietnam. Furthermore, with the economy moving more toward research and innovation, IPR becomes more relevant. Thus, a strong enforcement framework will also benefit the emerging local industry, the pharmaceutical sector as well as others.

III. SUSTAINABLE HEALTH FINANCING

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

Issue description

Vietnam has achieved a great feat with its 91 per cent universal health coverage. However, as with other social health insurance systems over the globe, Vietnam struggles with financial sustainability. The healthcare system has been heavily affected by both the pandemic and pre-existing issues such as disease burden, an ageing population, and overwhelmed healthcare establishments.

Through dialogue with government agencies, the industry is encouraged to see the determination to make changes in current health financing mechanisms to meet current and future healthcare demands.

Vietnam's social health insurance scheme can be improved by increasing population coverage and enabling access to high-quality medicine and treatment while ensuring these do not cause catastrophic out-of-pocket spending. To this end, a complementary health insurance package and other innovative mechanisms can be developed.

Three priority areas can be worked on: a favourable policy environment, the interest of insurers and digital capability.

Affordability is one of the most basic considerations to be made. To ensure healthcare affordability, insurance should offer sufficient compensation and benefits without cost-prohibitive deductibles. Additionally, the communication strategy around insurance uptake should be robust. There should be consistent messaging, especially coming from the government, that gives people the confidence to subscribe to supplemental or

8 Law 105/2016/QH13 dated 06 April 2016 of the National Assembly on Pharmacy.
9 Decree 54/2017/ND-CP dated 8 May 2017 of the Government on guidelines for implementation of the Law on Pharmacy.

complementary health insurance packages. Digital and online channels could be utilised to make sure there is enough access to information. These models need to be incentivised.

The political intent and stewardship are already there in Resolution 20[10] of the Central Committee on healthcare protection, including healthcare financing reformation and the need to "diversify health insurance packages, strengthen linkages and cooperation between social health insurance and commercial health insurance". It is highly recommended that substantial regulatory openness be exercised to uptake the new plans.

Potential gains/concerns for Vietnam:

Innovative funding helps contribute to the need for a responsive, equitable and grounded social health insurance scheme, which would resolve the rising mortality in non-communicable disease patients, catastrophic health costs, and underinvestment in non-communicable diseases.

Recommendations

We would like to make the following recommendations:

- Health Insurance Law revisions to include complementary health insurance and other innovative mechanisms such as value-based agreements;
- Enable service pharmacies within public hospitals to purchase drugs outside of bid-winning lists via a Pharma Law revision;
- Procurement and Reimbursement policies development and actual implementation should ensure the achievement of increased patient access and choice to new, safe, and high-quality drugs ; and
- Patient Support Programmes: revise Circular 31 to address practical implementation challenges.

ACKNOWLEDGEMENTS

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10 Resolution 20-NQ/TW dated 25 October 2017 of the 6th meeting of the 12th Central Committee on enhancement of citizens' health protection, improvement care in new situation.