CHAPTER 14 **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 fast and sustainable access to safe, high-quality, and innovative medicines for patients in Vietnam.

Operating on the basis of science and research, we believe in the power of innovation to help address the challenges facing our healthcare system and to drive the socio-economic development journey. We fully embrace the ambitious goals outlined in Resolution 20[1], Resolution 29,[2] Resolution 36,[3] and most recently, Decision 1165[4] approving the National Strategy for Vietnam's Pharmaceutical Industry Development by 2030 and vision by 2045.

To achieve such vision, we wish to contribute our proposals in this chapter across three key pillars:

1. Improve Patient Access to Innovation;
2. Foster the adoption of sustainable Healthcare Financing policies for innovation; and
3. Incentivise the development of an Innovative Pharmaceutical Ecosystem.

2024 will be a critical year as key legislations shaping the pharmaceutical sector for the next decade are being revised. We hope the chapter can add value to evidence-based policymaking and foster further consideration for investments in a resilient healthcare system and an enabling ecosystem in which further innovation can thrive.

Embarking on a new chapter following 25 years of partnership in Vietnam, Pharma Group renews its dedication to partnering with the Government and all actors in the healthcare system to achieve our shared goals for a healthier and more prosperous Vietnam.

I. IMPROVE PATIENT ACCESS TO INNOVATION

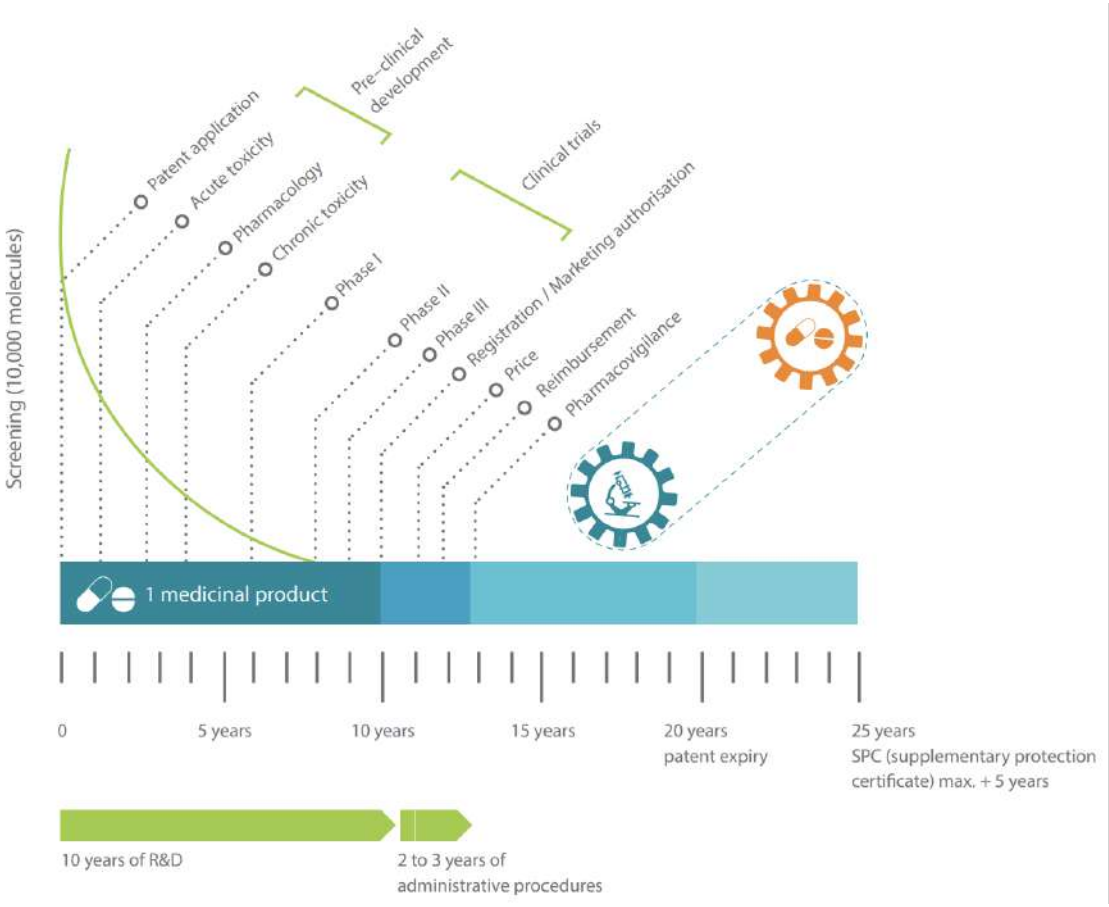
Relevant authorities: Ministry of Health (MOH), Vietnam Social Security (VSS), Ministry of Planning and Investment (MPI)

Issue description

All new medicines introduced into the market are the result of lengthy, costly, and risky research and development conducted by pharmaceutical companies. By the time a new medicine reaches patients, an average of 12-13 years will have passed since the first synthesis of the new active substance, and an estimated investment of US$2 billion. On average, only 1 to 2 out of every 10,000 laboratory-synthesized substances will successfully complete all stages of R&D to become a marketable product.[5] In light of the global health concerns, it is of critical importance for the innovative industry to be able to deliver safe and high-quality diagnostics, vaccines and treatments to patients as fast as possible.

1 Resolution 20-NQ/TW dated 25 October 2017 of the Party Central Committee on enhancement of citizen's health protection, improvement, and care in new situation (Resolution 20).
2 Resolution 29 - NQ/TW dated 17 November 2022 of the Party Central Committee on continuing to promote industrialization and modernization of the country to 2030, with a vision to 2045 (Resolution 29).
3 Resolution 36 – NQ/TW dated 30 January 2023 of the Party Central Committee on development and application of biotechnology for sustainable development of the country in the new situation (Resolution 36).
4 Decision 1165/QĐ-TTg dated 9 October 2023 of the Prime Minister approving the National Strategy for Vietnam's Pharmaceutical Industry Development by 2030 and vision by 2045 (Decision 1165).
5 "The Pharmaceutical Industry in Figures", *EFPIA*, European Federation of Pharmaceutical Industries and Associations, 20 June 2023. Available at: <https://www.efpia.eu/media/rm4kzdlx/thwe-pharmaceutical-industry-in-figures-2023.pdf >, last accessed on 19 December 2023.

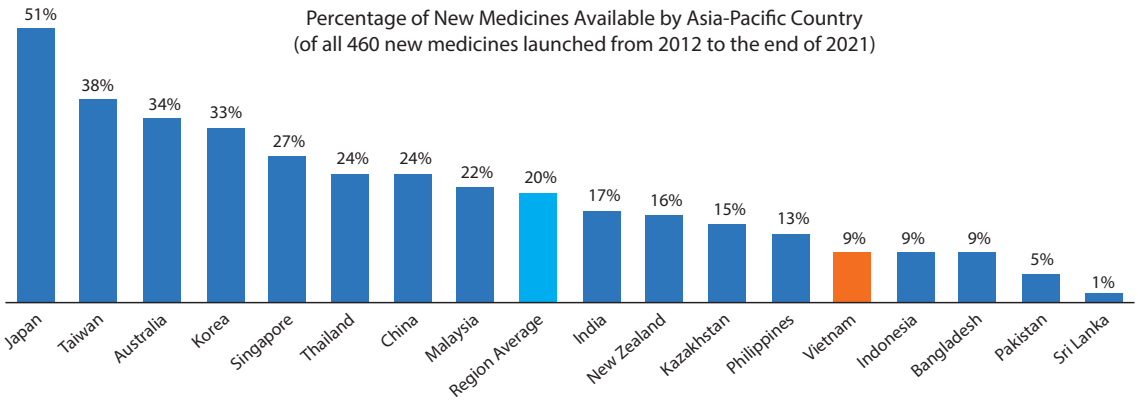
Figure 8: Phases of the Research and Development process (Source: EFPIA, 2023)



The significant investment and speed of innovation in the last decade provides an important opportunity to improve patient health outcomes. All actors involved in healthcare – from patients to doctors, researchers, manufacturers, regulators, payers – want to see patients across the globe benefit from advances in treatment. However, a significant number of new medicines are not yet available in several countries, including Vietnam. A recent report revealed that only 9 per cent - equivalent to 42 out of 460 – of the new medicines launched globally between 2012 and 2021 are available in Vietnam, compared to the Asia-Pacific average of 20 per cent.[6] Of this 42 new medicines, only 27 per cent are accessible in the public hospital channel through the National Reimbursement Drug List (NRDL). The industry shares concerns about the late market entry and unavailability of medicines, which are not unique to Vietnam. These are caused by different factors ranging from lengthy regulatory processes to reimbursement delays.

6 PhRMA analysis of IQVIA MIDAS and country regulatory data. October 2022. *Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021*

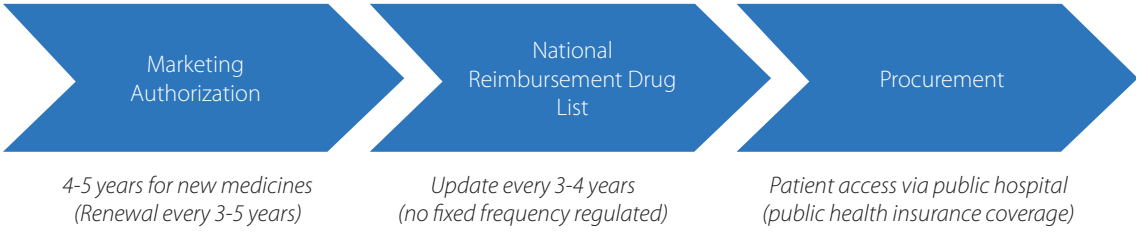
Figure 9: In 2022: 9 Per cent of new medicines are available in Vietnam (Source: PhRMA, 2022)



Vietnam has an opportunity through the upcoming revision of major legislations, including the Pharma Law and the Health Insurance Law, to improve patient access to innovation. Beyond direct benefits to individual patients, faster access can translate into long-term societal benefits – people live longer, healthier and more productive lives, contributing to the economy and easing the impact on caregivers. Having new medicines readily available can also benefit Vietnam in the long term as the country aims to position itself as a regional destination for medical tourism.

From our perspective, many of the challenges today can be resolved through policies and implementation commitments from all stakeholders.

Our recommendations focus on accelerating patient access, including proposals to speed up the regulatory procedures for market entry, to enabling medicines to reach patients when and where they need them.



Potential gains/concerns for Vietnam

- It takes **8-9 years** on average for a new medicine already approved for circulation by stringent regulatory authorit(ies) to reach patients in Vietnam via the public health insurance scheme. This includes the **4-5 years** it takes to obtain Marketing Authorization in Vietnam, and **3-4 years** for such medicine to be considered for inclusion in the NRDL;
- Throughout the product's lifecycle, delays in approval of changes (variations) or MA renewals can often lead to **supply disruptions and medicine shortages** as seen in recent years. Urgent measures granted by the National Assembly in recent the Resolution 80[7] temporarily addressed the medicine shortage issue, however **thousands of backlogged dossiers** remain, which require longer-term solutions;
- Among our membership, **76 new medicines** across **13 therapeutic areas**, including cancer, cardiovascular… and other life-saving medicines, are waiting for NRDL review; and

7 Most recently Resolution 80/2023/QH15 dated 9 January 2023 of the National Assembly regarding continuation in implementation of certain COVID-19 management policies and use of marketing authorization licenses of medicines or pharmaceutical materials expired from 1 January 2023 to 31 December 2024.

› Every year, patients in Vietnam spend approximately **US$2 billion** on outbound medical tourism to gain access to treatment solutions that are out of reach at home.

Recommendations

We would like to make the following recommendations:

› **Speed up the availability of new medicines by reducing the Marketing Authorization approval timeline** *(revision of the Pharma Law)*

a. **Regulatory reliance**, as recommended by the World Health Organisation (WHO), allows an authority to use the work of other trusted regulatory authorities when making its own decision. This can help reduce workload and prioritize resources. We strongly recommend adopting this mechanism in Vietnam to speed up the Marketing Authorization decision for new medicines, post-approval variations, and vaccines' batch-release testing, to enable timely access for patients while still ensuring the quality, safety and efficacy of medicines and maintaining Vietnam's regulatory responsibilities for decision-making.

› **Prevent medicine shortages of medicines via reduction of administrative barriers and regulatory harmonization** *(revision of the Pharma Law)*

a. **Renewal**, which is mainly an administrative procedure to be streamlined per Decision 1661[8] in 2021 should be made automatic to reduce the workload of both companies and the authority and most importantly, avoid supply disruptions as seen in recent years.

b. **Ensure a transitional measure is in place and in effect at the end of 2024** to maintain the validity of thousands of Marketing Authorizations extended by the National Assembly's Resolution 80 dated 9 January 2023, in case their renewal dossiers could not be reviewed on time and the automatic renewal mechanism is not yet in effect.

c. **Post-approval site change** should be classified as a Major Variations to harmonize with the ASEAN Variations guideline instead of a new registration dossier as currently stipulated in the Pharma Law, to reduce the significant administrative burden and approval timeline.

› **Improve patient access to new medicines in public hospitals via timely National Reimbursement Drug Listing** *(NRDL Circular)*

a. **Issue a comprehensive update of the NRDL in 2024**, after a 5-year delay, to include more advanced medicines.

b. **Enable more frequent updates of the NRDL**. The update process should be initiated **at least once a year**, in line with the Government's direction[9] to ensure faster and more equitable access to advances in treatment solutions, and help reduce household direct out-of-pocket expenditures per Resolution 20.

c. The process of proposing drugs for inclusion in the NRDL can be carried out at the time of Marketing Authorization submission. Product license owners, manufacturers or authorized entities are allowed to directly participate in providing information related to products in the process of submission for inclusion into the NRDL to ensure accuracy, completeness, timeliness, scientific soundness and transparency.

d. The requirement for **Health Technology Assessment** (HTA) should be considered carefully in the context of Vietnam, as building relevant databases and expertise will take time to ensure the quality, efficiency and transparency required. We recommend taking a flexible approach to HTA, in which cost-effectiveness evidence should serve only as a reference and not a deciding factor.

8 Decision 1661/QD-TTg dated 4 October 2021 of the Prime Minister approval of a plan to reduce and simplify regulations related to business activities under the scope of management functions of the Ministry of Health (Decision 1661).

9 Official Letter 294/TB-VPCP of the Office of Government dated 23 September 2022 regarding the conclusion of Deputy Prime Minister Vu Duc Dam at the meeting on implementing the Program to develop the pharmaceutical industry, domestically produced medicinal materials and early access to new drugs (Official Letter 294).

- **Ensure patient continuous access to innovative medicines in public hospitals** *(Tender regulations)*

  a. Ensure the **stability of procurement policies** by maintaining the brand name bidding package for 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.

- **Enable medicines' availability for out-of-pocket payment at public hospitals** *(Decree guiding Tender Law)*

  a. Provide a detailed guideline for healthcare establishments to effectively procure medicines which are not covered by the health insurance fund, and vaccines used for on-demand vaccination services, to address the major long-standing gap whereby patients at public hospitals with needs and with the ability to afford are not able to use the medicines[10] as per their demand.

II. FOSTER ADOPTION OF SUSTAINABLE HEALTHCARE FINANCING POLICIES FOR INNOVATION

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

Issue description

95 out of every 100 hospital beds in Vietnam are in public hospitals, illustrating the crucial role that Health Insurance (HI) plays in the country's public health. Up to now, Vietnam has been steadily expanding Universal Health Coverage (UHC), achieving nearly 93 per cent, and aiming to reach 95 per cent by 2025.

However, ensuring the sustainability of the Health Insurance Fund remains a significant challenge, with the rapidly aging population and a rising demand for advanced treatment solutions. A few notable issues:

- Difficulties in maintaining the public health insurance participation to achieve the UHC's 2025 goal while ensuring the sustainability of the Health Insurance fund due to the potential risk of 'adverse selection" where individuals join HI only during medical needs, or people opt out of public HI for other alternative options such as private insurance, out-of-pocket, etc.

- On the other hand, the proportion of out-of-pocket spending of Vietnamese people accounted for over 40 per cent in total health expenditures and could reach 55 per cent by 2025. This is much higher than the WHO-recommended rate and surpasses the levels observed in other ASEAN countries such as Thailand, Malaysia, Indonesia.

Through recent dialogues, the industry is encouraged to see the Government's determination to reform healthcare financing via the Health Insurance Law revision, to realize the goals outlined in Resolution 20 by 2025: (i) improving access to quality care and (ii) reducing out-of-pocket expenses for all citizens. Investing in innovative solutions and proactive reform of healthcare financing policies is crucial to navigate the shift towards a middle-income country with an aging population and safeguard healthcare for Vietnam citizens in the future.

Potential gains/concerns for Vietnam

Globally, the pursuit of UHC has been marked by a surge of innovative interventions that aim to improve life expectancy, quality of life, and diagnostic and treatment options, while also enhancing the efficiency and cost-effectiveness of healthcare systems.

10 Medicines constitute preparations containing pharmaceutical substances or herbal materials for human use for the purpose of prevention, diagnosis, curing, treatment, alleviation, and modification of physiological functions of the human body, including chemical medicines, herbal medicines, traditional medicines, vaccines and biologics – as stipulated in Clause 2, Article 2 of Law 105/2016/QH13 (Pharmacy Law) and reference to the concluding remarks made by Deputy Prime Minister Vu Duc Dam at the meeting on medicine supply to hospitals in Notification 275/TB-VPCP dated 2nd August 2018.

In the context of Vietnam, with the long access timeline as mentioned above, coupled with the rising demand for new treatment advances, it is important to empower innovation activities and access. Putting in place health financing policies that focus on improving access to innovation, at the same time diversifying the insurance packages to provide more choices, increase the scheme's attractiveness and help to release the burden on HI fund. Furthermore, this will also help to sustain HI participation and in turn, reduce the rate of households' out-of-pocket health spending to 35 per cent by 2025, and 30 per cent by 2030.

Recommendations

We would like to make the following recommendations:

- **Regulate the Supplementary Health Insurance package** *(revision of the Health Insurance Law)* to diversify the HI packages, enable optionality for patients and release the HI fund burden for the Government, in line with the direction in Resolution 20.
- **Develop new financing mechanisms**, including: the novel pricing models such as Market Entry Agreements tailored to the Vietnam's context to accelerate patient access while providing sufficient incentives for innovation; consider to facilitate new mechanisms that follow international experience (including financial and non-financial) such as to transfer revenues generated from excise duty imposed on products harmful to health (e.g. alcohol, tobacco) to the health insurance fund; expand and encourage the implementation of patient drug assistance programs…
- **Leverage health data to drive innovation and sustainability**: Regulate linkages, partnerships, and data exchanges between social health insurance and commercial health insurance actors. Consider assigning the Government to regulate implementation guidelines.

III. INCENTIVIZE THE DEVELOPMENT OF AN INNOVATIVE PHARMACEUTICAL ECOSYSTEM

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

Issue description

Vietnam aspires to be among the regional leaders in testing, research and manufacturing of high-quality medicines, striving for the contribution of over US$20 billion to national GDP by 2045. The new sector development approach (as mentioned in Resolutions 29/Decision 1165) focuses on innovation, technological advances and digital transformation as key drivers for success, will enable Vietnam to level-up its pharmaceutical sector.

In an era when countries, including those advanced economies who are world leaders in healthcare products and services, are competing to increase their attractiveness to pharmaceutical investment and innovation, it is critical that Vietnam builds on its own strengths, creates the right conditions for success and develops meaningful competitive advantages.

The seven key enabling factors to build an innovative

> *"Strategies are important, but implementation is key to success. First and foremost, it is critical to create a favorable investment environment for investors via attractive tax policies, good infrastructure, reliable regulations to protect IP and product development, train high quality human resources… Staying ahead of the curve, and being connected with the industry and having a knowledge base of the industry help open doors in the first instance."*
>
> **Dr. Mary Harney**, former Deputy Prime Minister, former Minister of Health & Children of Ireland at the EuroCham Pharma Group Healthcare Innovation Forum on October 18, 2023

sector, according to the report Building a Bioeconomy[11] which examines national strategies, innovation systems, biotech policies and sector development progress of 44 countries, are: *Human capital, infrastructure for research and development (R&D), intellectual property protection (IPP), policy and regulatory environment, technology transfer, market and commercial incentives, legal certainty (including the rule of law).*

Putting in place suitable conditions and a comprehensive set of forward-looking policies can help to generate ambitions into real-world outputs. One of the most relevant and notable example is the significant growth of the pharmaceutical industry in Ireland. Beginning as an agricultural country with the lowest starting point in the EU, The Republic of Ireland has evolved into a US$100 billion export economy for life science products up to now. The country is now the largest pharmaceutical market in the EU, with pharmaceutical exports accounting for over 50 per cent of the net export value. Ireland achieved the status of the world's largest exporter of pharmaceuticals by 2020, hosting 10 of the top 20 pharmaceutical and biological companies globally. The Irish Government's continuous support through policies and initiatives, coupled with favourable factors like low corporate taxes, tax credits for research and development (R&D), and intellectual property protection, further enhance the industry's appeal.

From Pharma Group's perspective, Vietnam holds a lot of potential and has an opportunity to become the next regional hub for healthcare innovation. This includes activities in testing, clinical trials, R&D, technology transfer which in turn will foster the creation of a vibrant, innovation-driven pharmaceutical sector and create spill over effects for other industries.

The key starting point in our view would be to address the current critical issues relating to market access, create a more business-conducive environment, and put in place incentives in policies that are closely linked with market access in order to attract and sustain investment. Most of this can be achieved via the on-going revision of the Pharma Law which will be ratified by the National Assembly in the upcoming period.

Potential gains/concerns for Vietnam

- Healthcare Innovation is not only a matter of sector development but is also linked with societal benefits for patients specifically and the public in general.
- Level up Vietnam's competitiveness among other emerging markets.

Recommendations

We would like to make the following recommendations:

- **Enablers** *(revision of the Pharma Law)*

    a. Enable Foreign Invested Enterprises with the right to import pharmaceuticals ("FIE Importers") to operate their legal entities more effectively, reduce complexities and cost of doing business, ensure smooth information flow throughout the supply chain and ensure continuity, efficiency, and timeliness of medicine supply.

    b. Enable FIE Importers to decide on and carry out investment projects such as local manufacturing (contract manufacturing, technology transfer), clinical trials, etc. with local partners, e.g. the ability to import and transport products used in clinical trials.

    c. Intellectual Property (IP) enforcement: Put in place policies and strict enforcement to protect clinical trial data, drug patents, and other confidential data during drug registration and circulation; Establish an IP enforcement agency to quickly and effectively resolve disputes, closely monitor and strictly inspect and handle cases of patent infringement, compromising clinical trial data, and counterfeit drug.

11 "Building the Bioeconomy", Pugatch Consilium, 3 June 2019. Available at: <https://www.pugatch-consilium.com/reports/BIO%202019%20report_final.pdf>, last accessed on 19 December 2023.

- **Incentives** (*revision of the Pharma Law and other guiding regulations to implement the National Pharmaceutical Sector Development strategy)*

    a. Develop a comprehensive set of incentives in policies, which should be based on the current advantages of Vietnam and well-align with, and even better than, existing incentives offered by other countries in the region. Stakeholder consultation is crucial throughout the development of these incentives to ensure attractiveness and feasibility.

    b. Incentives should be closely linked with market access, such as fast-track Marketing Authorization, NRDL, and procurement.

ACKNOWLEDGEMENTS

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