THE PRIME MINISTER	THE SOCIALIST REPUBLIC OF VIETNAM
_____	**Independence - Freedom - Happiness**
No. 1165/QD-TTg	_____
	Hanoi, October 09, 2023

DECISION
Approving the National Strategy for development of the pharmaceutical industry of Vietnam through 2030, with a vision to 2045

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THE PRIME MINISTER

Pursuant to the Law on Government Organization dated June 19, 2015; Law Amending and Supplementing a Number of Articles of the Law on Government Organization and the Law on Organization of Local Government dated November 22, 2019;

Pursuant to the Law on Pharmacy dated April 06, 2016;

Pursuant to Resolution No. 20-NQ/TW dated October 25, 2017 of the 12th Central Committee of the Communist Party of Vietnam on enhancement of citizens' health protection, improvement, and care in new situation;

Pursuant to Resolution No. 29-NQ/TW dated November 17, 2022 of the Central Committee of the Communist Party of Vietnam on the acceleration of the national industrialization and modernization through 2030, with a vision to 2045;

Pursuant to Resolution No. 36-NQ/TW dated January 30, 2023 of the Politburo on biotechnology development and application to serve the country's sustainable development in the new situation;

At the proposal of the Minister of Health.

HEREBY DECIDES:

Article 1. To approve the National Strategy for development of the pharmaceutical industry of Vietnam through 2030, with a vision to 2045 (hereinafter referred to as the Strategy) as follows:

I. DEVELOPMENT VIEWPOINTS

1. To ensure the proactive and timely supply of high-quality, safe, and effective drugs at reasonable costs to meet the needs of disease prevention, treatment, disaster recovery, crisis management, public health emergencies, and other urgent pharmaceutical demands, while supporting economic and social development and ensuring national defense and security.

2. To develop Vietnam's pharmaceutical industry sustainably, gradually moving towards modernization, with a focus on ensuring drug security; to advance the pharmaceutical, chemical-pharmaceutical, and domestically-produced medicinal material industries; to increase export value and integrate deeply into the global pharmaceutical supply chain.

3. To prioritize Vietnam's pharmaceutical industry as a key sector, allocating resources and implementing strong mechanisms and policies to encourage its development.

4. To develop a professional, modern, efficient, and tightly regulated system for the production, distribution, and supply of drugs; to enhance the efficiency of domestic companies in medicine supply and distribution in alignment with international commitments.

5. To ensure the rational, safe, and effective use of drugs through a comprehensive system of measures, with a focus on promoting and enhancing the capacity and effectiveness of clinical pharmacy activities, pharmacovigilance, and building a digital data ecosystem for the pharmaceutical sector.

II. OBJECTIVES

1. General objectives

To propel Vietnam's pharmaceutical industry to the forefront, on par with advanced nations in the region; to ensure that drugs remain accessible at reasonable costs; to bolster research capabilities and leverage available technology to produce original brand-name drugs and modern dosage forms; to aim for Vietnam to become a hub for manufacturing or contract manufacturing/technology transfer of original brand-name drugs within the ASEAN; to strive to elevate the country's domestic pharmaceutical industry to Maturity Level 4 in WHO's classification; to develop medicinal materials, and to develop drugs and products from domestic medicinal materials into high-quality, high-value goods; to enhance the production of medicinal ingredients; and to optimize medication usage.

2. Specific objectives to be achieved by 2030:

a) To ensure 100% proactive and timely supply of drugs for disease prevention and treatment; to safeguard drug security to meet the demands of national defense, security, disease prevention and control, and to address the repercussions of natural disasters, crises, public health emergencies, and other urgent pharmaceutical demands.

b) To strive to meet about 80% of the demand for domestically-produced drugs and 70% of the market value. To strive to achieve the target of producing 20% of the raw materials required for domestic drug production. Domestically-

produced vaccines will meet 100% of the demand for the expanded immunization program and 30% of the demand for on-demand vaccination services.

c) To strive to become a regional hub for high-value pharmaceutical production. To receive technologies for the production of at least 100 original brand-name drugs, vaccines, biologicals (including biosimilars), and certain drugs that Vietnam has not yet been able to produce, through exclusive technology transfer or contract manufacturing with technology transfer.

d) To establish 08 regions for the sustainable utilization of natural medicinal materials and 02 - 05 zones for large-scale production of medicinal materials. To reintroduce, import, propagate, and develop 10 - 15 species of medicinal plants with large-scale imported sources. To standardize 100% of medicinal raw materials (including extracts, essential oils, and powdered herbs) for domestic drug production.

dd) The national regulatory authority for chemical pharmaceuticals to achieve Maturity Level 3 or higher in WHO's classification while the national regulatory authority for vaccines to maintain and enhance its maturity level as benchmarked by WHO.

e) To sustainably maintain a 100% rate of drug businesses complying with good practice standards; to strive for 100% of drug testing facilities, vaccine testing facilities, and medical biological testing facilities to meet Good Laboratory Practice (GLP) standards; and to have 20% of drug manufacturing facilities meet EU-GMP, PICs-GMP, or equivalent standards.

g) To strive for 30% of generic drugs (excluding those with local effects, and those with systemic effects that have bioequivalence with the reference drug) to be produced domestically and imported drugs to have registration certificates evaluated for bioequivalence; and to ensure 100% of drugs on the market are fully monitored and managed for efficacy and safety according to the regulations of the Ministry of Health.

h) To ensure 100% of medical examination and treatment establishments involved in drug use have organized and implemented clinical pharmacy activities. To achieve a ratio of 01 clinical pharmacist per 100 inpatient beds and 02 clinical pharmacists per 1,000 outpatient prescriptions issued to insured patients per day. To provide high-quality pharmaceutical care services.

i) To complete the digital transformation of the pharmaceutical industry; to digitize 100% of information and data on approved drugs still valid in Vietnam and update it into the pharmaceutical industry database; to inter-connect 100% of drug manufacturing, wholesale, import/export, and retail facilities nationwide; to ensure 100% of level 4 online public services in the pharmaceutical industry are integrated into the National Public Service Portal

and maintained; and to implement artificial intelligence applications in the pharmaceutical industry.

k) To achieve a ratio of 4.0 pharmacists per 10,000 people, with at least 20% of pharmacists trained in clinical pharmacy.

3. Orientations towards 2045:

To ensure domestically-produced drugs meet domestic needs and enhance export value, with deep integration into the global supply chain; to proactively produce specialty drugs, new drugs, original brand-name drugs, vaccines, medical biologicals, and medicinal ingredients; and to develop original brand-name drugs from domestic medicinal sources that are researched, produced, and registered. To strive for the pharmaceutical industry's total contribution to GDP to exceed USD 20 billion. To achieve a level of pharmaceutical testing, distribution systems, clinical pharmacy practices, drug information, and pharmacovigilance equivalent to advanced countries worldwide.

III. KEY TASKS AND SOLUTIONS

1. Further legal and institutional improvement

a) To improve the legal system related to drug production, trade, import/export, supply, distribution, and use, including medicinal ingredients, ensuring strict and appropriate management that aligns with international regulations. This includes implementing investment policies with the highest incentives for activities such as research, technology transfer, production of innovative drugs, specialty drugs, high-tech formulated generic drugs, vaccines, reference biologicals, biosimilars, and drugs derived from Vietnamese medicinal plants with national branding, and medicinal ingredient production, etc.

b) To improve regulations on managing the drug distribution and supply system, focusing on bidding and procurement regulations to ensure transparency and prioritize high-quality drugs at reasonable prices, avoiding drug shortages.

c) To improve intellectual property protection and enforcement regulations for drugs in Vietnam, facilitating the registration of generic drugs nearing patent expiration, first biosimilars, orphan drugs, and vaccines pre-qualified by the World Health Organization.

d) To develop a phased roadmap to elevate Good Practices (GPs) standards for drug manufacturing and trading activities; to implement PIC/S-GMP or equivalent standards in drug production in line with international integration trends and encourage the adoption of EU-GMP; to explore participation in the Pharmaceutical Inspection Co-operation Scheme (PIC/S). To continue improving policies, legal documents, and professional guidance

related to clinical pharmacy, pharmacovigilance, drug information, and advertising.

dd) To adopt investment policies that encourage the establishment and development of internationally recognized clinical trial centers in Vietnam for new drug development and bioequivalence testing. To increase the number of active ingredients requiring bioequivalence study reports through a phased approach.

e) To adopt reasonable import policies that align with international agreements to which Vietnam is a signatory. To strongly promote the pharmaceutical chemical industry and adopt supportive policies for production of medicinal chemical ingredients and limit imports of medicinal chemical ingredients that Vietnam can produce domestically.

g) To develop long-term, transparent, and favorable policies to create an environment conducive to becoming a regional hub for high-value pharmaceutical production.

2. Planning

a) To allocate and reserve land for the development of research and pharmaceutical production facilities in accordance with the master plans approved by competent authorities.

b) To complete and effectively implement the State's system for drug and medicinal ingredient testing, ensuring the system's capacity to promptly meet management needs, support production and business activities, and open up the possibility for international integration. To promote socialization and public-private partnerships for investment and development of the testing system.

c) To reorganize the centers for bioavailability and bioequivalence (BA/BE) studies; invest in upgrading existing BA/BE centers, clinical trial centers, and preclinical trial centers, and establishing new ones.

d) To review and plan the drug supply system to ensure professionalism, modernity, and efficiency, with a focus on developing the drug supply system for ethnic minorities, and people in mountainous areas, islands, and socio-economically disadvantaged areas.

dd) To formulate master plans for medicinal material development suited to the specific natural conditions of each region, creating supply chains from cultivation to processing, production of drugs, medicinal ingredients, cosmetics, and functional foods for domestic use and export.

3. Investment in and enhancement of competitiveness, and improvement of linkages and participation in the value chain of the pharmaceutical industry

a) To mobilize all resources from domestic and international organizations and individuals to promote investment in research, testing, and the

development of pharmaceuticals, vaccines, and biologicals within the country; to invest in producing pharmaceutical ingredients; to invest in establishing centers for bioavailability and bioequivalence (BA/BE) studies and evaluation, as well as centers for international (multicenter) clinical trials.

b) To prioritize the allocation of resources for developing pharmaceutical industrial parks to attract investors in projects such as manufacturing of patented original brand-name drugs or contract manufacturing of drugs after the expiration of their patents or relevant certificates of exclusivity; specialty and therapeutic drugs; generic drugs with hi-tech formulations; vaccines and biologicals, polyvalent vaccines, and drugs and vaccines for emerging, dangerous, highly contagious diseases in the community and extended immunization programs. To explore the establishment of specialty laboratories for pharmaceutical research and development, where the Government is the key player and provides incentives to facilitate investments by businesses and research institutions.

c) To develop a roadmap to enhance the international competitiveness of the pharmaceutical industry. To regularly organize trade promotion activities to attract investment and transfer production technology from high-tech pharmaceutical manufacturers, foreign-invested companies, multinational pharmaceutical corporations, and companies from countries with advanced pharmaceutical industries.

d) To strictly manage the domestic drug distribution and supply chain system towards modernization, professionalism, and efficiency. To encourage the adoption of EU-GSP, EU-GDP, and EU-GPP (European Good Storage Practice, Good Distribution Practice, and Good Pharmacy Practice); to develop high-tech storage facilities and establish vehicle transport systems that meet advanced technical standards, to enhance connectivity and optimize the efficiency of linking pharmaceutical suppliers.

dd) To build pharmaceutical value chains and establish cooperation mechanisms that connect farmers, scientists, government authorities, and businesses in transferring plant varieties, cultivation techniques, harvesting, purchasing, processing, and producing domestic medicinal materials. To develop policies that encourage large Vietnamese enterprises to lead the pharmaceutical industry by offering incentives for the cultivation, utilization, and processing of medicinal plants, by transferring modern, high technologies to them, or by establishing a mechanism for the Government to place orders and assign tasks to them. To promote the implementation of policies that support small and medium-sized enterprises in joining the value chain of the pharmaceutical industry.

4. Enhancement of the capacity for management and control of the pharmaceutical market and medicinal ingredients

a) To study and complete reforms of the national organization model of the pharmaceutical industry, ensuring modernity and efficiency in accordance with international practices. To improve the capacity of State regulatory authorities for pharmaceuticals at both central and local levels, proactively integrate into the global framework to reach a maturity level comparable to developed countries.

b) To strictly manage the quality of drugs and medicinal ingredients across the entire process, from production, export, import, storage, marketing, and distribution, to the final use of drugs; to decisively prevent, combat, and address counterfeit and substandard drugs.

c) To strengthen post-market inspection and audit systems for pharmaceutical business activities to ensure order, discipline, and enhance legal compliance in the pharmaceutical sector.

d) To improve and enhance the capacity of the drug testing system, particularly for the inspection of vaccines and biologicals. To increase sampling, quality checks, and tight control over the quality of drugs and medicinal materials circulating in the market, especially imported medicinal materials, by conducting pre-import inspections based on registered quality standards.

dd) To intensify efforts to prevent and combat the smuggling and illegal transportation of medicinal materials across borders; to rigorously inspect import-export records and goods when there are signs of violations, in order to detect and prevent the export of valuable and rare indigenous genetic resources. To establish a system for monitoring and tracing the origins of medicinal materials. To conserve valuable and rare medicinal gene sources with high economic value, ensuring their sustainable utilization while limiting the export of endangered and rare medicinal plants.

5. Maintenance of rational, safe, and effective use of drugs

a) To effectively implement clinical pharmacy activities through a phased approach in accordance with relevant legal documents.

b) To improve the quality of pharmacovigilance activities at medical examination and treatment establishments and pharmacies; to focus on enhancing the role and capacity of pharmacists in advising on the rational, safe, and effective use of drugs, from central to local healthcare levels.

c) To complete and enforce good prescribing practices and good retail pharmacy practices; to strictly manage the dissemination of information and advertising of drugs.

d) To implement activities for effective monitoring of safety and risk management related to drugs during their circulation at pharmaceutical business establishments in Vietnam.

dd) To enhance public education and awareness about the rational and safe use of drugs for patients and the community.

6. Science, technology, human resources, and training

a) To promote research and international collaboration in the development of original brand-name drugs, specialty and therapeutic drugs, generic drugs with high-tech formulations, vaccines, reference biologicals, biosimilars, drugs from medicinal materials, and the application of modern drug formulation technologies; to conduct clinical trials and bioequivalence evaluations.

b) To perform scientific and technological tasks related to pharmaceuticals, focusing on the development of the pharmaceutical and chemical pharmaceutical industries.

c) To provide specific directions and a roadmap for standardizing basic, continuous, and advanced training for the pharmaceutical workforce. To improve the quality of human resources training for the pharmaceutical industry, prioritizing specific fields such as clinical pharmacy, quality management, research and development, contract manufacturing, and technology transfer to meet societal development needs and international integration. To enhance thematic training in vaccine and biologicals production, bioequivalence research, clinical trials, contract manufacturing, and technology transfer within pharmacy programs.

d) To prioritize research and application of advanced, modern technologies for conserving rare, economically valuable endemic medicinal plant species; to research and develop new plant varieties from domestic and imported genetic resources, with high-yield and high-quality cultivation techniques; and to focus on the preliminary processing, extraction, formulation, and standardization of medicinal materials and drugs from medicinal materials. To collect and study the traditional remedies and medicinal plant usage practices of various ethnic groups within the community.

7. International cooperation

a) To strengthen collaboration with multinational pharmaceutical corporations to enhance research and technology transfer for the production of original brand-name drugs in Vietnam and generic drugs with high-tech formulations.

b) To proactively and actively engage in bilateral and multilateral cooperation efforts, leveraging resources and technical support from other

countries and international organizations, including programs and projects aimed at improving the capacity and effectiveness of Vietnam's state pharmaceutical management authorities. To ensure sufficient resources for effectively implementing Vietnam's international agreements and commitments in the pharmaceutical sector.

c) To enhance cooperation and connectivity, facilitating the sharing of pharmaceutical management databases with relevant regulatory authorities. To promote the harmonization of dossiers, processes, and procedures related to pharmaceutical management in alignment with international standards; and to explore mechanisms for mutual recognition and acknowledgment in pharmaceutical management, adhering to global practices.

8. Information technology, application of Industry 4.0 technologies with the integration of artificial intelligence and digital transformation to modernize the pharmaceutical industry

a) To develop and enhance the national pharmaceutical database, utilizing Big Data technologies for the construction and storage of pharmaceutical industry data. To apply advanced analytics technologies to analyze data, establishing a synchronized system for tracking and monitoring pharmaceutical supply activities and optimizing medication use for patients nationwide, ensuring accuracy and timeliness.

b) To complete the online connection of pharmaceutical business data from production, import-export, wholesale, retail, and usage stages, with a focus on monitoring drug quality, pricing, information, and origins. To apply and manage product codes and barcodes for drugs and medicinal materials circulating in the market to trace their origin and manage quality.

c) To focus on leveraging postal infrastructure to promote e-commerce services, postal and logistics services in the packaging, sorting, storage, and transportation of pharmaceutical products, contributing to the development of the digital health economy.

d) To implement level-4 online public services and apply artificial intelligence in handling administrative procedures within the pharmaceutical sector.

dd) To adopt policies that encourage and promote, through a phased approach, pharmaceutical enterprises to standardize management processes and undertake digital transformation.

9. Information and communications

a) To strengthen communication efforts aimed at raising awareness among pharmaceutical businesses about the policies of the Party and laws of the

State regarding the pharmaceutical sector, as well as scientific and technological activities and integration trends in the pharmaceutical industry.

b) To mobilize resources to enhance communication and raise awareness among healthcare professionals in the fields of medical treatment and pharmacy, as well as improve patient understanding of safe, effective, and quality-assured medication use with clear origins.

c) To promote information about the quality, safety, efficacy, and reasonable pricing of domestically produced drugs, and to share details regarding the origins and effects of medicinal materials, particularly Vietnam's endemic medicinal materials.

d) To intensify the dissemination and promotion of pharmaceutical products and medicinal materials that bear national branding.

IV. FUNDS FOR IMPLEMENTATION

To diversify mobilized funding sources and effectively utilize available resources for the implementation of the Strategy:

1. State budget allocations (development investment and current expenditures) in accordance with the applicable State Budget decentralization regulation.

2. Funds incorporated in national target programs and public investment programs and projects for the 2022-2030 period.

3. Funds raised from or donated by foreign sponsors, WHO, international organizations, domestic and foreign businesses, organizations and individuals as well as ODAs and other lawful funds.

4. Other financial resources as prescribed by law.

Article 2. Implementation

1. The Ministry of Health shall:

a) Study and propose to the Prime Minister the establishment of a National Steering Committee for the development of Vietnam's pharmaceutical industry through 2030, with a vision to 2045.

b) Develop and finalize legal documents, mechanisms, policies, and plans, and then promulgate or approve those falling under its competence, or put forward them to competent authorities for promulgation or approval in order to carry out the tasks and solutions under the Strategy.

c) Assume the prime responsibility for, and coordinate with relevant ministries and sectoral authorities in developing plans for training and employing high-quality pharmaceutical human resources to meet the needs of research and drug production. Enhance capacity and ensure the effective performance of pharmaceutical regulatory authorities across the country.

d) Assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development in directing the development of medicinal plant cultivation areas, focusing on medicinal plants in which Vietnam holds an advantage and that have high economic value.

dd) Assume the prime responsibility for, and coordinate with the Ministry of Information and Communications and central-level press authorities to enhance information dissemination and communication activities regarding the National Strategy for development of the pharmaceutical industry of Vietnam; implement digital transformation in the pharmaceutical industry.

e) Regularly publish and update pharmaceutical mechanisms and policies to relevant units and international partners.

g) Continue to organize and effectively implement the campaign "Vietnamese people give priority to using Vietnamese drugs".

h) Guide, check, urge implementation of the Strategy, to periodically conduct preliminary and conclusive reviews; report to the Prime Minister on the implementation of the Strategy.

2. The Ministry of Finance shall:

a) Assume the prime responsibility for, and coordinate with the Ministry of Health and relevant ministries and sectoral authorities in reviewing and researching to submit to competent authorities amendments and supplements to regulations on tax, fee, and charge policies in the pharmaceutical sector, ensuring they are aligned with practical requirements at each stage.

b) Balance and allocate recurrent funding from the central budget to implement the components of the Strategy that fall under central responsibility, in accordance with State Budget decentralization regulations and aligned with the annual budgetary capacity.

3. The Ministry of Industry and Trade shall:

a) Assume the prime responsibility for, and coordinate with relevant ministries and authorities in developing and implementing initiatives related to the development of the pharmaceutical chemical industry, including the production of chemical medicinal ingredients and auxiliary products for drug manufacturing.

b) Coordinate with the Ministry of Health in formulating policies for the import of pharmaceutical products, including reasonable technical barriers, and enhance the implementation of trade promotion activities to support the export of domestically produced pharmaceutical products.

4. The Ministry of Planning and Investment shall:

a) Assume the prime responsibility for, and coordinate with the Ministry of Health and relevant ministries and sectors in reviewing, researching, and finalizing regulations to encourage investment in the pharmaceutical sector, including procurement and bidding, to foster the development of the domestic pharmaceutical industry.

b) Balance and allocate development investment capital from the central budget to implement the components of the Strategy that fall under central responsibility, in accordance with the State Budget decentralization regulations, the Law on Public Investment, and other relevant law regulations.

5. The Ministry of Science and Technology shall:

a) Assume the prime responsibility for, and coordinate with ministries, ministerial-level agencies, and Government-attached agencies in organizing the implementation of national-level scientific tasks in the pharmaceutical field.

b) Assume the prime responsibility for, and coordinate with the Ministry of Health in reviewing and proposing support, sponsorship, and incentives from the National Foundation for Science and Technology Development, the National Technology Innovation Fund, and the National High-Tech Venture Capital Fund for research and development activities in the pharmaceutical sector.

6. Other ministries and sectoral authorities shall, within the ambit of the functions and tasks assigned to them, implement this Strategy by themselves or in coordination with the Ministry of Health in the implementation.

7. People's Committees of provinces and municipalities shall:

a) Incorporate and implement the objectives, tasks, and solutions; execute the programs and plans of the Strategy locally, aligning with the advantages and practical conditions of their respective localities. Allocate local budgets to implement the components of the Strategy that fall under local responsibility, in accordance with the State Budget decentralization regulations.

b) Organize investment promotion activities, attract investments, provide financial support, and prioritize land allocation for the construction of pharmaceutical manufacturing plants, pharmaceutical industrial parks, research and testing centers, and the development of medicinal plants in their respective localities in accordance with the regulations.

Article 3. This Decision takes effect from the date of signing and supersedes Decision No. 68/QD-TTg dated January 10, 2014 of the Prime Minister approving the National Strategy for development of the pharmaceutical industry of Vietnam through 2020, with a vision to 2030.

Article 4. Ministers, heads of ministerial-level agencies and Government-attached agencies, chairpersons of People's Committees of provinces and

municipalities, and heads of relevant agencies shall be responsible for implementing this Decision./.

FOR THE PRIME MINISTER
DEPUTY PRIME MINISTER

Tran Hong Ha

APPENDIX

LIST OF PRIORITY PROGRAMS AND PROJECTS TO BE IMPLEMENTED

(Attached to the Prime Minister's Decision No. 1165/QD-TTg dated October 09, 2023)

No.	Name of the program or project	Unit assuming the prime responsibility	Coordinating units	Deadline for submission for promulgation
1	Project of Law on Pharmacy (revised)	The Ministry of Health	Relevant ministries and sectoral authorities	Following the timeline of the Law and Ordinance Development Program
2	Development Program for the Pharmaceutical Chemical Industry	The Ministry of Industry and Trade	Relevant ministries and sectoral authorities	2024
3	Comprehensive program to develop and promote the potential of medicinal materials	The Ministry of Health	The Ministry of Agriculture and Rural Development and relevant ministries and sectoral authorities	2024