Comprehensive Lifecycle Collaboration Plan for the Promotion of Pharmaceutical and Biotechnology Ventures[1]

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I. Background for Promotion

(Market Situation) The global pharmaceutical market is approximately three times the size of the semiconductor market and continues to expand. It is projected to grow at an average annual rate of 4.7% through 2028, with particularly strong growth in the biopharmaceutical sector, which is expected to record an average annual growth rate of 11.9% by 2028.

As of 2023, the global pharmaceutical market was approximately three times larger than the semiconductor market (USD 540 billion) and twelve times larger than the shipbuilding industry (USD 140 billion).

Korea's total pharmaceutical exports are ranked around 20th globally, while biopharmaceutical exports have grown significantly and are now ranked within the top 10 worldwide.

Total pharmaceutical exports: (2017) USD 4.06 billion → (2024) USD 9.27 billion (CAGR 12.6%), global rank: 20

Biopharmaceutical exports: (2017) USD 1.5 billion → (2024) USD 5.8 billion (CAGR 21.3%), global rank: top 10

(Domestic Situation) In the 2000s, the domestic pharmaceutical industry was primarily focused on the production of generic drugs. Entering the 2020s, the industry expanded into biosimilars and contract development and manufacturing (CDMO). At present, the industry is witnessing the emergence of blockbuster-level pharmaceuticals (annual sales exceeding KRW 1 trillion) and a full-scale entry into the global market.

(Biosimilar) Celltrion's Remsima recorded KRW 1.2 trillion in sales in 2024. (Innovative new drug) Leclaza, developed by Yuhan Corporation and Oscotec, received approval from the U.S. FDA in August 2024.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

From 2018 to 2023, the number of biotechnology IPOs reached 43, which is 4.8 times the number recorded in Japan (9 cases) during the same period. This reflects a dynamic market environment and indicates strong growth potential.

(Technology transfers) In 2025, domestic pharmaceutical and bio companies completed 22 technology transfer agreements with a total value of KRW 21.1451 trillion, representing the largest technology export value in history (previous record: KRW 14.0516 trillion in 2021).

(Example) In April 2025, ABL Bio signed a technology transfer agreement with GSK for Grabody-B, valued at KRW 4.1 trillion.

(Opportunity Utilization) To achieve the objective of positioning K-Bio pharmaceuticals among the world's top five global powers, it is necessary to commercialize the R&D achievements accumulated to date and implement a scale-up strategy.

Korea's pharmaceutical pipeline totals 3,233 projects, ranking third globally after the United States (11,200) and China (6,098) as of 2024.

Pharmaceutical and bio ventures, as developers of early-stage drug pipelines, possess sufficient capabilities and are expected to play a key role in strengthening the bio-pharmaceutical ecosystem.

(Leclaza) The candidate substance for Leclaza was initially developed by Oscotec (Korea), followed by research and development conducted by Yuhan Corporation, and subsequently transferred to Janssen (United States). This case represents a successful example of a venture–domestic company–global company relay model in new drug development supported by government R&D investment.

A support strategy to promote the growth and global expansion of pharmaceutical and bio start-ups will be prepared through inter-ministerial collaboration, enabling K-Bio pharmaceuticals to advance as one of the world's top five global powers.

II. Current Status and Implications

Through inter-ministerial collaboration, support can be provided by taking into account the company growth lifecycle and the overall industrial ecosystem.

The Ministry of SMEs and Startups (MSS) primarily classifies its support programs according to the growth stages of companies, providing various commercialization and R&D funding for the preliminary, early, and scale-up stages. In particular, MSS specializes in supporting early-stage start-ups and scale-up programs linked with private investment, and possesses policy financing instruments such as funds and guarantees.

In contrast, the Ministry of Health and Welfare (MOHW) provides R&D support according to the stages of new drug development, as well as support for the commercialization of promising technologies and global market expansion, thereby adopting a full-lifecycle perspective for pharmaceutical technology development and commercialization. Based on its expertise in the pharmaceutical industry, MOHW has strong capabilities in promoting collaboration among industry, academia, research institutes, and hospitals (open innovation, OI), developing specialized clusters, and addressing bottleneck stages for ecosystem formation and performance generation.

During the clinical stage, where the success or failure of new drug development is determined, support measures such as fundraising through policy funds, promotion of open innovation, linkage with hospital infrastructure, and advanced consulting for global market entry are provided to accelerate performance generation.

Establishing a Collaboration-Based Pharmaceutical and Bio Venture Fostering System by Linking Ministerial Strengths.

Due to recent trends such as rising development costs and global pharmaceutical companies' preference for late-stage technologies, the "valley of death" for venture companies is becoming longer.

Global pharmaceutical companies' investment strategies are becoming more selective and conservative, taking into account regulatory uncertainties such as tariffs and the risks of clinical failure.

Companies that have demonstrated competitiveness through fundraising and other achievements are jointly identified by the ministries, and R&D funding, commercialization funding, and guarantees are strategically concentrated and linked to support companies in overcoming the valley of death.

□ Responding to global clinical trials and regulatory approvals for new drug development is difficult for individual pharmaceutical ventures to manage solely with their own technology and financial resources. Accordingly, pharmaceutical ventures will be actively supported in identifying collaboration opportunities, and performance generation will be promoted through open innovation–focused support programs.

The MSS and MOHW have independently established and operated company support infrastructure, networks, and policy planning mechanisms, which has limited collaboration between the ministries.

Through enhanced cooperation, the two ministries will connect regional innovation hubs and R&D infrastructure while strengthening the regulatory innovation system and the policy research and survey foundation.

□ Based on feedback from the field, the two ministries will collaborate from the early stages of policy design in order to maximize synergies between policy support programs.

New joint initiatives will be planned and implemented, including:

① joint AI-based R&D between pharmaceutical ventures and pharmaceutical companies;

② the “K-Bio Technology Commercialization Together” program;

③ additional inter-ministerial collaboration projects tailored to the pharmaceutical and bio sectors.

III. Key Tasks

1. Basic Direction and Goals

Fostering “blockbuster-creation candidate companies”. Achieve KRW 30 trillion in pharmaceutical and bio technology exports by 2030

2. Tasks for Promotion

Based on the 4UP strategy, establish a convergent fostering system for pharmaceutical and bio ventures.

Task ❶ Uninterrupted Scale-UP through Innovation Funding

(R&BD Support) Provide substantial R&D and commercialization funding.

(Guarantees) Expand the supply of guarantees in order to provide bridge funding for companies during critical development stages.

(Funds) Establish a system to promote investment attraction at each stage of company growth.

(Early Value-Up) Provide close support for the establishment of development and investment strategies from the early stages.

Task ❷ Speed-UP Performance Generation through Open Innovation

(Global) Provide support across all stages of open innovation, including global collaboration and partnership development.

(Domestic) Promote collaboration among pharmaceutical ventures, AI ventures, and pharmaceutical companies in order to accelerate technology development and commercialization.

Task ❸ Level-UP Innovation Ecosystem Supporting Growth

(Resource and Network Sharing) Promote the joint use of research equipment by region and establish a system for sharing global networks.

(Policy Foundation Strengthening) Jointly promote regulatory improvements and conduct situation surveys to strengthen the policy foundation for the pharmaceutical and bio industry.

Task ❹ Synergy-UP through Field-Oriented Policy Design

Jointly plan and implement new projects through inter-ministerial collaboration.

Promote AI-based joint R&D between ventures and pharmaceutical companies.

Implement the "K-Bio Technology Commercialization Together" program.

a. Uninterrupted Scale-Up through Innovation Funding

(Concentrated R&BD Support) Provide substantial R&D and commercialization funding to promising pharmaceutical and bio ventures with strong technological capabilities in order to increase the likelihood of successful outcomes.

Research & Business Development (R&BD): A technology development approach that evaluates commercial feasibility from the early stage and adjusts research directions at each stage during implementation.

(R&BD Acceleration) Utilize the Scale-up TIPS R&D platform and jointly select promising companies through the relevant ministries, while concentrating support programs such as R&D funding and global expansion assistance.

Scale-up TIPS is a stage-by-stage growth program under which the government provides R&D support to companies identified and invested in by private operators.

Promising companies are identified and recommended through MOHW R&D evaluation, after which MSS provides investment attraction support and stage-linked R&D funding (KRW 2–3 billion) in connection with private investment.

Support includes regular IR opportunities and investment consulting provided through bio-specialized operators.

For selected companies, additional matching support is provided through programs such as the MOHW Global Expansion Package, MOHW–MSS biohealth infrastructure (e.g., K-Bio Lab Hub), and the MSS Export Voucher program.

The Global Expansion Package provides support for entry into global cluster hubs, professional consulting, global marketing, and costs related to global regulatory response (FY2026 budget: KRW 24.5 billion). Export vouchers provide marketing services necessary for global expansion, including design development, promotion, and participation in exhibitions.

A consultative body consisting of specialized institutions under both ministries will be established, and selection procedures will be integrated, including joint public calls for matching projects.

Selected Scale-up TIPS companies will be managed as a pool of promising pharmaceutical and bio ventures, and specialized and preferential support programs will be continuously identified and expanded, including through Global TIPS and related initiatives.

(R&BD Relay Support) For outstanding completed R&D projects in the field of new drug development, follow-up R&D and commercialization funding will be linked and provided.

For new drug development projects conducted under MSS Scale-up TIPS R&D, preferential evaluation treatment (additional points) will be granted when applying for MOHW's subsequent large-scale R&D programs.

Example: Conduct preclinical studies through Scale-up TIPS R&D → Apply for KDDF Phase 1 clinical trial funding (up to KRW 4.55 billion).

Through the MSS Technology Commercialization Package, pharmaceutical and bio specialized track, commercialization funding will be provided for outstanding completed MOHW R&D projects.

Services include diagnosis of the venture's commercialization roadmap, establishment of technology transfer strategies, patent and regulatory consulting, and other expert services provided in a menu-style format (up to KRW 150 million, newly established in 2026).

(Policy Fund Linkage) Establish a system in which pharmaceutical and bio policy fund investments are linked step-by-step rather than provided as one-time support (candidate compound → preclinical → clinical → commercialization).

Expand MSS investment funds, which are linked to follow-up investment from MOHW K-Bio and Vaccine Funds, to cover all bio-related funds (from 1 fund to 3 funds).

When a company receiving MSS pharmaceutical and bio fund investment is recommended to a MOHW bio fund operator, investment screening obligations are applied. Upon execution of the investment, the operator receives additional performance-based compensation, thereby providing incentives for successful follow-up investment.

(Technology Evaluation and Guarantee Expansion) Provide bridge guarantees to alleviate liquidity difficulties for pharmaceutical and bio ventures experiencing challenges in attracting follow-up investment.

For promising pharmaceutical and bio ventures, preferential treatment will be strengthened during the selection and evaluation process in order to expand large-scale guarantee funding through the "Pre-Unicorn Guarantee".

For unlisted companies with a corporate value of KRW 100 billion or more, guarantees are provided up to KRW 20 billion.

For companies selected under ministries' jointly selected or matched support programs, a new evaluation bonus will be applied (5 additional points for selection in inter-ministerial collaboration programs).

Applicable programs include:

① Joint MSS–MOHW Scale-up TIPS

② R&BD Relay Support

③ Global Open Innovation (technology transaction contracts)

Through the "R&D Commercialization Project Guarantee", newly established in 2026, funding will be supplied based on project-level evaluation of government R&D conducted by pharmaceutical and bio ventures.

This support is provided in addition to existing guarantee limits (working capital up to KRW 3 billion; including facilities up to KRW 10 billion). Guarantees may also be provided to companies with strong commercialization potential but weak financial structures.

For pharmaceutical and bio ventures recommended by the Korea Health Industry Development Institute (KHIDI) as possessing recognized technological capabilities, the Korea Technology Finance Corporation (KIBO) will provide linked support through the "Excellent IP Value-Plus Guarantee".

Maximum guarantee ratio: 95%, up to KRW 3 billion, with a guarantee fee reduction of 0.5 percentage points.

KIBO's pharmaceutical and bio technology valuation model is being enhanced in collaboration with KHIDI in order to increase the accuracy of guarantee evaluations and expand utilization, including the establishment of special guarantees based on technology valuation for pharmaceutical and bio ventures.

(Early Value-Up) Support early-stage pharmaceutical and bio start-ups in establishing mid- to long-term R&D and investment attraction strategies based on expert consultation.

Through the MSS "Deep Tech Startup Package", support will be provided for the establishment of R&D strategies. For outstanding companies, matching programs offered by MOHW, including education, consulting, and investment attraction support will also be provided.

b. <u>Speed-UP Performance Generation through Open Innovation</u>

(Global Support) Support all stages of open innovation (OI) between global pharmaceutical companies and domestic pharmaceutical and bio ventures, from initial company exchanges to the execution of technology transfer agreements.

(Stage-by-Stage Linked Support) Provide matching R&D and commercialization funding corresponding to each stage of technology transfer.

For companies selected under the MOHW "Global Open Innovation Activation Support Project," matching MSS support programs, including export-oriented R&D, will be provided according to the technology transfer stage.

Companies participating in linked projects will be granted preferential access to MSS and MOHW overseas hubs in the United States, Japan, and the European Union (e.g., Boston CIC, Shonan I-Park, GBC, KSC).

(Domestic Support) Combine support programs and infrastructure from both ministries to strengthen collaboration among pharmaceutical and bio ventures, domestic pharmaceutical companies, and AI ventures.

Pharmaceutical-Bio AX For MSS AI venture–pharmaceutical venture collaborative R&D programs, provide access to MOHW-standardized hospital medical data.

Support collaborative R&D projects using AI solutions for research design, experiment automation, and related activities (20 projects in 2026, up to KRW 1 billion per project over two years).

Provide medical data demand–supply matching through hospital data centers for selected collaborative R&D consortia.

A total of 43 designated hospitals nationwide will support the standardization and safe use of clinical and examination data in 2026 (KRW 20 billion).

Omics data (including genomics) and biosignal data will be utilized for AI-based new drug development.

(Collaboration with Domestic Pharmaceutical Companies) MSS supports R&D collaboration between pharmaceutical ventures and domestic pharmaceutical companies, and MOHW provides preferential support to pharmaceutical companies participating in open innovation, thereby strengthening venture–pharma collaboration incentives.

Support joint R&D projects combining compounds and existing technologies to expand the pharmaceutical pipeline (10 projects in 2026, up to KRW 3 billion per project over three years).

Revise the criteria for Innovative Pharmaceutical Company certification to recognize collaboration achievements with domestic pharmaceutical and bio ventures, enhancing participation in collaborative initiatives.

c. Level-Up of the Innovation Ecosystem Supporting Growth

(Establishment of Resource Sharing System)Develop a system for shared use of equipment, data, and other resources within regional clusters, and implement a virtual platform to extend access across all clusters.

Pilot an online utilization and management system for research equipment available for joint use at major pharmaceutical and bio hubs (Incheon, Osong, etc.).

K-Bio Lab Hub: MSS and MOHW will jointly participate in the operating committee and provide equipment reservation and utilization services within Songdo via the Lab Hub networking platform (target completion 2027).

Priority will be given to MOHW-operated bio-infrastructure in Songdo, with subsequent expansion to equipment owned by nearby universities (e.g., Yonsei University, Inha University) and resident companies.

(Advanced Medical Complexes) Establish cooperative systems for shared equipment use and linked technical services based on the specialized focus of each regional complex.

Osong: Biopharmaceuticals and BT-based medical devices; Daegu·Gyeongbuk: Synthetic pharmaceuticals and IT-based medical devices.

(Nationwide) Develop a virtual platform for infrastructure sharing—including facilities and equipment—across clusters, and for functional collaboration such as joint research. Initial implementation through ISP in 2026, with full build-out by ~2028.

(Connection of Innovation) Networks Leverage regionally embedded support institutions to identify promising venture companies and connect them with global innovation networks.

MSS ChangGyeong Center and MOHW K-Bio Health Regional Centers will identify and foster promising local companies and host customized global networking events.

Six regional sites, including Daejeon Technopark and Chungbuk Bio-Industry Convergence Center, will serve as cluster hubs from 2025–2027 to nurture and support local startups in connection with hospitals.

Identify promising companies in regional bio-clusters (e.g., Chungcheong, Incheon) and hold customized meetups with global VCs and pharmaceutical companies through Bosanjin (KBIC) and KVIC (linked with Bio Korea).

Consider establishing an online partnering platform to enable continuous networking, technology and company information sharing, company matching, and post-support services.

(Regulatory Improvement) Jointly identify regulations that impede performance generation of bio ventures and pursue improvements through whole-of-government bio governance mechanisms, such as the National Bio-Innovation Committee.

(Regulation Identification) Both ministries will jointly identify field-level regulations affecting pharmaceutical and bio ventures and prioritize items for regulatory improvement proposals.

Identification will be conducted continuously by the MOHW Regulatory Reform Task Force and MSS regulatory units (Ombudsman Support Team, Regulatory Legal Affairs Officer, Pharmaceutical-Bio Venture TF).

(Killer Regulations) From identified items, select those requiring urgent improvement, collect field input through joint meetings, and develop measures for regulatory amendments.

(Statistics-Based Monitoring) Establish a survey system to periodically track key trends of pharmaceutical and bio ventures, including startup activity, fundraising, and technology transfers.

Both ministries will jointly plan and select survey items specific to pharmaceutical and bio ventures and conduct an annual in-depth specialized survey.

Utilize the monitoring system to establish a tracking framework and guide the planning of new inter-ministerial collaborative projects.

d. Field-Oriented Policy Design to Enhance Synergy: Collaboration for Early-Stage Startup Development

(New Collaborative Projects) Based on field feedback, jointly plan new projects to address limitations and gaps in existing policies for early-stage pharmaceutical ventures.

(Field Feedback)•New drug development is difficult for a single company and requires a relay structure between ventures and pharmaceutical companies to sustain innovation. The segmented bio R&D investment structure across ministries must be addressed through a multi-ministry collaborative budget package.

Domestic bio ventures, despite strong technological capabilities, often lack expertise and networks to manage the full commercialization lifecycle, including infrastructure, regulatory approval, and global marketing.

Fewer than 20% of bio ventures have dedicated business development organizations, and global negotiation capabilities remain limited (Korea Bio Association, 2024).

AI-based drug development requires long-term validation and continuous learning; early-stage collaboration that fails to produce expected results quickly may lead pharmaceutical companies to terminate contracts prematurely due to concerns over ROI.

1)Pharma Venture AI + Open Innovation R&D

Establish a large-scale R&D program to promote early-stage research collaboration between pharmaceutical ventures and domestic pharmaceutical companies using AI in bio-pharma.

• Necessity: To improve productivity and success rates in new drug development, active support for AI utilization and inter-company open innovation is required.

• Example: InSilico Medicine (US) completes target discovery to Phase 1 clinical trials within 30 months using its AI-based platform.

• Open innovation impact: 72% of FDA-approved new drugs (2015–2022) were based on open innovation (Bayer Senior VP, Bio Korea 2025).

• Support Target: Consortia of pharmaceutical ventures and pharmaceutical companies capable of pursuing AI-based new drug development.

• Operating System: Establish a cross-ministry project team to jointly operate the program.

• Support Content: accelerate AI-enabled collaborative new drug development up to candidate compounds; provide linked support for preclinical and other performance relay stages to promote clinical entry and technology transfer.

2) K-Bio Technology Commercialization Relay

Establish an integrated technology commercialization support program that provides support from technology development strategy formulation to infrastructure utilization.

• Necessity: In the bio sector, research and development itself is a core component of commercialization; simultaneous support for commercialization and research infrastructure is required to achieve rapid growth.

• Infrastructure support includes advanced R&D equipment for candidate compound validation and manufacturing equipment for preclinical and clinical drug production.

• Support Target: Bio ventures in the pharmaceutical field with strong technological capabilities, seeking or preparing for global technology transfer, co-development, or investment attraction.

• Support is stage-based, with no restrictions on company age (e.g., within 10 years of founding).

• Operating System: Startup, commercialization, and investment support institutions, together with R&D, medical, and experimental infrastructure institutions, provide tailored and close support for each company.

• Infrastructure capability: In vitro efficacy evaluation, quality assessment, preclinical and clinical evaluation.

• Support Content: value-up support, including pharmaceutical and bio-specific diagnostics and company-specific roadmap development; customized technology services using in-house infrastructure.