

The Planning and Implementation of Multi-Ministerial R&D Programs: A Focus on Trans-Governmental Whole-Cycle New Medicine Development Projects in Korea¹⁾

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Abstract

Pan-ministerial policy planning, coordination, and evaluation for innovation have emerged as important challenges as a new policy paradigm of integrated innovation policy is now being emphasized as a solution for various social issues. In particular, countries like the U.S., Japan, or Germany, whose R&D systems are quite distributed, are now stepping up their efforts to enhance the linkage and integration between policies by strengthening the planning and coordination functions of the government organizations in charge of innovation policy as well as by implementing various programs for this purpose. These countries are now trying to build a joint research platform and strengthen inter-ministerial cooperation and linkage in the process of implementing innovation. This will help to the achievement of a government's overall goals rather than the achievement of narrower sector-oriented goals.

Under these circumstantial changes in policy environment, it is worth noting that the pan-ministerial whole-cycle program to develop new medicine is a good attempt at introducing integrated innovation policy. This program has been developed to overcome the silo mechanism in R&D, which had long been considered a stumbling block in new drug development programs. Among the many programs, this program can be said to reflect the perspective of integrated innovation policy to its fullest extent in terms of inter-ministerial R&D program planning, organization, budget, and implementation body.

This study will review this pan-ministerial whole-cycle new drug development program in Korea from an integrated innovation policy point of view. For this purpose, this study will review what integrated innovation policy is as a theoretical background, how it has emerged, and what specific policy measures exist for implementing an integrated innovation policy. For the purpose of serving the pan-ministerial whole-cycle program, this study will review the background and the contents of the program and will present policy suggestions required for achieving intended policy goals.

Keywords: multi-ministerial R&D programs, policy integration and cooperation, Trans-Governmental Whole-Cycle New Medicine Development Projects

1. Introduction

STI Policy and R&D programs of Korean governments are complicated as invest scale and participated ministries in the government R&D programs have

increased. Even though it is very important to promote cooperation and linkage among different ministries for increasing R&D efficiency, there is a lack of linkage among different ministries' R&D projects.

Innovation-oriented planning and implementation

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1) This paper revised "Attempts and Missions for Integrative Innovation Policies: A Focus on Trans-Governmental Whole-Cycle New Medicine Development Projects", *Science and Technology Policy*, Vol. 21, No. 2 (2011) (in Korean). Paper title has changed and theoretical background and methods of integrative innovation policy was added.

of multi-ministerial R&D Programs is emerging as important missions for all countries. A third-generation innovation policy goes beyond existing science and technology policies that pursued economic growth and the enhancement of national competitiveness. It has a focus on R&D that takes into account various social problems such as unemployment, social and economic polarization and sustainable development issues that integrated innovation policy emphasized as a new policy paradigm.

Countries with decentralized R&D systems such as the U.S. and Germany are making efforts to improve connectivity and integration among related policies through various cooperative programs with strengthened planning and implementation of multi-ministerial R&D. They are trying to achieve R&D performance through the establishment of common research platform and strengthening connectivity and cooperation among government departments. Cases in point are *the Science and Technology Connection Policy System of Japan*, *the Trans-governmental Program of the USA*, *the High-Tech Strategy of Germany*, and *the Framework Program of the EU*.

Integrative innovation policies that take into account innovation in all policy areas such as economy, society, and the environment need planning and implementation of multi-ministerial R&D programs but also self-examination and reorganization of the overall innovation governance. To this end, the policy planning process needs to go beyond the existing science and technology field to transform into an open-type policy network where various related parties such as users, consumers, and the public can participate. In addition, policy adjustment and evaluation processes must change to go beyond the balance and integration of different policy areas as well as the goals of existing segmental R&D project methods. In order to enhance the social ripple effects of technology and to strengthen the interaction between technology and society, cooperation and connectivity between government agencies providing technology and agencies demanding technology that are responsible for the environment, transportation, and construction need to be strengthened.

It is important to note the *Trans-Governmental Whole-Cycle New Medicine Development Project*, which will be initiated in 2011 after a preliminary feasibility examination in 2010. That is because this project is trying to develop optimal projects for the co-planning of practical cooperation and sustainable connectivity strategies between or among government agencies. The core element of the integrative innovation policy is to take into account vertical – horizontal – temporal coordination among related policies toward common long-term goals. This project is currently doing well in achieving the stated goals since it has established a connection system among all government agencies at all stages of planning, organizing, budgeting, project promotion, and management. This project goes beyond national boundaries to achieve specific goals and visions that “establish an R&D platform for developing new medicines and develop at least 10 new global medicines.” However, it also utilizes a series of methods such as planning, budgeting, organization, and evaluation to develop technologies at the trans-governmental level that can take precedence over agency jurisdictions.

This research examined the *Trans-Governmental Whole-Cycle New Medicine Development Project* of Korea from the integrative innovation policy point of view. We examined the theoretical background of the concept and history of the integrative innovation policy and specific realization methods. In addition, we looked at the implementation background, content, and system of the *Trans-Governmental Whole-Cycle New Medicine Development Project* and developed the policy missions necessary to realize the policy goals that were initially intended.

2. Theoretical Background

2.1 Emergence of the Third Generation of Innovation Policy

The Science and Technology Innovation Policy (innovation policy) is evolving from a first-generation policy that previously aimed at the enhancement

of national competitiveness to a second-generation policy aimed at economic growth and resolution of social problems, which will eventually evolve into a *Third Generation of Innovation Policy, or Integrated Innovation Policy*. According to these changes, policy focus has changed from the development and provision of technologies to the application of technologies and proactive responses to social demands, with various fields such as the environment, welfare, safety, national defense, and security being promoted in connection with innovation. To successfully realize planning – adjusting – evaluating processes of innovation policies, a holistic and integrated approach that takes into account all areas of the economy and society is necessary (OECD, 2005; Stead, 2008).

The innovation policies of major countries are evolving into a T-shape form in response to the changes of the policy environment. As the status of science and technology innovation policies elevate, their domains are expanding: horizontally going beyond existing policies that focused on science and technology industries toward environmental, energy, education, and welfare policies; and vertically from policies that focused on R&D toward service innovation, social innovation, and public technology innovation. Every nation emphasizes the openness, transparency, and responsiveness of innovation policies that present ways to connect and integrate the players of innovation activities in terms of complex systems (Seong & Song, 2007; Seong, 2010).

This flow of the evolution of innovation policies is in line with several changes in the policy paradigm. First is the emergence of the self-reflection of New Public Management (NPM) and innovative government. In the 1980s, when the NPM theory had

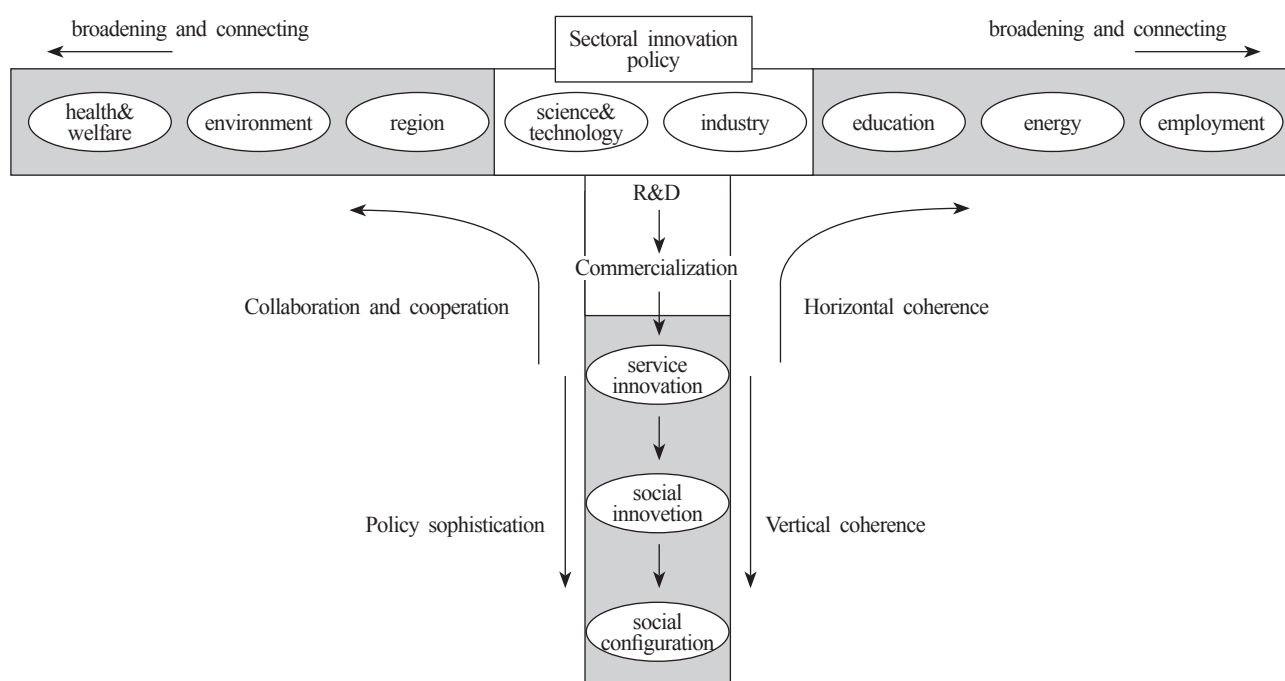
a strong effect on the world, the decentralization of public activities was achieved through privatization, authorization, and commercialization, which weakened connectivity among government agencies. An emphasis on respective goals and responsibilities of individual agency, department, and personnel led to higher vertical internal efficiency; however, it brought about lack of horizontal balance and cooperation that left problems at the agencies unresolved. These problems were intensified particularly in traditional Anglo-Saxon countries such as Britain, Australia, and New Zealand, and various policy efforts have been offered as alternatives.

Second is an emphasis on policy connectivity and integration as a new policy adjustment principle. Recently, the authority and responsibilities of governments are being decentralized whereas comprehensive policy issues such as poverty, equitable opportunities, and sustainable development are increasing; in addition, horizontally managing policy areas is becoming increasingly difficult (Arnold et al., 2003; Boekholt, et al., 2002). As policies become more complex, uncertain, contradictory, and conflicting among policy goals as well as related policy elements, sectors and areas are intensifying. Accordingly, the horizontal management of sector policies is emerging as a core agenda item for administration (Stead, 2007). In addition, the principles for policy adjustment and integration are also breaking away from the conventional class systems and market principles that are transforming toward a network or governance policy adjustment that has its basis in mutual reciprocity and trust (Peters, 1998). Furthermore, since the 1990s, sustainable development policy that comprehensive and integrative approaches to social,

Table 1 Taxonomy of innovation policy

Goals	Sectoral innovation policy	Multi-sectoral innovation Policy
Innovation policy, i.e. aimed primarily at innovating industries and economic growth	Innovation policy in a limited sense(basically technology and industrial policies)	Integrated STI polities
Innovation policy in a wider sense, i.e. aimed at economic growth and quality of life	Innovation policies in other sectoral domains, e.g. innovation policies in health, innovation policies in the environment	Horizontal/comprehensive/integrated or coherent/systemic innovation policies

Source: OECD (2005)



Source: Seong (2010)

Figure 1 STI policy evolution into a T-shape form

environmental, and economic elements have been emphasized to minimize conflict among related policies by stressing a proactive combination of related policies or the prioritization of innovation policies (Lafferty & Hovden, 2002).

2.2 Methods to Realize Integrative Innovation Policies

The policy planning – adjustment – evaluation systems as well as the systematic bases and working methods must change to go beyond individual policy systems and toward the realization of integrative innovation policies that take into account social and economic systems. There is no specific method presented for the realization of integrative innovation policies; however, the methods for connecting and integrating policies with a focus on innovation are as follows.

First, the integrative innovation policies should develop a comprehensive policy agenda suitable at the national level in accordance with the expansion of area and scope for science and technologies that reduces the differences among different policy goals

and values. It is important to establish long-term visions and strategies suitable at the national level so that systematic planning where a consensus can be formed to share the vision and values can be put in place. The previous government-led top-down policy establishment and execution methods will have limitations in aligning various long-term players.

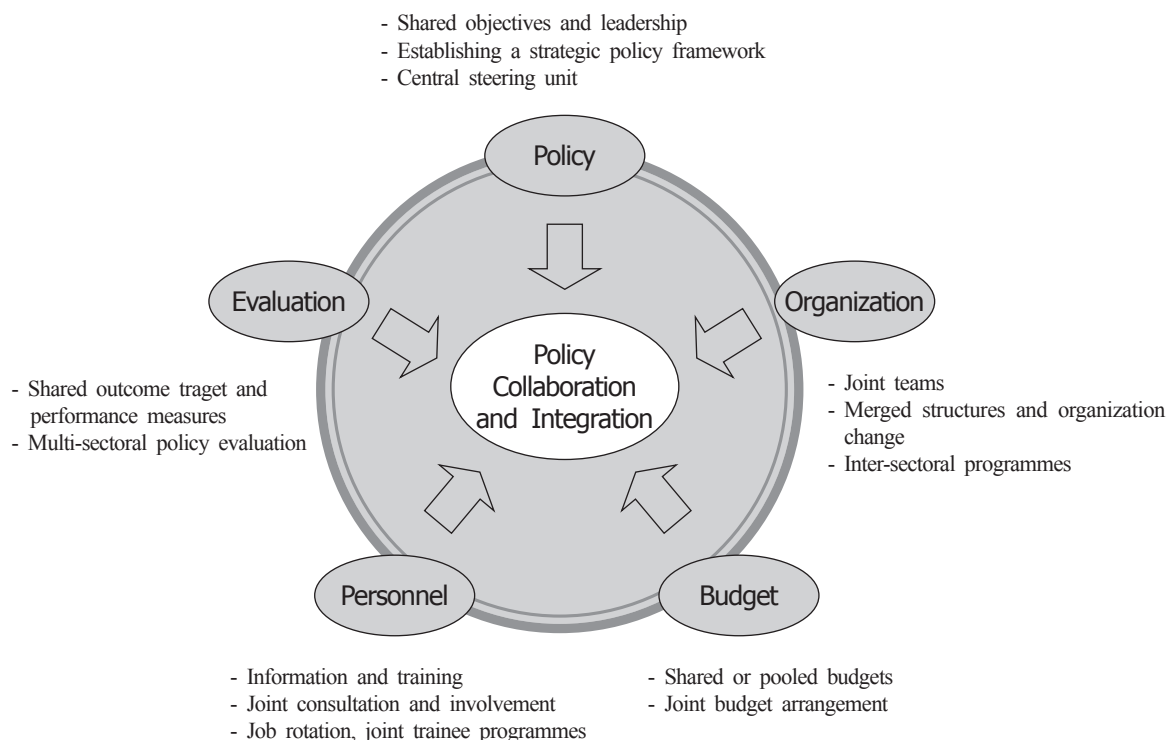
Second, we must develop measures to resolve problems as an individual department as well as an organization for conversion to a mission-oriented working system to connect the players and player network. We must renew and change the organizational structure and working process. It is important to allow the government architecture and organizational arrangement to include the integration of departments and functions, the establishment of new organizations and systems, and the granting of new authority – responsibility – obligation to existing organizations. In addition, policy cooperation and integration among related ministries converts the administrative structure to be function oriented or changes the organization status and budget distribution structure to integrate the system and organizations (Persson, 2004; Kim, 2005).

Third, as a policy decision process for allocating limited resources, budget becomes the core means for integrating policy adjustment. Policies having similar goals or purposes can be bound as a single budget program in order to implement the policy goal effectively and efficiently. In order to integrate related policies with the budget as the medium, in the situation of a particular project, it is necessary to introduce a trans-governmental integrated budget system where departments can jointly design and implement programs. In terms of developing and executing policies, it is possible to make the most of adjustments and the integration means of the budget to jointly operate the program or connect and integrate activities of funding execution organizations toward common visions and goals. In addition, we can make efforts in such a manner that the development of policies in detail and the means for achieving these policies could mutually support each another (Lafferty, 2002; Persson, 2004; Meijers & Stead, 2004).

Fourth, in order to realize integrative innovation

policies, it is necessary to adjust and integrate related departments that have different principles and interests. To this end, we could use trans-governmental committees that resolve practical problems, form a TF team (or use a joint working group), and have special organizations in charge of integrated work or bureaucrats for active mutual functioning and a close network. It is possible to resolve more problems through technology development, the establishment of various policies and systems for the cooperation of final and intermediate demanding departments where technologies are utilized and thorough procedures and rules that determine responsibility for the policies. In addition, policies could be adjusted and integrated strengthening education and training that 1) reduce differences among government departments, 2) utilize personnel exchanges, communication, and operating research committees, and 3) establish a joint knowledge basis (Lafferty, 2002; Persson, 2004; European Environment Agency, 2005).

Fifth, policy evaluation and monitoring are essential



Source: Stead (2008); Economic and Social Council (2006)

Figure 2 Methods of integrated policy implementation

to guarantee that various policy efforts lead to a single vision and goal. These efforts improve the policy decision and execution processes that are utilized as feedback material for follow-up policy planning based on the policy decisions and execution processes (Hjelt, et al., 2005; Foxon & Pearson, 2008). It is important to develop a regular monitoring and policy evaluation system so that various policy efforts created to realize visions and goals of the integrative innovation policy can develop positive policy performances. In addition, policy planning, execution, and evaluation must be integrated to create a series of processes that form a close system (OECD, 2002; European Environment Agency, 2005).

2.3 Integrative Innovation Policy and the Trans-Governmental All-Cycle New Medicine Development Project

The key of the integrative innovation policy is to reflect the complex and systematic characteristics that are the essential nature of innovation for the actual policy processes when the mission is to rearrange the policy direction of each department with a focus on resolving problems and duties. It is necessary to combine various needs and efforts to reach a consensus among related social players that creates a common vision and goal with an emphasis on joint planning, connection, and cooperation by various departments. Evaluating the performance focuses on short-term efficiency or performance at the individual-department level as well as on resolving problems at the national level that emphasize various policy

experiments and education.

The *Trans-Governmental Whole-Cycle New Medicine Project* is evaluated from an integrative innovation policy point of view as follows.

First, the most noteworthy point in this project is to remove the barriers among government organizations that create a long-term policy vision and that promote that vision and goal through trans-governmental joint planning. The intention is to contribute to achieving a national-level policy goal by establishing a connection and cooperation system among departments and organizations as well as establishing a close public-private cooperation system for a joint policy vision and goal.

Second, whole cycles of innovation have been taken into account for the project goal of developing global new medicines for the creation of a national growth engine. In the past, the base-application-development of science and technology policies were divided and separately promoted; however, this is a project that takes into account the cycles of innovation as well. Various programs are being implemented to change the mission planning as well as the management system and operation methods such as improvements to project selection, funding method, promotion system, progress management, result evaluation, and achievement utilization.

Third, this project establishes a National Innovation System (NIS) point of view that emphasizes mutual functioning and cooperation among innovation players. NIS means a cooperative network that organically connects the innovation capacity of corporations, universities, and research institutes that perform

Table 2 Summary of the *Trans-Governmental Whole-Cycle New Medicine Project*

Contents	
Project period	2011-2019
Total Project Cost	10,600 billion won - 5,300billion won(three ministries co investment) - 50% private investment
Volume of project	300-750 billion won(annual investment), around 200 projects (the total number)
Support terms	Government-funded
Enforcement subject	Korea Drug Development Fund (KDDF)

technological innovation activities and create, expand, and industrialize innovative achievements. NIS is significantly different from existing science and technology policies that have focused on inputting labor and capital (such as research, development, infrastructure investment) by individual departments. The NIS comprehensively internalizes human resources policies to strengthen the capabilities of industry, academia, institutional players, and industry policy that commercialize innovation achievements as well as health and welfare policies that were previously divided and promoted separately.

3. Background and Contents of the Trans-Governmental Whole-Cycle New Medicine Development Project

3.1 Promotion Background

3.1.1 Lack of Infrastructure for the Development of New Medicines and Lack of Cooperation Among Research Players

A new medicine development project is emerging from the IT industry as a core national industry to lead the growth of the economy in the future as the demand for health medical services increases due to the recent development of biotechnology (BT), new developments in medical technology, an aging society, and the increase in disposable income. Since the advent of medical market liberalization, for example the Korea-U.S. (KORUS) Free Trade Agreement, there has been recognition of the medical industry having global competitiveness as a national mission. Korea's R&D investment volume for new medicine development has

increased from less than 50 billion won in 2004 to 100 billion won in 2009, based on the KORUS – FTA strategy, and is expected to increase further. However, investment in new medicine development, the necessary infrastructure to support this investment, and related experts are all in short supply.

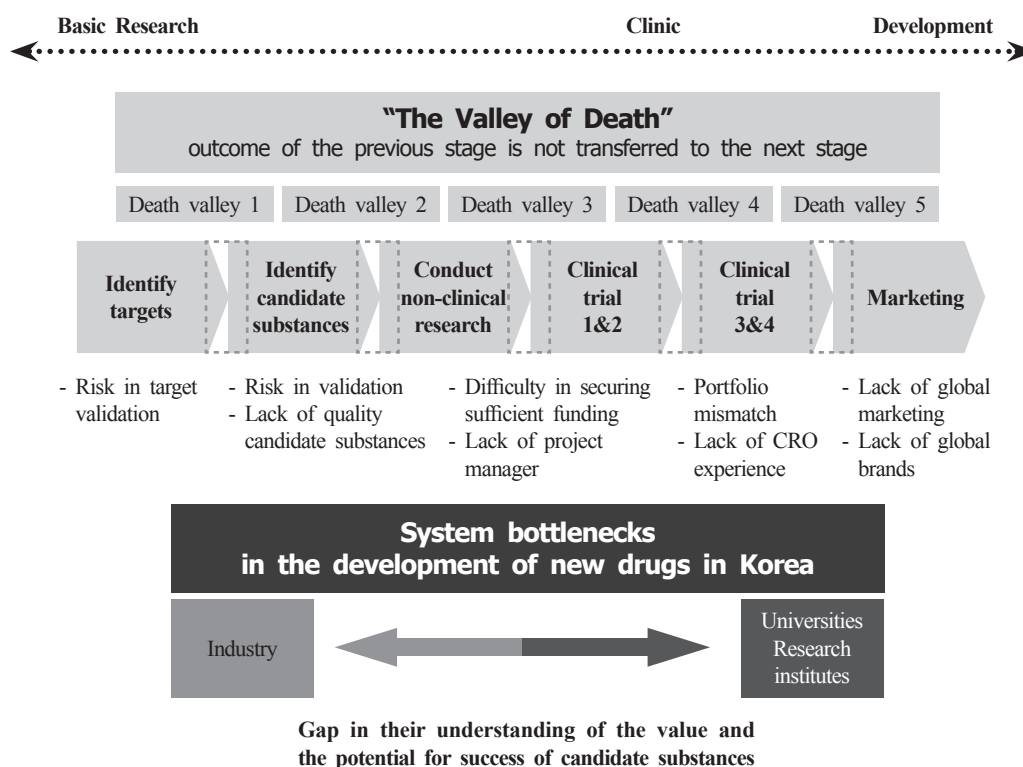
The market is so small that the number-one company in Korea is only one-hundredth the size of the number one company in the global market, and the R&D expense to revenue is only 1/5. Capability, experience, and investment in development of new medicines are insignificant compared with the global standard of market volume, market volume of the most-prescribed drug in Korea accounting for only about 100 billion won; Korea remains in a situation dependent on the selling of generic medicines.

There has been a lack of cooperation among industries, academia, and institute sectors in the development of new medicines. The disparaging of new materials by industries and discontent on setting prices by academia and the research sector are in conflict. In particular, there is “The Valley of Death” in the stages of the new medicine development process, and in this process there are problems such as lack of candidate material, lack of resources, and lack of chief research officer (CRO) experience (See Figure 3). Especially in Korea, a bottleneck phenomenon is significant in the prior stages, and the industry, academia, and institute sectors distrust one another. *The Trans-Governmental Whole-Cycle New Medicine Development Project* can be seen as a policy effort to transform the small medical industry into an industry that creates actual economic value to reduce the bottleneck phenomenon in the new medicine development stage.

Table 3 R&D volume of Korea compared with the world's top ten pharmaceutical companies

Pharmaceutical companies	Average sales revenue	Net profit/sales revenue	Average R&D expense	R&D/sales revenue
World's Top-ten companies (Pfizer and GSK)	40 billion dollars	19.2%	5 billion dollars	20%
Korea's Top-ten companies (Donga and Yuhan)	460 million dollars	8.6%	20 million dollars	4.3%

Source: MEST& MHW&MKE (2010)



Source: MEST& MHW&MKE (2010)

Figure 3 The Valley of Death for each new medicine development stage

3.1.2 Individual Rashes and Lack of Trans-Governmental Cooperation

There have traditionally been severe inter-departmental disputes over new medicine development projects. As of 2009, the in-depth evaluation conducted by the *National Assembly Budget Office* and *The Ministry of Strategy and Finance* identified the lack of performance from discontinuous project procedures and a lack of integration. *Trans-Governmental Connection Projects* are necessary to overcome the discontinuation from the cases to application and development for the successful creation of projects; in addition, the process of government support for R&D in new medicine development is proving to be inefficient. New medicine development is a project of high risks and high profits; in addition, as it proceeds to the later stages, economic value increases as well. It remains necessary to sustain long-term investment and development through government support. However,

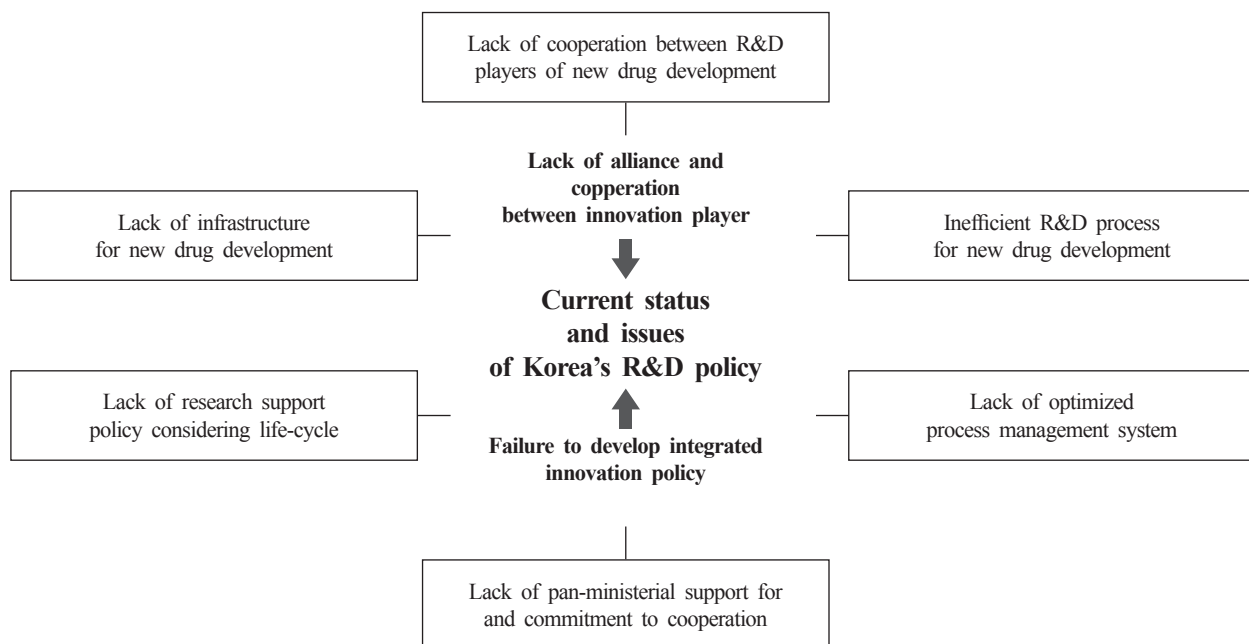
there are insufficient government policies to overcome this situation. Even though it takes from 100-200 million dollars to 800 million dollars to develop a new medicine, government support only totals about 1 billion won, driving down the feasibility of new medicine development strategies.

Researchers with responsibility for particular departments are required to focus on the application of support for the next project even before the previous project is completed. Accordingly, research is discontinued and subsequently sold to foreign pharmaceutical companies. Such research material that has been sold to foreign pharmaceutical companies sometimes develops into a project; however, there are many times when the material is just “buried” in order to avoid a competitive market. In addition, there is a lack of a product-connecting mechanism for basic research so that researchers tend to focus on independent research with little relevance to market demand, which creates difficulty in the revitalization

of the pharmaceutical industry (MEST& MHW&MKE, 2010; MEST& MHW&MKE, 2010. 7).

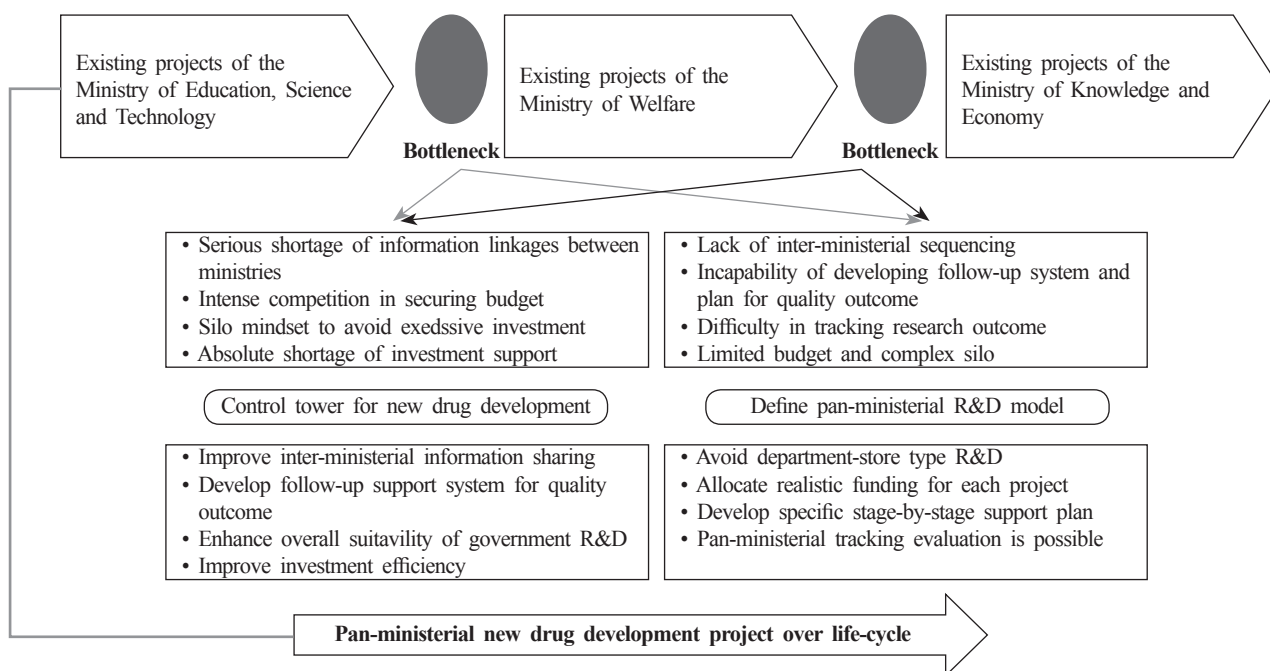
This is why there have been efforts to plan,

manage, and evaluate new medicine projects in all cycles at a trans-governmental level, which can overcome such limitations.



Source: MEST& MHW&MKE (2010)

Figure 4 Current situation and problems of the *New Medicine Development Project*



Source: MEST& MHW&MKE (2010)

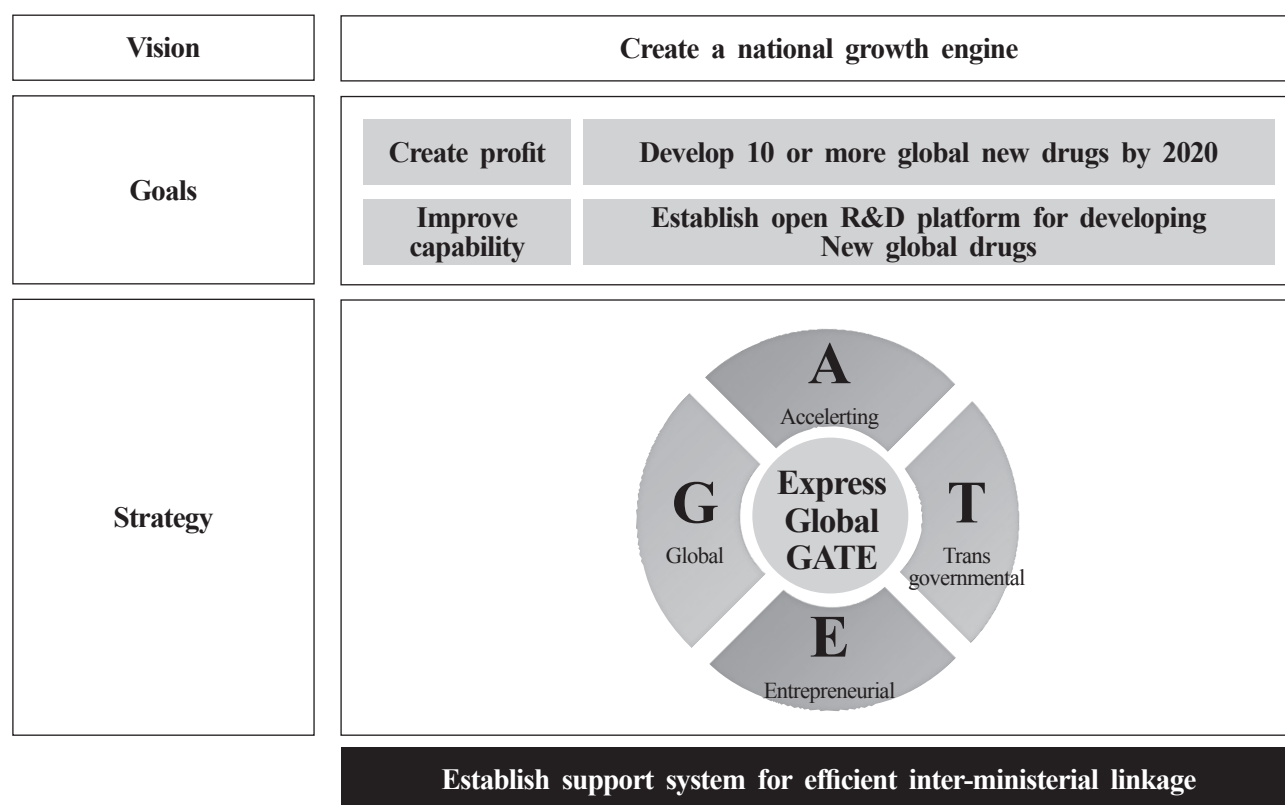
Figure 5 Background and facts of the *Trans-Governmental Whole-Cycle New Medicine Development Project*

3.2 Visions and Project Goals

The vision of this project is for Korea to become a global country developing new medicine that contributes to the enhancement of human health and welfare. Generic medicine and domestic medicine development are not subject to support since the purpose is to develop new global medicines. The long-term vision and goals of this project are to create a new domestic medicine development capacity to advance to another level by providing support to create new Korean medicine brands. We expect that by the time this trans-governmental project ends, ten will succeed, and about three will grow to account for more than 1 trillion won in annual revenue. Efforts have been made to integrate and manage the R&D projects that had been promoted by existing departments and to support prominent sectors lacking funding in order to form a virtuous structure.

3.3 Progress, Project Volume, and Period

This project started with the Global New Medicine Development Experts Commission for developing whole-cycle trans-governmental new medicines that was held five times over a period of eight months from April 2009. From May to November of 2009, related departmental conferences of the Ministry of Education, Science and Technology, Ministry of Health and Welfare, and Ministry of Knowledge and Economy were held for efficient development of new medicines at the government level. In February 2010, government and professional organization officials gathered to discuss the *Trans-Governmental Whole-Cycle New Medicine Development Project* plans. In April 2010, a comprehensive demand survey was conducted for R&D officials and working-level officials of industries, academia, and institutes related to the development of new medicine. Simultaneously, a subcommittee was



Source: MEST& MHW&MKE (2010)

Figure 6 Visions and goals of the *Trans-Governmental Whole-Cycle New Medicine Development Project*

Table 4 R&D invest budget of the *Trans-Governmental Whole-Cycle New Medicine Development Project*

Department	Stage 1			Stage 2			Stage 3			Total
	2011	2012	2013	2014	2015	2016	2017	2018	2019	
Ministry of Education Science and Technology	50	100	150	250	250	250	250	250	217	1,767
Ministry of Knowledge and Economy	50	100	150	250	250	250	250	250	217	1,767
Ministry of Health and Welfare	50	100	150	250	250	250	250	250	217	1,767
total	150	300	450	750	750	750	750	750	660	5,300

*Government investment amounts (private matching investment amount excluded)

Source: MEST& MHW&MKE (2010)

launched for planning of the project. The project is expected to be fully implemented by 2011 after public hearings and a preliminary feasibility survey.

The duration of this project will be nine years, from 2011 to 2019, with a total investment of 1.06 trillion won. Over nine years, the government will invest 530 billion won and the private sector will invest 530 billion won in R&D; however, the continued viability of the project will be determined after an evaluation of the program in 2020. Related sub-agencies will jointly provide an investment budget and will equally share the technology income (KISTEP, 2010. 8; MEST& MHW&MKE, 2011. 5).

3.4 Promotion Strategies

This project has *Global Approach*, *Acceleration Approach*, *Trans-governmental Approach*, and *Entrepreneurial Approach* (GATE) as its promotion strategy.

3.4.1 Application of Open-Type Innovation Concept (Global Approach)

This project has an open-type innovation concept as its basis. This project intends to promote R&D of a global standard that targets the development of global new medicines under the concept of Connection and Development (C&D).

3.4.2 Adoption of a Quick Research Development Method (Acceleration Approach)

This project stresses continuous research support in order to improve the situation of the team or researcher that shows excellent research performance having to move according to the assignments of different departments. Korea traditionally adopted the research development system of managing to avoid failure that focused on the creation of predetermined performance through systematic management and maintenance. However, developing new medicines is a field where research expense can be saved through quick development and termination, and it is efficient to adopt and proceed with a new research agenda with the leftover resources of terminated research.

We will create a single project that can overcome the bottleneck phenomenon of existing projects. It will manage all research-development stages by selecting candidate material for the third phase of clinical trials. In this method, excellent assignments are selected from each department project, domestic project, and overseas project. Other projects that fail to proceed to the next stage are dropped. In addition, new assignments can be added in the middle stages.

3.4.3 Trans-Governmental Approach

This project will follow the trans-governmental type of the Ministry of Education, Science and Technology, which used to be responsible for the non-clinical part of research, the Ministry of Health and Welfare, which used to take responsibility for non-clinical approval, and the Ministry of Knowledge and Economy, which used to take responsibility for

industrialization to overcome the divisions in each sector. Accordingly, this project has the following differences from existing or past projects. The first is planning. Past planning for the development of new medicines by a single department had to be limited to that particular department. However, after the integration of departments, it has become possible to carry out planning in terms of the new medicine R&D sector as a whole. The second is implementation. Due to the lack of department connectivity, resources were not utilized fully and the assignments of other departments were underestimated. However, with the establishment of a trans-governmental support system, continuous and integrative implementation has become possible. The third is the budget. Under this project, the budget is also executed concurrently under the concept that all three departments carry out the project together, regardless of stage. In particular,

there have been attempts to carry forward the budget in order to prevent intentional consumption of the budget within the year. This is in order to pursue the elastic operation of the budget. The fourth is evaluation. Related departments had theses, patents, and engineering fees as evaluation indexes for new medicine development assignments, and most R&D projects proceeded in line with this standard. Those working on R&D projects had cause for concern because there were no clear criteria for dropping assignments through stage evaluation and progress management. However, in *Trans-Governmental Whole-Cycle Projects*, the head of the projects can determine the sustainability (Go/Stop) through a milestone review, and there is no particular problem in the evaluation standard since there are clear and simple evaluation measures for overseas pharmaceutical companies and guidelines for each stage.

	Before	After
PLAN	<ul style="list-style-type: none"> • Individual ministry level • Within the scope of individual ministry's responsibilities 	<ul style="list-style-type: none"> • Cover the entire scope of national new drug development R&D • Jointly by involved ministries
DO	<ul style="list-style-type: none"> • Lack of inter-ministerial alliance • Not clear whether support can be sustained 	<ul style="list-style-type: none"> • Overcome silo mindset • Capable of providing foreseeable and sustained support
SEE	<ul style="list-style-type: none"> • Mix of disparate evaluation items • Regular but feedback after completion 	<ul style="list-style-type: none"> • Simple and clear evaluation items • Real-time, on-going, and by-stage filtering
Budget	<ul style="list-style-type: none"> • Separate investment by individual ministries • Relatively small scale 	<ul style="list-style-type: none"> • Joint investment by relevant ministries • Sufficient enough to satisfy the R&D needs of new drug development project
Cooperate	<ul style="list-style-type: none"> • Lack of alliance between industry, universities, and research institutes • Difficulty in cooperating with global companies 	<ul style="list-style-type: none"> • Encourage involvement in consortium • Active cooperation with global companies
Target	<ul style="list-style-type: none"> • Part of life-cycle of new drug development (relatively ambiguous) 	<ul style="list-style-type: none"> • Industrialization to new global drug at the end (relatively clear)

Source: MEST& MHW&MKE (2010)

Figure 7 Before and after of the *Trans-Governmental Whole-Cycle Projects*

3.4.4 Focus on Creating Economic Value (Entrepreneurial Approach)

New medicine development projects have high-risk and high-return properties that require long-term investment. Even though the probability of success is low, a high profit is guaranteed once the projects succeed. Due to these characteristics, this project does not equally divide R&D funding. Individual-project management is based on a milestone evaluation and focused on creating economic value. Early termination or suspension of a patent project is possible and earnest failures are tolerated without penalty. Therefore, unlike general R&D projects, this project does not adopt a management system that checks the extent of progress in real time. It is not possible to manage the projects using existing methods of progress management and stage evaluation since there is no predetermined rule regarding the stage a new assignment has achieved or failed to meet. Real-time inspection and regular monitoring are important (MEST&MHW&MKE, 2010; KISTEP, 2010. 8; MEST&MHW&MKE, 2011. 5).

3.5 Promotion System

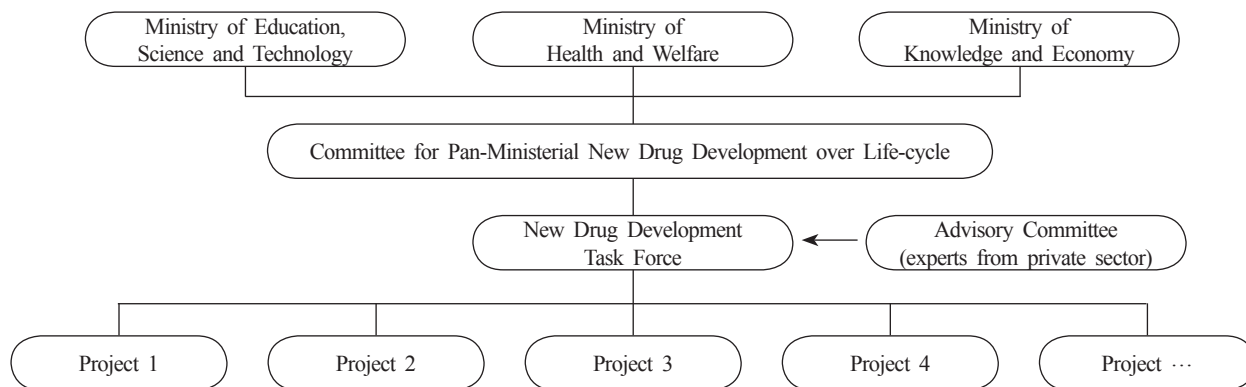
According to the promotion system of *The Trans-Governmental Whole-Cycle New Medicine Development Project*, participating departments jointly establish a *Trans-governmental Whole-Cycle New*

Medicine Development Promotion Committee. This committee is the highest-ranking decision-making organization that mediates between each department and determines policy decisions. Under this committee, a *New Medicine Development Project Group* will be established to promote planning, evaluation, research, development support, and administrative operation. It is the first time that various departments will operate one project group since the G7 mission.

Governmental organizations will grant authority to the project group to indirectly manage the project. The project group selects and proceeds with assignments with independent authority such as personnel, budget, and an independent advisory group that will provide support for selecting and evaluating assignments. The head of the project group will have full authority over developing, planning, and investing in the new medicine development projects. The related promotion system is as shown in Figure. 8.

4. Conclusion and Policy Implications

This research reviewed the promotion background, major content, and promotion system of *The Trans-Governmental Whole-Cycle New Medicine Development Project*, which is being promoted with the perspective of integrative innovation policies. Although this project is a new attempt at realizing integrative innovative policies such as connectivity among departments, cooperation among industry, academia, and institute



Source: MEST&MHW&MKE (2011.5)

Figure 8 Promotion system of *Trans-Governmental Whole-Cycle Projects*

sectors, and the establishment of a public-private cooperation network, there are several tasks to deal with in order to realize them specifically. The tasks are as follows:

First is the distance from the actual governance and inducing practical cooperation among departments. Since early 2000 there have been problems of project overlapping and a lack of cooperation surrounding the development of new medicines. Through the 13th *Science and Technology Ministerial Conference* agenda in 2006, there were discussions on dividing the responsibilities of departments, creating trans-governmental projects, and establishing a “control tower.” However, only the matter of dividing the responsibilities of the departments survived to create a conflict, and the division of work created a vacuum. There has been discord among related departments while promoting this project and the budget has been reduced. In order to encourage the departments cooperate with one another beyond the department boundaries, there needs to be a practical cooperation mechanism that is based on clear principles and causes.

Second, it is imperative to establish a feasible promotion system that can specify the project’s intentions. As for promoting organization, it is important to minimize government intervention so that plans are not frequently changed due to participation by various departments. R&D corporations should also function in a similar form and take on adjusting and integrating roles, whereas the government should only act in a supervisory capacity. Because the *New Medicine Development Project Group* aims at organizing a private company based on ROI, fairness, expertise, and independence are required for it to operate successfully. It is important to pick the right person with a successful business mind and leadership to head such a group.

Third, whether the trans-governmental joint R&D project (which is currently operating in a similar manner) will succeed is also important. The National Science and Technology Commission recently started a multi-departmental joint planning under a new concept influenced by trans-governmental new medicine

development projects. However, Because of the history and background, the probability of failure is high due to a lack of consideration of the characteristics of each sector; in addition, the combining of policies from among different departments has been carried out rather hastily. This is because of the typical top-down method and a lack of understanding of the significance of promoting trans-governmental R&D. Grand governmental projects cannot succeed when there is lack of indexes of a clear process. In order to succeed in multi-departmental joint planning and governance innovation, there needs to be a consensus among the participants or a clear direction and roadmap at the top stages of the top-down management system. Without clear goals, it is impossible to design specific activity strategies.

Fourth, trans-governmental whole-cycle joint planning projects of a particular area cannot be another alternative to complement the National Science and Technology Commission R&D planning and strengthening the adjusting functions. The National Science and Technology Commission and innovation headquarters are organizations possessing the unrealistic expectations of a strong control tower; however, an omniscience of the organization cannot be realized. It is also important for the National Science and Technology Commission to select what they can do better than the public and what they must do; except for these roles and functions, it is necessary to authorize related players and the public regarding other matters. Therefore, in this project, the National Science and Technology Commission should present a comprehensive direction and vision rather than micro adjustment, and evaluation recreates an environment where the promotion project group can proactively promote the project.

Fifth, in order for this project to develop into the realization of integrative innovation policies that major advanced countries emphasize, it should proactively reflect the social needs of the various players. Therefore, it is important to set goals and implement joint efforts in regards to what kind of medicines to develop, how to evaluate the results, and what to do with the achievements. When such efforts are made,

it will be possible to realize integrative innovation policies that will take into account the addressing of various social concerns such as the environment degradation, lack of safety, social polarization, and an aging society beyond the science and technology policies centered on economic growth. It is necessary to consider the needs of the global market and medical needs, while at the same time establishing a system that continues to monitor social problems and needs to develop those problems as missions. The board of directors, operation committee, and investment deliberation committee that form the project group should be able to assess the values beyond scientific, technological, and economic viewpoint in an integrative perspective through participation with social-policy-related personnel. In addition, the practice of dividing interests when promoting missions should be done away with and any possible conflict of interest should be prevented by transparently opening the procedures to the public.

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