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Short Communication

Biopharmaceutical Innovation System and the Influence of Policies: The Case of Taiwan (2000-2008)

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Abstract

This article discusses the influence of policies on the development of biopharmaceuticals. We choose the experiences of Taiwan for our empirical study and focus on the evolution between 2000 and 2008; in the period of time the country provides an interesting example for further exploration of biopharmaceutical policies. Among all the policies, the two National Programs (National Research Program for Genetic Medicine and National Science and Technology Program for Biotechnology and Pharmaceuticals) and the Law of Pharmaceutical Affairs showed the contrasting effects on the innovation system of biopharmaceuticals. As a result, the government generated very limited positive influence on the innovation of biopharmaceuticals.

Keywords

Biotechnology, Pharmaceuticals, Taiwan, Innovation System, Policy

Introduction

This article discusses the influence of policies on the development of biopharmaceuticals. The concept of innovation system which focuses on the network of actors for the accumulation and exploitation of knowledge is frequently applied for the analysis of research, technology, development and innovation policies policies (RTDI) (1–4). Thus; in this article we establish the analytical framework upon the concept of an innovation system. Since biopharmaceutical is developed upon a specific technology (biotechnology) adopted by a particular sector (pharmaceuticals) and intensively shaped by national institutions, we consider the *national, sectoral and technological innovation system* (NSTIS) (as shown in Figure 1) as the most suitable conceptual framework (5).

We choose the experiences of Taiwan for our empirical study and focus on the evolution between 2000 and 2008; in the period of time the country provides an interesting example for further exploration of biopharmaceutical policies. During 2000 to 2008, the Taiwanese government promoted various policies (as shown in Figure 2) to support the innovation of biopharmaceuticals, yet there has been little success. According to Figure 2, these policies included R&D, regulation[1] and business parks. Since our emphasis is the influence of policies, instead of discussing the detailed contents of each policy, we only choose the two National Programs (National Research Program for Genetic Medicine and National Science and Technology Program for Biotechnology and Pharmaceuticals) and the Law of Pharmaceutical Affairs (typically shortened to be the Law) which showed the contrasting effects on the biopharmaceutical innovation system for in-depth study. The contents of the two National Programs and the Law are displayed in Table 1. Even though the two kinds of policies were both promoted to support the development of biopharmaceuticals, the effects of the two kinds of policies reduced each other. As a result, the government generated very limited positive influence on the innovation of biopharmaceuticals.

We collected the first-hand resources through personal interviews; the list of interviewees is presented in Table 2. The article is structured as follows; at first we describe the ecology of firms. It is followed by an illustration of universities' roles. Lastly, we review the influence of the two kinds of policies on the innovation of biopharmaceuticals.

The ecology of firms

Between 2000 and 2008, local Small and medium enterprises (SMEs) were the pillars of innovation and manufacturing activities in the pharmaceutical sector. The pharmaceutical Multinational corporations (MNCs), which had started to sell their manufacturing facilities to local SMEs since the 1990s, sold out their manufacturing facilities. In the beginning of the 2000s the MNCs only operated their marketing divisions in Taiwan (6).

The main business of local pharmaceutical companies was manufacturing pharmaceutical intermediaries and generic medicines. The knowledge base of these firms was chemical engineering rather than biotechnology. The knowledge accumulation of these companies was in manufacturing activities. However, the majority of firms still lacked financial resources to do innovation. They mainly targeted the domestic market and competed with each other on a price-base. With limited technological capabilities, these firms' pharmaceutical products were hard to export to foreign markets (7).

The most significant ecological change of the pharmaceutical sector was the emergence of new biopharmaceutical companies. Compared with the local companies which focused on

[1]The Law was amended from 2000 to 2008 to add new clauses, such as the licenses of new medicines and data-exclusivity. As described by the Minister of the Department of Health (Intex3), he has once requested the Bureau to set up the agendas of the law not only to control the safeties of medicines but also to appropriately encourage the innovation of new biopharmaceuticals. This general direction was indeed consistent with the National Programs which aimed to support the growth of the pharmaceutical sector. Yet, we will show that after the implementation of the two policies, the effects of the two kinds of policies decreased rather than increased each other.

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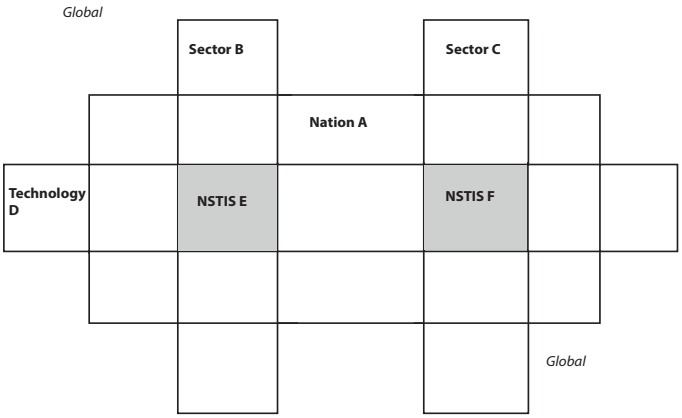

Figure 1. Relationship of National, technological and sectoral innovation systems and NSTIS [Source: Chung (5)]

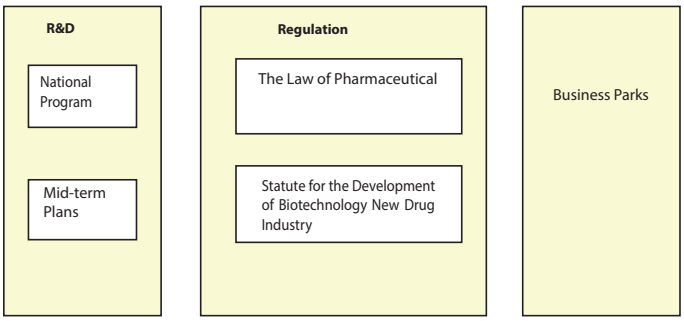

Figure 2. The structure of the biotechnology and related sectoral polices in Taiwan (2000-2008)

manufacturing pharmaceutical intermediaries and genetic medicines, the new biopharmaceutical companies had much stronger research capabilities for biotechnology and pharmaceuticals and concentrated on the innovation of new biopharmaceuticals. Since the knowledge accumulation of these new biopharmaceutical SMEs was still too weak to compete with MNCs, they usually focused on the innovation of Me-too medicines, rather than new medicines. Furthermore, due to the smallness and limited marketing[2] (8) capabilities of these new companies they usually targeted the sales of the domestic market (9).

The companies of Chinese herbal medicines also made obvious progress during this period. While the majority of companies of Chinese herbal medicines still emphasized the manufacturing activities of traditional herbal medicines (10), some larger companies started to invest in the innovation of new herbaceous medicines. In addition, a group of new companies of Chinese herbal medicines were set up in the late 1990s and at the beginning of the 2000s (9). Since these new companies were established, they emphasized the innovation of new herbaceous medicines. In fact, new companies and also larger ones of Chinese herbal medicines, had frequent interactions with academics. The main knowledge base of all these companies was the historical records of Chinese herbs. Modern biotechnology was mainly used by the companies to test the reliability of the historical records, to analyse the functional genes of herbs and to discover the effects of herbal genes on human cells. The new herbaceous medicines usually used a single extract of a specific herb. Strict clinical trials were widely adopted in the innovation of new herbaceous medicines (11). However, due to the smallness and limited marketing capabilities of these companies, they usually targeted the demands of domestic market only.

While biotechnology gradually spilled over in the pharmaceutical sector, the two National Programs also tended to facilitate pharmaceutical companies to absorb biotechnology and to develop new medicines; yet, most of the pharmaceutical companies were quite indifferent to the two National Programs. Indeed, the two National Programs which targeted the new biotechnological or chemical pharmaceuticals did not fit the manufacturing business of the firms of intermediaries and generic medicine whose knowledge base was the chemical engineering. While the majority of these companies were not incentivized by the two National Programs to do pharmaceutical innovation, only few larger companies of intermediaries and generic medicines, which were willing to invest in the innovation of new or Me-too medicines, transferred biotechnologies funded by the two National Programs (12). For example, Taiwan Tong Yang, which was one of the largest companies of generic medicine in Taiwan, transferred Thalidomide (a new chemical medicine for anti-liver cancer) from the National Science and Technology Program for Biotechnology and Pharmaceuticals and continued doing Phase III clinical trials (12). Besides, it was in fact the new biopharmaceutical companies and the companies of Chinese herbal medicines to benefit most from the two National Programs. With stronger research capabilities these companies were more willing to transfer the biotechnologies funded by the two National Programs. For instance, Phyto Health and SunTen Pharmaceutical have cooperated in the innovation of PDC-748 (a new herbaceous medicine of tussis) and received full funding from the National Science and Technology Program for Biotechnology and Pharmaceuticals to continue Phase II clinical trials[3].

We have interviewed three pharmaceutical companies which transferred biotechnologies funded by the National Science and Technology Program for Biotechnology and Pharmaceuticals, including one larger (SunTen Pharmaceutical) and one new company of Chinese herbal medicines (Pharmaceutical SME B), as well as one new biopharmaceutical company (Pharmaceutical SME A). All of the companies which transferred biotechnologies supported by the National Science and Technology Program for Biotechnology and Pharmaceuticals considered that the National Program positively encouraged them to cooperate with academics and positively increased their capabilities of innovation. However, besides SunTen Pharmaceutical which has not expressed its difficulties, the other two companies expressed that after they transferred the biotechnologies they found it very hard to continuously innovate the biopharmaceutical products due to the regulations. As described by the director of R&D of Pharmaceutical SME A (Intcomph3), the company transferred biotechnologies from the National Program for the innovation of new biopharmaceuticals, yet the regulatory body, the Bureau of Pharmaceutical Affairs under the Department of Health, which implemented the Law, was quite conservative to issue the company license for clinical trials. Furthermore, the president of R&D of another new company of Chinese herbal medicines (Intcomph4) expressed almost the same experience. The company transferred the biotechnologies funded by the National

[2]Me-too medicine in this article is defined as the medicine whose structure is very similar to the existing medicines but with minor differences (8).

[3]See the Official website of SunTen Pharmaceutical: http://www.stpt.com.tw/eng

Table 1. The contents of two kinds of policies in Taiwan

Policy Names	Policy Type	Policy Contents
National Research Program for Genomic Medicine	R&D	• Ministries: NSC (coordinator), MOEA, DOH • Year of promotion: 2002 • Policy objectives: to 'integrate limited resources, to capitalize the knowledge embodied in the human genome in order to promote medical research in Taiwan and also to act as an initiator for the local biomedical industry' • Policy instruments: funding • Targets: the research of genetic therapies for cancers, infectious diseases and highly heritable diseases
National Science and Technology Program for Biotechnology and Pharmaceuticals	R&D	• Ministries: NSC (coordinator), MOEA • Year of promotion: 2000 • Policy objectives: to 'gather all the allocated funding related to biotechnology and drug R&D of the National Science Council, the Ministry of Economic Affairs and the Department of Health to integrate the co-operation among industry, government, academics and the institutes' • Policy instruments: funding • Targets: the research of new chemical medicines, new protein of pharmaceutical intermediaries, and new Chinese herbal medicines which may be able to heal the four diseases among Taiwanese citizens, including cancer, diabetes, cardiovascular, and neurological diseases
The Law of Pharmaceutical Affairs	Regulation	• Ministries: DOH (Bureau of Pharmaceutical Affairs) • Year of promotion: 1970 • Policy objectives: to 'regulate the safeties of pharmaceutical affairs' • Policy instruments: penalties • Policy purpose of the new clauses: encourage innovation of new medicines • Policy instruments of the new clauses: license and protection

Abbreviation: NSC= the National Science Council, MOEA= the Ministry of Economic Affairs, DOH= the Department of Health

Table 2. Interviewees in Taiwan

Name	Code	Organization	Position	Dates of interviewing
Elected politicians				
Lee, Chong-Chou	Intex1	Science and Technology Advisory Group	Director of Biotechnology Office	20/01/2009
Anonymous	Intex2	National Science Council	Ex-minister	15/05/2008
Anonymous	Intex3	Department of Health	Ex-minister	23/10/2008
Anonymous	Intex4	National Research Program for Genetic Medicine	Leader	19/04/2010
Anonymous	Intex5	National Science and Technology Program for Biotechnology and Pharmaceuticals	Leader	30/10/2008
Administrators				
Anonymous	Intad1	National Research Program for Genetic Medicine	Project manager	13/04/2010
Anonymous	Intad2	National Science and Technology Program for Biotechnology and Pharmaceuticals	Officer	03/11/2008
Firms				
Hsu, Ming-Chu	Intcomph1	Taigen Biotechnology	Chief Executive Officer	20/04/2010
Anonymous	Intcomph2	SunTen Pharmaceutical	Ex-Chief Executive Officer	16/04/2010
Anonymous	Intcomph3	Pharmaceutical SME A	Director, R&D	01/19/2009
Anonymous	Intcomph4	Pharmaceutical SME B	President, R&D	03/02/2009
Academics				
Sun, Julie	Intac1	Taiwan Institute of Economic Research	Chief of Biotechnology Industry Study Center	08/05/2008
Anonymous	Intac2	Kaohsiung Medical University	Professor of natural products	23/02/2009

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Program for the innovation of new herbaceous medicines. Yet, because the Bureau of Pharmaceutical Affairs was conservative to issue the company license for clinical trials, the clinical trials of the company were slowed down.

The knowledge accumulation and the academic community

The roles of universities dramatically changed after 2000. Before that, universities were not allowed to directly interact with pharmaceutical firms. Yet, after 2000, universities were encouraged by the policies, such as the National Programs, to transfer biotechnologies to pharmaceutical companies as much as possible. Since the majority of local pharmaceutical SMEs were too small to do pharmaceutical related research by themselves, universities in fact burdened the responsibilities to do the majority of research, including the research of small molecule medicine, biopharmaceuticals and Chinese herbal medicines. The majority of research topics were chosen according to the research interests of individual scientists. However, with the promotion of the two pharmaceutical National Programs, the scientists with related research interests were gradually encouraged to establish networks with each other and to join research which emphasized the targets of the two National Programs.

Besides universities, the public research organizations under the Ministry of Economic Affairs and the Department of Health were also involved in the innovation of biopharmaceuticals and tended to play intermediary roles between universities and pharmaceutical companies. All of these research organizations, including the Industrial Technology Research Institute, the DCB and the National Health Research Institute, tended to transform the basic research from the universities to become applied research, and quickly to transfer the applied research to the pharmaceutical companies.

Even if the two National Programs have been directed to encourage academics within the universities to transfer biotechnologies to pharmaceutical companies as much as possible, not many academics were incentivized and the results of the majority of the research funded by the two National Programs remained in universities, rather than transferred to the pharmaceutical sector (as shown in the next section). As described by a professor of Chinese herbal medicines involved in the National Science and Technology Program for Biotechnology and Pharmaceuticals (Intac2), the two National Programs incentivized some scientists to collaborate with each other and to join research projects which focused on the pharmaceutical research of the four selected diseases. Moreover, from his perspective the National Programs also aroused the entrepreneurships of some academics and increased the incentives of these academics to transfer their technologies to pharmaceutical companies. However, as described by the leader of the National Research Program for Genetic Medicine (Intex4), besides a small group of scientists, many scientists funded by the National Program were more interested in pure academic research and were very reluctant to transfer their results to pharmaceutical companies. In other words, many academics were still not incentivized by the two National Programs to transfer the technology.

The roles of the government: the appropriateness of the National Programs and the Law

In this section we discuss the roles of the Taiwanese government through analysing the appropriateness of the National Programs and the Law. The appropriateness in this article is defined as the RTDI policies that match the development of the NSTIS through supporting the underlying logic of knowledge accumulation and exploitation in a particular technological field, clustering the network of actors and encouraging the production and innovation of a particular set of products. In the following paragraphs we will discuss the appropriateness of the National Programs and the Law first, and the appropriateness of the two policies afterwards.

The policy objectives and the policy instruments of the National Research Program for Genetic Medicine, as we are going to show below, were appropriate; yet, once being implemented, the National Program did not generate appropriate support to the biopharmaceutical NSTIS. As we have described in Table 1 the policy objectives of the National Program were 'to integrate limited resources', 'to capitalize on the knowledge embodied in the human genome', and 'to act as an initiator for the local biomedical industry'. However, the National Program which tended to 'capitalize on the knowledge' and 'to act as an initiator for the local biomedical industry' in fact tended to support the knowledge accumulation in genetic research and to cluster the networks between academics and companies. As the universities still did the majority of research and the local pharmaceutical SMEs lacked resources to fund their own innovations, the intended clustering of networks between the university and industry, in order to accelerate the technology diffusion from the universities to companies and to support the knowledge accumulation in the companies, was indeed appropriate for the Taiwanese biopharmaceutical NSTIS. The policy instruments which funded both universities and pharmaceutical companies to explore and accumulate knowledge of genetic therapies were also appropriate.

Yet, the National Program was not effective. Because of the time-lags of the National Program, we are unable to observe the long-term effects of the National Program. However, some economic indicators, such as the number of papers publishes from the results of the projects funded by the National Program, are able to show short-term effects which are clearly caused by the National Program. These short-term effects are able to help us to observe the extent for the National Program to appropriately match the biopharmaceutical NSTIS. Table 3 shows the economic index of the National Program published by the National Science Council in terms of papers published, patent applied, patent obtained, technology transfer, talents educated and number of pharmaceutical companies. On the basis of the statistical data shown in Table 3, in each year from 2002 to 2007 the National Program only transferred 0 to 15 biotechnologies to the pharmaceutical sector. The number of companies which transferred biotechnologies funded by the National Program only shared 0% to 4.6% of the total of pharmaceutical companies. Under the condition that more than 95% of pharmaceutical companies did not transfer biotechnologies funded by the National Program, it was hard for the National Program to claim that it was successful 'to act as an initiator for the local biomedical industry'. Furthermore, from 2002 to 2007 in each year the National Program only obtained 3-11 patents. The extent for the National Program to 'capitalize on the knowledge embodies in the human genome' was in fact very limited. Nevertheless, besides the quantitative economic index, we also collected some qualitative data through

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Table 3. The performance of National Research Program for Genomic Medicine and numbers of pharmaceutical companies from 2002 to 2007

Year	Papers published	Patent applied	Patent obtained	Technology transfer	Talents educated	Number of pharmaceutical companies
2002	86	3	3	0	299	425
2003	222	21	7	2	376	429
2004	354	48	9	5	419	414
2005	531	11	6	1	338	419
2006	216	7	10	10	600	328
2007	402	14	11	15	340	321

Sources: Science and Technology Yearbook (13), Biotechnology Industry in Taiwan (from 2001 to 2009)

our interviews with the leader of the National Program (Intex4) and the project manager in the Office of the National Program (Intad1). According to the interviewees the National Program did encourage some scientists to do outstanding genetic research and encouraged a small group of scientists and a small number of pharmaceutical companies to collaborate with each other through technology transfer. In another words, the National Program, to some extent, appropriately encouraged the knowledge exploitation of biotechnology in universities and encouraged some academics and pharmaceutical companies to cluster networks. Although in the short term the economic index did not show the appropriateness of the National Program, in the long term the National Program may be able to appropriately support the development of biopharmaceutical NSTIS in the future. In summary, the policy objectives and policy instruments of the National Program were appropriate, yet after being implemented, at least in the short term, the National Program had very limited support to the biopharmaceutical NSTIS.

The policy objectives and policy instruments of the National Science and Technology Program for Biotechnology and Pharmaceuticals, as shown below, were also appropriate; yet, the National Program generated very limited appropriate support for the development of biopharmaceutical NSTIS. As we have described in Table 1 the policy objectives of the National Program were to 'gather all the allocated funding related to biotechnology and drug R&D' of the three ministries and 'to integrate the co-operation among industry, government, academics and the institutes'. As the modern biotechnology was developed through interactions of actors and both scientists and companies are important in the innovation of biotechnology, the National Program, which sought 'to integrate the co-operation among industry, government, academics and the institutes', in fact tended to cluster networks between different actors. The policy instruments of the National Program which funded both the academics and pharmaceutical companies in order to encourage interactions and the knowledge accumulation of biopharmaceuticals on both sides were also appropriate. However, on the basis of the quantitative economic index published in the Science and Technology Year Book (12), from 2005 to 2007 the National Program has totally transferred 10 biotechnologies to the pharmaceutical sector. The number of pharmaceutical companies which transferred biotechnologies funded by the National Program only weighted 4% of the total number of pharmaceutical companies. Under the condition that more than 95% of the pharmaceutical companies did not transfer technologies funded by the National Program, it was difficult for the National Program to claim that it successfully encouraged the cooperation between the academics and industry. Besides, we have collected the qualitative data through the interviews with the leader (Intex5), the officer of the National Program (Intad2), the pharmaceutical companies (Intcomph2, Intcomph3, Intcomph4) and the academic (Intac2) involved in the National Program. According to those interviewees, the National Program did encourage the collaboration between some academics and a small number of pharmaceutical companies. Even if in the short term the economic index did not show the appropriate effect, in the long term the National Program may be able to appropriately support the development of biopharmaceutical NSTIS. In sum, the policy objectives and policy instruments of the National Program were appropriate, but the National Program generated limited appropriate effect on the biopharmaceutical NSTIS, at least in the short term.

The policy objective and the policy instruments of the Law, as we are going to show below, were inappropriate and only the policy purpose and the policy instruments of the new clauses of the Law were appropriate; once all clauses of the Law are implemented, the Law would not generate appropriate support to the biopharmaceutical NSTIS. The policy objective of the Law, as described in Table 1, which intended to 'regulate the safeties of pharmaceutical affairs' through penalties, in fact had no intention to support the knowledge accumulation, to cluster actors or to encourage the innovation of pharmaceutical products. The majority of the clauses of the Law were legislated in 1970 in order to control the manufacturing and the quality of medicines. From 1970 to 2000, the policy objective and the policy instruments of the Law were not changed. Only after 2000 the new clauses of the Law, such as pharmaceutical data exclusivity and the license for new medicines, were legislated to encourage local pharmaceutical companies to be involved in the innovation of new pharmaceuticals and new biopharmaceuticals. The policy purpose of the new clauses of the Law was appropriate, because the involvement of the pharmaceutical companies facilitated the knowledge diffusion of modern biotechnology in the pharmaceutical sector. Moreover, the policy instruments of the new clauses which licensed and protected the data exclusivity of the new pharmaceuticals and new biopharmaceuticals also encouraged the involvement of pharmaceutical companies in the innovation of modern biotechnology and were appropriate. Yet, once being implemented, according to the descriptions of the director of R&D of Pharmaceutical SME A and the president of R&D of Pharmaceutical SME B (Intcomph3, Intcomph4), the implementation body of the Law was conservative to issue the

license for clinical trials and to some extent, discouraged the pharmaceutical companies to innovate new pharmaceuticals. In other words, even if the policy purpose and policy instruments of the new clauses of the Law were appropriate, once being implemented, the new clauses did not appropriately support the development of the biopharmaceutical NSTIS.

While the two National Programs and the Law were promoted together, according to our interviews with the three pharmaceutical companies which transferred the biotechnologies from the project funded by the two National Programs, the limited appropriateness of the two National Programs was, to some extent, reduced by the promotion of the Law. After the promotion of the two policies, the Taiwanese government in fact had no obvious appropriate support to the development of biopharmaceutical NSTIS.

Ethical issues

Not applicable.

Competing interests

The author declares that he has no competing interests.

Author's contribution

CCC is the single author of the manuscript.

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