

Turning science into business in developing countries: The case of vaccine production in Vietnam

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***Turning science into business in developing countries:
The case of vaccine production in Vietnam***

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Abstract

Turning scientific discoveries into business opportunities is a difficult process, particularly in high-tech related area such as bioscience and/biotechnology. In developing countries, where research conditions are much less favorable than in the industrialized world, there are many additional constraints in terms of finance, investment, and human resources. However, the production of vaccines on the basis of research and technology transfer in Vietnam shows that this is possible provided the right policy and right people are available. Relying on transfer of technology from overseas, plus a combination of domestic efforts and international cooperation on R&D, Vietnamese research institutes have turned their research into business operations and turned some scientists into a businessmen and women. This in turn, has contributed to the eradication of certain diseases and Vietnam's self-reliance of key vaccines.

Subject classification: O31, O38,

I. Introduction

Vietnam is an agriculture-based developing country that has 70% of it labor force working in agriculture and forestry. The need for increasing the number of crops, crop yield, diversification of agricultural products, and the protection of varied natural resources and the health of its people make bioscience and biotech crucial for a poor country like Vietnam. In spite of being perceived as a high tech area, the development of bioscience and biotech in the context of developing countries is not only necessary but also feasible as in the cases of health biotechnology (Thorsteindottir et al. 2004).

This paper addresses the commercialization of research activities in bioscience and the introduction of biotechnology products such as vaccine production. This is a result of combination of various factors, including a suitable policy environment, the entrepreneurial ability of the people involved and international cooperation on the part of research community. The first section of the paper provides a general background of the bioscience and biotech innovation framework in Vietnam as well as the overall institutional and policy environment. The next section analyses a case experience in which international cooperation in vaccine research led to vaccine production in a company spun-off from its mother research institute. The paper concludes with a summary of findings and implications for academic and policy makers.

II. The bio-innovation system in Vietnam: a brief overview

2.1 The structure and actors

Overall, R&D activities in Vietnam are organized into three main domains: research institutes of the National Research Center which is now called the Vietnam Academy of Science and Technology (VAST), research institutions under line ministries such as the Ministry of Agriculture and Rural Development or the Ministry of Health, and bioscience and biotech faculties and departments of universities. There are about 50 research institutes and centers dealing with bioscience and biotech in three areas of agriculture, including aquaculture, healthcare and the environment.

The Ministry of Science and Technology, other ministries, and provinces have created a network of biotechnology laboratories for research, technology development and application. To date, this network includes 60 laboratories and research units located throughout the country. The Ministry of Science and Technology also provided the ministries with fund to establish and strengthen equipments for more than 30 laboratories. Investment for last few years has been about 80 billion VND (about 5 million USD). In addition, there are 30 simple experiment units of tissue culture in almost all provinces, with investment of 30,000 USD provided by the Ministry of Science and Technology through programs on science and technology application to support rural-mountainous development. In the coming period, upgrading and reorganization of these units are expected to result in investment estimated at about 5 million USD, an average of 130,000 USD per unit.

In 2002, in preparation for further biotechnology development in Vietnam the Prime Minister decided to build 5 national key biotechnology laboratories and more recently to invest in supplementary national laboratory of tissue culture technology in the South. These six national key biotechnology laboratories and 60 other laboratories and research units are the backbone of biotech research and training.

In universities, the system of biotechnology and bioscience mainly focuses on teaching, with less emphasis on research. The Ministry of Education and Training, other ministries and S&T organizations have various training programs for Bachelors, MSc, and PhD of biotechnology in several formats. Around 12 universities have created training programs and centers of biotechnology. So far, training has been conducted for more than 4,000 staff, of which 1,500 obtained bachelors degrees, 400 MSc degrees and 90 PhD degrees. But this training has not met the demand, especially in the major fields of biotechnology such as genetic technology, cell technology, enzyme-protein technology and microorganism technology. Along with universities, R&D institutes have also participated in training biotechnological staffs. During the 5-year period from 1996 to 2000, 23 MScs and 22 PhDs have been trained through this research program.

As for overseas training and programs of internships, MSc and PhD training has been carried out with State budget funds of 100 billion VND per year (or around 7 mln. USD). Through the Ministry of Education and Training more than 30 persons have been trained in biotech areas. In the framework of national research programs on science and technology, hundreds of biotechnology staff have collaborated with colleagues from developed countries through visits or research projects. In addition, scientists from overseas have been invited to Vietnam to train in research methodology with more than 200 groups of Vietnamese biotechnology scientists. In

recent years, Vietnam has also relied on some overseas scholarship schemes to send students to the US, Europe, Australia, Japan for training.

2.2 Performance

In agriculture, Viet Nam has implemented artificial insemination, preservation technology, embryo transfer and vaccine production technology. Technologies of forming new breeds such as tissue culture and cell generation have been applied widely in the production of rice, hybrid rice, maize, etc. Up to now, the contribution of biotechnology to Vietnamese agriculture has resulted in self-sufficiency of 25% demand of F1 hybrid rice, generating economic benefits of 30-50 million USD per year (MOST, 2003). New rice production has partially contributed to Vietnam's attainment of second position in the world rice export. New rice varieties produced by local scientists are used in 70% of rice-cultivated area. Another key achievement in this field is the provision of over 50 million trees of various types relying on tissue culture technology to meet demand of forestry development. In genetic preservation and conservation Viet Nam has created genetic reserves of animals, vegetation and microorganism. These reserves are run by 12 offices and 70 agencies belonging to 8 ministries and branches. Biotechnology has also begun to generate aquaculture species and preventing disease such as prawn species.

In health care and pharmaceutical products, for the last few years, artificial insemination technology has been applied widely at some clinics in Ho Chi Minh City and Hanoi. Genetic technology, DNA and protein chip are also explored in some research institutions and health care centers. They have applied fast diagnosis and early diagnosis technology in dealing with heredity problems in newborn babies and the prevention of epidemics such as poultry flu, and dengue fever.

The research projects for vaccine production have produced the most significant results in the field of medical biotechnology. Vietnam has mastered the technology and produced 9 out of 10 kinds of vaccine to serve comprehensive vaccinated programs. This contributed to the elimination of polio in the year 2002. Vietnam has recently succeeded in the research and technology development of a new type B-hepatitis vaccine based on DNA technology (recombination vaccine). The production of B-hepatitis vaccine since 1997 has brought turnover of more than 7 million USD. Four manufacturing enterprises for human vaccine produced tens of millions of doses per year to support comprehensive vaccination programs and these vaccines have been exported to India, South Korea, and Japan. Two types of vaccines have met 100% of demand and the remained have met 40-60% of demand in Vietnam.

In addition, genetic engineering, transgenic, GENE-CARD technologies were applied to national defense and public security areas in order to identify the remains of the dead from the national wars, recognize blood relations, and identify criminal.

In environmental protection, the application of biotechnology in the dioxin-intoxicated soil treatment process has been quite effective in terms of cost and safety. Micro organic technology applied to oil-polluted treatment has been implemented in many oil production areas. The application of micro organic technology in solid, liquid waste treatment has been used actively for processing organic, manure and oil pollution.

2.3 Problems

In the period before 1994, because of low *investment* in research activities, old and outdated equipments in laboratories and unskilled research teams, Vietnam had no access to modern scientific facilities and pool of knowledge. Thus, the bioscience and biotech development in Vietnam was insignificant. Both state and non-state investment for biotechnology was limited and fragmented in many projects under multi-layers/branches, This resulted in inadequate investment and the improper use of resources. Total investment from 1981 to 1993 for all bioscience and biotech related activities amounted to only 10 mln. USD. The total expenditure for R&D activities in biotechnology only reached 80 bil. VND (approx. \$US 5.5 mln.), for less than other countries allocation of hundreds of \$US mln. for a single biotechnological institute.

After 1994, especially within the last 5 years, Vietnam has explored modern technologies which are applied more actively into socio-economic activities. Following the Resolution of the government on promoting biotechnology development, some national key laboratories have received funding from 3-9 bil. VND (several hundreds thousands USD). However, these laboratories have not developed effectively, where new equipment was not used or used with low capacity, and necessary staffing was lacking. As such, the investment resources in biotechnological research and transfer have still been low and the use of these resources has not been effective. Due to the main reliance on the state budget, Vietnam did not have enough resources to invest in biotech R&D (Phan Van Chi, 2004).

In general, over the last 10 years, a system of laboratories from central to local levels has been established with relatively modern equipment. However, the operation expenditure is insufficient because there were no guidance on strategic tasks and no sufficient link between theory and practical production. Hence, the application of newly invested laboratories still has poor efficiency.

R&D on biotechnology has focused mainly on national key biotechnology programs. The Ministry of Science and Technology conducted the national research program on 'Biotechnology for developing sustainable agriculture, forest and aquaculture, environment and human health protection' (period 1996-2000) and has been implementing the research program, on 'Science and technology for biotechnology development' (period 2001-2005). It is unfortunate, however, that no realistic priority for the key program has been designed, with the research content designed primarily according to the existing background of the scientists. There has been a lack of market driven real need. For instance, a scientist with background in enzyme technology would propose strongly to develop research base (a program, an enzyme laboratory) in their respective area, and so on. As a result, though the results of research were deemed complete, not all of them have been implemented in production.

The role of *enterprises*, especially of private-sector enterprises in biotechnological research and application is weak and unclear. The driving force for development and competitive capability of the state-owned enterprises in biotechnology has also been weak. The system linkage among factors in the biotechnological innovation system (e.g. enterprises, institutes and universities), similarly in many other areas of innovation, has not been firmly seen (Tran Ngoc Ca, 2003). The current relationship between R&D organizations and enterprises is experiencing some constraints, such as a shortage of funds and capable human resources by the enterprises, in their collaboration with R&D institutions and their own conducting of R&D. When

cooperating with foreign firms, Vietnamese firms tend to follow the initiative of their partners. Vietnam still lacks the linkage and cooperation amongst scientists, as well as qualified research teams having international level of research capability. This has occurred despite the organization of several research programs.

Training also still has many shortcomings. In fact, there is lack of a well-designed strategy and specific structure for training programs. As a result, teaching contents have not been able to meet the demand. Biotechnology specialty for post-graduated training is little developed.

The bio-product market and demand for biotechnology development and biotechnological industry have been not developed. It has not made the critical pull for the biotechnological industry. The production base is narrow, bound to the national market via the primary, unprocessed bio-related product demand, which consists of mainly raw materials as tea, coffee, rubber, rice and aquaculture. This kind of products has enjoyed only temporary comparative advantage and have weak long-term competitiveness (Nguyen Manh Quan, 2004).

The *policies and institutional framework* for biotechnology and biotech industry have not been developed in a conducive manner. The Vietnamese government enacted the Resolution dated on March 11th, 1994 for biotechnology development until 2010. In 1999, the Government produced a report on the results after 5 years of implementing the Resolution and gave some directives for enhancing Vietnamese biotechnology development. At the same time, in order to promote more application of R&D results in production, the Prime Minister enacted the Decision 54/QD-TTg for developing the techno-economic program on biotechnology. In 2000, the MOST and other ministries formed the strategy for developing biotechnology till 2010. This strategy is an important part of national S&T strategy. In December 2003, the government approved a national S&T strategy, which contains the contents of biotechnology strategy (NISTPASS, 2003). Apart from overall policy documents, a range of other more specific government policies on crop and animal varieties, incubating vital young plants, state-supported agricultural contracts for high-tech agriculture, forest and aquaculture development programs have been promulgated. Despite all these efforts, current policies are deemed unclear and not specific enough to make an impact on biotech development.

For *international cooperation*, the government has encouraged organizations to employ both international experts or overseas Vietnamese with high professional qualifications as consultants or take part directly in development planning, training, and R&D activities. The government has also encouraged and financed international joint programs. Still, there is a view that these incentives are not sufficient for attracting more international involvement in innovation activities in the country. These factors, however, will have implications for future bioscience and biotech development of Vietnam.

III. From research cooperation to vaccine production

In 1977, two years after the Vietnam War ended, Vietnam and Sweden established a program to support research cooperation in the medical field. The first visit of Prof. Olof Kallings, director of SBL (Statens Bakteriologiska Laboratorium, National Laboratory of Bacteriology of Sweden) opened a long term and effective process of

cooperation in the research of preventive medicine in Vietnam (Phung Dac Cam & Nguyen Binh Minh, 2004).

Research cooperation started by focusing on support and upgrading diagnostic techniques in laboratory and *capacity building* for young Vietnamese researchers. With funds provided by SAREC (Swedish Agency for Research Cooperation), National Institute of Hygiene and Epidemiology (NIHE), Hanoi, under the Ministry of Healthcare and Statens Bakteriologiska Laboratorium (SBL), signed a program in collaborative research on infectious diseases. The objectives were to establish a Reference Laboratory for diagnoses of enteric bacteria. This activity began with a short training course in Hanoi. During the period 1978-1984, SBL provided training on ELISA technique to diagnose bacterial infections, on modern techniques to detect the toxin of bacteria and diagnostic methods for Rotavirus.

During the same period of training in Vietnam, Vietnamese researchers were also trained in Sweden. NIHE staff were trained in SBL on standard diagnosis of enteric bacteria, ELISA technique, toxin extraction, virology and classification of salmonella and susceptibility tests. Training courses lasted for various lengths, ranging from 3 months to one year. In addition to short-term non-degree training, degree training was conducted for post-graduate students. During the period 1988-1994, three Vietnamese PhD students spent time at Karolinska Institute in Stockholm and at the Huddinge University hospital, while other students did Master degrees. The extensive training component was the key part of the cooperation process.

After training, the focus moved to *vaccine research and production*. The first type of research vaccine is the shigella vaccine. With active support from SAREC, the joint Vietnam-Sweden research group from SBL and NIHE began research of a vaccine that can prevent shigellosis disease caused by shigella flexneri. The most notable component of this process was the transferred manufacturing technology of oral (drinkable) cholera vaccine, which NIHE has deployed since 1988. At present, the vaccine is manufactured at a large scale and has been used in the National Extended Program of Immunization (EPI) in order to minimize the occurrence of cholera epidemics in Vietnam.

Besides manufacturing of vaccine, the two sides began cooperation in more specific research projects related to different viruses like the infection of helicobacter pylori, of escherichia coli and a surveillance on HIV/AIDS transmitted from mother to child. Eventually, these research projects have contributed directly to the accumulation of knowledge, skills and new ways of dealing with scientific results of the Vietnamese staff at NIHE.

Research cooperation in the case of NIHE has come a long way starting with training to support building up research capability. This has produced expertise for Vietnamese researchers in the field of diagnosis, vaccine production and community epidemiology. Key research staff also has been created via research cooperation: one PhD became professor, two PhDs have associate professor ranks and 3 masters graduated from Sweden. They are heading key research groups in NIHE. The establishment of a National Reference Laboratory and a Unit to manufacture the oral cholera vaccine is another kind of collaborative result

SAREC/SIDA is one of the first organizations to have assisted Vietnam build research capacity, as well as funding and transferring technologies for research. This collaboration has led to notable research achievements beyond capacity building. In addition to Swedish cooperation, NIHE has many links with foreign scientists from the Pasteur Institute, Paris, Japanese cooperation under a program of WHO and has cooperated with American colleagues from some US universities. These all have contributed to capacity building for NIHE. This process of international cooperation initiated the research commercialization and the turning science into business results as the case below presents.

V. The spin-off: Vaccine and bioproducts Company No.1. (VABIOTECH)

As mentioned in the section above, NIHE with the support of international cooperation has built up certain level of research capacity in vaccine research. Depending on the kind of cooperation, different teams in NIHE have obtained expertise in production of different vaccines. Japanese scientists have trained NIHE staff on Japanese brain inflammation vaccine, while Swedish support has focused on the cholera vaccine. From 1991-1995, the Ministry of Science and Technology provided support for the Institute to carry out State-level research projects on application of advance techniques to complete the process of producing oral cholera vaccine and completing technology of producing both Japanese brain inflammation and other vaccines.

After the research results were successfully completed, the Institute continued to receive further support. During the period 1996-1998, a pilot project aimed at expanding production of class B hepatitis and oral cholera vaccines with total capital of two billion VND (about 130,000 USD) produced the investment rate of return of 80%.

On the basis of this success, and recognizing the need in Vietnam for vaccines of various types, NIHE decided to set up a business entity to deal with mass production of vaccines. The Institute proposed to the Ministry of Health the establishment of a company utilizing and developing the successful experiments of the pilot production project. The research carried out by the researchers of the three laboratories within the framework of international cooperation and later within government research projects was crucial for the company's start-up.

The Company for Vaccine and Bio-product No.1 – VABIOTECH was established in March 2000 by the Minister of Health (hereafter called as the Company) and operated under the NIHE. Originally it consisted of research team from three laboratories. The Company's founder is Madame Professor Nguyen Thu Van, PhD, who was then the head of one of the three laboratories – Laboratory of Class B Hepatitis Vaccine.

In addition to research results inherited from the Institute, start up facilities transferred from the Institute to the Company also was crucial for the initial period of operation. About 70% of the Company assets were transferred from the Institute in the forms of office facilities, machinery and equipment.

Thank to the Institute's research capabilities and transferred facilities, results of the research were applied immediately to production of vaccines. It should be noted that up to this time, most of vaccine available in the market were imported. Sale of vaccine products produced by the Company proved that their quality was equal to that of imported product, but were cheaper in price.

Currently, the Company has a total 124 staff, of which 80 employees have an undergraduates or higher degrees. Most of the professional staff with undergraduate education were transferred from the Institute. The Company employs about 20 people in functional departments, such as administration, accounting and management of business operation.

When transferred to business activities, the researchers became company staff and received salary from the Company. As such, the income and well being of staff all now depend on the Company's performance, which is an incentive for good work. This performance-based system has created the situation that they might not get paid if the production and business activities are not sufficiently sustained.

All, however, did not go smoothly at first. During the early stage, the Company lacked a stable source of income like that of the Institute, particularly for those who did logistic work. Besides, the staff were also under psychological pressures. There was a view within the Institute that "You should move into the Company if you seek for income and become rich; and if you wish to do scientific research, you should stay with the Institute". The same people who were regarded as "academic" yesterday were now supposed to become business men and women once they have been moved to the Company (Le Thanh Binh, 2004).

However, the Company still carried out its own research for product innovation. Interestingly, after the spin-off, there is little research relationship between the Company and the Institute, as a majority of the Institute's research staff in vaccine field was relocated to the Company. In fact, the company is feeding back the Institute and using the institute for its own research need. Annually, the Company allocates a fund (900 million VNDong in 2001 and 1.4 billion VNDong in 2002, or 60,000 and 90,000 USD respectively) for the Institute to proactively propose research projects, provided that these projects must be submitted to the Company's Scientific Board for comments before implementation. This ensures that the Institute's research will directly meet the Company's interests. The above fund is provided out of the Company's after-tax profits. As a result, the institute serves its own spin-off as a client.

At present, the Company produces and sells six main products, including plasma class B hepatitis vaccine, recombination class B hepatitis vaccine, inactive class A hepatitis vaccine, Japanese brain inflammation vaccine, oral cholera vaccine and rabies vaccine and other bio-products for diagnosis, treatment and precaution of disease. Annual production of main vaccines is as follows:

- Class B hepatitis vaccine: 4 million doses
- Japanese brain inflammation vaccine: 3 million doses
- Oral cholera vaccine: 1.5 million doses
- Rabies vaccine: 50,000 doses

This helps Vietnam partly achieve self-sufficiency in vaccines, essential for community health protection and saves a significant amount of foreign currency based on import substitution.

Still, there are several difficulties for the Company. Although being a firm, the Company cannot be responsible totally for its staffing and salary system due to its government spin-off organization status. The current salary regime is not appropriate, especially given the ceiling salary level imposed by several Ministries for all state

owned organizations. The salary regime remains egalitarian, which does not provide incentives for talents.

According to the Company's director, it is important for her organization is to be treated as a real company. This kind of technology based spin-off organization requires more specific and appropriate policy mechanisms and regulatory framework to be developed by the government.

VI. Conclusion

In the past few years, biotechnology has made a number of contributions to Vietnam's development. Initial infrastructure, organizational and institutional framework and personnel training for biotechnology have been created that has led to improvement of research and technological development. Its application into production areas has contributed to improvement of the quality of agricultural and aqua cultural products; production of vaccine and medical products in order to protect people's health and create more jobs. Still, in spite of starting relatively early, Vietnam is only taking the first steps toward development of modern bioscience and biotechnology. According to an assessment by the Biotechnology Atlas Project (MOST, 2003), among 10 ASEAN countries, Vietnam is ranked in the bottom half. Biotechnology in Viet Nam lags behind other regional countries and cannot meet the increasing demand necessary for socio-economic development and improved living standard. This is due to problems in the operation of the overall innovation system, including the legal, institutional and policy framework.

A number of issues related to situation of general biotech development and the case of vaccine production has been highlighted in this paper. First, international cooperation is crucial for starting research. This must be accompanied by government policies that provide a conducive environment to enable manufacturing to be transferred from the research sector. No less important is the market incentive regime that stimulates entrepreneurship of scientists. In this regard Vietnam is offering more policies to attract multinationals, first for industrial production capacity, then hopefully for related R&D capacity. The law on technology transfer currently being drafted will contribute to a better environment. Efforts to restructure the whole law and legal regulations as well policies for joining WTO is another big factor that will affect the sector and the recently enacted IPR Law and other regulations on biosafety would make things more reliable.

Second, although the Strategy for Vietnamese S&T development till 2010 was approved, and in which the priorities in biotechnology and bio-industry were defined, these strategy objectives need to be specified. It is necessary to further narrow priority fields in R&D and biotechnology application to make action plans more feasible. Biotech is an expensive game for everyone, and one country cannot do everything. In the context of Vietnam, it is wise to focus on a few activities and find the niche where the country's bioscience and biotech can best address it needs. Experiences from Cuba, South Africa and elsewhere revealed the importance of addressing local needs.

For Vietnam, finding its niche will serve multiple purposes. Production of vaccine can satisfy the self-sufficiency needs of the society, save foreign exchange from both import substitution and export potential. Upgrading expertise is a less visible goal, but important nevertheless. To achieve these ambitious goals, the mobilization of resources for future expansion and development of an industry is not an easy task.

Domestic savings together with attracting FDI can bring crucial financial resources. The role of Vietnamese diaspora who can bring both capital, knowledge and connections to market is emphasized strongly.

Third, learning is, as a rule, the key ingredient for any success. Learning from international partners, and internal learning from training are in place. One of the measures to address the fragmentation of investment, build up of innovation system, as well as breakdown institutional barriers is the creation of Centers of excellence in bioscience and biotech. The Millennium Science Initiative (MSI) with the involvement of the World Bank is being examined as an opportunity to address this issue in Vietnam.

The experiences provided in the case presented reveals that it is possible and feasible to turn scientific research result into successful business opportunities, given people with the right motivation and skills. The role of government, international cooperation mechanisms and market driven forces are all important for this to happen. In this particular case, turning biotech research to vaccine production to deal with specific conditions found in a country like Vietnam with a number of tropical diseases is the way to go forward. Finally, the important role of private actors and entrepreneurs endowed with management skills in the biotech activities must be emphasized ,

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