Health biotechnology in Malaysia: Issues and challenges faced by the innovative biotechnology firms

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7. Health biotechnology in Malaysia: issues and challenges faced by the innovative biotechnology firms

Gulifeiya Abuduxike and Syed Mohamed Aljunid

7.1 INTRODUCTION

Many developing nations have been attempting to develop a robust and competitive biotechnology sector over the last few decades. Biotechnology has been leveraged in several arenas, including healthcare, agriculture, industry, and environment to solve a number of pressing issues as well as to bring economic benefits to the country (Baianu et al., 2004; Daar et al., 2007). Particularly, applications of biotechnology in healthcare and medicine are the most significant as they have enabled prevention and treatment of numerous common as well as some "impossible" diseases and saved millions of people's lives (Boulnois, 2000; Acharya et al., 2004a; Baianu et al., 2004; BIO, 2008). Health biotechnology (HB) is applied mainly in the development of novel drugs, therapeutics and vaccines, genomics, in stem cell research, as well as for the development of numerous molecular diagnostic tests and medical devices to detect, prevent and treat diseases at the molecular level (Acharya et al., 2004a, 2004b).

Biotechnology is increasingly known as one of the sectors that drives global economy development. According to the Organisation for Economic Co-operation and Development (OECD), the economic impact of the biotechnology sector manifests itself in terms of high-return on investments on research and development (R&D), jobs and cost-effective therapeutic treatments and innovative drugs (OECD, 2005; Battelle, 2010; PhRMA, 2012). Biotechnology in Malaysia has been identified as one of the enablers in accelerating the transformation of the country into a knowledge-based economy and an industrialized nation by 2020. During the last decade, there has been remarkable development in the Malaysian biotechnology sector in terms of investments by the private and public sector, the number of biotechnology companies and research centres,

patenting intensity, as well as revenues and employment (BiotechCorp, 2014). However, a better understanding of the Malaysian HB sector development and of the challenges it faces is needed in order to ensure its sustainable development and the achievement of its targeted goals by 2020.

7.1.1 Economic Impact of Health Biotechnology Around the World

Biotechnology is playing a vital role in driving the growth of many national economies through science and technology innovation. For instance, according to some estimates, the US biotechnology sector consistently grew by 6.4 per cent in employment during the last decade and provided employment for 96,000 people, despite a decrease in other knowledge-based industries during the same period. From 1993 to 2010, the US invested about US$10.4 billion in basic sciences and gained US$976 billion as a return on investment, simultaneously creating 3.8 million jobs (Battelle/Bio, 2012). Over the years, the US biotech sector revenue is estimated to have grown an average of 10 per cent yearly, and the biopharmaceutical industry is currently one of the major income generators in the US economy, as the export value of biopharmaceutical products reached more than US$267.5 billion from 2005 to 2011 (Carlson, 2016; PhRMA, 2012).

Many developing countries have prioritized the HB sector by setting up national biotechnology policies and investing substantially in programmes that target local health problems. For instance, South Africa kick-started its biotech sector in 2001 with the Department of Science and Technology's National Biotechnology Strategy. The initial investment of US$75 million was planned for allocation through its four major Biotechnology Regional Innovation Centres (BRICs). The BRICs are active platforms from which to support biotechnology R&D, capacity-building, technology transfer and development, and to provide funding with two of them specifically focused on human HB (Cloete et al., 2006). The South African government also has set its ten-year plan for innovation beginning in the year 2008, which targets R&D spending to reach 2 per cent of gross domestic product (GDP) by 2018 (Al-Bader et al., 2009).

Two of the most populous developing countries, China and India, have developed HB sectors with a biopharmaceutical market worth of US$3 billion and US$2 billion in 2007 respectively (Frew et al., 2008). Private biotech firms in both countries have contributed significantly to industry growth by developing affordable and accessible biotech products that have focused on local health problems, such as the indigenously developed hepatitis B vaccine by the Indian innovative HB company Shantha Biotechnics and the only tablet formulation of a cholera vaccine by Shanghai United Cell Biotech, China (Chakma et al., 2011; Frew et al., 2008).

Cuba has invested around US$1 billion to build its HB sector since the 1980s, which brings economic benefits to the country and addresses the local health needs of Cuba. For instance, the Cuban HB sector has developed several innovative vaccines, including the world's first effective vaccine against meningitis B, the Cuban meningococcal BC vaccine (VA-MENGOC-BC®), as a response to its local meningitis B epidemics (Thorsteinsdóttir et al., 2004c; Evenson, 2007). Cuba has more than 300 biotechnology centres. Western Havanna Biocluster employs 12,000 workers and more than 7000 scientists. Cuba exports its HB products to 50 countries with the export value of around US$100 million a year (O'Farrill, 2010).

South Korea is one of the newly industrialized countries that has advanced the HB sector in Asia. The country is also a good example of developing its HB sector by encouraging private sector involvement and investment. The Korean government has invested about US$4.4 billion from 2000–07 in the HB sector with almost half of the R&D budget allocated to basic science (Wong et al., 2004).

7.1.2 The National Health Innovation System and the Role of Biotechnology Firms

Strong and advanced capabilities in Science and Technology (S&T) have become the core engine of economic development, particularly in the sustainable development of biotechnology, as it is a sector characterized by innovative technologies, processes, services and novel products based on innovation. S&T capabilities are the main driver of an effective National Innovation System (NIS) development, with innovation at the core of the technological change (Fischer, 2001; Freeman, 1995; Llerena et al., 2001). The NIS of a country consists of all the public–private entities that contribute to the creation, diffusion, and use of new economically beneficial knowledge, as well as the linkages and interactions between these institutions (Acharya et al., 2004a; Lundvall, 2007).

The NIS theory is applied as a conceptual framework to examine the interactions and linkages between different actors in the system and to assess their roles in the development of new knowledge and technologies using S&T capabilities in a country through knowledge creation and dissemination activities (Lundvall, 1985, 2009). Thus, building an adequate and effective NIS with strong S&T capabilities is essential for the sustainable development of the biotechnology sector (Lundvall, 1985, 2009; Freeman, 1995).

Health-related S&T capabilities determine the efficiency of the health innovation system in a country, which is directly associated with the development of the HB sector. Therefore, in order to have an efficient

biotechnology innovation system, building a competent health innovation system is needed, which is mainly determined by knowledge dissemination, interactions and partnerships between diverse actors with varied strengths, to come together and pursue the common goals for health innovation (Juma and Yee-Cheong, 2005; Mahoney and More, 2006).

These innovation actors include HB firms, public universities and research institutions, government and legal/regulatory agencies, education and healthcare systems. Several public sector features in the health innovation system determine the creation of scientific knowledge and its flow between other entities related to biotechnology, such as the traditional educational culture of a country; a basic research foundation; the integration of basic and applied research; funding mechanisms and availability of venture capital; interaction with foreign research institutions and universities; a national biotechnology policy; and the availability of a human capital pool in multidisciplinary, science and technology fields (Bartholomew, 1997).

Researchers have emphasized the role of firms and industries, as they are at the heart of an innovation system, which is driving the transmission of scientific knowledge into specific and tangible health products in the market (Fischer, 2001; Chung, 2002; Lundvall et al., 2002; Niosi, 2003b). Similarly, a biotechnology firm is the key player in the national biotechnology innovation system, which uses its scientific knowledge, expertise, resources and relationships to translate basic research and development into new commercial products and innovative processes to fulfil specific market needs (Abuduxike and Aljunid, 2012; OECD, 1997; Thorsteinsdóttir et al., 2004a, 2004b). As already mentioned, firms are the core entities for driving the growth of the biotechnology sector and there are many factors that impact upon the biotech firms' competitiveness, efficiency and innovativeness. Niosi (2003a) argues that the most vital factor in driving a firm's innovativeness is its capabilities and strong competencies in the biotech sector. At the same time, firms' ability to form alliances also plays an important role in improving their productivity and capabilities. Important types of collaborations include partnerships with research institutions to transfer knowledge; sharing of R&D resources, investments and risks through inter-firm collaboration; and collaboration with foreign companies to exploit foreign knowledge and technology (Niosi, 2003a; Lundvall, 2009).

In this chapter, we attempt to identify the main challenges faced by the Malaysian HB firms in order to evaluate the HB sector in the context of NIS theory. More specifically, we seek to answer the following questions:

- How does the Malaysian HB sector position itself in terms of innovative competitiveness in a global context?

- What are the main challenges and obstacles faced by HB firms in Malaysia?
- What can be done for the sustainable development of this sector from the perspective of HB firms?

7.2 METHODOLOGY

7.2.1 Study Design

This study applies a case study approach, an empirical inquiry that investigates and focuses intensively on a single phenomenon within its real-life context (Yin, 2004). Embedded single case study design is chosen as the most applicable method for this research, which examines more than one unit of analysis. The Malaysian HB sector is the case for this study, and each biotechnology company, public institute and government institution or agency represent multiple subunits of the case study. For the purpose of the study, biotechnology is defined as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods, and services" (OECD, 2005, p. 9). The focus on health-related biotechnologies suggests that genome-related technologies (such as Bioinformatics) and HB-related contract services (including R&D, clinical development, and manufacturing) are considered as a part of this study, whereas biotechnologies related to agriculture, environment and the industry are excluded.

In a case study, we strive to obtain an in-depth, comprehensive understanding of an issue, event or phenomenon of interest in its natural real-life context (Yin, 2009; Baker and Edwards, 2012). Thus, an attempt was made to cover as many firms related to HB as possible to ensure that our sample is representative of the Malaysian HB sector. A comprehensive sampling frame was developed to include enough cases for the study and volunteer participation was requested from the chosen companies via a formal invitation letter with an information sheet sent out to the participants.

The data was collected through four different sources including the background/historical documents, semi-structured interviews with key informants, a focus group discussion (FGD) with the representatives of the HB companies and a survey. The key informants were selected using a convenient sampling method from high profile management positions or the founders of the corresponded companies. They were chosen based on their expertise and experience in health-related biotechnologies in Malaysia. All interviewed HB companies were requested to fill out a

survey after the interview session and in some cases, questionnaires were sent and collected via email. These survey questionnaires were used to obtain some specific supplementary data from companies. Participants in the focus group discussions also were invited from the identified list of key informants who are the main players from the private HB companies in Malaysia.

Subsequently, the following types of analysis were performed separately depending on the data source: (1) systematic content analysis of the data from the secondary research; (2) integrated analysis of the information collected through interviews, FGD and survey based on the common themes such as the main challenges and issues related to R&D capabilities, funding resources, products, niche areas, human capital, collaboration and partnership activities, technology capability and policy and regulations. Respondent validation and triangulation were applied to verify the information obtained from the above sources, which was analysed based on the common themes, using the ATLAS-ti software.

7.3 RESULTS AND DISCUSSION

7.3.1 Science, Technology and Innovation Capabilities of Malaysia

Malaysia started its national S&T policy in the 1980s by setting up various research institutions and agencies to support and strengthen the S&T capacity of the country (MASTIC, 2014).

As a result, all the Science, Technology and Innovation (STI) indicators for Malaysia have shown an increasing trend during the 2000–12 period. This reflects growing financial support and research intensity in S&T areas including biotechnology in Malaysia. For instance, as an important indicator of the research intensity and capacity of a country, the gross expenditure on R&D as a percentage of GDP (GERD/GDP) has increased from 0.5 per cent to 1.13 per cent during the 12-year period until 2012 (MASTIC, 2014). However, Malaysia is lagging behind many developed countries in terms of GERD/GDP, including Finland, Korea, Japan and Sweden, all of which spend more than 3 per cent of their GDP on research and development. In Malaysia, the main sources of funding for R&D activities were from the private sector (56.7 per cent) followed by the government (43.3 per cent). About 66.5 per cent of total Malaysian R&D expenditures were spent on applied research, whereas experimental research and basic research received 16.4 per cent and 17.1 per cent respectively in 2011 (MASTIC, 2014). This is in a stark contrast to the developed countries that have been more committed to basic research.

R&D expenditures on biotechnology and medical and health science accounted for about 11.3 per cent of total R&D expenditure in 2011, which was two to three times less than R&D expenditures on Information and Communication Technology (ICT) and engineering fields (MASTIC, 2014). Moreover, there are huge gaps between these indicators in Malaysia and other developed countries in the region, such as Singapore, South Korea, and Japan. The lack of skilled workforce in S&T areas in Malaysia has been highlighted as one of the obstacles to innovations. This might be the result of consistently fewer students registered in S&T-related subjects compared to other subjects at the undergraduate and postgraduate levels in all types of Malaysian universities (MASTIC, 2014).

According to the Academy of Science Malaysia (ASM), the national S&T Policy II sets the goal of achieving a 60:40 ratio between students in science-related majors and students in the arts fields to ensure the success of the 2020 target. The current ratio, however, is barely 20:80 (ASM, 2013). Since the enactment of the Patent Act in 1983 in Malaysia, the number of patent filings and granted patents has gradually increased. Total patent applications have increased from 5062 in 2003 to 7350 in 2013, where 82.7 per cent of the total number of applications were by foreign applicants. A total of 2691 patents were granted during this time; 88.6 per cent of them were granted to foreign inventors and only 11.4 per cent to local ones, which goes in line with the distribution observed for patent applications (MyIPO, 2013). Similarly, the number of scientific articles in S&T areas has increased from 1048 in 2000 to 5985 in 2009. In terms of the subject fields of the S&T articles, the top research fields include Medicine, Chemistry, Genetics & Molecular Biology, which collectively comprised 24.6 per cent of total article output (MASTIC, 2010).

Malaysia is second after Singapore among the ASEAN countries in terms of the number of S&T publications. However, when comparing the number of patents and publications in Malaysia with selected developed countries, the figures show that Malaysia still lags behind developed countries in terms of R&D output indicators. A number of factors, such as lower R&D expenditures, innovativeness and competitiveness of Malaysian firms, research activities, and the technology transfer capacity of universities and research institutions are likely to contribute to such a state of affairs (OECD, 2016; MASTIC, 2010).

7.3.2 The Health Biotechnology Sector of Malaysia: Facts and Figures

Malaysia is home to a vast range of rich natural resources such as the world's oldest tropical rainforest; it is the 4th mega-diverse nation in

Asia and the 12th in the world with an estimated 15,000 flowering plant species (accounts for 9 per cent of world total) and 185,000 animal species (accounts for 16 per cent of world total) (BiotechCorp, 2008). It is believed that a good infrastructure, political stability, a multiracial and multicultural population coupled with a rich marine ecosystem give Malaysia a competitive advantage in the field of biotechnology (BiotechCorp, 2008).

Since the launching of the National Biotechnology Policy (NBP) in 2005, the Malaysian government has strongly emphasized the development of HB by stating it as the second thrust area in NBP, which focuses on leveraging the country's rich natural diversity and bio generic capacity in the market. The implementation initiatives of NBP were divided into three phases with specific strategies and targets within the timeframe of the Biotechnology Master Plan (BMP) 2005–20 as illustrated in Table 7.1 (BiotechCorp, 2012).

As can be seen in Table 7.2, the biotechnology sector has achieved, and even exceeds, the targets set by the BMP in terms of the amount of investment, number of companies and employment. However, as of the end of 2013, the annual revenue was still far behind the expectation (BiotechCorp, 2014).

The Biotechnology Corporation of Malaysia (BiotechCorp) was established as a one-stop centre for the biotech start-ups and has been acting as a facilitator and advisor to biotechnology companies in Malaysia via a variety of initiatives and programmes including advisory services, seed funding, tax incentives, training, public–private partnerships and business matching. BiotechCorp has defined a BioNexus status, which is the special status awarded to qualified local and international biotechnology companies. By the end of 2013, the number of BioNexus status companies reached 228 with the annual revenue of RM 2.9 billion (BiotechCorp, 2014). The total approved investment for BioNexus status companies reached RM 2.6 billion in 2012 and out of all, 3.7 per cent (RM 97 million) was spent on the R&D expenses by BioNexus status companies (BiotechCorp, 2012).

When comparing the achievements of BioNexus status companies in terms of key indicators in the three subsectors, health care, agriculture and manufacturing, it can be observed that while the level of approved investments for health care biotech companies was lowest among all three sectors (28.3 per cent of total investment for 2005–11), health biotech companies were the group who invested most in R&D activities (54 per cent for 2011). Additionally, the health care subsector had higher revenue (39 per cent for 2011) than other subsectors (BiotechCorp, 2011). These numbers illustrate well the specificity of the HB sector: higher risk in

Table 7.1 Malaysian Biotechnology Master Plan, 2005–20

PHASE 1: Capacity Building (2005–2010)
Setting up the building blocks

1 Adoption of policies, plans and strategies
2 Establishment of advisory and implementation Councils
3 Establishment of Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp)
4 Capacity-building in research and development
5 Industrial technology development
6 Develop agricultural, healthcare and industrial biotechnologies
7 Develop legal and intellectual property framework
8 Incentives
9 Bus Business and corporate development through accelerator programs
10 Bioinformatics
11 Skills development
12 Job creation
13 Regional biotechnology hubs
14 Development of BioNexus Malaysia as a brand.

PHASE 2: Science to Business (2011–2015)
Unblocking potential for the industry

1 Develop expertise in drug discovery and development based on biodiversity and natural resources
2 New products development
3 Technology acquisition
4 Promote Foreign Direct Investment (FDI) participation
5 Intensify spin-off companies
6 Strengthen local and global brands
7 Develop capability in technology licensing
8 Job creation.

PHASE 3: Global Business (2016–2020)
Attaining world class status

1 Consolidate strengths and capabilities in technology development
2 Further develop expertise and strength in drug discovery and development
3 Leading edge technology business
4 Maintain leadership in innovation and technology licensing
5 Create greater value through global Malaysian companies
6 Rebranding of Malaysia as a global biotechnology hub.

Source: BiotechCorp Annual Report, 2012. Reprinted with permission.

healthcare R&D projects, long gestation time for return on investments, as well as inadequate knowledge about healthcare biotechnology among investors, explain the relatively low level of investments in the health biotech industry in Malaysia.

Table 7.2 Key indicators for the Biotechnology Industry and achievements, 2013

Key indicators	TARGETS			Phase II Achievements as of 2013
	Phase I (2005–2010)	Phase II (2011–2015)	Phase III (2016–2020)	
Investment by Private Sector and Government	RM6 billion	RM9 billion	RM15 billion	**RM14.8 billion**
Number of BioNexus companies	25	25	25	**228**
Employment	60 000	80 000	160 000	**83 400**
Annual Revenue	RM20 billion	RM50 billion	RM100 billion	**RM2.9 billion**

Source: BiotechCorp Annual Report, 2014. Reprinted with permission.

We enrich these quantitative indicators by a detailed SWOT analysis of the Malaysian biotech sector, which is based on an extensive study of secondary data from public sources (Table 7.3). The strengths of the Malaysian HB sector are based on Malaysia's stable macro-economic conditions and a strong governmental support. These strengths are met with deficiencies with regard to human capital; specifically skilled knowledge workers for the HB sector are lacking while at the same time hiring foreigners is complicated. Bureaucracy in general poses a weakness for the HB sector. The opportunities for the Malaysian HB sector lie not only in the country's diversity – both in nature and in population – but also in the cost-advantage for both manufacturing and research and development activities. At the same time, such a cost-advantage can also be achieved by neighbouring countries, such as Indonesia and Thailand. However, exploiting the opportunities posed by the Biotechnology Park and the identification of niche markets combined with the creation of a Malaysian biotechnology brand may counteract such threats.

7.3.3 Main Challenges for HB Sector Development: Firms' Perspective

In this section, we present the analysis based on the information obtained from HB companies through semi-structured interviews and FGD as part of the Malaysian health biotechnology sector evaluation. HB companies representing a variety of activities such as molecular diagnostics, medical devices, herbal medicine and natural wellness products, Contract Research Organization (CRO), Contract Manufacturing Organization (CMO) and

Table 7.3 SWOT analysis of Malaysian Biotech Sector

Strengths	Weaknesses
● Strong policy support and political stability ● Stable economic growth, vibrant business environment and a well-developed financial system ● Recent increase in quality of life and awareness towards preventive medicine ● Educated human resource pool with English language proficiency ● Government funding support, BioNexus status and tax incentives ● IP rights protection ● National biotechnology policy ● Strong foundation in medical devices and diagnostics manufacturing ● Excellent infrastructure and GMP compliant facilities.	● Lack of Funding ● No clear regulatory pathway for biotech products ● No locally produced innovative, novel drug and vaccines in the market yet ● Lack of knowledge among investors and stakeholders towards biotechnology ● No balanced educational system which corresponds to the biotech industry needs ● Lack of local skilled workforce; brain drain ● Complicated immigration process for hiring foreign skilled human capital ● Bureaucracy, complicated procurement procedure ● Lack of support for locally produced biotechnology products ● Lack of awareness among medical professionals and general public.
Opportunities	**Threats**
● Rich biodiversity and natural resources: Over 1,000 species of flora are reported to have therapeutic value that can be tapped for medicinal potential. ● Multiracial population base provides a diverse genetic pool and positions Malaysia as a great hub for clinical trials ● Being the 17th largest trading nation with huge potential to export its biotechnology products ● Creation of a Malaysian brand by identifying niche markets based on country's strengths in biodiversity and natural resources ● Cost competitiveness and free market ● Cost effectiveness in conducting research and development ● Bio-XCell, the first dedicated Biotechnology Park and ecosystem for biotechnology and industrial biotechnology companies, mainly focus on R&D and manufacturing.	● Competitive regional and global biotechnology environment ● Global economic instability ● Cost competitive workforce in neighbouring countries, such as Indonesia, Thailand.

Source: Author's own elaboration.

vaccine areas participated in this study. Having a national biotechnology policy with comprehensive agendas and a specific implementing agency such as BiotechCorp is the strength of the Malaysian biotech sector, as many developing countries do not yet have such a comprehensive biotech policy. However, similar to any other policies, NBP Malaysia has some weaknesses, demonstrated during its implementation and enforcement by the government.

The participants indicated numerous challenges and barriers to successful innovations by the HB firms. The major challenges were summarized into five themes based on the information obtained from interviews, FGD and a complementary survey. These challenges are related to 1) Malaysian innovation system for HB development, 2) funding and R&D capabilities, 3) human capital, 4) niche areas and 5) government policy and regulations towards the biotechnology sector (Table 7.4).

7.3.3.1 National Innovation Systems to support the development of the HB sector

The majority of respondents pointed out that an NIS for the development of the biotechnology industry in Malaysia has not yet been established. The institutional and business environment is not conducive to the growth of private HB firms. One of the main barriers that interviewees pointed out is the lack of trust among the various actors within the HB sector and the poor linkages among the various governmental institutions, which impedes a consolidated public policy for the HB innovation system.

> We have been hearing from BiotechCorp that there is an ongoing discussion within the Ministry of Health (MOH) about firming up regulations and so on. But it has never happened. We carry around BioNexus status by the government, but other agencies don't recognize it. In Malaysia, there is no link between agencies, they don't talk to each other. [Bioinformatics firm]

> There is no clear understanding and close relation between ministries, including, Ministry of Health, Ministry of Science, Technology and Innovation (MOSTI), even like Ministry of International Trade and Industry (MITI). The National Innovation System in Malaysia is still developing; it's not fully developed yet. That's why there is no interaction and integration of resources. [Medical devices firm N1]

> I feel that we don't have the biotechnology industry. It's not that we have a good industry and there are no suitable local students. There are no opportunities for the science students. The amount of money the government puts into biotechnology growth is very small. There is no collaboration even at ministerial level; instead of working together, they sometimes compete with each other. [Molecular diagnostics firm N1]

Table 7.4 Summary of the main challenges and barriers faced by HB firms in Malaysia

Main themes	Challenges and barriers
Innovation system of country	• Lack of adequate, conducive innovation system for a sustainable HB sector • Lack of know-how in universities • Lack of linkages/connections between universities, research institutions and health biotech firms. • No communication and interconnections between government agencies • A resulting insufficient knowledge dissemination and technology transfer
Funding	• Shortage of funding for HB firms, especially during commercialization stage and for long-term R&D and HB product development • Bureaucracy & lack of transparency in the process of funding allocation • Venture capitalists rarely invest in health biotech startups • Affected by the lack of understanding and practical knowledge of the HB products& technology
Human capital	• Lack of an adequate and necessary local human capital • Insufficient & inadequate knowledge and wrong mental set of new graduates • Lack of training curriculums on practical skills to prepare for industry needs • Mismatching of skill sets of industry and university students • Complicated regulatory process to employ expatriates • Lack of efficient utilization and maintenance of existing research facilities and infrastructure
Niche areas	• Very broad and unclear focus areas in the HB sector • Lack of understanding on HB led to a wrong identification of niche areas • Currently identified areas do not reflect the strengths of Malaysia • Tend to take a short cut and looking for an easy way to get fast result
Government policy and regulations	• Lack of clear regulatory pathway in cutting edge HB areas • Lack of an effective commercialization chain • Difficulty in registering, patenting and commercialization of HB products locally • Some regulations are good, but with poor implementation • Procurement policy by MOH is not favourable to local HB firms and their products • Takes a long time to finalize an act, regulations or guidelines related to HB

Source: Author's own analysis based on the Interviews and FGD.

> About commercialization, the universities don't have the funding and also don't have an adequate know-how to get their products progressing through the cycle. [Contract manufacturing organization]

Some HB firms have collaborations with foreign firms in the areas of licensing, training staff and marketing. However, most of the respondents stated that local collaborations are weak or non-existent. Some participants named the lack of trust and confidence in each other's capabilities as the main reasons for sparse local collaborations.

> Although there are a lot of resources and encouragement from the government, and there is a strong scientific community in Malaysia, however, there is no scientific communication or collaboration between scientific bodies. Even between universities, there are no successful collaborations. [Molecular diagnostic firm N2]

> The Malaysian biotech industry is very young and small with few growing companies. So, when academics look at the industry, they don't think the industry is doing well because only a few front-runners are driving the industry such as Holista, Pure cycle, Bioven, and so on. The understanding of the academics towards these young companies is not sufficient enough to evaluate the HB industry. [Medical device firm N2]

7.3.3.2 Funding issues

Most of the interviewed firms enjoy the BioNexus status and received seed funding to start up business activities; some obtained venture capital (VC) funding for specific projects. However, the availability of VC funds is limited and cannot provide the necessary support to firms in HB. As a result, insufficient funding is mentioned as another major obstacle, along with the relatively low R&D expenditures on HB, a lack of investments and of R&D involvement on the part of governmental research institutions, and insufficient attention to basic research and technology transfer activities among sectors. The study participants raised concerns related to the weaknesses in government policy and enforcement, complicated funding procedures and a lack of transparency in funding evaluation.

> Until now we are facing funding challenges. Biotechnology business takes longer time to develop [products] and even banks do not want to provide funding. We don't have the investment to expand the business. This is the problem that most of the companies are facing. I have approached Malaysian Technology Development Corporation (MTDC), but they said they don't have the system to fund this business. [Molecular diagnostics firm N3]

> The government is not willing to put money into the vaccine industry because they are very conservative due to the long-time horizon of vaccine development. They prefer short-term investments due to faster turnaround time. Another reason is that investment in the vaccine can be very risky and very few projects can be successful. NineBio can be a good example of a failure in vaccine investment, it failed because of poor planning and misuse of the funds by a few people; in this case, corruption was the root of the problem. [Molecular diagnostics firm N4]

Some companies emphasized that in some instances, stakeholders and staff in regulatory agencies lack scientific knowledge; as a result, they often do not understand new health technologies and products. This lack of understanding significantly affects the process of product registration, funding application, and commercialization of the new local products:

> There are lots of challenges in running this company here as the business we are doing is very new in Malaysia. Nobody understands what we are trying to do. We applied to get the MOSTI Techno Fund twice and tried to explain to them what we do, but it's very difficult. Also, we tried to explain to investors what we do, but they don't understand because it's a new industry. I think for us the biggest challenge is the construction because this is an international standard quality facility. [CMO]

> I think there is very poor understanding of what biotechnology in Malaysia is, especially amongst the government and industry towards the various stages of product development in biotechnology. And the amount of funding, which we have received, is too small to complete the phase 3 clinical trial for our product and to bring it to the global level. There is no vaccine industry in Malaysia and there is no awareness about vaccines for cancers in particular [Vaccine and therapeutic firm]

> In Malaysia, venture capitalist doesn't really understand the biotechnology industry and what our technology is, because the sector is new. Venture capitalists are not comfortable with investing in biotechnology. When we approach VC investors, we always have difficulty to explain our technology and business. [Medical device firm N3]

7.3.3.3 Human capital issues

There appears to be a mismatch between the human capital needs of the industry and the availability of suitable university graduates. Some firms stated that it is difficult to find employees with the right skill sets that suit particular industry requirements. And in some cases, it is difficult to retain talented or skilled personnel due to a lack of incentives and financial support.

> Another biggest challenge for us has been recruitment. Biotechnology, especially bioinformatics, is a new field, only about 10 years old. Not only there are no talents in Malaysia, there is very little talent all over the world. This challenge is not unique to Malaysia. So, it was the biggest challenge for our company. However, we overcame the challenge by going through bioinformatics community and using our own network to look for the right person to work with us. [Genomic/CRO firm]

> In comparison to Singapore, the cost of labour is cheaper here in Malaysia, but again they have more expertise in biotechnology. One of the reasons is that Singapore government policy toward hiring expatriates is easier than here, in terms of work permits, the timeline for the application process is much faster than here. [Manufacturing firm]

Some respondents raised the concern over the education system policy and stressed the importance of focused industrial training and strengthened basic research in university curricula, particularly in highly specialized areas such as bioinformatics, genomics, and vaccine and drug development.

> Especially in the development of the vaccine field, there is not enough skilled experts or professionals to work in Malaysia. When you look at the vaccine industry, you need to look at two basic things, one is the relevancy of the vaccine in development with the needs of the people, and another one is the manufacturing capabilities. This requires two different kinds of skills and we don't have either one of them. The whole generation of people has lost the knowledge, skills regarding this field and this might be related to our education policies. [Vaccine and therapeutic firm]

> In terms of workforce and experience, the differences are so wide. If this company was in the UK and if I was looking for the positions like I am looking for here, I would fill demand three weeks ago. But here I need to do lots of scarifies and recruitment managers could not get what they want. So they need to look at what is the most important technical skill this person needs to have. Probably they are not going to have it all. [CMO]

Some interviewees highlighted that Malaysian institutions possess a good infrastructure in terms of equipment, buildings, and research facilities. However, the common concern was the effective utilization and maintenance of these facilities and equipment. Some respondents mentioned that they are lagging behind many developed countries in terms of technology advancement and availability.

> If talk about infrastructure in terms of equipment, buildings, and facilities . . . yes, we have very advanced laboratories with the latest equipment. However, the weakness is a lack of proper use, maintenance of the equipment and there are no skilled people to utilize the specialized equipment. Our problem is that

we always invest in equipment and buildings, but not in proper utilization and maintenance. [Molecular diagnostic firm N3]

7.3.3.4 Niche areas

Respondents expressed concerns over the wide and unstructured scope of the biotechnology industry in Malaysia and emphasized the need to identify niche areas, according to the Malaysian strengths and capabilities and to focus on developing these particular sectors.

> In the area of healthcare biotechnology such as diagnostics, medical devices and so on, if you look at innovation by itself, it is very hard to stimulate if you do not provide incentives to the entrepreneurs and researchers. Just think about the research in healthcare, it's very difficult to do if there is no clear focus. Countries like the US, Europe, Cuba, Japan, Korea and others spent a lot of time to create the momentum of the building of healthcare biotechnology. We want to do it in a very short period of time with very broad ambition, I think it is very difficult to do. [Medical device firm N2]

> I think the first thing you have to understand is which part of the biotechnology that you want to focus on. A lot of people misconstrue. If a big pharma comes to Malaysia and sets up a manufacturing plant here, of course, it is not considered as biotechnology. That's real state. You should take it, open it up and then see what sector you want to focus on. Either it is going to be service based, or CRO based or biologic manufacturing or generic manufacturing based. Manufacturing itself is so wide and the problem is, the understanding of that is not clear. [Medical device firm N1]

> I think the lack of focus is the main issue. If the focus were there, we would have the competencies to be built. Then the industry will drive the biotechnology, and the government will have to listen. Now we don't have the competency, only two or three players in each sector, so how are we going to lead the sector? If we have the focus and competency, then we can sit around and tell them we are not being helped here. Now everybody is running in their own direction. This is not the way. [Molecular diagnostics firm N4]

7.3.3.5 Government policy and regulation

Some respondents from the private sector expressed major concerns over the difficulty in accessing the local market due to regulations and restrictions imposed by the MOH procurement policy and other related regulations.

> We faced challenges when we needed to register our products and commercialize the kits. However, there is no single regulatory body that does the registration for the molecular diagnostics and there is no pathway for the registration as well. We have spent a long time and many resources to develop a diagnostic product, but the commercialization was delayed due to no regulatory pathway to register. [Molecular diagnostic firm N1]

> There is no local market and support from MOH to buy the products which are manufactured here. There is no support for the BioNexus companies to get into the procurement policies. The entire circular is there. For the myDankit which is the only first molecular diagnostic kit for dengue infection, even though it was recommended to the regulatory agencies, but the Malaysian devices bureau does not accept it. [Molecular diagnostic firm N2]

> Of course our product is much cheaper and cost-effective, about 50 per cent. But most of the central procurements are being made only through one or two companies include pharmaniaga. [Orthopedic device firm]

The respondents also stressed that even though regulations exist, implementation may be very poor, so that Malaysian biotech companies often do not have fair access to the local market.

> If you look at the 9th and 10th Malaysian plan, everything is there, even the procurement policy. But in terms of the real operation, there is no support. The execution and standard operation of procedures don't exist. [Molecular diagnostic firm N3]

7.3.4 What can Malaysia do to Develop the Sustainable HB Sector?

The study participants were asked about their recommendations and suggestions to improve the current situation and foster HB development. Their responses were summarized based on the main themes identified above (Table 7.5). Almost all respondents agreed that the inadequate innovation system of the country is the basis for most other challenges. With the existing ineffective knowledge dissemination and technology transfer system and a lack of linkages between actors, it is very difficult for new ideas to become tangible innovative products in the local market.

The study participants pointed to a number of areas, where changes are urgently needed for the HB sector to move forward. Foremost, priority should be given to the identification of niche areas, which are targeted to solve the health needs of the local population. For instance, there are some tropical infectious diseases such as Malaria and Dengue Fever, which are endemic in Malaysia and other Southeast Asian countries. Development of health biotech products that help a quick diagnosis, treatment, and prevention (in the form of vaccines) of these diseases could be good examples of the regional niche areas to focus on.

At the same time, the niche areas should reflect the strengths of Malaysia and exploit the advantages in natural resources, rich biodiversity, geographic and racial dynamics in the country and region. The identification process of the niche areas should be transparent, inclusive to all actors in the NIS and well informed of the real situation of the country and health status of the people.

Table 7.5 The main perspective from HB firms to develop the sustainable HB sector in Malaysia

Main aspects	Recommendations and strategies
National Innovation System	● Government should encourage collaborations between private and public sector ● There should be the effective knowledge dissemination between universities and firms ● Technology transfer offices in the universities should work together with HB firms for the ideas to become tangible HB products in the market ● Sectors should be encouraged to share and combine resources to work efficiently on similar research projects
Regulatory aspects	● Clear guidelines, acts and regulations should be set for all HB subsectors, increasing transparency and reduce the bureaucracy in the operation ● Existing guidelines should be followed by developing and enacting clear pathways and procedures, especially for locally developed products ● A stakeholders approach to decision making should be utilized; all related experts should be included in the decision making process, not only one or two agencies ● Regulatory bodies should be knowledgeable and able to act as consultants to HB firms and let them understand the procedure, requirements, etc. ● There is a need for an agency that can specifically support and assist HB firms
Niche areas	● Biotech sector should focus on one or two areas of competitive advantages such as biodiversity, natural products ● Supported areas should reflect the health needs of the nation, such as infectious diseases as well as non-communicable diseases ● Country's assets such as multiracial population and resources should be promoted, protected and effectively utilized in clinical trials ● More focus should be given to the basic and fundamental research
Funding	● Fund review procedures and processes should be transparent and devoid of favouritism ● Funding mechanisms should be available for the whole production chain of HB ● More private sector involvement and investment in the sub sectors is needed ● There is a need to attract more Foreign Direct Investments and multinational companies to invest and set up their companies in Malaysia

Table 7.5 (continued)

Main aspects	Recommendations and strategies
	● Collaborations/partnerships between public and private players can be useful in sharing investments, risks and outputs of research, such as IP Intellectual property rights (IPR), revenues etc. Such collaborations may facilitate human capital development
Human capital	● The education system should be modified to suit the industry and niche areas of research and development ● Universities should make sure new graduates have adequate knowledge capability and practical skills related to biotechnology ● More specific training and support programs should be provided to improve the qualifications of the labour force ● Stressing science and technology as the main subjects since primary school education may be a fruitful idea ● There is a need for additional funding and programs for students to pursue higher degrees, like masters and PhDs according to the needs of the industry

Source: Author's own analysis.

Focusing strategies and resources on promising HB niche areas in Malaysia would facilitate the development of industry hubs that can serve as locomotives for the HB sector and the Malaysian economy. Therefore, once the niche areas are identified, the next step should be the logical allocation of available resources and funding. There are a number of R&D institutions with world-class facilities in various universities in Malaysia, which are working independently on similar projects, without collaboration and resource sharing between them. Such a working culture only results in further weakening the NIS in the country and in a waste of resources.

Thus, R&D resources, existing human capital and funding mechanisms should be mobilized and most importantly coordinated to focus on the identified niche areas. R&D institutions and universities should conduct extensive R&D activities and collaborate with HB firms in the process of technology transfer or the joint development of tangible HB products to be commercialized in the local and global markets.

Throughout the product development (PD) chain, numerous issues are important and should be tackled strategically and wisely. Funding is one of the key mechanisms to drive the PD process smoothly, including R&D, human capital, product development and commercialization. Thus, for the funds to be effective in promoting the areas of high potential, the

allocation of available monetary resources should be transparent and devoid of favouritism and corruption.

Currently, the Malaysian government is trying to attract Foreign Direct Investment (FDI) into the biotech sector to foster its development. However, in order to attract FDI, Malaysia should be able to compete with neighbouring countries like Singapore and Taiwan in terms of technology, human capital and advanced R&D capacity. At the same time, other countries such as Thailand, Indonesia and Vietnam also are having competitive advantages in low-cost production and cheaper labour force. All of these factors pose significant challenges to Malaysia in its desire to be the target for FDI in biotechnology.

To overcome these challenges, Malaysia should fully utilize its existing financial resources through its financial institutions and venture capital entities to support the niche areas and create its own unique competitive advantages among these countries. During all the stages of PD, the government should play an active role as a facilitator to support and monitor the HB sector, based on the market demand. Government agencies such as BiotechCorp should continuously support the HB sector by creating unique platforms and opportunities for various NIS actors to collaborate and strengthen the linkages in order to effectively utilize existing resources and capabilities.

HB firms should improve their own capabilities, and strengthen the feasibility and credibility of their business plans in order to secure a sustainable financial support and investment. After the development of an innovative and viable business plan, it is important for a start-up HB company to improve its R&D capacity and competencies based on collaborations and partnership activities with other local and international companies.

Regulations and registration processes pertaining to HB products should be streamlined and simplified. The interviewees suggested that government agencies such as the National Pharmaceutical Control Bureau (NPBC) and the Performance Management and Delivery Unit (PEMANDU) should hire personnel with knowledge and practical experience within the HB field to assist firms. During the policy decision-making process, private firms should be a part of the process, as it directly affects their products, business and daily operations.

It would be helpful to set up a specialized agency with the goal being to support, assist and manage regulatory, collaborative and funding aspects of HB firms. Such a need follows on from the fact that HB is different from other subsectors, as it is directly related to the healthcare system, as well as the economy of the country. The HB sector relies on the expertise of professionals with multidisciplinary knowledge and experience in medicine, chemistry, microbiology, health economics, business and other

specialty areas. The proposed specialized agency should be well positioned to assemble a well-qualified staff in one place, which would support, advise and assist the sector to develop its competency in a global arena.

Finally, an inadequate university training in HB-related fields results in a shortage of qualified labour and is another primary obstacle to the success of the Malaysian HB sector. Wider dissemination of information about the role of the HB sector, as well as university training with more emphasis on science-related courses, appear to be promising. Raising new generations of curious, entrepreneurial and innovative graduates is a task of paramount importance to teachers of all levels of education. Universities with biotechnology subjects should introduce more applied curricula that would prepare students for biotech jobs in the future.

7.4 CONCLUSIONS

This chapter evaluated the obstacles and issues faced by HB firms in Malaysia on their journey towards developing a successful, innovative and sustainable HB sector. For countries that aspire to that end, an inadequate innovation system that is unable to support the biotechnology sector is at the root of most challenges. Without improving the Malaysian National Innovation System currently characterized by weak communications, linkages and interactions between sectors related to biotechnology, all challenges identified in this chapter will continuously exist.

Since the NBP launch, the Malaysian government has put considerable effort into the development of the biotechnology sector in the country. However, more specific services and support are needed to strengthen the intellectual property rights and regulatory system, funding mechanisms and public–private collaboration. Focusing more on the fundamental, scientific research and human capital development in S&T will help strengthen the foundation of the HB industry in Malaysia. Meanwhile, the country is well positioned to leverage its natural diversity and multiracial population in order to develop cutting-edge technologies in genomics and bioinformatics and to become a regional hub for clinical trials.

There is considerable room for improvement in human capital development, the funding allocation process and transparency, and identification of niche areas in HB based on local health needs and capabilities. A major change in the education system is warranted in order to improve the qualifications of biotechnology graduates and to change the general attitudes of the younger generation who are expected to think creatively and innovatively.

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