

Issues and Challenges in the Development of the Herbal Industry in Malaysia

Farizah Ahmad
Pusat Pengajian Ekonomi
Fakulti Ekonomi dan Pengurusan
Universiti Kebangsaan Malaysia
Emel: fariz.bnm@gmail.com

Dr Mohd Azlan Shah Zaidi
Pusat Pengajian Ekonomi
Fakulti Ekonomi dan Pengurusan
Universiti Kebangsaan Malaysia
Emel: azlan@ukm.my

Dr Noorasiah Sulaiman
Pusat Pengajian Ekonomi
Fakulti Ekonomi dan Pengurusan
Universiti Kebangsaan Malaysia
Emel: rasiahs@ukm.my

Dr Fadzilah Adibah Abdul Majid
Fakulti Kejuruteraan Kimia
Universiti Teknologi Malaysia
Emel: adibah@cheme.utm.my

ABSTRACT

The Malaysian herbal industry has been marked as a new source of growth and identified as one of the entry point project (EPP) under the agriculture new key economic areas (NKEA) in the economic transformation programme (ETP) which commenced in early 2011. The Malaysian economy is blessed with mega biodiversity, with natural flora and fauna with more than a thousand plants having been identified containing medicinal values. Being a jungle of pharmacy, our biodiversity holds huge potential for the herbal industry to grow endogenously and increase economic activities both in the upstream and downstream and across the whole value chain, thus able to contribute to higher share in the economic pie within the agriculture sector and the GDP of the country. The industry has to transform and do a quantum leap in order to fast track and play catch up with other economies already advanced in herbals. The NKEA EPP1 project is in line with the current national health policy to enhance traditional and complementary medicines towards integrative medicine for the improvement and better quality of life of the *rakyat*. Nevertheless, the herbal industry involves and is linked to many ministries and agencies in its landscape and eco-system, and coordination and implementation can be an onerous task. In addition, hitherto to the NKEA project, there is no single lead agency to oversee the growth and development of the industry. But under the NKEA EPP1 initiative, a lead agency was established under the Ministry of Agriculture and Agro-based Industries. Under the EPP1 project, the main aim is to raise the scientific content of the herbal products of the local companies which can be considered as a path-breaker for the industry and the country. They are tasked to produce standardised high value herbal products through the R&D of the preclinical and clinical studies to generate the safety, quality and effectiveness data in order to gain approval for health claims of the products. This paper draws on the status of the herbal industry and the EPP1 initiatives undertaken by the government to develop the herbal industry and highlights several major issues and challenges confronted in implementing the project.

Keywords: Malaysian herbal industry; agriculture; NKEA project; preclinical and clinical studies; entry point project (EPP)

ABSTRAK

Industri herba Malaysia telah dikenal pasti sebagai subsektor sumber pertumbuhan baru dan salah satu projek permulaan (EPP) di bawah bidang ekonomi utama baru (NKEA) pertanian dalam program transformasi ekonomi Negara (ETP) yang mula dilaksanakan pada awal tahun 2011. Ekonomi Malaysia telah dianugerahkan dengan biodiversiti yang mega, dengan flora dan fauna yang menarik serta lebih seribu tumbuhan dikenal pasti mempunyai nilai ubatan. Diiktiraf sebagai hutan farmasi, biodiversiti negara mempunyai potensi bagi membolehkan industri herba berkembang secara endogenous di peringkat hulu dan hiliran dan di sepanjang rantaian nilai, serta dapat meningkatkan aktiviti ekonomi di dalam negara, seterusnya memberi sumbangan yang lebih besar kepada sektor pertanian dan KDNK negara. Industri herba perlu mengorak langkah pantas dan membuat transformasi untuk bersaing dan mencapai tahap kemajuan seperti negara lain. NKEA EPP1 adalah seiring dengan dasar kesihatan negara yang menggalakkan perubatan tradisional dan komplementari ke arah perubatan integratif untuk penjagaan kesihatan dan kualiti kehidupan rakyat yang lebih baik. Namun begitu, pembangunan industri herba adalah di bawah kuasa pelbagai kementerian dan agensi, dan sehubungan itu usaha dan koordinasi pelaksanaan pembangunan dan pertumbuhan industri herba bukanlah satu perkara yang mudah. Sebelum bermulanya projek NKEA, industri herba tidak mempunyai sebuah agensi pelaksana yang bertanggungjawab ke atas pembangunan dan pertumbuhan industri. Di bawah projek NKEA EPP1 yang diterajui oleh Kementerian Pertanian dan Industri Asas Tani, sebuah agensi pelaksana telah ditubuhkan sebagai sebuah pusat sehenti. Objektif utama projek EPP1 adalah untuk memajukan industri herba negara di samping meningkatkan kandungan saintifik produk herba kepunyaan syarikat tempatan yang merupakan satu inisiatif baru yang belum pernah diceburi. Produk syarikat perlu dipiawaikan kandungan ekstraknya dan ditambahbaik nilai melalui proses pelaksanaan R&D kajian praklinikal dan klinikal untuk membuktikan keselamatan, kualiti dan keberkesanannya bagi memperoleh kebenaran tuntutan kesihatan yang lebih tinggi ke atas produk tersebut. Kertas kerja ini memberi gambaran mengenai status industri herba dan inisiatif EPP1 yang dilaksanakan oleh kerajaan serta menguraikan beberapa isu dan cabaran yang dihadapi dalam melaksanakan projek ini.

Kata kunci: industri herba Malaysia; pertanian; projek NKEA; kajian praklinikal dan klinikal; projek permulaan (EPP)

INTRODUCTION

The herbal industry is a fast growing industry worldwide. The growing trend in herbal industry is led by the increased demand in herbal supplements, health functional food, herbs-based energy drinks and skin cares. Globally, trends are on the rise for consumers' demand for natural products, plant based phytochemicals in crude form and plant based skin care products with the connotation of safer and natural. High incidence of adverse drug interaction in allopathic medicines is also a contributing factor to the shift in the demand for alternative medication, from traditional medication systems such as Traditional Chinese Medicine, Ayurveda, Kampo, Jamu to other folk medication systems.

Malaysia with its vast biodiversity and multi-ethnic cultures offers a unique combination for the development of the herbal industry. Malaysians in general welcome alternative medications of TCM, Ayurveda, Jamu and others. In fact many folks' medications based on local herbs have long been widely practised in Malaysian households. This folk medication system can be outsourced for potential lead of herbal medicines and herbal products of Malaysia. The strategic location and rich soil offer domestic supply and good source of raw materials.

Realising the blend of huge economic potential and local heritage in herbal knowledge, Malaysia has initiated the high value herbal products initiatives under the Economic Transformation Program (ETP) new key economic areas (NKEA) EPP1 which has been put under the governance of the Ministry of Agriculture and Agro-based Industries Malaysia. This program consolidates the researchers from local universities and the local research institutes, the herbal industrial players as well as the regulatory authorities to plan and execute the program. In this paper, we highlighted the EPP1 initiatives and the issues and challenges in ensuring the timely delivery of the program by year 2020.

GLOBAL OVERVIEW OF THE HERBAL INDUSTRY

Today, the herbal industry is booming. The Global Industry Analysts Inc. based in USA projected the herbal market to reach USD115 billion by the year 2020¹. The industry is led by Europe and followed closely by fast growing Asia-Pacific region with 9.1% CAGR. The growth is supported by the changing mind set and awareness movement initiated around the globe on alternative health care and disease prevention. The demand for alternative medicinal products increases when herbal based supplements are being regarded as safer alternatives compared with allopathic medication and the need for intake of health supplements for health maintenance and disease prevention².

The past few years saw efforts being made by companies to generate safety and efficacy data on herbal supplements based on preclinical studies and clinical trial reports. Countries like India, China, Japan, Thailand and Germany improved their traditional multi-herbal medicines through intensive scientific studies comparable to modern medication systems with strong support by their governments. These efforts increase the confidence of the public towards the herbal based medications and supplements. Most importantly, the herbal medicines with proper clinical studies qualify as therapeutic medication and with wider market segments as they can be prescribed by doctors in hospitals and clinics.

Since the beginning of human civilization, herbs have been an integral part of society, valued for both their culinary and medicinal properties. Herbal medicines have made many contributions to commercial drug preparations manufactured today including ephedrine from *Ephedra sinica* (ma-huang), digitoxin from *Digitalis purpurea* (foxglove), salicin (the source of aspirin) from *Salix alba* (willow bark), and reserpine from *Rauwolfia serpentina* (snakeroot), to name just a few.

With the advancement in pharmaceutical research and accumulated scientific data, and past discovery of potent drug from plants, the role of herbs in medication is expected to grow steadily alongside biologics and synthetics drugs. Furthermore, two modes of herbal based products, namely herbal supplements and therapeutic herbal drugs, will always be the preferred choice cost wise.

Interestingly, multi-herbs supplements are taking to lead with 7.7% CAGR as compared to single herb supplements. The western herbalism is still on the lead with 50.9% followed by Traditional Chinese Medicine (34.6%), Homeopathy (8.2%) and Ayurveda (6.3%). In Japan medication system³, Kampo formulations are available from physicians as prescriptions and as OTC formulations from regular pharmacies. Kampo formulations for prescription have fixed national drug prices and are covered by the national health insurance (NHI) which keeps patient payments fractional. Currently, 148 kampo formulae are approved as prescriptions in Japan.

The research publications on herbal products especially on the preclinical and clinical studies experienced a steady increase over the years in reputable journals. This indicates the serious steps taken by many countries and research groups to find the alternative cure for various health related problems using herbal products. The publications at such level could raise confidence level among physicians and pharmacists on the use of herbal medicines. In this regard, it is vital for any initiatives to use herbal products as new economic entity to seriously channel the effort towards improving the quality and image using scientific tools.

Naturally derived herbal and botanical extracts will experience some of the fastest growth among the major nutraceutical ingredient groups⁴. The growing trends in major nations are seen in countries such as the USA, China and India. Approximately 314 million Americans are serious about their health and 23% of them are using herbs and botanicals⁵. 1.3 billion in China are helping fuel the estimated \$11 billion dietary supplement market⁶. It is forecasted that soon, China will evolve into the largest global producer and consumer of nutraceutical ingredients by 2020, surpassing the U.S. and Western Europe. India's tradition of herbal medicine is thousands of years old and modern research often supports traditional usage. Growing incomes in India are helping support the estimated \$2 billion Indian Ayurvedic market⁷. The key industry players (in ayurvedic medicines in India, Kampo medicines in Japan, TCM in China) use modern scientific data to support sales and marketing worldwide.

¹ http://www.strategyr.com/MarketResearch/Infographics_Images/MCP-1081/1081.jpg

² Ibid

³ http://hdais.coa.gov.tw/htmlarea_file/web_articles/hdais/1354/980108_1.pdf

⁴ World Nutraceutical Ingredients : Industry Study with Forecasts for 2015 & 2020, Freedonia Group, Cleveland, OH, November 2012

⁵ 2012 survey commissioned by the Council for Responsible Nutrition (CRN), Washington, (March, 2012)

⁶ Op cit

⁷ On The Hunt for Personalised Medicine, Nutrition Business Journal, October 2012

The trend indicates the huge potential of herbal business to expand and flourish in near future. In fact, the triple A's company like Amway is opening its new health nutrition manufacturing facility and R&D worth USD42 million in California to be operated in 2015 to support future growth in herbal and nutrition products⁸. In 2014, 43% of USD10.8 billion Amway sales were from Nutrilite sales section. Recently, a multinational herbal ingredient company, Naturex has succeeded in its stated ambition to become the world's biggest independent botanicals extracts supplier by striking a deal that brings on-board the ingredients division of Spanish company, Natraceutical⁹.

The positive and progressive ventures into herbal industrial expansion by international players indicate strong potential future economic growth. Countries with diverse bio-resources like Malaysia should quickly embark into this exciting economic transformation in catching up with the global trend in herbal business.

THE HERBAL INDUSTRY IN MALAYSIA

The Ministry of the Natural Resources and Environment estimated the herbal local market to expand by 15% a year from RM7 billion in 2010 to around RM29 billion by 2020¹⁰. Based on a survey conducted by the Forest Research and Institute Malaysia (FRIM) in 2012, households in Malaysia consuming herbal products were estimated at 73%¹¹, which is lower compared with 80% estimated by the WHO for developing countries. On the supply side, growers of herbal plants were mainly in Pahang, Johor and Perak¹². At the national scale, herbs plantation acreage is projected to increase from 1,000 ha in 2010 to 4,000 ha by 2020¹³. The performance on the downstream activities showed that there was a significant increase in products being registered with NPCB under traditional use and for general health. On a cumulative basis, the products under traditional medicines/natural have shown increasing trends since the 1990s, reported to reach 8,550 in 2000 and has more than doubled by 2013 (Table 1 &2). Nevertheless, for the natural products, data on an annual basis showed that the number of products registered has been declining, recording 1,729 in 2006 to 578 in 2013.

NKEA agriculture entry point project – high value herbal products

The primary objectives of EPP1¹⁴ are i) to achieve an increase of RM2.2 billion GNI by 2020, ii) to produce safe, high quality and efficacious high-end herbal products, iii) to strengthen the supplies across the value chain, and iv) to enhance R&D in herbs and to secure the IPR from local herbs. The positive development of the industry is expected to create 1,800 job opportunities, 300 new herbs entrepreneurs and increase income for some 1,500 of the nation's farmers. In the beginning, the EPP1 project focused on the commercialisation of five types of herbs namely tongkat ali, kacip fatimah, misai kucing, hempedu bumi and dukung anak.

The EPP1 project initiative, which emphasizes on improving product quality and marketing efforts to tap the global demand in the dietary and herbal supplements as well as the botanical drugs, has contributed to the robust activities in the local herbal industry both in the upstream and downstream segments. The success factors will be contributed by various sectors to overcome issues and challenges.

The EPP1 project emphasizes on enhancing the scientific content of the herbal formulation towards high therapeutic claim. This is a new initiative in the country and can be considered as a path-breaker. Established herbal companies are invited to participate in the project and their existing herbal products are put to test on rats and cells and ultimately on human to prove its safety, quality and effectiveness. Hence, to a large extent, the downstream development of the EPP1 project falls under the purview of the Ministry of Health. Furthermore, the path of the R&D of the herbal products follows closely to that of the pharmaceuticals. Hence, understanding the rules and regulations under pharmaceuticals is imperative by the herbal industry.

Herbal products with clinical or therapeutic claims qualify for clinical prescription and can be shelved side by side with allopathic medications in hospitals and pharmacies. To qualify to such standard, health regulatory authorities in each country set certain standard for medication to be utilised/trade in respective countries. The regulatory authorities such as Food Drug Association (FDA)

⁸ <http://www.nutraingredients.com/Suppliers2/Naturex-buys-Natraceutical-to-form-botanicals-giant>

⁹ Ibid

¹⁰ Malaysia's lucrative herbs market, Bernama, 13 December 2013

¹¹ Malaysia's effort in developing the herbal industry, paper presented at the 8th INTRACOM by Herbal Development Division, MoA, Nov 2014

¹² Ibid

¹³ National Agriculture Policy 2011-2020, Ministry of Agriculture and Agro-based Industries Malaysia

¹⁴ Program booklet NKEA EPP1, 2011 Ministry of Agriculture and Agro-based Industries

in USA and European Medicine Agency (EMA) are among the referrals for many countries around the world. Therapeutic products are defined as drug that can have therapeutic claims such as to treat or to reduce clinical conditions.

In harmonisation exercise among ASEAN countries, Malaysia adopts guidelines of FDA and EMA for medicine control in Malaysia. In retrospective, in 1996, the National Pharmaceutical Control Bureau (NPCB) was given an international recognition by the World Health Organisation (WHO) as a "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals". NPCB's main objective is to ensure that therapeutic substances approved for the Malaysia market are safe, effective and of quality and also to ensure that cosmetic products approved are safe and of quality¹⁵.

In a nutshell, any therapeutic substances including herbal products for therapeutic use must have certain quality based on safety and efficacy. There are three main phases before any new drug/herbal drug qualify for any therapeutic claims – i) standardisation and product development, ii) preclinical studies and iii) the three phases of clinical studies.

The therapeutic products are undergoing stringent quality control by respective manufacturer/importer countries. All medicinal related products/devices must be registered with designated regulatory authority. In Malaysia, the National Pharmaceuticals Control Bureau (NPCB) is responsible for the regulation and control of pharmaceuticals in Malaysia. Products with therapeutic claims (mild or high claims) must provide evidences of product quality with relevant clinical data. There are four groups of products classification - 1. Medicine 2. Food-Drug Based 3. Medical Device-Drug Based 4. Cosmetic.

After the herbal products are classified by NPCB, be it under medicine, herbal supplement, traditional or food, if they wish to have therapeutic claims, then they must undergo clinical trials. The manufacturing of these products will depend on their category for clinical trials which must obtain approval for manufacturing/importing for the purpose of the clinical trials. No registration is required for products meant for clinical trials in Malaysia. The guideline to follow is CTIL/CTX guideline¹⁶.

i) Standardisation and product development

In herbal extracts, the plant is boiled, use a solvent to extract the active compounds, and then prove that their biological activity meets quality control standards. To qualify as herbal drug, however, the concentration of active compounds within an extract needs to be standardised. Each dosage must be safe and have consistent effects¹⁷.

ii) Preclinical studies

Preclinical studies are a series of experimental work that need to be fulfilled by each new drug product including herbal formulation using single or multiple standardised extracts. The main studies to be covered under preclinical section are: toxicology studies in rodents and non-rodents, in vitro ADME, in vivo PK studies, safety pharmacology and efficacy studies both in vitro and in vivo. Under ICH guidelines, toxicology studies and safety pharmacology must be carried out in GLP certified facilities¹⁸. The costing for the studies are very expensive especially under GLP set up. Most preliminary studies on drug development cover efficacy studies and cytotoxicity screening. These research activities can be carried out using reputable protocols by various research groups both from private laboratories and government supported research entities. Usually, those research findings are regarded as preliminary data to support the evaluation for future drug candidate. Should it be selected, then full flesh and intensive preclinical studies will be carried out. Such activities usually being carried out by business entity as part of commercialisation exercise. Data from preclinical studies are used to create Investigational Brochure (IB) that will be submitted to the regulatory body for approval of clinical studies and to be referred to by the clinical investigators during clinical studies.

iii) Clinical studies

There are three main phases of clinical studies; Phase I, II and III prior to product registration with regulatory authority. Phase I involves the study on the effect of new developed drug on healthy human volunteers. The safety report from Phase I then is used to proceed to Phase II clinical study. Phase II will involve patients with clinical conditions to be treated with newly developed drug. At this phase, placebo control is used and limited number of patients involved. In Phase III, wider population of patients are involved including testing on different races.

Each product to be tested follows different unique pathways depending on the type of disease to be investigated. Clinical experts are required to work closely with the sponsors (company) and

¹⁵ <http://portal.bpfk.gov.my/>

¹⁶ Malaysian Guideline for Application of CTIL and CTX, National Pharmaceutical Control Bureau, 6th Edition, Oct 2014

¹⁷ Mining for Bio-billion\$, The STAR newspaper, 21 May 2014

¹⁸ ICH guideline M3(R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals EMA/CPMP/ICH/286/1995

regulatory authorities to developed investigational protocols and the design of the clinical studies. These activities could be a challenging task for the anchor companies with no clinical trial experiences. Furthermore, it is also a learning curve for Malaysia to have local herbal business companies to go to such extent in developing new herbal products with therapeutic claims. The obstacles ahead within the next few years will be a challenging one.

Clinical studies are very expensive and involve hiring of clinical contract research organisation (clinical CRO). Most expenses in drug development are incurred during clinical research phases. Such studies are conducted by drug companies and/or supported by government. In Malaysia, such initiative in developing herbal products with therapeutic claims must undergo similar process. Malaysian Government, under NKEA programs has selected anchor companies with potential herbal products for commercialisation and financially, supports the preclinical and clinical studies. To ensure the success of the program, companies are closely monitored by the Herbal Development Department (HDD) and work progress is directly reported to the ministry.

The Malaysian national health policy

The NKEA EPP1 project is in line with the current national health policy to enhance integrative medicine for the improvement and better quality of life of the people. The Ministry of Health supports efforts to integrate the traditional and complementary medicine (T/CM) with modern medicine, and will introduce it incrementally where appropriate into the mainstream of the national health system. The World Health Organisation encourages member states to support T/CM and the continuous evaluation, formulation of policies with appropriate regulations suited to their specific national health systems.

Policy statement on the national health policy –

‘The traditional/complementary medicine (T/CM) system shall be an important component of the healthcare system. It will co-exist with modern medicine and contributes toward enhancing the health and quality of life of all Malaysians’.

‘The Government will facilitate the development of T/CM in the country and ensures the quality, safe practices and products of T/CM. It will support the identification of its health, economics and social benefits.’

- National Policy of Traditional and Complementary Medicine,
Ministry of Health Malaysia 2007

The culture

Malaysia is a multi-racial and multi-cultural nation. Along with it, there are many traditional herbal medicines available within the communities. The Chinese with their traditional Chinese medicine system, the Indians with Ayurveda system and the Malays with jamu, traditional Malay medicines and Islamic medication system. Furthermore, being a centre of trading in the Eastern Asia, many other medicinal systems have been fused into the local medication system. Today, a variety of medicinal herbal plants are available both indigenously and brought in by colonials and traders. The Malays are known with their strong influence from Indonesia, practicing traditional medicine through the traditional healers, *bomoh*, *pawang*, *dukun* and the like. Many families inherited various traditional medication formula passed down from one generation to the next.

Despite the rapid modernisation, traditional medication is still relevant in Malaysia especially in the rural areas. Interestingly, today, with the new waves in alternative medicines, the demand for herbal supplements for various diseases is on the rise in Malaysia and gaining acceptance by the middle and upper income classes of the population. This positive move will help to increase the economic value of herbal products in the country.

Plant Diversities

Malaysia is blessed with a rich jungle with plants which have medicinal values. It is regarded as a ‘jungle of pharmacy’. Despite current listing of 1,200 medicinal plants in the forests, many new plant discoveries are awaiting. Malaysia has one of the oldest rain forests in the world and one of 12 countries with mega bio-diversities. This natural heritage is already an extra mileage to Malaysia.

ISSUES AND CHALLENGES

The concerns surround on whether the Government is committed in developing high value herbal products and whether the NKEA Agriculture EPP1 project can be sustained till 2020. The Malaysian Government's firm decision to tap the high-end of the herbal industry as highlighted in the ETP which commenced in 2011 raised the above questions. Being a path-breaker initiative under the agriculture sector as a new key economic area (NKEA), the entry point project (EPP) for high value herbal products can be considered a major deliverable and challenging project. To date, no Malaysian herbs have led to high-claim drugs emerging on the market. Currently what is selling are herbal teas or supplements for general health and ailments. Despite the huge potential of local herbs, the only products available are low-claim products, without any guarantee of efficacy. This may in fact be the necessary stage in nurturing the local herbal products, and avoid strangling but instead helping to support and develop this new fragile enterprise. Being a laggard industry, the expectation is high on both the public and the private sectors to deliver the objectives of the project. The industry has to transform and do a quantum leap in order to fast track and play catch up with other economies already advanced in herbs. The challenges and hurdles are indeed real, both at the activities in the upstream and downstream including matters related to procedures and regulations under the purview of various ministries. In addition, the project deliverables are dependent on the effective implementation of R&D&C. Marketing and promotion later to be done on the high claim products by the companies will also remain a challenge to be faced. Nonetheless, in the immediate term, both the public and private parties involved in the EPP1 project will need to face and address, among others, the following issues and challenges –

Issue 1 – institutional set up and industry development

While public-private partnership has become a major enabler in implementing many government projects, the crux of the issue is on what form or model set up should the lead agency (LA) be instituted or established. An orderly and appropriate institutional set up of a LA is crucial for an industry as a central focal point and one stop centre for coordinating and overseeing industry's growth and progress as well to ensure the ensuing success of the implementation and process flow of projects, what more in ensuring an orderly growth and development of an industry. Major industries like palm oil industry have MPOB as LA, the biotechnology has Malaysian Biotechnology Corporation (MBC) as LA, the halal industry has Halal Development Corporation as LA (HDC), the ICT has Multimedia Development Corporation (MDEC) as LA. But the Government has also set up a LA for too small an industry which has not shown significant impact on the economy such as kenaf. Hitherto, although the herbal industry has been in existence for a long time since independence, growing at a small scale and running backyard industries, and has wide spread impact on the local economy both in the upstream and downstream and across the whole value chain, yet there was no LA for the industry. Efforts by the Government to establish an LA in 2000 with the setup of a Malaysian Herbal Corporation backfired when the entity could not sustain its establishment. The herbal industry which encompasses medicinal and aromatic plants (MAPs) covers a very broad scope of economic sub-sector activities such as health and dietary supplements, functional food and drinks, skin cares and spa, phyto-pharmaceuticals, and other herbs-based products and by-products. Crude estimate of the value of the industry amounted to RM7 billion in 2010¹⁹ which can be underestimated.

Various initiatives to develop the herbal industry by the Government has been reported in various documents by various ministries and agencies way back since 1990 such as in Vision 2020 (written in 1990), 3rd National Agri Policy 1998, Biodiversity Policy 1998, National Policy on Traditional & Complementary Medicine 2000, Science & Technology Policy 2003, Biotechnology Policy 2004 and many more. These various reports are reflective of the many ministries and agencies involved in respective line of responsibilities touching the industry which are under the purview of each of the entities. There is therefore no one central agency which the industry can refer to on issues facing the industry. On the other hand, it also depicts the situation of a fragmented, uncoordinated and silo approach to the development of the industry. Hence, prior to the NKEA in 2010, the industry was without a LA to oversee its growth and development. Under the NKEA Agri EPP1 initiatives, the proposed establishment of Herbal Development Office (HDO) was applauded by the herbal industry community. The project was awarded with a RM533 million R&D grant, to move the herbal industry up the value chain towards high value herbal products. The HDO is to oversee the monitoring and

¹⁹ Malaysia's lucrative herbs market, Bernama, 13 December 2013

progress of the grant. In October 2014²⁰, the Ministry announced the formation of herbal development division (HDD) to replace HDO. The issue is, can HDD be sustained? Will it face the same situation as MHC? Or will it survive just like kenaf? Coordination from all parties to form an integrated approach is crucial to unlock the value and support the growth of the herbal industry. Is HDD under MoA as an institutional set up for lead agency of the industry considered an appropriate model as a lead agency?

Issue 2 – Funding for R&D of high value herbal products

A dedicated herbal fund of RM533 million from public funding has been established beginning from 2011 which includes grants to support upstream research and funding of pre-commercialisation activities such as pre-clinical, product development and clinical studies²¹. Fourteen products are offered to undergo preclinical and clinical trials under the EPP1 project²². There have been eleven pre-clinical trials and four clinical trials undertaken as at the end of 2013²³. The cost for the herbal products to undergo preclinical and clinical are certainly expensive and surely the grant is inadequate to support more products. The issue is, would the Government continue to support such R&D activities in the long term? Being an R&D subject matter, the results are 50-50 chance of success.

Quote a USM researcher - ²⁴

'The length of time and money to get a drug to market is one investment few Malaysian companies are prepared to make. And with no private sector players willing to partner and invest in commercialising the work of research institutions, there is no product. This is the general landscape of drug development in Malaysia. To date, no Malaysian herbs have led to high-claim drugs emerging on the market. The only products you will find are herbal teas or supplements for general health and ailments'.

Would the Government stop at only these 14 products? Certainly it is realised that a lot of transformation in the form of regulations, procedures, and landscape need to be formulated and changed to accommodate the new initiatives. But if the private sector players are not seen to invest, would the project be fully dependent on Government's support and would it be sustainable? This initiative is in line with the national health policy on integrated medicine, and hence the Government should not stop short.

Issue 3 – Regulation vs development

The NKEA EPP1 high value herbal products initiative is a path-breaker in the country. It is a transformation in the true sense of the word to most ministries and agencies involved and dealing with the herbal community. There are a lot of new things to take on, from upstream to downstream and across the whole value chain. One major concern in determining the smooth implementation of the initiative is product registration and health-claim regulation. This is where the trade-off between regulation and development can be either supportive or detrimental to the industry. With respect to the EPP1 project, the guidelines for claims on high value herbal products are not available, and the ministry's main references applied are the USFDA, EMEA or TGA. Even if the health ministry were to issue such similar guidelines, this has yet to be tested its applicability to the local industry. Whether the guidelines are supportive or detrimental to EPP1 project is yet to be seen. This requires the HDD to do consistent monitoring and tracking of the implementation timeline of the R&D of the projects and to see through until final award of claim on products. The second major concern is regarding the cross-border movement of the herbs raw materials. To date, there is no clear ruling on the exports of local herbs²⁵ be it in crude form or extracts. Hence, demand by foreign parties can result in the local herbs raw materials being illegally taken out from the country. For herbs which are limited in supply domestically and perennial in nature, this is a serious major cause for concern and put into question the sustainability aspect of the production of local herbs. The third major regulation concern is on the intellectual property right (IPR) and protection of local herbs from being exploited in terms of research and product patents. A good IPR system and regulation would augur well for the herbal industry and prevent biopiracy, and quick measures would need to be implemented to ensure proper protection mechanism is in place if want to prevent the EPP1 initiative from being jeopardised.

²⁰ Bahagian Pembangunan Herba ditubuh, mula operasi 15 Oktober 2014, Utusan Malaysia newspaper, 10 Oktober 2014

²¹ PEMANDU Annual Report 2011

²² PEMANDU Annual Report 2014

²³ Going global in nutraceuticals, advertorial Malaysiakini, 18 July 2014

²⁴ Mining for bio-billion\$, The STAR newspaper, 21 May 2014

²⁵ Telephone interview with the Managing Director of one EPP1 anchor company, 01 July 2015

Issue 4 - R&D GLP Lab for preclinical studies

On April 10 2013, Malaysia was awarded the GLP lab status in accordance with the OECD standards. Malaysia has joined the OECD system for the Mutual Acceptance of Data (MAD) in the Assessment of Chemicals, ensuring that its non-clinical safety data related to the protection of human health and the environment will be accepted by all 40 countries adhering to the MAD²⁶.

Under the EPP1 project since 2011, three agencies received funding for upgrading of their labs towards compliance of GLP standards, namely IMR, SIRIM and Melaka Biotech²⁷. Approval is based on test facilities and not the whole lab of the entities. Hence, the issue is, for the herbal products, there is a list of preclinical studies that need to be undertaken, and given the limited test facilities available at the three agencies locally, the companies would still need to conduct several preclinical studies overseas, in a foreign GLP lab, especially for companies which want their products to penetrate the OECD countries. This will need to continue for some time to come, until the GLP lab system has significantly improved in their landscape in the country. If funding from the Government is still expected for the GLP eco-system to be developed, then the challenge remains for the herbal companies to access local expertise and facilities. Hence, the award status is like a false alarm.

Issue 5 – Financing constraint by the anchor companies

In October 2011, the ministry obtained approval from the Ministry of Finance for a new disbursement mechanism specifically designed to implement the EPPs under NKEA Agriculture²⁸. The reimbursable financing mechanism requires the companies participating in the project to make a claim on their expenses incurred, as the ministry will not pay any sum in advance. Given that participation in the NKEA project is like a bonus project to the companies, which is above and beyond their business-as-usual running of the companies, they therefore require extra cash flow or advances to pay upfront the R&D activities required as stipulated in each of the company's project schedule. An example of the funding requirement of a company's financing commitment for the R&D activities is as illustrated in Table 3.

From the above table, a company needs to fund three R&D activities within 4 months as the payment is due, hence requiring a large sum of cash flow. What are the financing options available to the company?

- i) Internal funding;
- ii) Bank loan;
- iii) Loan shark;
- iv) Crowdfunding;
- v) Private equity;
- vi) Venture capital;
- vii) Angel capital.

Since most of the herbal anchor companies participating in the NKEA project are SMEs, they have little option to choose from the above list. Difficult for herbal companies to get private funding especially for R&D²⁹, and not many will get approval on bank loan as bridging finance to support the R&D activities, as R&D is one area where the banks will not want to invest in and the bank has no appetite to fund these kind of risky ventures. If companies face financing constraint to manage their cash flow to finance the R&D activities from the standardization up to preclinical and clinical studies, then there will be limited participation by companies in the EPP1 project as the companies are not incentivised.

In addition, a few companies will need to invest in new or upgrade their own manufacturing and production facilities since the GMP facilities for high claim will require different specifications in the production line and quality control. Therefore, additional private investments are required to be expended by the companies. This is the expectation on companies which are approved to be under the EPP1 project. Hence, a few herbal companies, which have products that are deemed to be attractive and have good potential to move up the value chain, will not want to participate and will shy away from participating in the EPP1 project due to financial constraints³⁰. Towards this end, participation support from herbal companies will dwindle and lack of support from financial institutions will not incentivise the industry players to venture into this field of business.

²⁶ <http://www.oecd.org/env/ehs/malaysia-joins-oecd-agreement-on-mutual-acceptance-of-chemical-safety-data.htm>

²⁷ PEMANDU Annual Report 2011

²⁸ Ibid

²⁹ Telephone interview with the Managing Director of one EPP1 anchor company, 01 July 2015

³⁰ Ibid

Issue 6 – The herbal industry's statistical constraint - Unclassified in the agriculture sector composition

The herbal industry lacks good statistical data to support healthy analysis and good policy decision making. Being an immature industry, looking in the economic database of the country, the data for the herbal industry historically is hidden in 'other agriculture' under the agriculture sub-sectors classification (Table 4). Thus, a major exercise will need to be undertaken to bring out the performance of the herbal industry and develop a proper database time series for selected major indicators. The impact of the NKEA EPP1 project will require statistical reporting to be made in order to measure the progress and achievements. Without adequate data to reflect the progress and underlying growth and development of the industry especially post-NKEA, it would be difficult to assess the spill-over benefits and significant impact of the project on the economy and hence deter improvement in policy decision making by the government and the industry alike.

CONCLUSION

With its ancient rain forests and biodiversity, Malaysia should capitalise on the opportunity to tap into the growing global interest in the healing properties of plants³¹. Hence, the Malaysian Government, under the NKEA initiatives of the Economic Transformation Program, is seriously taking efforts to develop and strengthen the fundamentals and the eco-system of the local herbal industry as an important economic source of growth currently and by the year 2020 and beyond. The efforts in materialising the program was planned and was executed since 2011 where herbal products of anchor companies are progressively undergoing preclinical and clinical paths in order to achieve therapeutic claims. The initial set up of HDO as a lead agency was institutionalised as a division within the ministry to take on a broader scope of industry development for the herbal sub-sector, in addition to overseeing and ensuring the successful implementation of the NKEA EPP1 initiative for delivery of high value herbal products by the year 2020. To achieve the target, it is important for the public authority to aggressively and closely monitor and evaluate the progress of the project and to facilitate the project management of the anchor companies as well as facilitate the improvement in the ecosystem and landscape of the industry. The current pertinent issues need to be immediately addressed and tackled and challenges need to be pre-empted and pro-active measures will need to be implemented to successfully support EPP1 in particular, as well as ensure orderly and robust growth and development of the herbal industry in general. To support the development and growth momentum of an endogenously driven industry of local treasures, it is indeed crucial for the relevant ministries and agencies to work together and be well coordinated and supportive as well as accord high priority to facilitate the needs and pre-requisites of the herbal industry players, given the cross-agencies web-like linking the herbal industry's requirements and jurisdiction. It is hoped that we are able to thrive and catch up with the other economies already advance in the development of their herbal industries and stay competitive to generate revenue and ultimately able to raise the income of the herbal community and the country.

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TABLE 1: Number of Products Registered

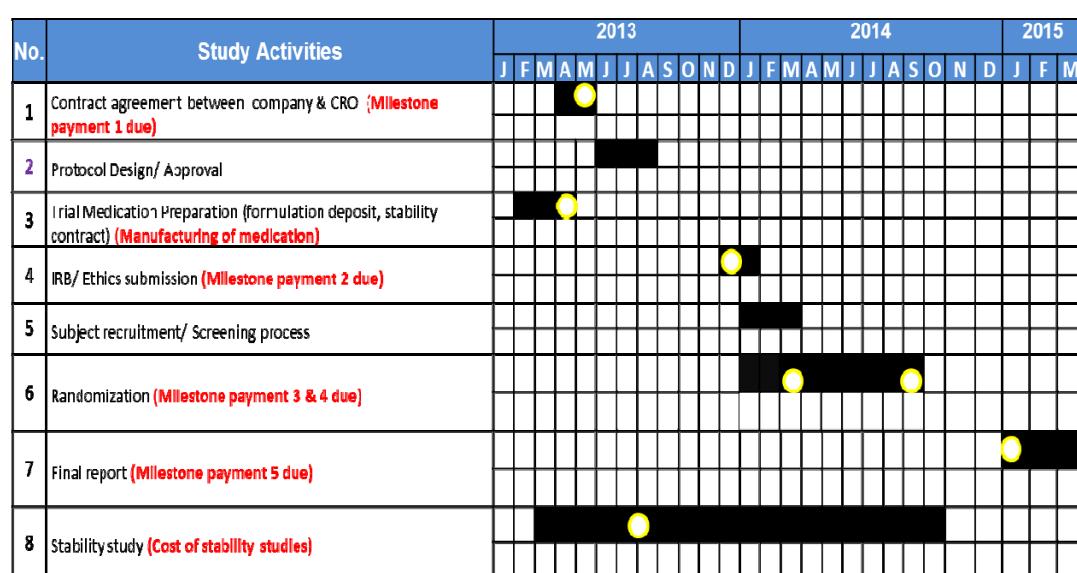
	2006	2007	2008	2009	2010	2013
Prescription	533	449	409	412	441	241
Non-prescription	696	413	272	313	235	54
Natural/ traditional	1,729	1,342	953	1,040	582	578
Health Supplements	0	0	0	0	0	85
Veterinary	0	0	0	0	54	63
Total	2,958	2,204	1,634	1,765	1,312	1,021

TABLE 2: Number of Products Registered (cumulative)

	2006	2007	2008	2009	2010	2013
Prescription	11,356	11,805	12,214	12,626	13,067	13,308
Non-prescription	8,685	9,098	9,370	9,683	9,918	9,972
Natural/ traditional	16,858	18,200	19,153	20,193	20,775	21,353
Health Supplements	0	0	0	0	0	85
Veterinary	0	0	0	0	54	117
Total	36,899	39,103	40,737	42,502	43,814	44,835

source: National Pharmaceutical Control Bureau (NPCB)

TABLE 3: Example of payment schedule for preclinical/clinical activities



Source: ICH Guidelines EMA

TABLE 4: Composition of Agriculture Sector

	Growth (%)		Share of Agriculture (%)	
	<u>2012</u>	<u>2013</u>	<u>2012</u>	<u>2013</u>
Sub-sector				
Oil Palm	-0.3	2.6	36.5	36.7
Rubber	-7.9	-10.1	8.2	7.2
Livestock	8.1	9.4	11.7	12.5
Other agriculture	6.7	8.2	18.2	19.3
Forestry & Logging	-4.5	-7.8	11.0	9.9
Fisheries & Aquaculture	4.3	1.6	14.4	14.4
Agriculture	1.3	2.1	100.0	100.0

source: Department of Statistics