



**UNIVERSITI PUTRA MALAYSIA**

***SUSTAINABLE ENTREPRENEURSHIP PRACTICES AND  
PERFORMANCE  
AMONG MALAYSIAN HERBAL-BASED SMEs***

**ABDULLAHI MUHAMMAD AUWAL**

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**SUSTAINABLE ENTREPRENEURSHIP PRACTICES AND PERFORMANCE  
AMONG MALAYSIAN HERBAL-BASED SMEs**

**By**

**ABDULLAHI MUHAMMAD AUWAL**

**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in  
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**April 2018**

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## DEDICATION

I specially dedicate my dissertation work to my parents, Alhaji Auwalu Abdu Hamza and Hajiya Fatima Muhammad (Hajja Gana), who relentlessly supported me and prayed for me in love throughout the entire doctoral program. My wife, Farida Faruk Jega, who has been a best friend and supporter throughout my life, this dissertation wouldn't be what it is without her perseverance and prayer. Thank you for your endless love! And my lovely kids, Fatima, Umar Faruk and Zainab, you are my champions. I love you so much.

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Finally, I give thanks to all my friends and many others for being with me throughout the Ph.D. program.

Abstract of the thesis presented to the Senate of the Universiti Putra Malaysia in fulfillment of the requirement for the degree of Doctor of Philosophy

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**April 2018**

**Chairman: Professor Zainal Abidin Mohamed, PhD**  
**Faculty: Agriculture**

Entrepreneurial activities have contributed greatly to environmental pollution. Such pollution has caused a disastrous effect on us and has also been transferred to our future generations. In the light of this, sustainable entrepreneurship practice (SEP) has been promoted as a resolution of environmental problems capable of addressing environmental pollution, climate change issues, public health, and safety concerns, diverse consumption patterns, and has become critical for competing in international markets. Recently, the Malaysian government has made a strong commitment to strengthening sustainability stressing on the importance of implementing SEP to address environmentally friendly issues. Despite this, the level of herbal-based SMEs involvement is still low because of low awareness and knowledge of its importance among the herbal-based SMEs and consumers in Malaysia. Therefore, there is need to determine the SEP implementation level of the Malaysian herbal-based SMEs and how it benefits them in controlling activities that may adversely affect the environment at various stages of manufacturing, distribution and retailing sub-sectors. Literature shows that sustainability drivers; external pressure (EP) and top leadership culture (TLC) provide the impetus for small and medium-sized enterprises (SMEs) to achieve competitive advantage and thus compete successfully in the marketplace. This study intends to investigate the standpoints of herbal-based small and medium-sized enterprises (SMEs) with emphasis on level of SEP implementation towards achieving sustainability performance within business dynamics in Malaysia. The study explores the effectiveness of EP, TLC and strategic sustainability orientation (SSO) on the SEP implementation towards performance among the respondents.

300 herbal-based SMEs were surveyed using structured questionnaire. The respondents were asked questions on SEP awareness, current SEP implementation level, sustainability performance, and lastly their firm profile. Items were measured using 5-point Likert Scale statements, and data collected were analyzed using exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and Structural Equation Model

(SEM). The empirical findings showed that SEP implementation has an impact on sustainability performance (economic, environmental and social) among the Malaysian herbal-based SMEs. Besides, the findings again provide a better understanding on how the herbal-based SMEs formulated SSO as a business strategy, and how the SSO mediated the relationship between EP, TLC, and SEP implementation to effectively create favorable sustainability performance, accounting for 62 percent variance. The result also indicated that higher level of SEP implementation was positively related to sustainability performance (economic, environmental and social) among the respondents in the industry, accounting for 47 percent variance. Moreover, the moderation effect results revealed that both general awareness on SEP and Good Management Practice (GMP) certification moderated most of the exogenous construct paths.

In sum, the findings contribute to Triple-Bottom-Line (TBL) literature based on the incorporation of Institutional Theory (IT), Strategic Choice Theory (SCT), Strategic Orientation Theory (SOT), and Resource-Based View Theory (RBV) in entrepreneurship sustainability framework, as such framework is lacking within Malaysian herbal industry. In terms of practical implications, the findings will serve as a relevant benchmark for sustainability, that is, how SMEs generate a sustainable competitive advantage in Malaysia. In conclusion, this research suggests that the government (through agencies like DOA, FRIM, MARDI, and NPRA) should come up with dedicated policies and programs on the importance of forming SSO towards implementing SEP through enlightenment campaigns, showcasing its influence on business strategy formulation and performance enhancement.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

**AMALAN DAN PRESTASI KEUSAHAWANAN MAMPAN DALAM  
KALANGAN PERUSAHAAN KECIL DAN SEDERHANA BERASASKAN  
HERBA DI MALAYSIA**

Oleh

**ABDULLAHI MUHAMMAD AUWAL**

**April 2018**

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**Fakulti: Pertanian**

Aktiviti keusahawanan telah banyak menyumbang kepada kemusnahan alam sekitar. Hal ini bukan sahaja menyebabkan kesan buruk kepada kita tetapi juga kepada generasi akan datang. Justeru itu, amalan keusahawanan mampan (SEP) telah diperkenalkan sebagai resolusi terhadap masalah alam sekitar di mana ianya mampu menangani isu pencemaran alam sekitar, perubahan iklim, kesihatan awam, keselamatan dan kepelbagaian corak penggunaan yang menjadi kritikal untuk bersaing di pasaran antarabangsa. Dewasa ini, kerajaan Malaysia memberi komitmen yang padu untuk mengukuhkan kemampanan alam sekitar dengan menekankan kepentingan mengiplikasikan amalan keusahawanan mampan (SEP) terutama dalam isu-isu mesra alam. Walaupun demikian, tahap penglibatan industri kecil dan sederhana (IKS) berasaskan herba masih rendah kerana tahap kesedaran dan pengetahuan tentang amalan keusahawanan mampan dalam kalangan pengusaha industri kecil dan sederhana (IKS) dan pengguna berasaskan herba di Malaysia. Oleh itu, terdapat keperluan untuk menentukan persepsi industri kecil dan sederhana (IKS) berasaskan herba di Malaysia ke atas amalan keusahawanan mampan dan bagaimana ia memberi manfaat kepada mereka dalam mengawal aktiviti yang boleh menjejaskan alam sekitar di pelbagai peringkat subsektor seperti pembuatan, pengedaran dan peruncitan. Kajian lepas menunjukkan bahawa pemacu kemampanan; *tekanan luaran (TL)* dan *budaya penurupin atasan (BPA)* mampu mendorong industri kecil dan sederhana (IKS) untuk mencapai keunggulan kompetitif dan bersaing dengan jayanya di pasaran. Kajian ini bertujuan untuk mengkaji sudut pandang indutri kecil dan sederhana (IKS) berasaskan herba dalam aspek yang berbeza dengan memberi penekanan kepada kesan pemacu dan strategi kemampanan ke atas aktiviti keusahawanan mereka bagi meningkatkan pencapaian prestasi yang lebih baik (ekonomi, alam sekitar dan sosial) dalam perniagaan yang dinamik. Kajian ini juga meneroka keberkesanan *external pressure (EP)*, *top leadership culture (TLC)* dan orientasi kemampanan strategik (SSO) terhadap amalan keusahawanan industri kecil dan sederhana berasaskan herba di Malaysia.

Kajian yang menggunakan soalan soal selidik berstruktur telah dijalankan dalam kalangan 300 pengusaha industri kecil dan sederhana (IKS). Responden ditanya mengenai amalan keusahawanan mampan (SEP), amalan keusahawanan semasa, prestasi, dan akhirnya profil firma mereka. Item diukur menggunakan pernyataan Skala Likert 5-titik, dan data yang dikumpul dianalisis menggunakan analisis faktor penerokaan (EFA) dan pengesahan (CFA) serta Model Persamaan Struktur (SEM). Penemuan empirikal menunjukkan bahawa penerimaan amalan keusahawanan mampan (SEP) mempunyai kesan ke atas prestasi (ekonomi, alam sekitar dan sosial) dalam kalangan industri kecil dan sederhana (IKS) berasaskan herba di Malaysia. Di samping itu, penemuan ini juga dapat memberikan pemahaman yang lebih baik tentang bagaimana industri kecil dan sederhana berasaskan herba merumuskan orientasi kemampanan strategik (SSO) sebagai strategi perniagaan, dan bagaimana orientasi kemampanan strategik (SSO) sebagai perantara antara hubungan antara pemacu kemampanan dan amalan keusahawanan untuk menghasilkan pencapaian yang berkesan terhadap ekonomi, alam sekitar, dan sosial, yang disumbangkan oleh 62 peratus variasi dalam amalan keusahawanan mampan (SEP). Hasil kajian juga menunjukkan bahawa tahap tertinggi amalan keusahawanan mampan adalah positif dan berkaitan dengan prestasi ekonomi, persekitaran dan sosial di kalangan responden dalam industri, yang menyumbang variasi sebanyak 47 peratus. Selain itu, kesan kesederhanaan menunjukkan bahawa kedua-dua kesedaran am terhadap amalan keusahawanan yang mampan (SEP) dan amalan pengurusan baik (GMP) mensyaratkan sebahagian besar laluan pembinaan eksogen.

Kesimpulannya, hasil penemuan menyumbang kepada teori *Triple-Bottom-Line* (TBL) berdasarkan pemahaman *Incorporation of Institutional Theory* (IT), *Strategic Choice Theory* (SCT), *Strategic Orientation Theory* (SOT), dan *Resource-Based View Theory* (RBV) dalam rangka kerja bidang keusahawanan mampan, kerana rangka kerja itu kurang dalam industri herba di Malaysia. Dari segi implikasi praktikal, penemuan ini akan berfungsi sebagai penanda aras yang relevan untuk kemampanan, iaitu, bagaimana industri kecil dan sederhana menjana kelebihan daya saing yang mampan di Malaysia. Kesimpulannya, kajian ini mencadangkan agar kerajaan (melalui agensi seperti DOA, FRIM, MARDI and NPRA) mewujudkan polisi dan program mengenai kepentingan orientasi kemampanan strategik (SSO) dalam mengaplikasikan amalan keusahawanan mampan (SEP) melalui kempen kesedaran, memperkenalkan fomulasi strategi perniagaan dan peningkatan prestasi.



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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfillment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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## LIST OF ABBREVIATIONS

AGFI	Adjusted Goodness of Fit Index
AMOS	Analysis of Moment Structures
APEC	Asia-Pacific Economic Cooperation
AVE	Average Variance Extracted
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CMIN/DF	Chi-Square/Degree of Freedom Ratio
DoS	Department of Statistics Malaysia
EcoP	Economic Performance
EFA	Exploratory Factor Analysis
EP	External Pressure
EPPs	Entry Point Projects
ETP	Economic Transformation Program
EnvP	Environmental Performance
FRIM	Forest Research Institute Malaysia
GDP	Gross Domestic Product
GFI	Goodness of Fit Index
GMP	Good Manufacturing Practice
GNI	Gross National Income
GOF	Goodness-Of-Fit
GTFS	the Green Practices Financing Scheme
HACCP	Hazard Analysis and Critical Point
ICT	Information and Communication Technology
KeTTHA	Ministry of Energy, Green Technology, and Water Malaysia
MATRADE	Malaysia External Trade Development Corporation
NAFP	National Agro-Food Policy (2011-2020)
NAP3	National Agricultural Policy (1998-2010)
NFI	Normed Fit Index
NKEA	National Key Economic Area
NPRA	National Pharmaceutical Regulatory Agency
NSDC	National SME Development Council
OECD	Organization for Economic Cooperation and Development
PURBATAMA	Traditional Malay Medicine Manufacturers Association
R & D	Research and Development
RBV	Resource-Based View
RMSEA	Root Mean Square Error of Approximation
SCT	Strategic Choice Theory
SEM	Structural Equation Model
SEP	Sustainable Entrepreneurship Practice
SIRIM	Standards and Industrial Research Institute of Malaysia
SMEs	Small and medium enterprises
SocP	Social Performance
SSO	Strategic Sustainability Orientation
TBL	Triple-Bottom-Line
TLC	Top Leadership Culture
TLI	Tucker-Lewis Index

## CHAPTER 1

### INTRODUCTION

This chapter will discuss general agriculture in Malaysia, small and medium-sized enterprises, Malaysian herbal industry, and the herbal-based SMEs in Malaysia. The chapter also highlights the problem statement, objectives of the study, scope and limitation of the study, the significance of the study as well as the organization of the study. Besides, the chapter aims to provide an insight into what determines the adoption of sustainable entrepreneurship practices that can be used to achieve higher business performance among the herbal-based SMEs in Malaysia.

#### 1.1 Background of the study

The Malaysian economy has undergone substantial structural changes from a real agriculture-based economy to manufacturing industries, and to the services sectors. These economic transformations started at the outset of the nation's independence, through the 1980s and 1990s, then in recent decades (Othman & Jafari, 2014). The share of the manufacturing sector to the nation's GDP slightly declined from 23.5 percent in 2011 to 22.9 percent in 2013, then maintains a 23.0 percent share from 2014 to 2016 despite various types of support from the government (DoS, 2016). Table 1.1 highlight the contribution of different sectors to the GDP from 2011 to 2016.

**Table 1.1: Percentage Share to GDP by Kind of Economic Activity, 2011-2016**

Kind of economic activity	2011	2012	2013	2014	2015	2016
Agriculture	10.2	9.8	9.5	9.2	8.9	8.1
Mining & quarrying	9.9	9.5	9.2	9.0	9.0	8.8
Manufacturing	23.5	23.2	22.9	23.0	23.0	23.0
Construction	3.4	3.8	4.0	4.3	4.4	4.5
Services	52.0	52.5	53.2	53.4	53.5	54.3
Import duties	1.0	1.1	1.1	1.1	1.3	1.4
<b>Total</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

(Source: DoS, 2016)

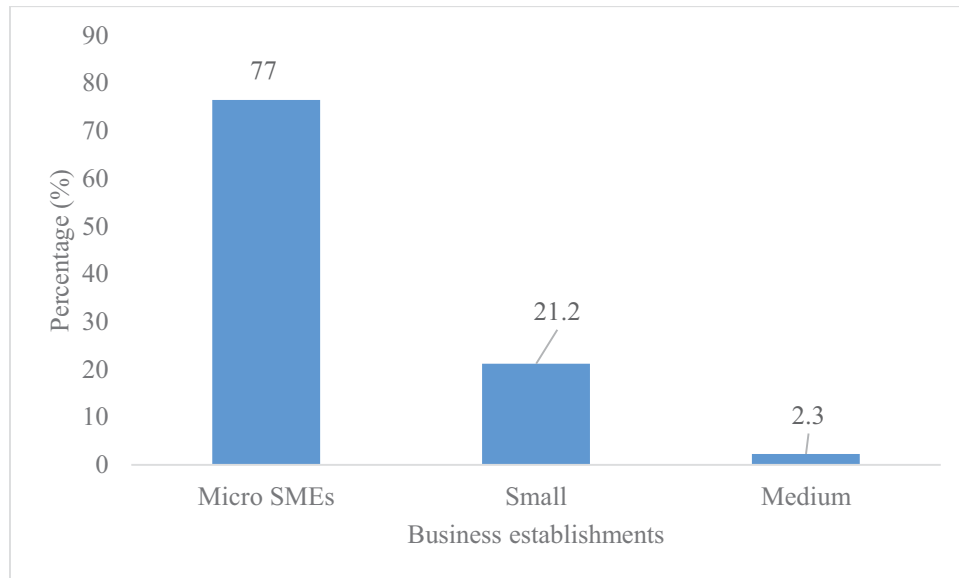
While the share of the services sectors increases during the same period in 2016, where it recorded 54.3 percent (Department of Statistics Malaysia, 2016). Other developing countries such as Taiwan and Korea exhibited a similar pattern of successful transformation from an agrarian to industrial economy (Arshad *et al.*, 2007). They reported that such countries' economy became highly developed today because their agriculture and non-agriculture sectors progressed simultaneously together. They also reiterated that, even though the development path of Malaysia appears to emulate those economies, it is quite unlike what it seems because the Malaysian agriculture sector has not progressed in tandem with the non-agriculture sectors in many ways.

Nonetheless, such statistics may depict the actual worth of the Malaysian sectors. Contemporary agriculture and non-agriculture comprise of the broader perspectives regarding their influence on the total economy, via inter-sectoral connections and multi-functional roles, including a role in sustaining the liveliness of rural areas and resources. Such roles are missing in the standard national income accounting system. Although the achievement of some socio-economic goals, such as poverty reduction has shown some progress, income inequality between small and medium-sized firms and large commercial firms persists and even widens with time. Technological progress has been very sluggish, and food import bills are on the rise, severe labor shortage and resource constraints are hindering further growth. These among other roles have turned multi-functional, as the matrix of development includes the need to ensure sustainability, to help reduce global warming and to preserve the rural community.

## **1.2 Small and Medium Enterprises (SMEs)**

Small and medium-sized enterprises contribute significantly to economic growth and employment in virtually all countries around the world (OECD, 1987). The SME impact seem relatively small, but they impart substantial impact collectively. Schaper, 2002 reported that SMEs typically represent about 95 percent of all private sector businesses in modern nations, forming a significant portion of all economic activity. Small and medium enterprises (SMEs) are an essential when developing sustainable entrepreneurs in the society because of their contribution to economic development of a country. For instance, SME accounted for 90 percent of all businesses and had employed 60 percent of the workforce in the APEC region (Koe & Majid, 2013).

Small and medium enterprises (SMEs) constitute the most common form of enterprises in Malaysia. They are known as significant contributors to the nation's economy and sustainable development through employment and social growth (Singh & Mahmood, 2014). SMEs operate in all sectors of the economy in Malaysia; agriculture, construction, import duties, manufacturing, and the services sector. Currently, SMEs constituted 98.5 percent (907,065) of the entire business establishments within the country (DoS, 2016); out of which 76.5 percent are micro, 21.2 percent comprises of small while 2.3 percent forms the medium enterprises (SME Corp., 2016). SMEs contributed 36.6 percent to the economy and recorded a strong GDP growth of 5.2 percent (DoS, 2016). Figures 1.1 and Table 1.2 presents the new SME descriptions in the context of Malaysia.



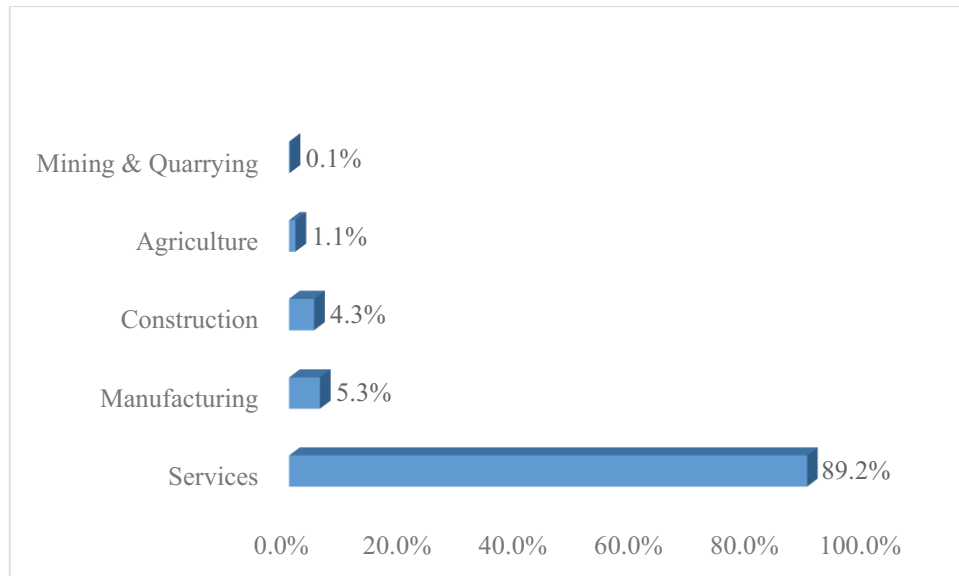
**Figure 1.1: Composition of SMEs in Malaysia**  
(Source: SME Corp., 2016)

**Table 1.2: Contribution of SMEs to the Economy from 2010 to 2016**

	2010	2011	2012	2013	2014	2015	2016
GDP (%)	32.2	32.8	33	33.5	35.9	36.3	36.6
Employment (%)	57.1	57.3	57.2	57.5	65	65.5	65.3
Export (%)	16.4	16.9	17.5	17.8	17.8	17.6	18.6

(Source: SME Corp., 2016)

SMEs cut across all sectors of the economy in Malaysia with the majority (89.2 percent) in the services sector; as can be seen in Figure 1.2, manufacturing sector constituted 5.3 percent of the total SMEs, followed by construction sector with 4.3 percent. Unfortunately, agriculture sector forms just 1.1 percent of the total SMEs, while lastly, mining and quarrying sector forms 0.1 percent of the total SMEs in the country (SME Corp., 2016). The dominance of the services sector has clearly illustrated the transformation of the Malaysian economy from agrarian to industrial one as reported by Arshad *et al.*, (2007).



**Figure 1.2: Percentage of SMEs across All Sectors of the Economy**  
(Source: SME Corp., 2016)

### 1.2.1 Definition of SMEs

The Malaysian government has endorsed new definition of SMEs at the 14th National SME Development Council (NSDC) meeting in July 2013 (refer to Table 1.3). This action is due to the economic developments like such as change in business trends, price increases, and structural changes, and. The new definition explain that manufacturing SMEs have a sales turnover not exceeding RM50 million and employs not more than 200 full-time employees. While SMEs in the services and other sectors have a sales turnover not exceeding RM20 million and employs not more than 75 full time employees.

The new definition of SMEs became effective on 1st January 2014. This action implies that eligibility for SMEs development programmes and SMEs statistics compiled from 2014 onwards followed this definition. All statistics compiled before 2014 remained status quo (followed the previous definition) and will not be affected by the new definition.



**Table 1.3: New Definition of SMEs**

Size	Micro		Small		Medium	
	Sales Turnover	Employees	Sales Turnover	Employees	Sales Turnover	Employees
Manufacturing	< RM300,000	< 5 employees	RM 300,000 to < 15 Million	5 to < 75 employees	RM 15 Million to ≤ 50 Million	75 to ≤ 200 employees
Services & Others			RM 300,000 to < 3 Million	5 to < 30 employees	RM 3 Million to ≤ 20 Million	30 to ≤ 75 employees

(Source: SME Corp, 2014)

Even though SMEs are unquestionably a significant part of the business community and are a vital component of the Malaysian economy, their overall contribution to the economy was only 36.6 percent of the GDP (DoS, 2016). This contribution is relatively low when compared with developed and other developing nations. Such as Japan (53 percent), Germany (53 percent), United Kingdom (51 percent), Korea (49 percent), Singapore (49 percent), Vietnam (45), Thailand (38 percent), and Indonesia (48 percent). Under the SME Master Plan 2012-2020, SMEs have been targeted to contribute 41 percent of GDP (NKEA, 2012).

In line with achieving the National Agro-Food Policy (NAFP 2011-2020) objective, the Malaysian government has directed its focus on improving the managerial aspects of the SMEs particularly for environmentally friendly issues, to ensure that they are committed to implementing SEP. Therefore, the top management of SMEs should give more emphasis to building proactive and committed top leadership culture capable of inculcating sustainability entrepreneurial behavior. In their study, Senik *et al.*, (2010) identified firms' unique resources and capabilities as essential drivers of sustainability among SMEs in Malaysia apart from networking. Also, Singh and Mahmood (2014) posited that owner/managers with more information would have an edge in making decisions on business strategies to achieve competitive advantage and enhance performance.

Literature has shown that a firm's internal resources determine its performance, and by paying more attention to internal resources the firm will be able to improve its performance and support strategies (Peng 2001; Barney, 1991; Penrose, 1959; Peteraf, 1993). Similarly, SMEs can use this strategy in creatively finding the opportunities outside their domestic market and taking advantage to exploit it and thus develop competitive advantage (Zahra & George, 2002). This strategy involves making choices between competing expansions and selecting strategies that depend on the market situation, firm's resources and managerial goals and vision (Reid, 1983). Given the internationalization of business today, exporting has become an essential and necessary strategic option, and it is essential for the SMEs to start considering overseas market opportunities for the capture of and sustainability of competitive advantage (Tiang,



2015). The current business environment competes based on firm's ability and available resources including its skills, expertise and firms' ability to leverage its competitive capabilities and strategically mobilize their valuable assets. A firm's resources and capabilities in organization processes that take place will improve the firm performance particularly in formulating strategy and in determining the profit. Based on the resources-based theory, the collection of a firm's internal resources and capabilities may generate competitive advantage that leads to superior performance (Singh & Mahmood, 2014).

### 1.3 SMEs and Sustainability

Sustainable Development was defined as "a development that meets the needs of the present generation without compromising the ability of future generations to meet their own needs" (World Commission for Environment and Development [WCED], 1987). Due to concern for environmental preservation and economic stability, the nations united for sustainable development across their borders. Munasinghe (1994), described sustainable development as a means of expanding 'the spectrum of alternatives allowing individuals and communities' to achieve their goals and capacity for development and simultaneously preserving the regeneration ability in economic, social, and ecological approaches. Over the years, scholars argued that due to the intense focus on sustainable development by governments led to the development of sustainability regulations and market regulations on business operations (Hall *et al.*, 2010; Ciegis *et al.*, 2009).

Sustainable Entrepreneurship Practice (SEP) refers to a firm's intra-organizational and inter-organizational practices for managing upstream suppliers, internal operations, and downstream customers to simultaneously achieve firm sustainability performance (economic, environmental, and social). SEP is an off- shoot of sustainable development capable of producing sustainable products, services, and processes (DeSimone & Popoff, 2000; Lawal *et al.*, 2016). Although implementing SEP is intentional and a planned behavior (Krueger *et al.*, 2000), firms would only decide to engage in it after careful thoughts, triggered by specific stimuli (Koe & Abdul Majid, 2013). Therefore, herbal-based SMEs who implement SEPs are sustainability minded entrepreneurs who ensure a balance between economic prosperity, environmental quality, and social justice in their business conduct (Gagnon, 2012; Majid & Koe, 2012).

Over the decades, managing firms regarding quality maintenance, long- term, strategic relationships by selecting prospective suppliers, reducing the supplier base, and developing supplier programs have been long emphasized (Chen & Paulraj, 2004; Li *et al.*, 2005). Mentzer *et al.*, 2000 argued that firms culture, trust and sharing of information should be developed to preserve and strengthen their relationships with major stakeholders. Scholars (Modi & Mabert, 2007; Narasimhan *et al.*, 2008; Yang *et al.*, 2010) believe that SEP related to the selection of suppliers, supplier assessment and development have become crucial towards firm performance improvement initiatives. A new framework to illustrate the integration of sustainable development into business activities introduced by Elkington (1997), known as the triple- bottom- line. According to Elkington, triple- bottom- line emphasizes on economic prosperity, environmental

quality, and social justice. The concept has also been widely accepted in explaining sustainable entrepreneurship development (Dixon & Clifford, 2007; Hall *et al.*, 2010; Schlange, 2006).

#### 1.4 Herbal Industry in Malaysia

Herbal-based products constitute products made from natural plants rich in medicinal and pharmaceutical potentials. According to the Global Industry Analysts Inc., the global market value of the herbal industry is projected to reach USD115 billion by 2020 (GIA Inc., 2014). Countries that recorded the highest retail sales of herbal medicinal products were Europe, Asia, and North America. However, in developing countries like China and Sri Lanka the use of herbal medicine as an alternative treatment have been endorsed officially in their healthcare systems. Similarly, in developed countries like United States, Canada, European Union, and Japan, report show that 50 percent of their population exhibit high tendency to use herbal medicine (NAFP, 2011). This scenario has led to increased sales of herbal products in the countries; United States USD4.6 million, Eastern Europe, USD1.2 million and the Asia Pacific, USD21.1 million (Euromonitor International, 2016). The worldwide increased demand for herbal products is mainly due to the awareness of healthy lifestyle (Ab Karim, Nasouddin, Othman, Mohd Adzahan, & Hussin, 2011). Similarly, Rezai *et al.*, (2016) reported that herbal industry growth is because of the continued acceptance of herbal products, functional foods, health supplements, natural personal care products and organic food in both domestic and international markets.

Malaysia is one of the 17 megadiverse countries in the world and is ranked 4th in Asia as the most biodiverse country. Blessed with rainforest occupied with various flora and fauna, Malaysia has over 2000 plant species with healing qualities. Its biodiversity has very high potential value for the herbal industry (EPU, 2013). In line with Malaysia's aspiration to become a developed nation, the herbal industry has been identified as one of the economic drivers that could potentially make a significant contribution to the economic growth of the country (Rohana *et al.*, 2017). The Malaysian herbal industry market estimate was RM10 billion in 2008 with a projected annual growth of 15 percent over the next ten years. Considering Malaysia's rich heritage, factors such as a shift in healthcare, the global increase in nutraceuticals, and preference for natural products have been identified as crucial factors for Malaysia to become a significant player in the global herbal market (Sumin *et al.*, 2016). Total estimated consumption of herbal products by households in Malaysia was estimated at 73 percent (FRIM, 2012), the figure is lower than the 80 percent WHO estimated for developing countries (Ahmad *et al.*, 2015).

Malaysia adopts Food Drug Association (FDA) of the US and European Medicine Agency (EMA) guidelines for medicine control (herbal products inclusive). In 1996, the National Pharmaceutical Regulatory Agency (NPRA) was recognized internationally by World Health Organization (WHO) as a Collaborating Centre for Regulatory Control of Pharmaceuticals, with a sole aim of ensuring the production of safe, effective and qualitative products for both Malaysian and international markets (NPRA, 2015). The performance of the herbal industry mainly focuses on low-value products. Statistics

show that 81 percent of herbal products belong to the lower value segment, such as personal care products (e.g., facial creams and soaps), nutraceuticals (also known as functional foods). While only 19 percent are in the higher value segments, and most of these products are involve exotic herbs (NKEA, 2011). This scenario has demonstrated insufficient R&D, clinical studies, and marketing done to tap into the premium markets that offer higher margins by the herbal-based SMEs.

The development of high-value agriculture particularly in herbal industry is expected to create jobs, expand business opportunities and increase global and domestic investments. This involvement can also increase income of farmers and herbal-based SMEs and maximize existing resources. Twelve national key economic areas (NKEA, 2011) such as oil and gas, palm oil and related products, financial services, wholesale and retail, tourism, information and communication technology (ICT), education services, electrical and electronics, business services, private healthcare, agriculture have been identified to spur the Malaysian economy. Under the Agriculture National Key Economic Area (NKEA), 16 Entry Point Projects (EPPs) were identified, these EPPs focuses on transforming a traditionally small-scale, production-based sector into a large scale high value agribusiness industry that contributes to economic growth and sustainability. This transformation is based on an integrated and market-centric model that focuses on economies of scale and value chain integration. The transformation strategy comprises of four key themes:

1. Capitalizing on competitive advantages
2. Tapping premium markets
3. Aligning food security objectives with increasing Gross National Income (GNI)
4. Participation in the regional agriculture value chain

Based on the themes, the NKEA Agriculture Lab in 2010 mapped out the 16 EPPs as follows: EPP1 (High value herbal products); EPP2 (Production of swiftlet nests); EPP3 (Mini estate for seaweed); EPP4 (Fish rearing in cages); EPP5 (Cattle rearing in oil palm estates); EPP6 (Replication of integrated aquaculture model (iZAQs); EPP7 (Premium market for fruit and vegetables); EPP8 (Strengthening the export capability of the processed food industry); EPP9 (Introducing fragrant rice variety for non-irrigated areas); EPP10 (Scaling up and strengthening paddy farming in MADA areas); EPP11 (Scaling up and strengthening of paddy farming in other irrigated areas); EPP12 (Strengthening current anchor companies in cattle feedlots); EPP13 (Establishing dairy clusters in Malaysia); EPP14 (Establishing a leadership position in regional breeding services); EPP15 (Securing foreign direct investment in agriculture biotechnology); EPP16 (Investing in foreign cattle farming).

The Malaysian government has supported the herbal industry development through agriculture NKEA, that is EPP1 (developing high-value herbal products). EPP1 focuses on strengthening the quality and marketing potentials of Malaysian herbal products to penetrate global export markets. The primary objective of this initiative includes; to achieve an increase in GNI contribution; to produce safe, quality and efficacious high-end herbal products; to strengthen the supplies across the value chain; and to enhance R&D in the herbal industry (NKEA, 2011). Over the years, sales of herbal products have been increasing due to the implementation of Economic Transformation Program (ETP).

The herbal industry performance result shows that there was progress regardless of numerous industry challenges. Revenue generation from sales of herbal products under EPP1 Key Performance Indicator (KPI) moved from RM1.05 million in 2011 to RM4.47 million in 2016 (see Table 1.4). This increment is a clear indication of the gap between current sales and the 2020 set target, (NTP, 2016). High-value herbal products were projected to contribute RM 3.25 billion to GDP after successful completion of clinical trials on 24 selected products by 2020. However, the industry recorded only ten completed clinical trials by the end of 2016 (ETP, 2016). Most of the local herbal products produced are mainly in the low-end market segment such as fortified beverages (ETP, 2011). Diversification towards high-end herbal products based on standardized extracts and validated by clinical studies remains weak due to lack of industry champions, weaknesses in local R&D, the substantial investment required for clinical studies and difficulty in penetrating international markets.

**Table 1.4: Revenue generation from Herbal Product Sales, 2011-2016**

Year	Target (RM million)	Actual (RM million)	Percent Achievement
2011	1.00	1.05	105.0
2012	2.00	2.20	110.0
2013	2.50	2.30	92.0
2015	3.50	3.85	110.0
2016	4.50	4.47	99.3

(Source: NTP, 2016)

Figures from the Ministry of Agriculture and Agro-Based Industry showed that land used for herbal cultivation increased by 15 percent a year, so projected a plantation acreage increase from 1000 hectares in 2010 to 4000 hectares in 2020 (NAFP, 2011-2020). During this period, production of herbal products is estimated to increase from 17,000 tonnes to 73,000 tonnes or a growth rate of 15.4 percent per annum. However, the downstream activities showed increased production and registration of herbal products (NPRA, 2015). Table 1.5 presents the registered herbal products from 2006 (16,858) to 2015 (22,512). From Table 1.5, category wise, the most registered products were herbal (22,512), followed by prescription (13,823), non-prescription (10,065), health supplement (449), while veterinary (364) was the least registered on a cumulative basis.

**Table 1.5: Herbal Products Registered with NPRA, 2006-2015**

	2006	2007	2008	2009	2010	2013	2014	2015
Prescription	11356	11805	12214	12626	13067	13308	13543	13823
Non-prescription	8685	9098	9370	9683	9918	9972	10024	10065
Herbal	16858	18200	19153	20193	20775	21353	21943	22512
Health Supplements	0	0	0	0	0	85	213	449
Veterinary	0	0	0	0	54	63	270	364
<b>Total</b>	<b>36899</b>	<b>39103</b>	<b>40737</b>	<b>42502</b>	<b>43814</b>	<b>44781</b>	<b>45993</b>	<b>47213</b>

(Source: NPRA, 2015)

Another prominent issue bedeviling the industry is the fluctuation in product registration and licensing, which forms non-compliance with the quality and safety standards set by the NPRA among some herbal-based SMEs. revealed that 46.5 percent of the products that failed laboratory testing were herbal products (NPRA, 2015). Annual Report of NPRA in 2015 revealed that 46.5 percent of the products that failed laboratory testing were herbal products (NPRA, 2015). NPRA normally conducts label checking, and verification of products in response to queries from enforcement division and suggests regulatory action if the product labels do not comply.

Meanwhile, total herbal products export including processed products is expected to increase from RM152 million (USD45 million) to RM1.3 billion (USD382 million) per annum (NAFP, 2011-2020). Report of UN Comtrade Database DESA (2017) showed that the import and export value of herbal products indicate that Malaysia is a net importer of herbal products. The trend indicated a continuous rise in the volume of herbs importation for successive years beginning 2011 to 2017 (currently, the importation value stands close to 2 billion USD). The export value witnessed a continuous rise also throughout the period (from 2011 - 2017), with a value of 149 to 343 (million USD) 2011-2017 cumulatively. Overall, the balance of trade in the industry is about 1.5 billion USD (see Table 1.6). Although the herbal industry remains on target regarding herbal products exportation, the continuous rise in the volume of herbal products importation has become a serious concern. Thus, becoming a severe threat to self-sufficiency initiative. The local markets then get infiltrated with the imported, the domestic herbal market utilize raw materials with substantial value and volume imported from many countries, notably China, Singapore and India (Zakaria, 2015).

**Table 1.6: Export & Import Trend of Herbal Products in Malaysia, 2011-2017**

Activity	2011	2012	2013	2014	2015	2016	2017
Export (USD Million)	149	173	179	212	284	330	343
Import (USD Million)	1038	1182	1246	1407	1536	1673	1821
BOT (USD Million)	-889	-1009	-1067	-1195	-1252	-1343	-14785

(Source: UN Comtrade Database DESA, 2017)



However, the performance of the industry shows a massive trade deficit, insufficient R&D, clinical studies and marketing done to tap into select markets that offer higher margins (NAFP, 2011). Therefore, there is the need to identify the factors that influence the herbal-based SMEs to venture into the production of high-value products. Previous studies have attempted to address the issue but focused mainly on internal dimensions, such as entrepreneur characteristics (Devonish *et al.*, 2010; Birdthisle, 2008; Ismail *et al.*, 2009). Researchers neglect external dimensions such as environmental and social dimensions in most psychological-or cognitive-based studies. Both environmental and social dimension factors are not only capable of influencing large-size business firms but also SMEs. However, research regarding their influence on herbal-based SMEs is still scanty. This neglect has resulted in lack of understanding about their roles on business practitioners' sustainability practices. The poor understanding of sustainability concept could result in improper planning for SEP development and hence prohibit engaging in it by the business operators.

#### 1.4.1 Registered Herbal-based SMEs

Herbal-based SMEs venture in chiropractic agribusiness which consists of healing philosophies, approaches, and therapies to modern diseases, this led to the growth of traditional medicine companies in Malaysia. So far, NPRA through its Centre for Compliance and Licensing (CCL) has issued a total of 1,885 licenses to various SMEs; they comprised of 266 Manufacturer's License, 455 Import License, and 1,165 Wholesaler's License. As shown in Table 1.7, out of the 1,885 licenses issued, only 532 herbal-based SMEs were eligible for the license (that is, 28.22 percent). They comprised of 178 (66.92 percent) SMEs involved in the manufacturing of traditional and complementary medicine, 196 (16.82 percent) for companies registered as a wholesaler or distributor and 158 (34.73 percent) for importing companies listed under the National Pharmaceutical Regulatory Agency (NPRA, 2015).

**Table 1.7: The Herbal-based Companies Registered under NPRA, 2015**

<b>Company Category</b>	<b>Total Companies Registered</b>	<b>Herbal-based Companies Registered</b>	<b>Percent Share</b>
Manufacturer	266	178	66.92
Wholesaler	1165	196	16.82
Importer	455	158	34.73
<b>Total</b>	<b>1885</b>	<b>532</b>	<b>28.22</b>

(Source: NPRA, 2015)

Meanwhile, the Centre for Compliance and Licensing (CCL) conducts Good Manufacturing Practice (GMP) inspections on all registered products to ensure their compliance towards the current GMP requirements. CCL also ensure the adherence of importers and wholesalers to the current Good Distribution Practice (GDP) requirements, with the assistance of the State Pharmacy Enforcement Division. The

category of premises covered varies from pharmaceutical (poison and over-the-counter), herbal, cosmetic and others (includes veterinary, health supplement, and active pharmaceutical ingredient).

Despite heavy commitments and investments into the industry via numerous incentives and subsidies, the number of GMP certificates issuance continue to decline. This decline indicates that some herbal-based SMEs conduct their business not following the industry standard. As presented in Figure 1.3, GMP certificates issued increased from 339 in 2006 to 603 in 2010, at the onset of NTP. Then started declining from 529 in 2012 to 470 in 2015 (NPRA, 2015). Continuous yearly inspections conducted on herbal-based SME premises indicated reduction or non-compliance with good management practices in business conduct.

Even though GMP certification campaign has been ongoing for years, it still receives low acceptance from small- and medium-sized business practitioners, especially in the Malaysian herbal industry (NPRA, 2015). These SMEs attributed their compliance difficulties to inaccessibility to new technology, the small and variable scale of operation, low capital investment, low-profit margins, and low productivity. As such the Government of Malaysia mandated that the herbal-based SMEs should ensure compliance to set standards in their business (NTP, 2014). Since the common practices SMEs adopt have simple procedures that allow flexibility, immediate feedback, and short decision-making chains, identifying the drivers and strategies which expedite the compliance to implement SEP becomes critical, specifically among herbal-based SMEs in Malaysia.



**Figure 1.3: GMP Certification Status of Herbal-based SMEs, 2006-2015**  
(Source: NPRA, 2015)

#### 1.4.2 Malaysian Government Action

In recent years, the Malaysian government has made a strong commitment to strengthening sustainability development. With a full understanding of the country's nature, where sustainable economic growth depends on the careful protection of the environment, the establishment of the Ministry of Energy, Green Technology and Water Malaysia or (KeTTHA) in 2008 intensified the efforts to promote sustainable practices among all the industries in the country. Recognizing that sustainable practices can provide opportunities for entrepreneurs to penetrate the overseas market, the Ministry of Energy, Green Technology and Water (KeTTHA) in Malaysia has provided various forms of incentives economically such as Green Practices Financing Scheme (GTFS) and sales tax and import duty exemptions on equipments based on sustainable practices.

In its effort to boost the agriculture NKEA sector's productivity and raise the value chain under the National Transformation Programme (NTP), the Malaysian government has invested approximately RM2.4 billion in the sector (NTP, 2011). Since the inception of the NKEA, various investment initiatives focused towards developing a sustainable agriculture economy capable of yielding increment in productivity and exports, penetrating new markets, higher standards adoption and development of new growth areas. One of the edges recorded recently is the exploration of the Internet of Things (IoT) technologies within some sectors of the economy. With the realization of IoT as a critical technology to enhance productivity in key sectors under the 11th Malaysia Plan, agriculture has been selected to pilot the use of sensors among other sectors (NTP, 2015).

To maintain the concept of green earth, the 11th Malaysian Plan (2016-2020) supports previous plans (9th and 10th Malaysian Plans) in the conservation of nature through a focus on managerial aspects to ensure sustainable development. It provides a critical platform for the Malaysian economy and industries to join the list of high growth emerging and green economies by 2020. In line with the Vision 2020, the government emphasized that compliance to Good Manufacturing Practice (GMP) is mandatory for the application of a manufacturing license as well as product registration. Good Manufacturing Practice (GMP) is a standard that should be followed by the herbal-based SMEs to ensure that their product is safe, efficacious and of quality. The standard covers herbal-based SMEs' business activities like making or assembling of herbal product; enclosing or packaging of the product in any container in a suitable form suitable for administration or application, and the labeling of the container; and the carrying out of any process of any of the preceding activities. However, the herbal-based SMEs involvement is still low because of low awareness and knowledge on the benefits of sustainable practices among the manufacturers and consumers in Malaysia (Eltayeb & Zailani, 2009).

All herbal-based products produced in Malaysia needs to be checked, certified and registered with NPRA. Nonetheless, possession of GMP certification tells the following regarding the activities of herbal-based SMEs:

- i. Satisfactory compliance with the requirements for product registration, as well as to apply for operating license with the Drug Control Authority (DCA);



- ii. Employment of controlled manufacturing operations as uncontrolled operations may be detrimental to consumer health;
- iii. Assurance that the product is safe, efficacious and of quality, and thus gain consumer confidence.

For the herbal-based SMEs to attain a GMP status, the standard has provided guidelines based on different business category requirement of the industry. The traditional medicines and health supplements category provide GMP guideline for herbal-based products (NPRA, 2015). The guideline states that any therapeutic substance including herbal products used for therapeutic reason must be of certain quality grounded on efficacy and safety (NPRA, 2015). Accordingly, new herbal drug needs to pass through three main stages for therapeutic claims: i) product development and standardization ii) preclinical studies and iii) the three phases of clinical studies. NPRA also states that evidences (clinical data) on the quality of products should be provided in support of therapeutic claims (mild or high claims) else they must undergo clinical trials. Hence, the category for clinical trials determines manufacturing the herbal products prior to approval for manufacturing/importing for the clinical trials. Products meant for clinical trials in Malaysia requires no registration, instead, the herbal-based SMEs need to follow the Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) guideline as follows:

i) Product development and Standardization: For herbal extracts, the plant is initially boiled, and using a solvent, its active compounds are extracted, and their biological activity is proven to meet the quality control standards. Before it qualifies as herbal drug, however, the concentration of the active compounds within the extract needs to be standardized. Ensuring that its dosage produces consistent effects while being safe (NPCB, 2014).

ii) Preclinical studies: Preclinical studies involves series of experimental work that each new drug product including herbal formulation needs to fulfil by using single or multiple standardized extracts. The focal preclinical studies are: toxicology studies in rodents and non-rodents, in vitro absorption, distribution, metabolism, and excretion (ADME), in vivo pharmacokinetic (PK) studies, safety pharmacology and efficacy studies both in vitro and in vivo. Under the International Council for Harmonisation (ICH) guidelines, toxicology studies and safety pharmacology must be carried out in good laboratory practice (GLP) certified facilities. This procedure makes preclinical studies very expensive especially under GLP set up (NPCB, 2014).

iii) Clinical studies: A product undergoes through three main phases of clinical studies (that is, Phase I, II and III) prior to registration with regulatory authority. Phase I involves studying the effect of the newly developed drug on healthy human volunteers. The safety report from Phase I then is used to proceed to Phase II clinical study. Phase II involves treatment of patients with clinical conditions with the newly developed drug. In the last phase, Phase III, a broader population of patients are involved including testing on different races. Depending on the type of investigation, each product to be tested follows

different unique pathways. Clinical experts are required to work closely with the sponsor companies and regulatory authorities to develop investigational protocols and the design of the clinical studies.

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. Clinical studies are very expensive and involve hiring of clinical contract research organization (clinical CRO) as most of the expenses in drug development are incurred during clinical research phases. In Malaysia, such initiative in developing herbal products with therapeutic claims must undergo similar process. The Malaysian Government, under NKEA programs has selected some anchor companies with potential herbal products for commercialization and financially, supports the preclinical and clinical studies. And to ensure the success of the program, the companies are closely monitored by the Herbal Development Department (HDD) and work progress is directly reported to the ministry of health Malaysia (NPCB, 2014).

### **1.5 Sustainability Issues in Malaysian Herbal Industry**

Herbal industry is an essential industry in the country that has numerous potentials to contribute significantly to the economic growth of Malaysia. The herbal industry belongs to food and beverage sub-sector of the manufacturing sector (Malaysian Standard of Industrial Classification 2008) which contributes to about 10 percent of Malaysia's manufacturing output (DOS, 2011). Of the total 47,698 SMEs in the manufacturing sector, 530 SMEs are involved in the manufacturing and processing of herbal products, constituting about 1.11 percent of the manufacturing sector (DOS, 2016). Entrepreneurial activities of these SMEs affect the environment, human health, and social order due to continued increase in waste generation. In recent years the manufacturing industry has been identified as one of the primary sources of environmental problems worldwide. (Agamuthu, 2015).

In 2010, Agamuthu projected that the quantity of municipal solid waste generation in Malaysia would reach 30,000 tons/day by 2020, because agro-based industry produces a significant amount of post-processing waste and residues. A review by Aja & Kayiem (2014) found that in 2013 alone, waste generation in Malaysia has increased to 33,000 tons/day which exceeded the projection cited earlier. Similarly, a recent review by Fazeli *et al.*, (2016) reported that the increasing economic growth of Malaysia contributes to environment degradation through high energy consumption and high waste generation. According to the Department of Environment's definition, "waste is any substance prescribed to be scheduled waste or any matter whether in a solid, semi-solid, or liquid form, or in the form of a gas or vapor, which is emitted, discharged, or deposited in the environment in such volume, composition, or manner as to cause pollution" (DoE, 2001). Scheduled wastes refer to the categories of waste listed in the First Schedule of the Environmental Quality (Scheduled Wastes) Regulations 2005 (Jamin & Mahmood, 2015).

The Malaysian Environmental Quality Act (EQA) 1974 defined Environmentally hazardous substance (EHS) as “any natural or artificial substances including any raw material, whether in a solid, semi-solid, or liquid form, or in the form of gas or vapor, or in a mixture of at least two of these substances, or any living organism intended for any environmental protection, conservation, and control activity, which can cause pollution” (DoE, 2012). Currently, there are 3,839 items under 77 categories in the EHS reference list (DoE) which are classified into five groups as presented in Table 1.8. The five groups are: i) Metal and metal-bearing wastes; ii) Wastes containing principally inorganic constituents which may contain metals and organic materials; iii) Wastes containing principally organic constituents which may contain metals and inorganic materials; iv) Wastes which may contain either inorganic or organic constituents; and v) Other wastes. The wastes in the five groups are from different sources such as industrial sector, agricultural sector, health sector, and households (Abdullah, 1995; Foo *et al.*, 2011; Fauziah & Agamuthu, 2008; Razali & Ishak, 2010; Ghasemi & Yusuff, 2016).

**Table 1.8: Grouping of First Scheduled Waste in Malaysia**

<b>SW1:</b> Metal and metal-bearing wastes
<b>SW2:</b> Wastes containing principally inorganic constituents which may contain metals and organic materials
<b>SW3:</b> Wastes containing principally organic constituents which may contain metals and inorganic materials
<b>SW4:</b> Wastes which may contain either inorganic or organic constituents:
403: Discarded drugs containing psychotropic substances or containing substances that are toxic, harmful, carcinogenic, mutagenic, or teratogenic
404: Pathogenic wastes, clinical wastes, or quarantined materials
405: Waste arising from the preparation and production of pharmaceutical product
<b>SW5:</b> Other wastes

(Source: DoE, 2001)

The herbal-based SMEs waste generation falls under the fourth group, that is, wastes which may contain either inorganic or organic constituents. The SW4 group have 32 sub-groups, however, the herbal-based SMEs are viewed under SW403: Discarded drugs containing psychotropic substances or containing substances that are toxic, harmful, carcinogenic, mutagenic, or teratogenic; SW404: Pathogenic wastes, clinical wastes, or quarantined materials; and SW405: Waste arising from the preparation and production of pharmaceutical product. Therefore, the NAFP was formulated to ensure that manufacturing activities of SMEs meet the environmental protection rules and regulations. Because of this, the Malaysian government focused on the managerial activities of the SMEs such that risks, and significant adverse effects are minimized on the environment and human health. The process involves cross-sector commitment of all stakeholders to coordinate approaches and common principles in the implementation and strengthening of sustainable practices for a safe and ecologically sustainable management regime (Kamarulzaman, 2015).

## 1.6 Herbal-based SMEs Waste Generation

The manufacturing sector was the first sector identified with waste (both hazardous and toxic) generation in Malaysia (Aja *et al.*, 2016). In the post-independence era, between 1970s and 1980s, the problems began; this was connected to the boom in the manufacturing sector between 1966 and 1988. In 2008, the total waste generated by the pharmaceutical category was 26,967.95 metric tons while in 2011, it grew to 44,674.52 metric tons (Ghazali, 2012). It was found that the change in pharmaceutical waste increased by 17706.57 metric tons between 2008 and 2011, with a percentage increment of almost 68 percent (Aja *et al.*, 2016). The waste generation of the pharmaceutical category for 2016 was projected as 75,053.19 metric tons using a constant percentage increment. However, the herbal-based SMEs waste generation was 28.5 percent of the total pharmaceutical category, so the average waste generation of herbal-based SMEs in 2016 is 0.354 kg/cap/day. The result surpasses the 0.210 kg/cap/day projected by Agamuthu (2015). This continuous increment in waste generation attracts the government attention to address the issues caused by this trend because of the negative impact its causing to the economy, environment, and people. Table 1.9 presents the total waste generation by the pharmaceutical category for 2008 and 2011 respectively.

**Table 1.9: Pharmaceutical Category Waste Generation, 2008 and 2011**

Waste Category	Waste Code	2008 Waste Generation		2011 Waste Generation	
		MT/Year	Percent	MT/Year	Percent
Pharmaceutical	SW 403, 404, 405	26967.95	2.07	44674.52	2.75

(Source: DoE, 2012)

As the entrepreneurial activities of the herbal-based SMEs in the industry increases, waste generation also increases causing severe hazards and environmental pollution due to the small collection, recycling or treatment and uncontrolled disposal of the waste in ordinary dumps and landfills (Agamuthu, 2015). The waste contains hazardous materials such as Lead (Pb), Mercury (Hg), and Cadmium (Cd), as well as a range of greenhouse gases such as Sulphur (S), and Carbon-dioxide (CO<sub>2</sub>). Some of the waste leachates into water sources like rivers, hence subjecting the environment to more pollution risk. At the same time, greenhouse gases (GHG) are emitted into the atmosphere, contributing to another issue of grave concern, that is, climate change.

Othman & Jafari, (2014) argued that increasing awareness on environmental sustainability and green consumerism concerns have given rise to many unprecedented challenges at the global and national level, which further impinges upon the herbal industry in Malaysia. These trends, without adequate adaptation strategies, may impede the industry's contribution to national development in the long-run, particularly the rural economy.

A report by World Energy Outlook (IEA) shows that manufacturing industries contribute nearly 36.8 percent of CO<sub>2</sub> emission to the environment globally (IEA, 2015). Malaysia is gradually becoming an industrialized country backed by well-planned economic and industrial development by the government (Khan *et al.*, 2017). Although the herbal industry contributes around 1 percent to the GDP, statistics indicate that their activities contribute around 588,914 million metric tons of total CO<sub>2</sub> emission. The manufacturing sector contributed around 53 million metric tons to CO<sub>2</sub> emission, making it the third substantial contributor to CO<sub>2</sub> in the country with 26.26 percent after transport, power and electricity generation (DoS, 2016). Therefore, efforts to achieve sustainability becomes a priority towards attaining sustainable development.

Also, there has been a continuous rise in the amount of Biological Oxygen Demand (BOD) in river basins from the increased waste generation in Malaysia (CES, 2015). Table 1.10 shows the total number of river basins monitored and water quality based on Biological Oxygen Demand (BOD) from 2005 to 2015 in Malaysia. Of the total 146 river basins monitored in 2005, total polluted was only 28, then 41 were slightly polluted, and 77 were clean. This trend of higher clean river basins continued till 2009 when out of 143 river basins monitored, the number of clean river basin suddenly dropped to 28 while polluted river basin rose to 42. From 2013 to 2015 virtually all the river basins monitored were either slightly polluted or thoroughly polluted.

Similarly, the National Water Services Commission has reported that water demand is expected to increase by 63 percent from 10,833 million meters cubic in 2000 to 17,675 meters cubic in 2050 for domestic, industrial and drainage sectors (NWSC, 2012).

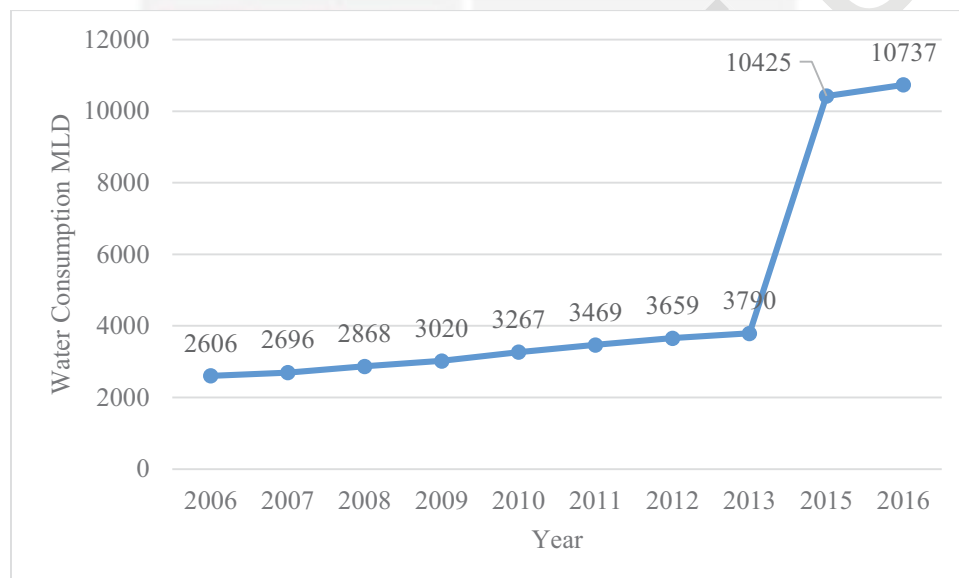
**Table 1.10: Status of River Water Quality Based on Biochemical Oxygen Demand, 2005-2015**

Year	Total River Basins Monitored	Biochemical Oxygen Demand (BOD)		
		Polluted	Slightly Polluted	Clean
2005	146	28	41	77
2006	146	22	28	96
2007	143	12	37	94
2008	143	18	46	79
2009	143	42	73	28
2010	143	52	79	12
2011	140	57	80	3
2012	140	59	69	12
2013	140	94	46	0
2014	140	125	15	0
2015	140	121	19	0

(Source: DoS, 2015)



However, currently water consumption in Malaysia is 70 percent more than the recommended usage by United Nation, this scenario poses a threat to the ability of Malaysia to sustain its potable water source in meeting its water demand (NWSC, 2016). Figure 1.4 shows the volume of water consumption in a million liters per day (MLD) based on data from the National Water Services Commission (2016). In both 2015 and 2016, the water consumption reached its highest peak of 10,452 and 10,737 due to economic factors like rapid population growth (that is, about 4 percent per year) and increased industrialization (Hasnan *et al.*, 2014). There are two categories of water consumption in Malaysia; domestic and non-domestic water consumption. The domestic water consumption refers to water consumption by non-commercial individuals while non-domestic consumption refers to water consumption in commercial establishments, industries, construction sites and offices. As can be seen in Figure 1.4, the water consumption shows increasing trend from the year 2006 to 2016.



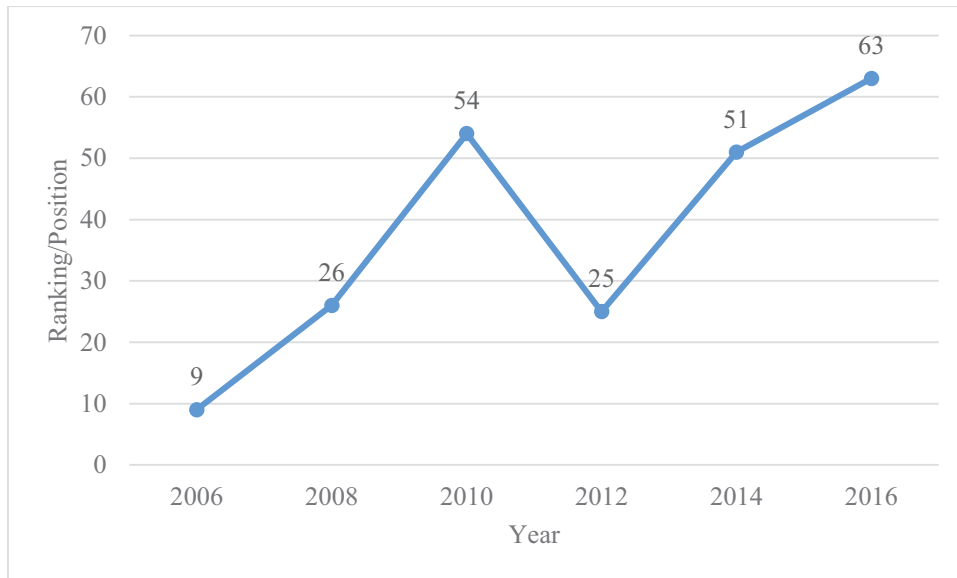
**Figure 1.4: The Malaysian Water Consumption MLD, 2006-2016**  
(Source: National Water Services Commission, 2016)

The non-domestic water demand has continued to increase with increased industrialization in Malaysia. For instance, the industrial water use is estimated to increase as high as 9,756 MLD by 2020, and this will overstretch the maximum limit of river basins supply in the country (Seong, 2013). Furthermore, potable water shortage has been reported in many states and city centers where the water demand is high (Hasnan *et al.*, 2014). The intensive use of water in herbal manufacturing and processing industry is because water is the primary processing medium throughout all steps in the whole process either as an ingredient or as a process aid (Lee and Okos, 2011). Hasnan *et al.* believe that water use becomes essential for equipment washing processes, sanitation, cooling, package processing, utilities and auxiliary wants in most type of product manufacturing and processing activities.

The concept of sustainability entails productivity enhancement, environmental quality, efficient utilization of non-renewable resources, economic viability and improvement in the quality of life, so it becomes imperative to study the sustainability issues in the herbal industry under the three pillars of sustainability, namely; economic (profit), environmental (planet), and social (people). In the last 20 years, information on a range of sustainability practices has become available to the business environment, ranging from proactive to reactive approaches. The proactive approaches are reflected in the unbinding and innovative operations that go beyond the laws, while the reactive approaches are often driven by minimum compliance standards, which are meant to minimize liabilities and pressures (Rasi *et al.*, 2012). This study takes the view that sustainable entrepreneurship practices involve all practices that ensure the production of the healthy consumable product; minimizes adverse environmental effects; minimizes the chemicals contained in the product; cares for people health and safety, and cares about employees' welfare (Capone *et al.*, 2014; Magkos *et al.*, 2006; Rezai *et al.*, 2013).

#### **1.6.1 Environmental Issues**

Statistics have shown that a significant portion of the country's environmental problems is associated with the activities of the SMEs (Rezai *et al.*, 2016). According to Compendium of Environmental Statistics Malaysia report 2016, although the manufacturing sector contributes substantially to GDP, it is also one of the leading contributors to environmental pollution (with the herbal industry contributing 1.1 percent of the total pollution). The report shows that the environmental protection expenditure of the government rose from RM 2.244 billion in 2014 to RM 2.55 billion in 2015. This scenario indicates an annual growth rate of 3.9 percent in 2015 as compared to 0.3 percent in 2014 (DOS, 2016). The report shows that in 2014 the manufacturing sector alone has contributed RM 1.62 billion (72.1 percent) to the environmental protection expenditure, mainly to reduce the environmental damage caused by the activities of SMEs. Worryingly, Malaysia has been performing poorly regarding environmental performance. Malaysia's current ranking on the Environmental Performance Index (EPI) substantiate the claim; the EPI report shows that Malaysia has been unstable from the last decade to date. As presented in Figure 1.5, the country ranked 9th, 26th, 54th, 25th, 51st, and 63rd in 2006, 2008, 2010, 2012, 2014, and 2016 respectively. When compared to Singapore another ASEAN member country, Singapore has improved on the EPI ranking significantly by improving from lowest 52nd in 2010 to 14th in 2016.



**Figure 1.5: Environmental Performance Index, 2006-2016**  
(Source: EPI Asia Pacific, 2016)

The report indicated that entrepreneurial activities of SMEs in the country gulped 17 percent of the total environmental protection expenditure in 2016. The expenditure comprises of environmental pollution prevention, pollution abatement and control, waste management, environmental assessment and audits, and protection and conservation of wildlife and habitat (DOS, 2016). However, environmental pollution is now becoming a dominant issue in Malaysia due to increased entrepreneurial activities of SMEs, who constitute 98.5 percent of the total business establishments in the country (SMECORP, 2016).

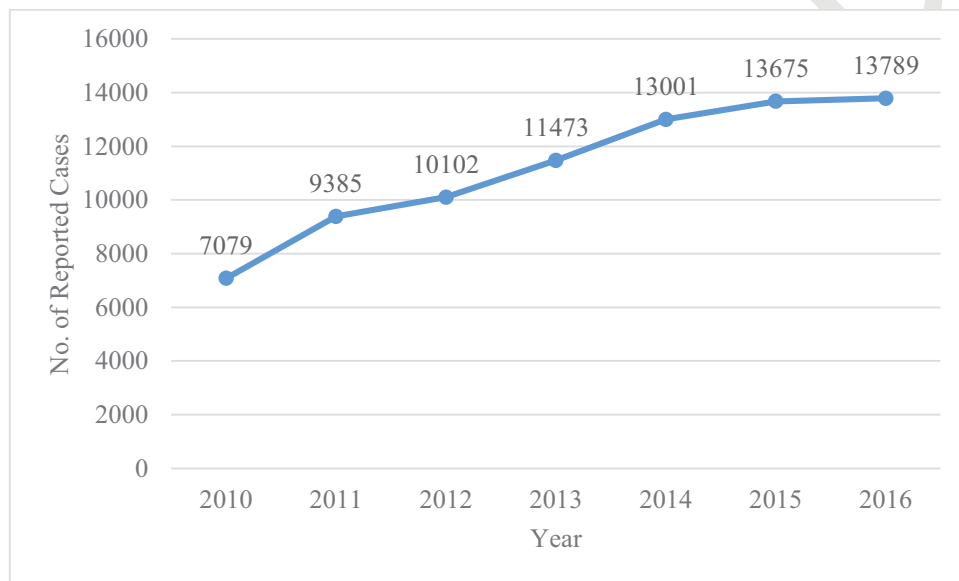
### 1.6.2 Economic and Social Issues

Activities in the herbal industry show mainly the production of low-value products that cannot penetrate premium markets by SMEs. This scenario is because most of them are micro SMEs with less than five employees, a small variable scale of production with manual system/equipment (Rohana *et al.*, 2017). Majority of the products end up in the local markets due to lack of standardization and proper marketing strategy. The average annual income of the herbal-based SMEs is less than RM300,000.00. This figure indicates that the annual income is not enough for the purchase and adoption of improved technology as well as production of high-value products that attract premium markets (NAFP, 2011-2020).

In recent years, the non-compliance to ethical manufacturing and processing activities by SMEs in the herbal industry resulted in numerous food hazard incidences, prominent among which include unhygienic and misguided production methods. Product surveillance by NPRA finds that 57.5 percent of herbal products inspected failed quality



testing due to adulteration, microbial and heavy metals presence (arsenic, cadmium, mercury, and plumbum) in excess limits (NPRA, 2016). As a result, causes many complications like inflammation, nausea, and body pain (NPRA, 2016). Figure 1.6 shows the increase in Adverse Drug reactions due to products intake. Also identified was the failure in compliance with the Hazard Analysis and Critical Control Points (HACCP) and Good Manufacturing Practice (GMP) by the SMEs. The GMP and HACCP certification ensures the product safety and hygiene which is internationally recognized by many developed countries. The process is still cumbersome for Malaysian manufacturing sector especially for Small and Medium Enterprises (SME) in the herbal industry to fulfill (Hasnan *et al.*, 2014; Khan *et al.*, 2017). This scenario is evidenced by the low number of herbal-based SMEs that have successfully obtained GMP certifications as shown in Figure 1.6.



**Figure 1.6: Malaysian Adverse Drug Reaction Report, 2010-2016**  
(Source: NPRA, 2016)

However, information regarding compliance with labeling checks also revealed that 72.9 percent of the SMEs failed to comply with the latest labeling requirements (NPRA, 2016). Based on this figure, 64 percent of the sampled products did not pass the labeling compliance leading to their recall from the market. This instance is an indication that most of the Malaysian herbal-based SMEs are incapable of meeting the accepted international and national level of product safety and hygiene. However, the few SMEs that can meet the certification requirement are the multinational companies (Hasnan *et al.*, 2014; Rezai *et al.*, 2016). SMEs greater obstacle in implementing GMP and HACCP is due to many reasons. One of the reasons being highlighted by World Health Organization is inadequate infrastructure and technology which make it challenging to fulfill GMP and HACCP certification. Another reason is the nonchalance attitude towards implementing practices base on GMP and HACCP requirements. Furthermore, they are unable to pay for the high costs of consultation charges for GMP and HCCP certifications due to financial constraint. It is therefore very common to find SMEs

running their food production in houses or shop-lots converted into factories, for example with broken walls, floor, and ceiling.

### **1.7 Problem Statement**

Despite the fact that the Malaysian government has made concerted efforts to support the herbal industry in the country in terms of production of safe, quality and efficacious high-value herbal products under the national key economic areas (NKEA), specifically through entry point project one (EPP1), not so many herbal-based SMEs are implementing sustainable entrepreneurship practices. These herbal-based SMEs attribute their difficulties to numerous constraints such as low capital investment, low-profit margins, the small and variable scale of operation, and low productivity. Previous studies have shown that most of the herbal-based SMEs in Malaysia produce low value products and market the products locally. Hence engage in unsustainable entrepreneurial practices that cause environmental degradation, affecting the environment, human health, and social order through increased waste generation, severe hazards and environmental pollution (both air and water). This in turn affects business activities economically by lowering contribution to the economic development through increase waste disposal costs, inefficient production and consumption of products and materials, and decreasing business opportunities. At the same time increasing negative environmental impact through the emission of pollutants to the environment, raising the GHG emissions, subsequently leading to global warming. It also leads to the pollution of the water sources posing a threat for the country to sustain its potable water source. Lastly, the production of adulterated herbal products with microbial and heavy metals presence affects human health and causes social issues (like negative company image and reputation, low employee motivation, and shunning of corporate social responsibilities). Therefore, to overcome these challenges, herbal-based SMEs needs to develop an organizational culture through sustainability that will enable them to implement sustainable entrepreneurship practices. However, sustainability drivers and sustainability strategy factors have become crucial factors that could drive the success of herbal-based SMEs in the future.

Although sustainable entrepreneurship practice campaign has been ongoing for years, it still receives low acceptance from small-and-medium-sized business practitioners, particularly among the herbal-based SMEs. Previous literature shows that although most of SMEs in Malaysia are aware and have the intention of implementing SEP, only few implement it. Some scholars argued that the few SMEs that implement sustainable entrepreneurship practices are the foreign based companies with wider market coverage not the indigenous ones. Sustainable entrepreneurship practices have been identified as a potential sustainable solution to reduce environmental degradation and improve herbal-based SMEs contribution to sustainable economic development through the production of high-value products and creating new business opportunities. In the long run, this will translate to the attraction of premium markets capable of providing higher returns for the herbal products. Therefore, increased entrepreneurship practices with barriers and numerous challenges without proper sustainable management will not only improve the situation but instead lead to wastage of precious resources and economic problems.

Literature also show that SEP has provided information on how to conduct business ethically, while promoting environmental quality and social justice. Unfortunately, the reduction in the number of certifications and recalling of some products from the market due to adulteration reported by National Pharmaceutical Regulatory Agency (NPRA) indicates that some herbal-based SMEs in Malaysia have been conducting their business unethically over time, violating most of the set standard for the industry. However, due to pierce competition faced by Herbal-based SMEs from within the industry and globally, there is a need for them to become more entrepreneurial through transforming and improving their sense of direction, they should be ready to create necessary changes within the firm; most importantly, they should improve their firm performance through developing an effective sustainability culture. They also need to strategize on long-term profit generation through innovation, internalization, compliance with regulations and government policies and create competitive advantage.

Therefore, it is imperative to examine the extent to which sustainability drivers (EPs and TLC) and SSO factors influence sustainable entrepreneurship practice (SEP) implementation to create a favorable entrepreneurship performance (economic, environmental and social) among the Malaysian herbal-based SMEs.

### **1.8 Research Questions**

The study addresses four specific research questions. The questions focus on understanding the level of sustainable entrepreneurship practices implementation among the Malaysian herbal-based SMEs, and the factors that influence its adoption, and firm performance. The primary research questions are:

1. Do sustainability drivers (EP and TLC) positively influence SEP among Malaysian herbal-based SMEs?
2. How can sustainability drivers (EP and TLC) influence SSO towards SEP implementation among the Malaysian herbal-based SMEs?
3. Do SSO mediate the relationship between sustainability drivers and SEP implementation among the Malaysian herbal-based SMEs?
4. Could the company profile of the herbal-based SMEs influence the SEP implementation as potential moderators of the relationship between the variables and performance among the Malaysian herbal-based SMEs?

### **1.9 Objectives of the Study**

The general objective of the study is to investigate the implementation of sustainable entrepreneurship practices towards sustainability performance among herbal-based SMEs in Malaysia. While the specific objectives of the study are:

- i. To identify sustainability drivers (external pressure (EP) and top leadership culture (TLC) as important antecedent factors among Malaysian herbal-based SMEs sustainability;
- ii. To investigate the effects of external pressure (EP) and top leadership culture (TLC) on the strategic sustainability orientation (SSO) towards sustainable entrepreneurship practice (SEP) implementation among Malaysian herbal-based SMEs;
- iii. To examine the mediation effect of strategic sustainability orientation (SSO) in enhancing the implementation of sustainable entrepreneurship practice (SEP) among the Malaysian herbal-based SMEs;
- iv. To analyze the moderation effect of company profile on the relationship between sustainable entrepreneurship practice (SEP) implementation and the economic, environmental and social performance among Malaysian herbal-based SMEs.

#### **1.10 Scope of the Research**

This study is limited in the following ways:

- i. The study focuses on herbal-based SMEs who engaged in the distribution, wholesale/retail, and manufacturing stages in the herbal-based value chain.
- ii. The herbal-based SMEs involved are those registered under the National Pharmaceutical Regulatory Agency of Malaysia either as manufacturers, importers or wholesalers.
- iii. The principal business activities of the herbal-based SMEs constitute of herbal-based-products categorized as traditional and complementary medicine under the National Pharmaceutical Regulatory Agency of Malaysia.
- iv. The study will also focus on the factors of SEP and how they influence economic, environmental and social performance among the herbal-based SMEs registered under the National Pharmaceutical Regulatory Agency of Malaysia.
- v. For Economic performance, the study considers indicators like operational, market, and financial performance; For Environmental performance, the study considers specific indicators like pollution control and resource efficiency; while for Social performance, the study considers indicators like an employee and community-oriented outcomes.
- vi. In this study, we want to look at the joint effect of sustainability antecedents, strategic sustainability orientation on SEP and its overall influence on performance among Malaysian herbal-based SMEs.

#### **1.11 Significance of Study**

The outcome of this study will contribute to the literature on herbal-based SMEs entrepreneurship sustainability drivers, strategic orientation, practices, and performance. Many of the previous studies in this area of research have focused on developed

countries so that this study will provide empirical evidence of the applicability of these concepts to a developing country like Malaysia.

This study could potentially offer a better understanding of the forms of sustainability drivers, strategic orientation, practices, and performance that would be appropriate and effective for Malaysian herbal-based SMEs. This study is essential since the culture, operating environment and values in Malaysia are different from those of the rest of the world especially, developed countries. Some variables or factors might be relevant in the developed countries but are not within the scope of herbal-based SMEs in Malaysia, and vice versa. Adjustments are made to some of the developed concepts of sustainability drivers, strategic orientation, practices, and performance to make them better suited to Malaysian herbal-based SMEs.

Practically, the outcomes of this study will benefit government-related agencies such as FRIM, NPRA, SIRIM, and SME Corporation Malaysia (SME Corp. Malaysia) towards the development of SMEs in Malaysia. For example, a more robust and specific training program may be initiated by the government through one of the agencies on how herbal-based SMEs can formulate entrepreneurship sustainability strategy. Then how to find the specific ways of efficiently implementing the formulated strategy to create favorable performance (economic, environmental and social) that would develop sustainable business in Malaysia.

### **1.12 Organization of the Study**

There are five chapters in this study. The first chapter comprises of introduction that discusses the background to the topic of the research addressed by this study; problem statements, objectives of the study, the hypotheses of the study, scope and limitation of the study, the significance of the study and organization of the thesis. Chapter 2 contains a literature review relevant to sustainable entrepreneurship practices, SEP in the context of SMEs. Institutional Theory, strategic choice theory, Strategic Orientation Theory, and the resource-based view of the firm theory. All four theories that are relevant to external pressure, top leadership culture, strategic sustainability orientation, sustainable entrepreneurship practices and performance are discussed extensively and followed by reviews of all relevant literature on independent variables, moderating variables and dependent variable. In Chapter 3 of this study focuses on the methodological approach of the study; this comprises research design, population sample, sample size, validity and reliability, pilot tests, data collection procedure, data analysis and summary of the chapter. In Chapter 4 the analyses of the results of the study will be presented. It consists of an introduction, data collection process and survey responses, responses rate, descriptive analysis of respondent, assessment of AMOS-SEM path model result; assessment of measurement model followed by an assessment of structural model, results of the structural model, moderators, assessments of the variance explained in the endogenous latent variable. Finally, Chapter 5 will present the discussion on the findings and conclusion per the objectives of the study, research questions of the study and its implication. In this chapter, a limitation and suggestions for the future research will also be discussed and suggested.



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