

**EVALUATION OF PERCEPTIONS AND
KNOWLEDGE TOWARDS THE USE OF
NON-CLINICALLY PROVEN HEALTH
SUPPLEMENTS AMONG THE COMMUNITY
PHARMACISTS AND CONSUMERS
IN THE STATE OF PENANG, MALAYSIA**

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UNIVERSITI SAINS MALAYSIA

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by

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LIST OF ABBREVIATIONS

AU\$	Australia Currency
BD	Barat Daya
CAM	Complementary and Alternative Medicine
CP	Community Pharmacists
HS	Health Supplements
MWU	Mann-Whitney U Test
NCCIH	National Centre for Complementary and Integrative Health
OTC	Over-the-counter
SPS	Seberang Perai Selatan
SPT	Seberang Perai Tengah
SPU	Seberang Perai Utara
TL	Timur Laut
USA	United States of America
USD\$	United States of America Currency

**PENILAIAN PERSEPSI DAN PENGETAHUAN TERHADAP
PENGUNAAN MAKANAN TAMBAHAN KESIHATAN YANG TIDAK
MEMPUNYAI KESAN KLINIKAL TERBUKTI DALAM KALANGAN AHLI
FARMASI KOMUNITI DAN PENGGUNA DI PULAU PINANG, MALAYSIA**

ABSTRAK

Makanan tambahan kesihatan (HS) memainkan peranan yang penting dalam sistem penjagaan kesihatan kerana keprihatinan dalam penjagaan kesihatan yang semakin meningkat. Tujuan kajian ini adalah untuk menilai persepsi, pengetahuan dan amalan pendispensan HS oleh ahli farmasi komuniti (CP); untuk mengenal pasti kekerapan dan sikap terhadap penggunaan HS dalam kalangan pelbagai kumpulan sosio-demografi. Pendekatan kualitatif (Fasa I) dan kuantitatif (Fasa II) telah digunakan dalam kajian ini. Fasa I melibatkan temubual dengan dua belas orang CP dan dua belas orang pengguna di negeri Pulau Pinang, Malaysia. Semua wawancara telah dianalisis dengan menggunakan pendekatan analisis kandungan bertema. Tiga tema telah dikenal pasti daripada kumpulan CP (persepsi, pengetahuan dan amalan) dan dua tema daripada kumpulan pengguna (persepsi dan pengetahuan) masing-masing. Hasil kajian fasa I menunjukkan pihak CP dan pengguna berpandangan positif terhadap penggunaan HS. Tetapi, ketidakpastian dari segi isu keberkesanan and tuntutan kesihatan HS telah dikesan di kalangan CP. Manakala, kenalan rapat telah menjadi sumber penting penggunaan HS di kalangan pengguna. Fasa II melibatkan kaji selidik melalui pos di kalangan CP (n=121) antara empat negeri Utara di Semenanjung Malaysia dan kajian selidik melalui borang soal selidik di kalangan pengguna (n=440) di negeri Pulau Pinang, Malaysia. Analisis data telah dilakukan

dengan menggunakan “Statistical Package for the Social Sciences®” (SPSS) versi 22.0. Hasil kajian fasa II menunjukkan pihak CP dan pengguna berpandangan positif terhadap penggunaan HS (CP=91%; consumers=71%). Namun demikian, menepati hasil kajian fasa I, persetujuan lemah telah dikesan dari segi kesan sampingan (CP=41%; consumer=46%) dan label tuntutan kesihatan (CP=46%; consumer=48%) HS di antara kedua-dua kumpulan. Akibatnya, CP dan pengguna memantau keberkesanan HS daripada maklum balas pelanggan (71%) dan pengalaman pengguna lain (75%). Kesimpulannya, hasil kajian fasa II telah membuktikan hasil kajian daripada kajian fasa I. Oleh yang demikian, peningkatan pendidikan HS di kalangan CP dan program pendidikan HS di kalangan pengguna amat diperlukan untuk memastikan kualiti penggunaan HS. Cadangan-cadangan telah dibentangkan bagi pihak-pihak tertentu di peringkat akademik, pelakar polisi, CP dan pengguna bertujuan membangunkan polisi dan garis panduan HS bagi memastikan penggunaan secara berkualiti produk HS.

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ABSTRACT

Health supplements (HS) play an important role in the healthcare system as its use had become a growing part of health care behaviour. However, there are limited studies in addressing attitude towards the use of HS in Malaysia. The aims of this study are (i) to evaluate the community pharmacists (CP) perceptions, knowledge and their practices in the area of HS dispensing; (ii) to identify the prevalence and attitudes on HS used among consumers in various socio-demographic groups. Mixed method using qualitative (Phase I) and quantitative (Phase II) approach is adopted in this study. Phase I involved face to face semi-structured interviews with twelve CP and consumers in Penang state, Malaysia. All interviews were transcribed verbatim and analysed using thematic content analysis approach. Three themes were identified from CP (perception, knowledge and practice) and two themes were from consumers (perceptions and knowledge). Result from phase I study observed that both CP and consumers demonstrated positive view with regards to the use of HS. However, uncertainties in term of efficacy and health claims of HS exist among CP. Whereby; close contacts became an important source of HS among consumers. Phase II involved a mail survey for CP (n=121) in four Northern state of Peninsular Malaysia and self-administered questionnaire survey for consumers (n=440) in Penang state, Malaysia. Data analysis was performed using the Statistical

Package for the Social Sciences® (SPSS) version 22.0. Result from phase II revealed that both groups illustrated positive attitude (CP=91%; consumers=71%) towards the use of HS for general health improvement. However, similar to phase I result, weak agreement was identified in term of side effects (CP=41%; consumer=46%) and current health claims label of HS (CP=46%; consumer=48%) among both groups. In fact, CP and consumers review the efficacy of HS based on customer's feedback (71%) and other user's experience (75%). As a conclusion, phase II result has confirmed the result of phase I. Therefore, education enhancement among CP and consumers intervention program is needed in ensuring the quality use of HS. In line with this, recommendations have been made for the stakeholders at academia level, policy makers, CP and consumers in the development of policy and guidelines in quality use of HS.

CHAPTER 1

GENERAL INTRODUCTION

1.1 Background

The multivitamins and multi-mineral were first introduced into the North America market as food supplement in the 1930s (Pilzer, 2012). Since then, food supplement has become one of important nutrient resources despite natural diet for the intense to filling up the nutritional gap to prevent any nutrient deficiency. Over the 80 years, the evolution of food supplement or health supplements (HS) in this study continues to spike on its product variety and vast functionality. The products now also included the non-vitamin and non-mineral supplements. In addition to preventing nutrient deficiency, the function of HS also applied to prevention and treating of diseases (Grzywacz et al., 2005). Nowadays, people took HS for some reasons such as to compensate potential inadequacy in the diet, reducing risk of developing of chronic diseases, to relief symptoms of non-deficiency disease, specific requirement due to illness or pregnancy, to boost up immune system and to improve athlete's performance (Webb, 2006c).

Being part of Complementary and Alternative Medicine (CAM), HS were in high demand due to widely used among pharmacy customers as claimed by Braun et al (Braun et al., 2010a). A review published by Harris and colleague in 2000 and 2012, concluded that consistently high prevalence of CAM use by the general population over the past 10 years. Particularly in the USA and Australia (Harris and Rees, 2000, Harris et al., 2012). There was also some evidence that the use among cancer patients has increased considerably over the past years (Horneber et al., 2012). The use of

CAM is believed to be closely associated with socio demographic variables such as gender, age, education, and income (Thomas and Coleman, 2004, Kristoffersen et al., 2014). Population survey from the USA (Eisenberg et al., 1998, Millen et al., 2004, Barnes et al., 2007), Canada (Vatanparast et al., 2010), United Kingdom (UK) (Thomas and Coleman, 2004), Norway (Kristoffersen et al., 2014) and Australia (MacLennan et al., 2002) identified that CAM users were more likely to be female, better educated and had higher income.

1.2 Evidence Based Approach and Health Supplements

As constantly high prevalence among the general population, current data available on the efficacy and safety of HS is conflicting (Masoodi, 2011). Moreover, selectively published studies without additional confirmation studies by the HS companies for the sake of financial profit and CAM products in many countries do not required proof of efficacy has put HS stay well in the market (Sarris, 2012).

In a systematic review of safety and efficacy concluded that insufficient clinical evidence of multivitamins and multi minerals in primary prevention of cancer and chronic diseases (Huang et al., 2006). Although observational studies supported the possibility of vitamin E intake either from food or supplements may reduce risk of cardiovascular disease; however, limitations presented from the review sustained insufficient data in justification of vitamin E in chronic disease prevention (Gaziano, 2004). Whereas in another review based on cancer chemo preventive and anticancer efficacy of grape seed extract and other grape-based products from various studies

concluded that both are excellent sources of various anticancer agents (Kaur et al., 2009).

In a Cochrane intervention review of randomized controlled trials for effectiveness and safety of Echinacea preparations over the placebo in treating and preventing of common cold, authors concluded that there is neither significant result nor clinical relevance in treatment trials and large numbers of adverse events in prevention trials (Karsch-Völk et al., 2014). While debates on clinical evidence continue, academia and healthcare providers claimed that HS is no more effective than placebo (Bouldin et al., 1999, Tiralongo and Wallis, 2008, Bland, 2008, Segar, 2012). It can be concluded that there still a gap in standardization of controlled trials between HS and prescribed medicine, which differentiate among them (MacLennan et al., 2002). Hence, CP generally used personal judgment based on experience and anecdotal evidence to recommend HS products due to the lack of credible evidence associated with them (Kanjanaarach et al., 2006, Brown et al., 2008, Hanna and Hughes, 2012, Rutter and Wadesango, 2014). Also, American Cancer Society has commented that people's belief on health supplement is based on anecdotal evidence, evidence that based on personal experiences or opinions rather than controlled research studies (American Cancer Society, 2015). This is not surprising as various studies revealing that respondents always referred to friends and family members as their source of recommendation and information on HS used (MacLennan et al., 2002, Evans et al., 2007, Levine et al., 2009, Awad and Al-Shaye, 2014).

1.3 Definition

Literature search figured out that HS is evaluated under the term of complementary medicines (CMs), complementary and alternative medicine (CAM) or natural health products (NHPs) by other researchers (Naidu et al., 2005, Braun et al., 2010a, Culverhouse and Wohlmuth, 2012, Awad and Al-Shaye, 2014, Kheir et al., 2014, Singh et al., 2004).

The definition of CAM has been subjected to great debate. It was a collection of different approaches to diagnosis and treatment (Barnes, 2003a). CAM often referred to “complementary, “alternative”, “integrative”, “unorthodox”, “unconventional”, “unproven”, “natural”, “traditional”, and “holistic” medicine (Wootton and Sparber, 2003, Kotsirilos, 2005). It was forms of “*treatment which are not widely used by the conventional healthcare professions, and the skills of which are not taught as part of the undergraduate curriculum of conventional medical courses*”(Kotsirilos, 2005).

In the USA, CAM was defined by NCCIH as “*a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine*”(Ventola, 2010a). There were differing in classification of various CAM therapies and products according to different countries. For example, USA NCCIH further divided CAM into five forms (Ventola, 2010a):

- i. Whole medical systems such as homeopathy, naturopathy, traditional Chinese medicine, and Ayurveda.
- ii. Mind-body medicine such as meditation, prayer, mental healing, art therapy, music therapy, and dance therapy.
- iii. Biologically based practices such as dietary supplements, herbal supplements, and scientifically unproven therapies such as shark cartilage.
- iv. Manipulative and body-based practices such as spinal manipulation (both chiropractic and osteopathic) and massage.
- v. Energy therapies such as qigong, reiki, therapeutic touch, and electromagnetic therapy.

Furthermore, Dietary Supplement Health and Education Act (DSHEA) 1994 were established in order:

- i. to ensure the continued consumer access to a wide variety of DS
- ii. to provide consumers with more information about the intended use of the DS (Dickinson, 2011)

Under the act, HS was defined as DS and DS is “*a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substances for use by man to supplement the diet by increasing to total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients*”. DS may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. DS not represented for use as a conventional food or as a sole item of a meal or the diet; and is labelled as a dietary supplement (Food and Drug Administration, 2015c).

In Canada, under the Natural Health Products Regulations (NHPR), which came into effect on January 1, 2004, natural health products (NHPs) are defined as (Health Canada, 2015a):

- i. Vitamins and minerals
- ii. Herbal remedies
- iii. Homeopathic medicines
- iv. Traditional medicines such as traditional Chinese medicines
- v. Probiotics
- vi. Other products like amino acids and essential fatty acids

In Australia, complementary medicines (also known as 'traditional' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy and homeopathic products. Complementary medicines may be either listed or registered, depending on their ingredients and the claims made (Therapeutic Goods Administration, 2015a).

In the UK, food supplements (FS) is defined as “*any food the purpose of which is to supplement the normal diet and a concentrated source of a vitamin, mineral or other substance with a nutritional or physiological effect, alone, or in combination, sold in dosage form*”(Department of Health United Kingdom, 2013)

Comparing classification between countries, HS is a subgroup from CAM fall under the umbrella of biologically based practices in USA, natural health products in Canada, complementary medicine in Australia and food supplements in the UK. Therefore, most common terminology observed from other countries as follows: dietary supplements (DS), herbal supplements, vitamins and minerals, and herbal remedies (Ventola, 2010a, Department of Health United Kingdom, 2013, Health Canada, 2015a, Therapeutic Goods Administration, 2015a).

In Malaysia, HS was enforced by the National Pharmaceutical Control Bureau (NPCB), which defined HS as: *“Product that are intended to supplement the diet taken by mouth in forms such as pills, capsules, tablets, liquids or powders and not represented as a conventional food or as a sole item of a meal or the diet”* (National Pharmaceutical Control Bureau, 2011). It may include ingredients such as vitamins, minerals, amino acids, fatty acids, probiotics, natural substances of plant/animals, and enzymes substances with nutritional or physiological function (National Pharmaceutical Control Bureau, 2015).

Based on a different definition as discussed, one can conclude that HS is not part of conventional medication or practices. HS purpose is to supplement the diet and not as a replacement for natural food for a balance diet.

For simple understanding, HS can be classified as below according to Pati K (Pati, 2007), as illustrated in Figure 1.1.

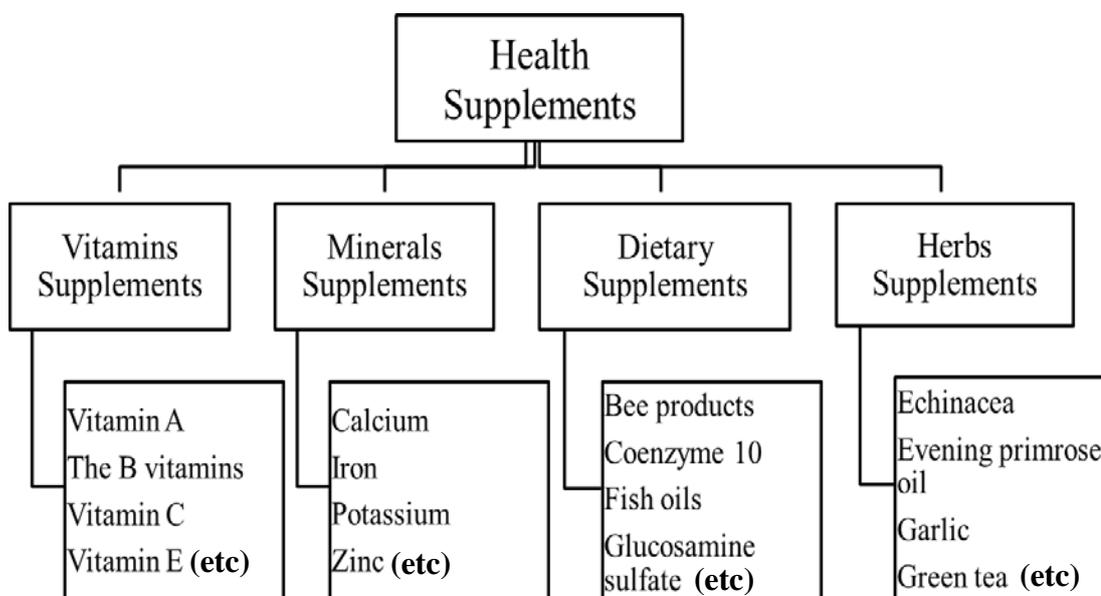


Figure 1.1 Common classifications of health supplements

For this study, we used definition created during the Malaysian Adult Nutrition Survey (MANS) conducted in 2003, which allowed the following definition:

HS in this study referred to non-prescribed, oral administrated biologically based therapies used by consumers to maintain or treat illness, which included:-

- i) Vitamin and mineral supplements (VM)
- ii) Non vitamin and non-mineral supplements (NVNM)

VM supplements were defined as mineral, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage form, such as sachets, capsules, liquids, lozenges, powders or tablets.

NVNM DS were defined as product with health claims that are made from natural food or food derivatives (for example western herbs, garlic and bee-pollen) (Ministry of Health Malaysia, 2003)

1.4 Health Supplements Legislative in Malaysia

In Malaysia, HS are regulated according to Control of Drugs and Cosmetics Regulations 1984 (CDCR), supported by the Sale of Drugs Act 1952, Medicines (Advertisement & Sale) Act 1956 and Drug Registration Guidance Document 2013 (DRGD). DRGD are administrated by the Drug Control Authority (DCA) of National Pharmaceutical Control Bureau (NPCB). DRGD serve as a reference guide help in product classification, product registration, application procedure, quality control, GMP licensing, labelling requirements, post marketing surveillance and pharmacovigilance activities (National Pharmaceutical Control Bureau, 2015). All HS products intended for sale in Malaysia must register with DCA using NPCB portal (online Quest 3 system) prior marketing. Unlike pharmaceutical drugs, no pre-market review of efficacy for HS. In this case, HS and natural products (traditional) are evaluated according to safety and quality criteria (Rajagopal, 2011).

Similar to pharmaceutical drugs, HS and natural products will be assigned a 13 digit MAL number (MALYYMM\$\$\$\$@##) once registered with DCA, which must be displayed on the label. MAL is refers to Malaysia, YYMM represented year and month of registered, \$\$\$\$ is serial numbers of the product being registered, @ refers to product category code and ## is an administrative code used by NPCB. Therefore, HS was given product category code of N and T for natural products (National

Pharmaceutical Control Bureau, 2015). Claims for the prevention and treatment of disease states are prohibited. However, certain functional claims (claims that describe the physiological role of nutrient in normal body function) were allowed on the label (Rajagopal, 2011, National Pharmaceutical Control Bureau, 2015). Whereas, natural products are required to briefly explain the recommended usage of the product, which started with the phrase “Traditionally used for...” (National Pharmaceutical Control Bureau, 2015).

1.5 Current Community Pharmacy Practice in Malaysia

A CP is an expert in providing pharmaceutical care, pharmacotherapy and health promotion to the community they served. Their professional role included providing good quality of products, advice on health and drugs; and communication to the patients or other health care providers (International Pharmaceutical Federation) (FIP). CPs also refer patients to other sources of help and healthcare providers when necessary (Kelly, 2007).

In Malaysia, CP are part of a private healthcare system providing services such as consultations and dispensing of prescription medications, over-the-counter medications as well as HS (Hassali et al., 2014). In the current practice, private general practitioners served the rights for one stop prescribing and dispensing medication from their clinics. Under the limitation of dispensing chance, the role of CP is not maximizing in the delivering of pharmaceutical care (Wong, 2001, Anonymous, 2008, Hassali et al., 2014). In 2001, it was reported that many CP do not even receive one prescription in a single day (Wong, 2001).

In 2007, after six years of the previous study, an observational study on the utilisation of CP by the general public revealed that community pharmacy received only an average of 1.6 prescriptions per pharmacy per day. Moreover, 65.6% and 93.4% of the counselling services provided in community pharmacy related to HS (Chua et al., 2013, Ooi, 2015). The amount of prescription filled by CP in Malaysian study is far lower compared to 880 prescriptions per week in Australia (Benrimoj and Roberts, 2005). Hence, CP in Malaysia plays an important role in educating consumers on HS since HS and herbal consultation (87.8%) are the most expecting pharmacy services by their customers (Bahari and Yip, 2010).

Another challenge faced by the community pharmacy in Malaysia is the price war issue. Price war mainly due to no standardized recommended retail price for prescription medication sold in community pharmacy and unethical pharmaceutical company tends to set different bonus scheme for different professionals for the sale of prescription medication (Hassali et al., 2010b, Hassali et al., 2013b, Hassali et al., 2014). The huge medicine price competition among community pharmacy contributed to the sales of various over-the-counter products such as HS in order to gain profit margin for the survival in the business (Hassali et al., 2013a, Hassali et al., 2013b). Additionally, chain-store pharmacy needs to offer a proportion of non-professional services and activities alongside the traditional professional services (Wong, 2001). Non-professional services can be defined as “selling of goods between vendor and purchaser for non-health related products” (Davies et al., 2014).

1.6 Problem Statement

The HS intake in Malaysia is prevalent. Results based on three nationwide studies, namely Malaysian Adults Nutrition Survey 2003 (MANS), National Survey on the Use of Medicines 2008 and 2012 (NSUM) indicated consumer use of HS of 48.7%, 43.2% and 62.3% respectively (Ministry of Health Malaysia, 2003, Ministry of Health Malaysia, 2008, Ministry of Health Malaysia, 2012). Since there is an uncertainty of safety and efficacy on HS, consumers were at potential health risk of supplements overdose, drug-supplements interactions and unwanted side effect. Despite high levels of consumption in developed countries, many studies revealed that CP do not have confidence in counselling their customers of issue of HS (Dolder et al., 2003, Bushett et al., 2011). This was mainly due to the lack of scientific evidence behind the perceived therapeutic benefit, lack of knowledge on HS and lack of reliable information resources on HS (Koh et al., 2003, Welna et al., 2003, Brown et al., 2005, Semple et al., 2006, Tran et al., 2013).

1.7 Research Questions

This study being carried out with the intention to investigate the current situation on HS in Malaysia which came out with the following research questions:

- i. What is the prevalence of over-the-counter HS consumption?
- ii. What is the belief of CP with regards to over-the-counter HS?
- iii. How does a CP perceive their knowledge on over-the-counter HS?
- iv. What is current practice in the community pharmacy setting pertaining dispensing on over-the-counter HS?
- v. What is consumer attitude with regards to over-the-counter HS?
- vi. What is a consumer source of knowledge on over-the-counter HS?

1.8 Research Objective

This study aims to evaluate the CP knowledge of HS and their practices in the area of HS dispensing and to identify and describe the prevalence and attitudes of non-clinically proven HS used among consumers in various socio-demographic groups with regards to health issues and maintenance. Specifically, the objectives of the study were further divided into four main items as stated below:

- i. To assess the CP perceptions of non-clinically proven HS
- ii. To explore the CP practices in the area of non-clinically proven HS
- iii. To evaluate the consumers' perceptions of non-clinically proven HS
- iv. To ascertain the consumers' trend of using non-clinically proven HS

1.9 Overview of Thesis

Chapter 2, Literature review begins with discussion on overall review of current trends regarding global regulatory and market of HS. This chapter ended with the review of safety issues, CP and consumer's perceptions on HS.

Chapter 3 briefly outlined general methodology for qualitative and quantitative approaches. This section provided introduction on study design, sampling method and data analysis for both approaches in general. Subsequently, described the selection of method and ethical approval for present study.

Chapter 4 reported results from the findings of Phase I qualitative interview with 12 CP and 12 consumers the state of Penang, Malaysia with regards to their personal view towards HS usage. Findings from Phase I study will provide a baseline data for in-depth study in the Phase II using quantitative method.

Chapter 5 described findings from Phase II (a) quantitative study. This stage comprises a larger sample quantity of respondents from the CP group. The results revealed the demographic characteristic, perceptions of HS, CP knowledge and practice in the area of HS.

Chapter 6 reported results from Phase II (b) quantitative survey. This section discussed the outcome of consumer's perceptions on HS, their demographic characteristic and information sources regarding HS.

Chapter 7 presents the general conclusion of discussions in Chapter 4, 5 and 6. Finally, recommendations for future research were provided in the thesis.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

As discussed in Chapter 1, global prevalence of health supplement (HS) continues with to the rise, although its theory of evidence based still under scepticism. This chapter will further discuss topic on HS, related to current issues happening around the globe and additionally provided a deep understanding regarding community pharmacist's (CP) and consumer's perceptions and knowledge towards the use of HS.

The chapter begin with review on current regulatory trends for HS with discussion on international policies on HS and health claims. This session continues with an explanation on pattern of HS including current market trends as well as intake in both developed and developing countries. Furthermore, there is a review to rise up concern on quality and safety issues such as interactions with prescribed medications, potential side effects, toxicities and possibilities excessive intake of HS in the population with the intention to highlight the risk associated with misuse and overuse of HS. Finally, this chapter ended with literature review on an accessible relevant article on CP and consumers survey with regards to perceptions and knowledge towards the use of HS.

The aim of this chapter is to provide comprehensive background information to guide on the research objectives and research questions as in Chapter 1, in which the outcomes of the study will be detailed in Chapter 4, 5 and 6.

2.2.1 International health supplements policy

In Australia, HS are referred to CM, are regulated under the Therapeutic Goods Act 1989, supported by Therapeutic Goods Regulations and Australian Guidelines for Complementary Medicines 2011 (ARGCM), which is administrated by the Therapeutic Goods Administration (TGA) in Department of Health Australia. All CMs must be registered or listed with the Australian Register of Therapeutic Goods (ARTG) before they can be marketed depending on their ingredients and the claims made:

- i) Registered medicines - which assessed by the TGA for quality, safety and efficacy of the product. For example: all prescription medicines, most over the counter (OTC) medicines and some CM were registered under this category.
- ii) Listed medicines - containing pre-approved ingredient permitted for use in listed medicines, low-risk ingredients and that make limited claims, which assessed by the TGA for quality and safety but not efficacy. For example: some OTC medicines and most of CM were listed.

Each “Listed CM” product will be assigned a unique AUST L number once registered with ARTG, which must be displayed on the medicine label. Health claims requirement is in accordance to Part 2 Appendix 6 Therapeutic Goods Advertising Code 2007 (TGAC), where diseases, conditions, ailments and defeats for which the advertising of serious form is restricted (Therapeutic Goods Administration, 2015b).

In Canada, HS are referred to NHP, are regulated under Natural Health Products Regulations 2004 (NHPR), which is administrated by Natural and Non-prescription Health Products Directorate (NNHPD). Health Canada applied risk-based assessment approach to evaluate quality, safety and efficacy of NHPs. Under such approach, products or ingredients were categorized into three levels of risk, namely low level, medium level and high level risk. All NHPs must register with Health Canada prior marketing and were assigned an 8-digit Natural Product Number (NPN) which displayed on the label. Health Canada prohibits the advertising and labelling of natural health products, for the treatment, prevention or cure of the diseases, disorders, or abnormal physical states listed on Schedule A (Food and Drugs Act 1985) (Health Canada, 2015b).

In the United Kingdom (UK), HS is referred to food supplements (FS), is regulated according to EU Food Supplements Directive 2002/46 2005 and implemented by the Food Supplements (England) Regulations 2003, supported by Food Safety Act 1990, Food Labelling Regulations 1996 and the Trade Descriptions Act 1968 in which are administrated by the Department of Health United Kingdom (DH). Unlike Australia and Canada, it is depending on how a HS is classified it and subject to different regulation in the UK.

Vitamins and mineral supplements were regulated according to the Food Supplements (England) Regulations 2003, DS is regulated under Food Safety Act 1990, and herbs supplements considered as medicinal products were regulated under Traditional Herbal Medicines Directive (THMR) which is administrated by the

Medicines and Healthcare Regulatory Agency (MHRA) (National Health Services of England, 2011). The Trade Descriptions Act 1968, The Food Safety Act 1990, The Food Labelling Regulations 1996 and Joint Health Claims Initiative (JHCI) 2007 is responsible to oversee the HS market to ensure descriptions of goods, labelling requirements and health claims on the HS is legally accepted and not misleading (Webb, 2006a, Legislation of United Kingdom, 2015a, Legislation of United Kingdom, 2015b, Legislation of United Kingdom, 2015c). Overall, in the UK, FS is not required to demonstrate their efficacy before marketing. It is the responsibility of the manufacturer, importer or distributor to ensure that their product complies with the necessary legislation (2015).

In the USA, HS is referred to DS, are regulated under Dietary Supplement Health and Education Act 1994 (DSHEA), which administrated by the USA Food and Drug Administration (FDA). Under DHSEA, DS are regulated as foods rather than medicinal products by the FDA, each DS must have nutrition labelling of “Supplement Facts” panel, which identify the dietary ingredient in the product (Food and Drug Administration, 2015a). There is no pre-market review of quality, safety and efficacy for DS in the USA, with the exceptions given to “new dietary ingredient (NDI)” (a dietary ingredient in DS that sold in the USA after 15 October 1994), where pre-market review for safety is needed. It is the responsibility of the manufacturer for the overall safety and labelling of the products. Whereas, FDA is responsible to monitor the safety and appropriateness in labelling after products reached the market (such as potential unsafe or misleading claims). Thus, manufacturers do not have to get FDA approval to market their products (Webb,

2006a, Food and Drug Administration, 2015a). Conclusively, DS is considered safe until FDA has proven evidence that such products can cause harm to the public.

USA Nutrition Labelling and Education Act 1990 (NLEA) have permitted certain well-supported “health claims” in food labelling (Dickinson, 2011). Commonly, there are four types of label claims allowed on the DS label, namely nutritional claims, claims of wellbeing, structure/function claims, and health claims. Except “health claims”, these claims do not require FDA’s pre-approval (American Cancer Society, 2015). However, when making structure and function claims, disclaimers such as “This statement is not been evaluated by the FDA” and “This product is not intended to diagnose, treat, cure or prevent any disease” is required under DSHEA (Food and Drug Administration, 2015a).

According to USFDA regulations Title 21 CFR Part 101.14 (a) (1), health claims means *“any claim made on the label or in labelling of a food, including a DS, that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition”* (Food and Drug Administration, 2014). The FDA must review scientific supported documents and pre-approve of all health claims (disease reduction claims) of DS prior enter the market (American

Cancer Society, 2015). FDA has established quality standards involving the manufacturer, quality control, packaging, labelling, and distribution of DS, in which all must comply with the Dietary Supplements Good Manufacturing Practices (CGMPs). In addition, several other independent organizations such as USA Pharmacopeia, ConsumerLab.com and NSF International implemented quality testing on DS to help ensure their quality standards. Products that passed quality testing may display their seals of approval on the label. However, this shall not be the guarantee of safety and efficacy (Office of Dietary Supplements, 2011).

As a conclusion, HS was classified as low risk non-prescriptions OTC products. They were regulated as drugs within Australian and Canada; regulated as food under the USA and UK legislative. Except the USA, all products intended to market as HS need to be registered. In Australia and Canada, the manufacturer is required to demonstrate product efficacy before product reach consumers whereas in the USA and UK, there is no such strict requirements. Claims associated with treatment or prevention of disease are not permitted when a product marketed as HS.

2.3 Current Trend of Health Supplements

In this section, explanation of the market of HS, trend of intake in both developed and developing nations, the reason associated with HS intake will be discussed.

2.3.1 The growing market of health supplements

Dispensing of pharmaceutical products can be a good earning as approximately 30% of gross income of most community pharmacy came from sales of non-prescription medicine including HS (Chapman and Braun, 2011). Consumer annum expenditure on the HS is in increasing trend where in Australia, AU\$360 million in 1992/93, AU\$621 million in 1996 and as high as AU\$4.13 billion was spent annually on the purchase of HS (MacLennan et al., 1996, Xue et al., 2007). In the USA, the amount was much higher in which USD\$21.2 billion spent in 1997 (Eisenberg et al., 1998), USD\$22.0 billion spent in self-care products and USD 14.8 million for NVNM/natural products in 2007 (Nahin et al., 2009) and USD\$30.0 billion in the annual sales of HS was reported in 2011 (Owens et al., 2014). In Malaysia, the estimated value of OTC products, therefore was subject to a 70% rise from USD\$393 million to USD\$557 million in 2015 (Business Monitor International, 2011). HS represent a substantial, growing industry with manufacturing jobs and export potential in Asia. Industry revenue is currently AU\$3.5 billion and is expected to grow to AU\$4.6 billion in 2017–18. Over this period, employment is anticipated to rise to 45,000 (National Institute of Complementary Medicine, 2015).