REGULATING THE HEALTH SUPPLEMENT INDUSTRY DURING THE SPREAD OF COVID 19: LEARNING FROM OTHER JURISDICTIONS

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ABSTRACT:

Consumers during this spread of the COVID-19 pandemic continue to believe in the concept of 'prevention is better than cure'. However, the preventive measure adopted varies from the traditional method where the latter resort to consuming healthy food in its original form and the earlier consumes so called healthy supplementary products that has intervention of new technology. Consumers lose clarity in understanding the method, composition, and components of health supplement items as the supplements sector expands with new inventions and advances in technology. This is made worse by deceiving marketing strategies adopted by the producer. The bold act of the producer in claiming that their product may cure serious diseases is not only unethical, but it is also a crime. Government of different jurisdictions adopts various monitoring measure to protect the rights of the consumer. In addressing this issue, this study aims at analysing the legal framework in selected jurisdictions that includes Singapore, Australia and United States of America with a view of identifying the best practices and proposing an effective legal framework. The study uses qualitative methods incorporating critical analysis on the legal framework of the selected jurisdiction. The area that is analysed consist of the accepted definition (to date this has become the main issue in regulating supplementary products), the registration process, the governing authority, and the post-registration monitoring. The analysis of data gathered through qualitative methods entails content analysis, which is supplemented by semi-structured interviews with respondents who were purposefully chosen. The findings to the study disclose the strength and weaknesses of the Malaysian legal framework that can be remedied by learning from the selected jurisdiction method. The output of this study may assist the government, policymaker, industry players and the consumer in reforming the protection of consumers to the supplementary products.

KEYWORDS: *Supplementary products; consumer protection, Monitoring of supplementary product, Malaysia legal framework on supplementary product*

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1.0 INTRODUCTION

In combatting the spread of COVID-19 pandemic, world population continue to believe in the concept of 'prevention is better than cure' (Boindala & Lewis, 2019; Jones et al., 2021; Loo et al., 2020). Boindala & Lewis (2019) highlighted that the consumer resorted to health supplement as they acknowledged the objective of producing health supplement is to substitute the source of nutrients and vitamins to keep them nourished and healthy, thus helping to shield the attack of COVID-19. According to the study, consumers who are more concerned with their health are more likely to use supplements since they are associated with preventive health habits. (Willis & Stafford, 2016). Many people prefer herbal remedies over pharmaceutical alternatives because they believe the latter are ineffective or dangerous. (Morehead & McInnis, 2020). Loo et al. (2020) certifies that

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there is an increase in consumption of health supplement among Malaysian consumers. With the increased in demand, the health supplements industry expanded and introduce new innovations with the aid of advanced technology (Dewita et al., 2020; Jairoun et al., 2020; Jones et al., 2021). As a result, the production process, composition, and components of health supplement products have become more complex. It has been disclosed (Ismail et al., 2020; Kamangar & Emadi, 2012; Kuanysh, 2019; Jones et al., 2021) that the new innovations of health supplement product are susceptible to side effects that requires the interference of the law. In hope and prayers for us to surviving the COVID-19 attack, we need to avoid other health complications due to consuming harmful health supplementary products. The increase in number of people infected with the COVID-19 virus move alongside with many promotions and sale of health supplement products. This is made worse by deceiving marketing strategies adopted by the producer (E.Ulate, 2015; Klepacz, 2015). The bold act of the producer in claiming that their product may cure serious diseases is not only unethical, but it is also a crime. Some studies highlighted on the difficulties in governing health supplementary product due to its non-uniformed definition that leads to the non-effective monitoring and control system (Bhavani et al., 2020; Boindala & Lewis, 2019; Dwyer et al., 2018; Ismail et al., 2020). Other than definition issues, these studies, Bhavani et al. (2020) also concur that in different district there are no uniform regulatory requirements. Most of the countries have put the trust in the growth of the supplement industry in order to ensure the safety and health of their citizens and the government across all jurisdictions actively commit to introducing certain rules and regulations governing this industry as dietary supplements have come under fire for their lack of regulation and dubious claims (Bhavani et al., 2020; Kamangar & Emadi, 2012; Mohamed Ansari & Omar, 2017; Willis & Stafford, 2016).This scenario has become a global issue, experienced by many countries. Government of different jurisdiction adopts various monitoring measure to protect the rights of the consumer. This study aims at analysing the legal framework in selected jurisdictions which includes Singapore, Australia and United States of America in learning the best practices and proposing a functional legal framework.

2.0 METHODOLOGY

The study uses qualitative methods incorporating critical analysis on the legal framework of the selected jurisdiction. The area that is analysed consist of the accepted definition (to date this has become main issue in regulating supplementary products), the registration process, the governing authority and the post-registration monitoring. The analysis of data obtained through the qualitative method includes content analysis, which is supported by semi-structured interviews with respondents chosen using a purposive approach.

3.0 RESULTS AND DISCUSSION

The findings to this study uncover some similar challenges face by the government of the selected jurisdiction on monitoring and controlling the health supplement industry. The findings are summarised in sub-topics that includes definition issue where there is no clear definition and categorization of health supplement product, overlapping jurisdiction of laws and regulatory body, ineffective registration process and challenges during the post-marketing surveillance. The summary of the findings is described through tables and diagrams.

3.1 Definitional Issues

When it comes to discussing the law of dietary supplements, the fundamental difficulty is that there is no specific worldwide consensus in detailing the

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types of product referred to in various countries as dietary supplements, natural health products (NHPs), complementary medicines, or food supplements should be defined. (Dwyer et al., 2018). For example, while melatonin is regulated as a prescription medicine in Australia, it is considered as a dietary supplement in the United States and as a natural health product in Canada which shows the disparity between jurisdictions. Another example, for dehydroepiandrosterone (DHEA), it is widely available as a dietary supplement in the United States, however in some jurisdictions, it is regulated as a controlled substance and is subject to extensive supervision of regulations. (Brown, 2017) distinguish between common types of dietary supplements such as vitamins, specialty supplementation such as herbal or botanical products, and sports supplements. (Thelen, 2015) According to this study, aphrodisiac goods, sports performance products and weight loss products are some of the categories of supplements that commonly connects to medical issues. The following are the discussion on definitional challenge of the selected jurisdictions.

Dietary supplement products in Malaysia are not explicitly defined as food or medications, and some of these goods are not properly characterized as food or drugs. (N., Abdul Aziz et al., 2020; N.,Abdul Aziz et.al., 2019). These products, which include a variety of ostensibly health products, are referred to as food-drug interaction (FDI) products. In 2000, the National Pharmaceutical Regulatory Agency (NPRA) and the Ministry of Health's Food Safety and Quality Division (FSQD) established the Committee for the Classification of Food-Drug Interphase Products. The committee's primary mission is to give guidance for the relevant sectors in order classify dietary supplement products that are not precisely characterize as foods or drugs. (N.,Abdul Aziz et al., 2020). Table 1 elaborate the category of food-based and drug-based dietary supplement product.

While therapeutic goods under the Therapeutic Act 1989 in Australia are defined as dietary supplement products, dietary supplement products that have therapeutic purposes, or for use as ingredients or components in the manufacture of therapeutic goods such as bandages, pregnancy testing kits, herbal remedies, and paracetamol, are products covered by the term. (Thakkar et al., 2020). Therapeutic use is defined in the Act as usage in or in conjunction with diagnosing, preventing, treating, or mitigating a disease or affliction, among other things. Fourteen years after Malaysia, Australia has taken the similar step by introducing “Food-Medicine Interface Guidance Tool” in August 2014. This is to aid manufacturers and importers in determining whether their products will be controlled as therapeutic goods or as foods, as well as to enable customers to determine whether the products they are using are appropriately classed and regulated. (Thakkar et al., 2020). Therapeutic goods, such as medicinal drugs, are regulated at the federal level by TGA, although foods with health claims are primarily regulated by territorial food control authorities and regulatory organizations.

The United States of America (U.S) has had in place a specific law regulating dietary supplement when in 1994, the United States Congress passed the Dietary Supplement Health and Education Act (DSHEA). Under the U.S Food Drug Control Authority (FDCA), foods, pharmaceutical, and food additives were regulated variously. DSHEA refers "dietary supplement" to a product consumed orally which contains a dietary or some nutrient element intended to augment the diet. (Boindala & Lewis (2019) DSHEA is likely the first Act that considers supplements to be foods, despite the

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fact that they are promoted in formats normally associated with medicinal products, such as pills, tablets, or capsules. Dietary supplements are controlled under the wide category of food rather than pharmaceuticals, according to the DSHEA. Before DSHEA was established, dietary supplements were described as vitamins and minerals mainly for supplementing the diet, however the definition gets wider by including herbal remedies and botanicals medicine.

In Singapore, products relating to health which are derived from nature are known as natural health products and are defined broadly into three groups: first, alternative medicines, which consist of traditional medicines and homeopathic medicines as defined in the Exemption Order. Second, Chinese proprietary medicines, as defined in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order and thirdly, Health Supplements, which are defined under the Health Sciences Authority (HSA) Health Supplements Guidelines as products that are used to supplement a diet, with benefits beyond those of normal nutrients, or to support or maintain the healthy functions of the human body. To be classified as a health/dietary supplement, a product must contain at least one of the following ingredients: vitamins, minerals, or amino acids (natural or synthetic); and substances derived from natural sources, such as non-human, animal, or botanical materials in the form of extracts, isolates, or concentrates. Additionally, a dietary supplement must be administered in small unit quantities via capsules, soft gels, tablets, liquids, or syrups.

Table 1: Definitional Issues

Country	Definitions	Drug / Medicine category	Food category
Australia	✸ Therapeutic Goods Regulations 1990 - "a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14". ✸ TGA released "Food-Medicine Interface Guidance Tool"	TGA regulates therapeutic goods, including medicinal products, on a federal level.	Foods with health claims are primarily regulated by the territorial food control authorities and regulatory bodies.
United States of America	The word "dietary supplement" as used in the DSHEA refers to a product taken orally that contains a dietary element intended to augment the diet.		Dietary supplements are controlled under the wide category of food rather than drugs, according to the DSHEA.
Singapore	Health supplements fall under the scope of "complementary health products" (CHP). The Complementary Health Products (CHP) Classification Tool helps in determination of appropriate category.	1. Chinese proprietary medicines, as defined in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order. 2. Alternative medicines, which consist of traditional medicines and homeopathic medicines as defined in the Exemption Order. 3. Health Supplements, which are defined under the Health Sciences Authority	

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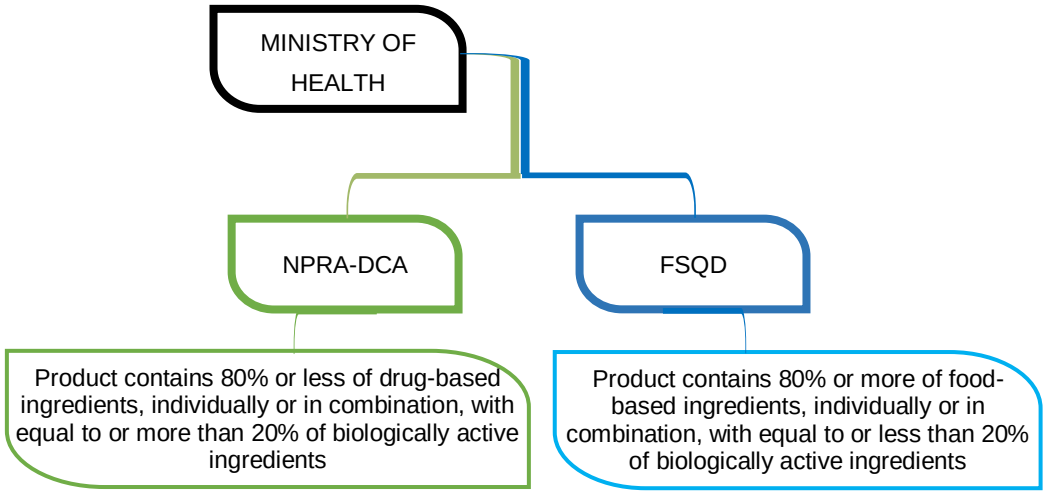
		(HSA) Health Supplements Guidelines as products that are used to supplement a diet.	
Malaysia	✸ Dietary supplement products are not defined in any way including "food" and "drog". ✸ Both NPRA and FSQD have formed the Committee for the Classification of Food-Drug Interphase Products in 2000.	NPRA classified a product as pharmaceutical product if the ingredients are : * > 80% Food based; and * < 20 % active substances. Tongkat ali, pegaga powder, and other herbal goods are examples of items that include only natural elements that are not usually consumed as food but have medical potential.	FSQD will be in control for food product that has ingredients: * 80% or more food based substance; and * separately or in combination with equal or > 20% biologically active elements. For example minerals.

3.2 Regulatory Control

According to the definition of a dietary supplement product in Malaysia, the rules that govern them are divided into two categories: drug-based products and food-based products (Refer Diagram 1). All drugs-based health supplements must be registered (CDCR, 1984) before they can be made, sold, supplied, imported, possessed, or given in Malaysia, according to the Control of Drugs and Cosmetic Regulations 1984 (Revised 2009) (CDCR, 1984). Only local distribution companies are allowed to submit a drug-based product registration application under the law. As a result, foreign enterprises without a Malaysian presence must appoint a Marketing Authorization Holder (MAH) as their local agent. According to Regulation 7(1)(a) of the CDCR (1984), MAH is responsible for the application of the product as well as the quality, safety, and effectiveness of the product.

NPRA revised the Drug Registration Guidance Documents (DRGD) in June 2014 and made an amendment requiring the declaration of the raw source of animal-derived ingredients either it is active or excipient substance on the labelling of all registered drugs. This has benefited in ensuring the halal status of dietary/health supplement products that carry a halal certification. (N.,Abdul Aziz et al., 2020). Other than the registration, licensing and labelling requirement, the government also monitor and control the health supplement product by way of batch-marking and product bans. During the pre-marketing time, batch marking is performed, and it has capabilities that also assist in the monitoring of post-marketing operations. Defective health supplement products can be tracked down and recalled or refunded using batch marking. In contrast, product bans are a mechanism that allows the authority to take immediate action to restrict the promotion and sale of a health supplement goods that has been found to be defective and potentially harmful to consumers. (N.,Abdul Aziz, 2017). The main legislation regulating food-based supplement are the Food Act 1983 and Food Regulation 1985. Food processing and serving facilities are inspected on a regular basis, and food samples are collected for microbiological, chemical, and physical testing.

Diagram 1: Malaysia: Categorization issue and the regulatory agency



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The Therapeutic Goods Act 1989 governs the regulation of items containing components such as herbs, vitamins, minerals, and nutritional supplements in Australia, which are classified as medicines. The Federal government of Australia did not assume responsibility for the enforcement of health supplements until 1991, when the Therapeutic Goods Act 1989 came into effect. In addition, dietary supplements were governed prior to 1991 to conform with food requirements according to the laws of individual states and territories (Brownie, 2005) . The regulatory body that is responsible in the assessment and monitoring of health supplement activities in Australia is the Therapeutic Goods Administration (TGA), a Division of the Australian Department of Health established under the Therapeutic Goods Act 1989 (Pinder & Ghosh, 2019). TGA aims to set up a nationwide control system for therapeutic goods in use in Australia, whether produced in Australia or elsewhere, or sourced from elsewhere.(Archer et al., 2013). Within the authority of the TGA, the legitimate supply of any therapeutic good in Australia requires that the product to be included in the Australian Register of Therapeutic Goods (ARTG). A three-tiered risk-based framework (Pinder & Ghosh, 2019) is introduced in order to balance regulatory efforts with customer safety. In Australia, three different types of complementary medicines are now available to consumers via the ARTG (Australian Register of Therapeutic Goods) entries. (Refer Diagram 2.) Each type of nutritional supplement is characterized according to the types of ingredients it contains and by the therapeutic indications (health benefits claimed) that it uses.

For registered goods, the registration requires a thorough evaluation of the consistency, protection and effectiveness of products on the basis of controlled clinical trials or other well-accepted sources.(Archer et al., 2013). However, for listed goods, the listing is afforded to medicinal products that are deemed to be less harmful and used for self-treatment by individuals (Pinder & Ghosh, 2019; Davey, 1997). Listing requires a low-cost approach to gauge the therapeutic goods' efficiency, protection, appearance, manufacturing process, and equivalency with standards. The third and most recent process for sponsors to submit specified complementary medications to the ARTG has been adopted. Pre-market and pre-approval medicines are evaluated by the TGA for efficacy and safety, and must adhere to TGA-compliant standards (Pinder & Ghosh, 2019). This is a great path for medications whose efficacy is evaluated as "intermediate-level". The TGA shall decide whether the products are suitable for listing and assessed

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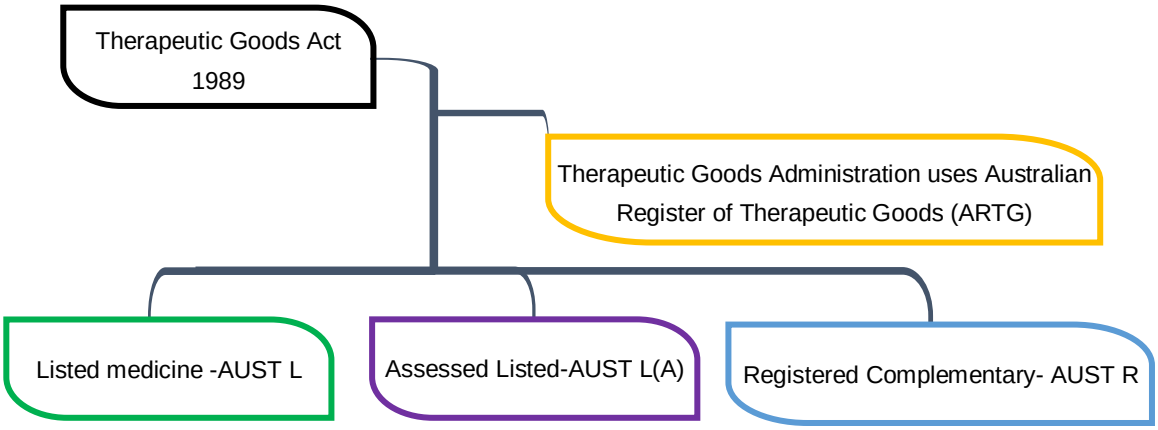
listing and require for registration. It is not permissible for manufacturers to state or imply in their advertisements or promotional materials for their therapeutic products that inclusion in the ARTG is a recommendation or endorsement by the Therapeutic Goods Administration.

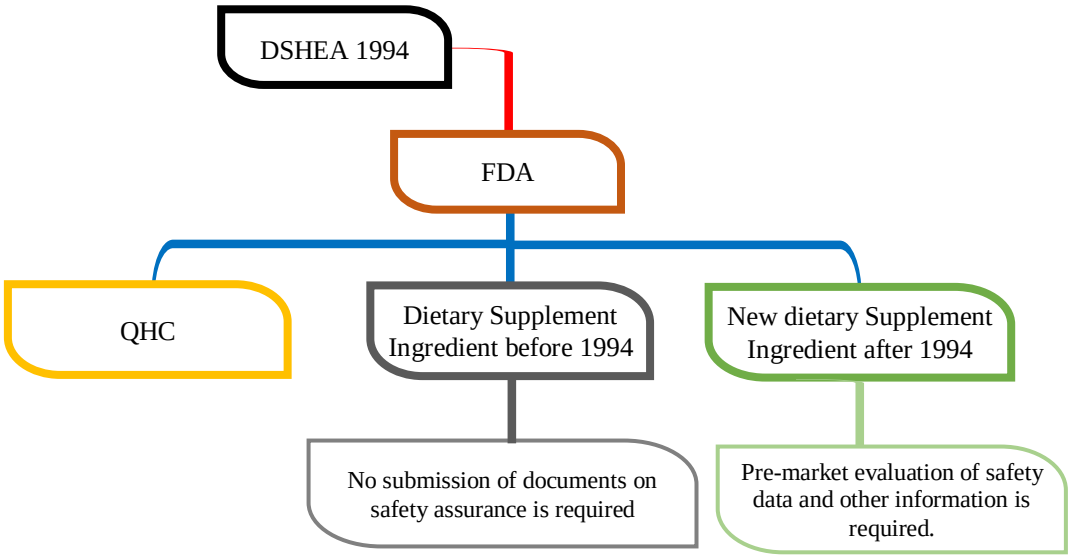
Diagram 2: Australia: Categorization of complementary medicine and regulatory framework



In the United States, the Federal government regulates marketed food and drug products that are sold in interstate commerce (U.S. Food and Drug Administration Dietary Supplements, 2017). The Food and Drug Administration (FDA), established in 1995, is part of the implementation of the Dietary Supplement and Health Education Act of 1994 (DSHEA), and the Office of Dietary Supplement (ODS) is the lead federal agency devoted to the scientific research of dietary supplements. Dietary supplements were regulated just like other foods prior to the enactment of DSHEA. Later, the (DSHEA) was passed, amending the Federal Food, Drug, and Cosmetic Act and establishing a new regulatory framework for the safety and labelling of dietary supplements. (Hill, 2006).

DSHEA gives companies that make or distribute dietary supplements primary responsibility for determining the safety of their products, and ensuring that any representations or claims they make about them are supported by evidence especially in proving that the claim are not false or misleading. (Hill, 2006). This means that dietary supplements do not require FDA approval before being marketed, (E.Ulate, 2015) with the exception of new dietary ingredients, which are subject to pre-market assessment for safety data and other information. The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994. (See section 413(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 350b (d)).The Food and Drug Administration (FDA) also regulates qualified health claims (QHCs) for voluntary use by companies on food and dietary supplement labels (.U.S. Food and Drug Administration Dietary Supplements, 2017). QHCs convey scientific certainty regarding diet-disease links that aren't backed up by substantial scientific consensus among certified specialists. These allegations stem from a federal case that found QHCs to be a violation of the First Amendment. (Berhaupt & Amanda, F.,2016).

Diagram 3: U.S Regulatory Framework for Dietary supplement.



Like Malaysia, dietary/health supplement products in Singapore are governed by two authoritative bodies namely Health Supplement Authority (HAS) and Singapore Food Agency (SFA). The HSA is responsible for natural health products (under the Medicines Act and related legislation), while the Sale of Food Act and Food Regulations govern food-based products. The SFA provides a Food-Health Product Classification to determine whether a natural health product comes within the 'food' category or otherwise. The HSA provides a guideline on health claims in the form of a Health Supplement Claims guideline which specifies what claims are allowed and what claims are prohibited in detail. A claim is an expression on a product by means of a statement or representation. (Gaw, 2020; HSA List of Supplement Claims, 2019). It is in the strict rules governing advertising, labelling, and promotion of health supplements that no therapeutic claims can be made.

According to Seah & Chan (2020), health supplements products would be subject to the laws applicable for advertisements and promotion of products namely the Consumer Protection (Fair Trading) Act (Cap. 52A) (CPFTA). Section 4 of the CPFTA establishes the primary prohibition against marketers advertising or promoting consumer products. The prohibition is that a Marketer cannot engage in any "unfair practice" when promoting or advertising their product. An "unfair practice" is one in which the Marketer does or says something, or fails to do or say something, that reasonably deceives or misleads a consumer; makes a false claim; or engages in any prohibited act listed in the CPFTA's Second Schedule.

Table 2: Laws and Regulatory Agency

Country	Laws	Related Monitoring action	Regulatory Agency
Australia	✸ Therapeutic Goods Act (TGA) 1989. ✸ Therapeutic Goods Regulations 1990.	Food-Medicine Interface Guidance Tool to characterize a product.	✸ The Therapeutic Goods Administration (TGA) regulates therapeutic goods (including medicine) at the federal level. Food (food with a health claim) is mostly governed by state authorities and regulatory bodies that oversee food in a certain

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			territory.
United States of America	✸ Dietary Supplement Health and Education Act (DSHEA) 1994. ✸ Natural Health Products Regulations 2005. ✸ The US Food and Drug Administration (FDA) regulate and authors qualified health claims (QHCs) for voluntary use by companies on food and dietary supplement labels.	-	-
Singapore	a. Medicines Act (Chapter 176) & subsidiary law b. Medicines (Advertisement & Sale) Act (Chapter 177) c. Sale of Drugs Act (Chapter 282) & its Regulations especially: d. Poisons Act (Chapter 234) & Poisons Rules.	Except for products categorized as medical or quasi-medicinal, health supplement advertisements and promotions are not subject to permit approval.The HSA also provides a platform where the public can report any adverse events of medicinal products.	✸ The Health Sciences Authority (HSA), a government agency that monitors pharmaceuticals, complementary medicines, medical devices, and other health products. ✸ The Singapore Food Agency (SFA) monitors the food based supplement.
Malaysia	✸ The Food Act 1983 & regulations ✸ Drug Registration Guidance Documents, 2017 ✸ Sale of Drugs Act 1952 ✸ Control of Drugs and Cosmetics Regulations 1984 ✸ Dangerous Drugs Act 1952 ✸ Poisons Act 1952 ✸ Medicines (Advertisement & Sale) Act 1956	-	✸ The National Pharmaceutical Regulatory Agency (NPRA). ✸ The Food Safety and Quality Division (FSQD), ✸ Both NPRA and FSQD is the regulatory agency under the Ministry of Health Malaysia.

3.3 Post-Marketing Surveillance

If a health supplement product is registered with the National Pharmaceuticals Regulatory Authority (NPRA) in Malaysia, the product will be regularly monitored by the NPRA through post-marketing surveillance operations, which include continuous examination of the labels and packaging. One of the major post-marketing controls are to monitor the continuous compliance to the formulation, production process and business particulars that have been declared in the documents submitted during registration. Although there are strict control of safety, efficacy, and quality during the pre-marketing stage, yet the trend (NPRA Annual Report, 2014) shows an increase in the numbers of unsafe drug-based products in the market. Most of the abuse is on the illegal variation done on the formulation of registered drug-based products. The manufacturer is responsible for all products placed on the market during the lifetime of a drug-based product. If there are any amendments made to the product, the product registration holder must comply with the Malaysian Variation Guidelines for Pharmaceutical Product 2013 and the amendments must be approved by National Pharmaceutical Regulatory Agency (NPRA).

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The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) provide information on the regulation of complementary medicines in Australia for manufacturers, sponsors, general public and the healthcare professionals. This includes the guidance on post market regulatory activity of complementary medicines through therapeutic product vigilance activities. Manufacturers of therapeutic goods are routinely inspected to ensure they adhere to good manufacturing practices. (GMP) (Pinder & Ghosh, 2019). The Therapeutic Goods Act (TGA) monitors complementary medicines by firstly, by pre-market assessment on the therapeutic goods followed by the post market monitoring and enforcements of standards of the goods and finally, investigating Australian manufacturer licenses and ensuring that international manufacturers adhere to the same requirements as their Australian competitors. The TGA adopts an attitude of risk control for the regulation of the therapeutic goods (Brownie, 2005; Pinder & Ghosh, 2019; Thakkar et al., 2020).

In the United States, the DSHEA states that once a product is on the market, the FDA must prove that it is "unsafe" before taking steps to restrict or remove it from the market.(Hill, 2006). Manufacturers and distributors of dietary supplements, on the other hand, are required to keep track of, investigate, and report any major negative effects related with the use of their products to the FDA. These reports, as well as any other reports made directly by healthcare providers or consumers, can be used by the FDA to detect early warning signs that a product may pose a risk to consumers' safety. The FDA can recall a dietary supplement if it has been determined to pose a significant risk of illness or harm. Because the FDA bears the burden of proof, it must gather adequate evidence that a supplement is hazardous before taking action such as recalling it (i.e., prohibiting its sale). The FDA can only withdraw dietary supplements from the market when customers have had negative experiences with them and the FDA has been able to produce adequate evidence that the negative experiences were caused by the supplement. (Dodge, 2016).

In Singapore, HSA will conduct post-market surveillance on health supplements to ensure the safety of these products and to rapidly recall products that have been recalled. In this approach, samples of items on the market are chosen at random and a monitoring system is set up to pick up on early signs of product failure. A proven dangerous product will be removed from the market.

Conclusion

The findings of this study disclose the fundamental challenges in all jurisdictions to regulate dietary supplements which include, the absence of a global standardised definition on the term "dietary/health supplements, natural health products (NHPs), complementary medicines, or food supplements". This is an apt suggestion for the relevant sectors to take action at international or at least regional level. As the industry rapidly grows during the spread of this pandemic, sales and marketing activities are not confined to domestic market, but it thrives in the global market. Another challenge is that the health supplement products are subject to diverging views. While some argue that these products should be treated similarly to conventional pharmaceuticals and foods, others argue that a more personalized way is required because they typically have a traditional or historical evidentiary foundation and often contain many substances. We can see that Singapore has rather a comprehensive regulatory framework relating to advertisements and marketing of health supplements. The framework provided by the HAS and the Singaporean

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government in general can be something to be benchmarked and emulate by other jurisdictions.

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