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Comparison Study of Western Medical service versus Eastern medical service:

Trade Barriers on Traditional Chinese Medicine in Europe

유럽에 있는 중국의학의 무역장벽 연구

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서울대학교 국제대학원

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Comparison Study of Western Medical service versus Eastern medical service:

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A thesis submitted by

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지도교수 안 덕 근

이 논문을 국제학석사학위논문으로 제출함

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Abstract

Traditional Chinese Medicine (TCM) has been a significant symbol in China. TCM takes on a –holistic approach when compared to Western Medicine, with elements of culture and history deeply rooted in the medicine. TCM has been practiced for centuries, and has recently started to gain popularity in the West, especially in Europe. It has established a good foundation in Europe, which became a catalyst for improving standardization, research and regulation. Despite the rising popularity, TCM is currently facing many difficult challenges in Europe. For example, exporting TCM to Europe became more difficult after the European Union (EU) Directive of 2004/24/EC, which made TCM registration the largest obstacle for entry into Europe. Moreover, there are trade barriers prevalent in the areas of; safety, registration, and labeling. This paper examines the trade barriers of TCM market occupied in Europe, followed by an analysis of such barriers from a legal perspective. The paper concludes with recommendations to lower the trade barriers, by suggesting improvement of standardization, in addition to proposing possible amendments in the Japan-EU Mutual Recognition Agreement.

Keywords: Traditional Chinese Medicine (TCM), Europe, EU Directive of 2004/24/EC, Trade Barriers

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I. Introduction

With thousands of years of practice and development, Traditional Chinese Medicine (hereinafter "TCM") has set significant achievement in the world. As one of the unique symbols in China, TCM represents a prominent advantage of lifestyle within the Chinese healthcare system. As TCM grew in demand, it had also gained a reputable recognition within the Western countries. TCM established a solid foundation in Europe, after the Chinese adopted to implement policy reforms. Hence, the awareness for TCM grew in European countries, which resulted in an increase consumption of TCM products, that helped to push through opportunities. However, despite the rising popularity, TCM posed a great threat to the TCM industry in Europe.

TCM is facing many challenges in the international market. When compared to the Western medicine, TCM promotes holistic approach of thinking. It relies on traditional knowledge and old secret ingredients[1]. Compared to the Western medicine which uses advanced technology and good quality control, TCM lacks in both categories. Not only that, there are other obstacles TCM is currently facing in Europe. For instance, one of the

[1] World Health Organization. (n.d.). *Traditional Chinese Medicine Could Make "Health for One" Tru* . Retrieved January 4, 2018, from http://www.who.int/intellectualproperty/studies/Jia.pdf

largest obstacle of TCM is registration.[2] According to the EU Directive of 2004/24/EC, it made TCM harder to enter into the European market. Furthermore, TCM entering into Europe as either food or food supplements, are confronted with issues of intellectual property rights that are of a high concern for the Chinese government.

However, a few years ago, the World Trade Organization (WTO) held a conference in Shanghai on 11 September 2015, to discuss the current status of TCM. The conference was titled "WTO and health: The Law and Policy of Traditional Chinese Medicine", with the agenda primarily focusing on the latest progress in the WTO negotiations, such as public health issues, internationalization of traditional Chinese medicine, legal protection especially intellectual property protection of traditional Chinese medicine, and standardization of traditional Chinese medicine. The conference marked the significance of TCM in international trade.

This paper examines the trade barriers of TCM in Europe. The author will probe into legal perspective under the WTO and the EU law. In terms of the WTO, it will focus primarily on the technical barriers of trade (TBT), and for the EU law, it will focus on the EU regulatory regimes for TCM. Before going into the legal analysis, the author will

[2] Liu, Y. (n.d.). Barriers and countermeasures in developing traditional Chinese medicine in Europe. *Frontiers of Medicine, 10*(3), 363. Retrieved January 4, 2018, from http://libproxy.snu.ac.kr/a64da1d/_Lib_Proxy_Url_Https/link.springer.com/article/10.1007/s11684-016-0455-x

carefully explain the history behind the revolution of TCM as well as its current status in regards to its position in the international market.

Against this backdrop, the paper will move onto discussing the importance of the EU market for TCM, its current developmental status as well as future opportunities and challenges. This is followed by a legal analysis examining the compatibility of TCM under the EU law, and how such legal framework is restricting of TCM export to Europe. In such manner, an examination of TCM under WTO rules will also be discussed from the WTO legal perspective.

Finally, the author proposes its recommendation for the future of TCM in Europe. One of the recommendations is promoting education and standardization of TCM. Despite the popularity of TCM in Europe, there are lack of awareness on the importance of TCM amongst many European citizens. Therefore, both China and the EU are in need of serious consideration and acknowledgement in the importance of healthcare sector.

II. Background

1. Explanation of the Traditional Chinese Medicine

TCM is a traditional style medicine built on the foundation of more than 3,000 years of Chinese medicine practices.[3] TCM encompasses different practices, including acupuncture, herbal medicine, Chinese therapeutic massage (tui na), dietary therapy and tai chi and qi gong (practices that combines specific movements or postures, coordinated breathing, and mental focus).[4] TCM is based on holistic medical approach and is rooted in the ancient philosophy of Taoism. Practicing Traditional Medicine also exists in other South East Asian countries.

The Yellow Emperor is one of the first ancient texts that provides evidence of TCM in China.[5] The ancient text holds fundamental principles of TCM, as well as other practices

[3] Switzerland, World Health Organization. (n.d.). *WHO Traditional Medicine Strategy 2014-2023*. Retrieved October 4, 2017.
[4]Ibid.
[5] Yang, E. S. (2011). Ancient Chinese medicine and mechanistic evidence of acupuncture physiology. p.631.

including, herbal medicine and acupuncture. Many written records of the Chinese TCM practices are found in the medical history, as well as the treatments of diseases and Traditional Chinese Medicinal Products (hereinafter "TCMP").

According to the World Health Organization (hereinafter "WHO"), TCM is defined as "[T]he sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health… as well as to prevent, diagnose, improve or treat physical and mental illnesses."

The WHO description of TCM is well - defined and it covers the unique features and perspectives of TCM.[6] The WHO also acknowledged the positive contribution TCM has on economic development and healthcare.

In 1983, the WHO held a conference in the Philippines to integrate traditional medicine into primary healthcare.[7] There were several TCM scholars and practitioners to discuss the future of TCM. In 1991, representatives from over forty countries and government officials, joined in Beijing to discuss TCM status in the international community and how it can be incorporated into the Western medicine.[8]

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[6] Ibid.
[7] World Health Organization. (n.d.). *WHO Traditional Medicine Strategy 2002–2005*.
[8] Ibid.

It helped to modernize the traditional medicines, including TCM in the world. TCM has spread over 180 countries and regions. And in China, more than half still use the TCM. According to the statistics, there are roughly around 100,000 TCM clinics in the world, not including China, and more than 500,000 medical professionals have received TCM training.[9]

2. Comparison of Western Medicine and Traditional Chinese Medicine

Western Medicine (hereinafter "WM") is the predominant practice in today's health medical service known for its effectiveness and performance. However, after China introduced TCM to the world, both WM and TCM have been utilized to treat the patients. WM and TCM have the same objectives. Both disciplines practice different methods to cure the disease or treat the patients. Furthermore, the various aspects of medical side effect have been claimed to come from both practices.[10]

For instance, Surgery is essential tool for Western medicine but it might lead to someone's death. Much similarly, acupuncture can also lead to cause major pain or even death. In

[9] Ibid., p.362.
[10] Huang, N. (n.d.). Utilization of Western Medicine and Traditional Chinese Medicine Services by Physicians and Their Relatives: The Role of Training Background. (Accessed November 4, 2017).

TCM, herbal medicine can cause serious side effects. For example, common herbal medicine such as green tea extract and comfrey tea can cause damage to liver. Some common Western medicine cause nausea, or an upset stomach.

Major differences of WM and TCM can also be found in their philosophy.[11] Western medicine use modern pathology, physiology, microbiology and pharmacology knowledge to study human disease, which proceeds from macro to micro research. Although its history is not long, the theory updates quickly. On the other hand, TCM use the theory of Ying and Yang and five elements of the human body, on the basis that when the entire system is in balance, optimal health occurs.[12] Disease occurs when there are difficulties to the flow of Qi or imbalance of Ying and Yang. Despite the long history, TCM theory has seen little or no change for centuries. When compared to WM, it also lacks in scientific evidence.

Based upon different theories and practices WM and TCM is disparate. WM looks at the data of natural liquids and tissues to contrast and the ordinary range in order to evaluate which parts of the body is harmed. WM prescription uses superior technology to check the internal organs. For instance, specialists utilize X-ray to look at the chest to

[11] Ibid.
[12] Ibid.
[13] Ibid., p.365

decide the ailment of the lung.[13] Conversely, TCM use clinical perception to discover the internal sicknesses. TCM specialists ordinarily utilize "Wang, Wen, Wen, Qie", which implies looking, tuning in, noticing (the primary Wen contains two implications), asking and touching. Looking consists of remarks of patients' faces, tongues, standard bodily proportions and secretions consisting of urine and vomit. Touching is the most vital technique of the TCM. Physicians contact pulses to sense their frequencies electricity, that are related to Qi, to diagnose the sickness.[14] On the contrary, WM examines the data of physical fluids and tissues to compare with the regular range to estimate which elements of the body has damaged.

The aims of TCM and WM is to cure patients, even though they have side effects. While, TCM is a method utilizing "Wang,Wen, Qie" in view of guideline of Ying and Yang.[15] WM is reliant on scientific innovations such as high tech machines and the results of scientific clinical trials.

3. Current Development of TCM in the US

[14] Ibid., p.621
[15] Ibid.

TCM has gained consumer recognition in the United States in the last 30 years, when former president Nixon's third exchange delegation to China covered the subject of herbal pharmacology, and many Americans became familiar with herbal medicine and acupuncture.[16] One of the reasons for Americans to welcome TCM into the American society, was that there were many Americans who were not completely satisfied with Western Medicine, due to the high cost of healthcare and lack of government aids. Also, the many variant side effects from prescribed drugs gave a negative impression to avoid Western medicine. Thus, an opportunity for TCM to enter into the American society approached, with the impression that the home remedies and herbal medicines are safer and cheaper than Western medicine. The TCM herbal medicine in the US have been prepared as capsules, tablets and other forms for consumers to consume.[17]

A Food and Drug Administration (hereinafter "FDA") report in 1999, shows the growth of dietary supplements sales in different cities in the United States, with details of its growth in sales from $3.3 billion to $6.5 billion between 1990 and 1996.[18] According

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[16] Liu, W. I., & Lu, D. P. (2013). Impact of Chinese Herbal Medicine on American Society and Health Care System: Perspective and Concern. *Evidence-Based Complementary and Alternative Medicine, 2014*, 1-6. (Accessed December 14, 2017).

[17] Ibid.

[18] Li, W. (n.d.). Botanical Drugs: A Future for Herbal Medicine. Retrieved January 4, 2018.

[19] Cline, R. J. "Consumer health information seeking on the Internet: the state of the art." Health Education Research. (Accessed January 04, 2018).

to A Reuters Health Information article in 1999, it shows that 40%[19] of US citizens say that they used some form of alternative medicine in 1997, with US spending more than $21.2 billion on alternative medicine practitioners.[20] Despite the growing demand for TCM products in the US, concerns of market access into the US from the Chinese medicine exporters came to the attention.

In the US, Chinese pharmaceutical industry is not regulated and therefore, differs significantly from state to state.[21] Since each state doesn't have a regulatory regime on TCM, there have been many cases of factories that produce counterfeit or unregulated drugs. Due to the highly unregulated domestic products in the US, production standards could not meet the consumers' standards. According to the US. and Foreign Commerce Service (hereinafter "USFCS") report, only 18 of 4000 pharmaceutical factories met the Good Manufacturing Practice standards.[22] Another concern regarding TCM in the US market, is found in the act of US pharmaceutical companies counterfeiting or misbranding the TCM under the US laws. However, needleless to say, the demand for alternative medicine and oriental health products continued to grow.

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[20] Ibid.
[21] Ibid.
[22] Ibid., p.782.

TCM therefore became critical to the US economy. The growing demand for TCM as well as its dietary supplement industry in the US has grown too big and politically important to be ignored.

4. Current Development of TCM in Europe

The increased acceptance towards TCM in developed nations, has helped to grow the demand for TCM in the international market. The European Union (hereinafter "EU") is the world's largest importer of TCM products, especially herbal ingredients. EU takes more than 40% of the botanical medicine in the global market.[23]

According to the WTO's data which shows the findings of the 129 countries, 80% of them now recognize the use of acupuncture.[24] To enhance and practice TCM, the EU member states have developed regulations on the quality, quantity, accreditation and education structures for T&CM (refer to Traditional medicine and complementary medicine).

[23] Ibid.
[24] World Health Organization. WHO traditional medicine strategy 2002–2005. Geneva, 2002 (WHO/EDM/TRM/2002.1)

Lately, TCM has been ascending in the European market. TCM clinics and practitioners can be found in various locations. Currently, about 20,000 TCM practitioners[25] are in Switzerland and over 3,000 TCM clinics[26] are located in Britain. Compared to other European Countries, Netherland has flexible market environment for TCM. According to statistics, there are roughly around 1600 TCM clinics and 15% of patients like to visit TCM practitioners.[27]

TCM and TCMP has been accessible across Europe. Unlike the Western medicine, TCM can be used as an alternative medicine, which can help to cure chronic diseases or other serious conditions.

In spite of a rapid development, TCM has been facing barriers to enter into the European market. Only few European countries are dealing with standardization of TCM, the market access, and the registration difficulties. Herbal Medicine and Acupuncture has gained a legal status in European countries and has been incorporated into the medical insurance system of some of the EU nations. However, TCM is considered alternative medicine or therapy in most cases within the EU. This is due to the apparent lack of government involvement that provides little or no basis for TCM to be regulated in medical facilities. As such, currently there are only 2 approved TCM products in Europe.

[25] World Health Organization. WHO medicines strategy 2004–2007. Geneva, 2004 (WHO/EDM/2004.5)
[26] Ibid.
[27] Ibid.

Until 30 April 2004, the EU regulatory system for TCM in the Europe was lenient and undemanding. Since each member of the EU had its own laws and regulations for medicinal products, there were no distinct EU regulatory regimes applicable to TCM. However, the following portion of this paper will look more closely into the TCM trade concern after the EU Directive of 2004.

III. EU Directive of 2004/24/EC and TCM Trade Concerns

1. EU Regulatory Regime

On 31 March 2004, EU Directive 2004/24/EC has been enacted by European Parliament and the Council of the EU. Directive 2004/24/EC is also known as Traditional Herbal Medicinal Products Directive (TCMP), and it intended to simplify a legal situation of TCM in European Countries. It provided a single framework for handling medicinal products. Under the directive, traditional herbal medicines products had to go through seven-year transitional period. The directive stipulates that, applicant must need to show evidence showing that TCM products is not harmful in the specified condition of use, as well as the evidence proving that the product had at least 30-year history of safe use, out of which 15 years are from the EU.

Since the implementation of the EU Directive, Chinese herbal medicine exports to EU has significantly declined. According to the China Chamber of Commerce for Import & Export of Medicines & Health Products, export values has increased by 6.4% in 2011 to US$ 13.32 million, but reduced by 22% in 2012 to US$ 10.34 million.[28] It fell by 5.85%

[28]China Chamber of Commerce for Import & Export of Medicines & Health Products. Statistical Data, Nov. 16, 2015. http://www. cccmhpie.org.cn/Pub/3317_List.shtml
[29]Ibid.
[30] Yan, Liu et al. (2015), *2014 Nian Zhongyao Shangpin Jin Chu Kou Fenxi [An Analysis on the*

annually in 2014[29] because of the low demand from the EU. Furthermore, one of the main TCM products Zhong Cheng Yao, had also experienced a decrease in export value of 6.25% on year-on-year from 2004 to 2015[30].

The EU Directive on traditional botanical medicine has restricted Chinese medicines to EU. Some of the EU countries demanded the Chinese medicine suppliers to create a registrations and certifications procedures. Chinese patent medicines and Chinese medicine has strictly regulated by the EU directive and it has prevented entry into the EU market. TCM suppliers shared concerns about the unseen implications EU directive has on the categorization of TCM as food or food supplement but not as medicine or drugs.

1.1 TCM AS 'FOOD'

TCM is still not legislatively protected and its medical framework is still having difficulties getting approved by EU countries. Most of the TCM products can be marketed as food or food supplements in the EU, and it created major obstacles for Chinese TCM

Export and Import of Traditional Chinese Medicinal Product 2014], 17(3) (Accessed December 2017).

producers and TCM domestic market. Such as in Germany, TCM can only be sold in Western pharmacies.

The EU General Food Law accounts for 'all stages of the production, processing and distribution of food', and defines 'food' as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" and includes 'drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation and treatment'.[31] According to the Council Directives 65/65/EEC and 92/73 /EEC medicinal products is not included. However, TCM herbal medicines like *Lycium barbarum* (Gouqi), which can be used both as food or medicine, it has been defined as 'food'. Another popular TCM product named, *Six Ingredient Rehmania Pills* (Liuwei Dihuang Pills) and *Bak Foong Pills* (Wuji Baifeng Pills), have also been registered in the EU market as 'food'. Hence, the TCM products categorized as 'food' have alerted concerns and discouragement to the Chinese medicine industry and the TCM exporters.

1-2. TCM AS 'FOOD SUPPLEMENT'

[31] EU General Principle of Food Law

Another possible categorization of TCM is that of food supplement. In EU, food supplement is regulated by the EU Directive. The food supplement directive define food supplement as follows:

> "Foodstuff the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients and other substances with a nutritional or physiological effect, alone or in combination, marketed in does form, namely forms such as capsules, pastilles,
> tablets, pills or similar forms, sachets of powder, ampoules of liquids
> , drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

According to its definition, TCM products that are identified as 'food supplements' needs to be in a pre-packaged form, before its delivered to a consumer. Nevertheless, popular TCM products such as *Six Ingredient Rehmannia Pills* (Liuwei Dihuang Wan), have been marketed as a food supplement in the EU however sold in pills. Nevertheless, it still bears

the same restrictions applied to products under the category marked as ‘food’. Similarly, there are TCM products that are covered by the Directive categorized and sold as ‘food supplement’. The fundamental issue for TCM products labeled as ‘food supplement’ therefore, is found in the inability to make any medical claims on the basis of its medical merits, which defeats the purpose of promoting the benefits of TCM.

1-3. TCM AS ‘MEDICAL DEVICE’

Another way to categorize TCM is as a ‘medical device’. The legal structure of this Directive can be found in Council Directive 93/42/EEC, under the article ‘medical devices and their accessories’. As evidently shows, the coverage of the article is limited and does not apply to ‘medicinal products’. According to Medical Devices Directive, it defines ‘medical device’ as the following:

> ‘Medical device’ means ‘any instrument, apparatus, appliance, software, material or other article intended by the manufacturer to be used by human beings for the purpose of:
> -diagnosis, prevention, monitoring, treatment or alleviation of disease,

-diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

-investigation, replacement or modification of the anatomy or of a physiological process,

-control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'

The last paragraph is indicative for vast majority of TCMs to be exclude from this particular EU directive.

The three-possible product category identified above, presented the difficulties of categorizing TCM products in the EU market. The stringent application of EU Directives on TCM and TCMP is giving unfavorable conditions to the future of TCM. It discourages the many TCM producers and TCM practitioners in the EU.

IV. Analysis of TCM's Trade Barriers

Thus, the TCM industry is currently facing major trade barriers due to the stringent EU regulatory regime on TCMs. Against this backdrop, the WTO is no exception to such strict rules and regulations. Trade barriers relating to TCMP can be explain by technical barriers to trade (hereinafter "TBT"), Sanitary and phytosanitary measures (hereinafter "SPS") and General Agreement on Trade and Service (hereinafter "GATS").[32] TBT and SPS illustrates the significance of the WTO in adopting technical barriers, which are applicable to the trade of TCMs in EU member states. TBT aims to ensure that technical regulations and standards are upheld appropriately without any unnecessary obstacles to trade. The author recognized the disadvantage of TCMs under the jurisdiction of simplified registration procedure prevalent in the EU Medicinal Products Regulation.

1. Simplified Registration Procedure

Simplified Registration Procedure is also called Traditional use registration.[33] It eliminates the need for costly clinical trials to prove the safety and efficacy for ingredients found in TCMP. Yet, the proof for safety and quality of the ingredients are still mandatory.

[32] Ibid
[33] EU Directive of 2001/83/EC Article 16a.

However, there are number of criteria for eligibility for simplified registration procedures, which created a major obstacle for TCMs to be registered in the EU. The following section examines this further through a case study, demonstrating the difficulties involved in market access of TCM P into the EU market.

2. First Approved TCM Drug in EU

On March 14, 2012, Di'ao Xin Xue Kang became the first approved TCM drug in the EU market. Di'ao Xin Xue Kang derives from the Japanese yam root and is used for the treatment of myocardial ischemia.

The product was developed by the Di'ao Pharmaceutical Group in Chengdu, China. The drug was granted registration from the Medicines Evaluation Board (hereinafter "MEB") of the Netherlands. According to MEB public assessment report, the applicant chose the simplified registration procedure to apply. By submitting the application as simplified procedure allowed for the registration of Di'ao Xin Xue Kang, which had been approved by the Netherlands without any proof of safety tests or clinical trials. Sufficient evidence from safety and clinical trials can be exempted, if the applicant can provide sufficient evidence of medicinal use of the product for at least "30 years prior

to the application for the EU market authorization, of which at least 15 years came from the EU."[34]

Another interesting point portrayed by this case, reveals that most TCM medicines are made out of compound formulas. However, the Di'ao Xin Xue Kang capsules contained only single components. Many other TCMP formulas are made up of compounds and thus creates technical difficulties for TCM companies to prove any scientific evidence or safety tests. To register in the EU, it requires clinical tests of ingredients to show the relationship between chemical and physical reactions. Thus, given the circumstances, it regrettably always falls into either a successful application or no application due to the high costs involved.

As mentioned above, Di'ao Xin Xue Kang was granted registration from the MEB of the Netherlands. In order to register in the EU market, the applicant must be of a registered EU company. In evaluating such requirement from the WTO perspective, the EU is in violation of the National Treatment, on the basis of protecting the rights of foreign and local goods. Moreover, the act of authorizing only the EU companies to register caused issues relating to discrimination in the TCMP market.

In terms of the implementation of the new EU directive for TCM, it is very difficult to satisfy the EU requirements. Hence, there are only two TCM drugs approved to date in the EU market.

[34] European Directive on Traditional Herbal Medicinal Products.

3. The Inconsistency of EU's Registration Procedure

On February 2015, Phynova became the second approved TCM drug in the EU market. Phynova Joint and Muscle Relief tablets are used for relief backache, minor sports injuries and general aches and pains in the muscle and joints. And is based on traditional use only. Phynova, a life sciences company based in Oxford, UK, collaborated with Xiangxue Pharmaceuticals Co, and file an application for registration with the Medicines and Healthcare products Regulatory Agency (hereinafter "MHRA"), for their second product, Isatis Cold and Flu Relief. What is interesting to note in this case is that, Phynova Isatis Cold and Flu Relief had not attained its traditional form, given the adaptation of the lemon-flavored powder in a sachet. As such, there have been inconsistent application of such regulations, most notably evident in the text of MHRA document. MHRA of Phynova Cold and Flu Relief Powder for Oral Solution states the following:

> "This registration is based exclusively upon the longstanding use of
> Isatis root as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the

> Traditional Herbal Registration Scheme to prove scientifically that a product works."

The statement of "longstanding use" can be regarded as a discrimination against other TCM herbal medicines. The history of TCM is over 2,500 years and it has been widely used since then. It is unfair treatment to other traditional herbal medicines that have failed to register in the EU market. From the WTO perspective, the National Treatment Principle can be applied in this condition. The EU Traditional Herbal Medicinal Product Directive was drafted on the basis of the MHRA, which eliminated many TCM medicines from being available for consumer in the EU Phynova's is not the first company that found the loophole in the MHRA rules. There has been another record of TCMP that was able to successfully registered in the EU under Traditional Herbal Remedies (hereinafter "THR"). Likewise, it is evident that the MHRA needs to provide more opportunities and be flexible to accommodate other TCM herbal medicines.

Phynova's Joint and Muscle Relief tablets contain an active ingredient called *Sigesbeckia*. Phynova Joint and Muscle Relief tablets were approved by MHRA, without the requirements to fulfill the proof of any safety and clinical trials. In this way, the registration was approved upon the basis of "longstanding use" of *Sigesbeckia*. In regards to the matter of safety concerns, MHRA noted "No new or unexpected safety concerns arose from this application". It clearly stated that, there is not going to be unexpected

safety issues by taking the tablets. However, on the Phynova Joint and Muscle Relief Tablets packaging, there is no sight of an explanation of side effects contained in the active ingredients. Sigesbeckia is a non-toxic herb which causes no apparent discomfort if it is taken orally in the conventional dose. However, overdose can cause adverse reactions like nausea and loose stool. According to the information on TCMs, patients diagnosed with deficiency of blood and Ying, should not take the Sigesbeckia. Phynova's claim to have no side effects in Phynova Joint and Muscle Relief Tablets however, as explained above, caution should be paid to individual patients and their dosage levels. Hence, these issues raise concerns for the EU member states as well as the consumers in the EU TBT aims to ensure technical regulations and standards, in a similar manner, the SPS focuses on protecting "human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages, or feedstuffs," as well as from "disease-carried by animals, plants or products thereof." It can be argued that EU traditional Chinese medicine directive is not consistent with its obligations under the SPS principle.

4. An Unnecessary TCM Registration Requirement of EU Directive of 2004/24/EC

The E.U Directive of 2004/24/EC changed the scene in the TCM industry. As noted above, the E.U directive made unnecessary obstacles for TCMP in the market. One of the most challenging requirements that an applicant had to fulfill for a TCMP product, was in providing a proof of the history of its longstanding use of the product. This is exemplified in the actual text of the EU directive, conveying the difficult process one has to satisfy in order to register in the EU market. The EU Directive of 2004/24/EC article 16(c) states:

> "bibliographical or expert evidence to the effect that the medicinal
> product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community."

Firstly, TCM has a history of more than 2,500 years. Its proven efficacy coupled with a growing demand from the West reveals otherwise. However, the phrase "at least 30 years" and "at least 15 years" is necessary to examine more closely from the WTO's perspective. TCM did not enter into the EU market until mid-1990s, and most of the TCM products to enter into market were as foods or food supplements. It is questionable of the EU

Directive's intensions to require TCMs to provide evidence of its longstanding use. To most of the Chinese producers and importers in the EU, bearing the proof of15-year use of their products is a serious challenge, because they did not reserve the customs papers. Several TCMP companies failed to register with their top products or sellers, due to lack of documents available to provide as evidence to prove safety, in addition to the high cost of testing the products. In saying that, by no means that the EU Directive is targeting TCM products per se, however it is damaging the TCM industry as a whole. It is creating unnecessary obstacles to TCMs in international trade.

EU and China are both members of the WTO and it is expected that trade is carried out under the jurisdiction of the WTO legal framework. The opening statement of the TBT Agreement, highlights the importance of fair trade in eliminating unnecessary obstacles. It reads:

> "however, to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade."

Then, is EU violating the TBT Agreement? The answer is probably no, since the TCM is not treated under the WTO legal framework. However, as seen in the TCM unfair treatment under the EU Directive, there are apparent evidences of unnecessary obstacles interfering with international trade of TCM products.[35] Article 12.3 of the TBT agreement also stresses the importance of deflecting unnecessary obstacles among members. It reads:

> "Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedure do not create unnecessary obstacles to exports from developing country Members."

Under the TBT Agreement, there should be no discrimination or unnecessary obstacles created for one another, which the WTO members are obliged to follow. The EU Directive have also set up such standards to register TCM medicines being imported into the EU, but it has proven to be very difficult to reach the standards, due to the lack of scientific evidence and clinical trials. Since the implementation of the EU Directive, TCM has been

[35] TBT Article Preamble

in a very tough situation. It resulted in the banning of thousands of TCM herbal medicines in the EU market with enormous loss of its reputation and spirit.

V. Recommendations

TCM exerts great influence in Europe and garners unprecedented attention from the international community. However, the huge cultural difference between Western and Eastern medicine, hampers the TCM development in Europe. Thus, the WTO has organized conferences to discuss opportunities and challenges for TCM in the WTO negotiations.

In addition to the work done by China and the E.U under WTO legal framework, achieving transparent communication is crucial to the development of TCM in EU. However, most European countries doesn't recognize TCM as a medicine, but as food or food supplements. Furthermore, some European countries does not allow TCM Therapists to treat the patients, since most of EU citizens don't recognize TCM practitioners as registered medical practitioners. These unfortunate situations have restricted and created trade barriers for TCMs in the EU.

The purpose of protecting TCMs in Europe, is not only to give more opportunities but to enhance cooperation amongst other countries. In order to do that, TCM must set up international standards in Europe to set a base in the market

1. Improve TCM standardization in EU – Establishing an International Standard for TCM

Hand in hand with its legacy of tradition and popularity, TCM has gained notable reputation in Western countries. Despite the growing demand in international market, TCM is still considered as an alternative supplement or dietary supplements in Western countries. Furthermore, there are no qualification standards for TCM practitioners to practice acupuncture or prescribe herbal medicine to patients. In order for TCM to survive in the EU market it needs build a practical and effective quality standard system.

Although TCM is widely used, it does not proceed through with any clinical trials or show scientific evidence before prescribed to patients. In order to make TCM globally acceptable, and to set certain standard for the EU consumers, it needs to adopt a scientific approach and claim the rightful health benefits of the TCMs. The reason for EU consumers dissatisfaction with TCM herbal medicine is due to the side effects that some Chinese herbal products tend to bring. And it can be contaminated with high toxicity, heavy metals as well as having unidentifiable ingredients that had not been listed. Therefore, to enhance the safety of TCMs, Chinese herbal medicine should incorporate Western standards as references of quality, such as embodying a scientific approach in quality control as well as the production process. Combining TCM and Western medicine will lead to TCMs to explore its own standards. Chinese and European government should establish a quality system universal in international standards. The international standards should be on the basis of current difficulties faced by TCMs in Europe and the its production. Since the

Chinese government does not have a set legal framework for traditional herbal medicine, the system can provide the entire process from the cultivation of herbal medicine ingredients, production, and processing from packaging to sale. According to the Medium & Long term Development Plan of TCM Standardization, China will focus on establishing a set of TCM standard systems, including basic standards, technical standards, and management standards. And it will also improve their communication with international organizations such as WHO and International Organization for Standardization (hereinafter "ISO"). It will ensure to set higher standards for consumers in the world and enhance further establishment of international standards.

To reach the standards of the EU consumers, it is critical to have consistent safety regulations on TCM herbal medicine. While some TCMs has been recognized to have toxicities and some side effects, the Chinese government should introduce regulations on the amount of heavy metals and pesticide acceptable during production stage of TCM. The Chinese government needs to sets high standards on herbal medicines by limiting harmful substances and toxic ingredients.

In order for TCMs to become globally renowned, an alternative approach is to make TCM into an evidence based medicine. As TCM is a practice - based medicine with a holistic approach, it is difficult to prove any sort of evidence. Currently, there are no shortage of clinical studies in TCM, there are around 436 trials on TCM and 607

acupuncture trials globally.[36] However, the issue persist in the lack of good quality evidence - based trials.

Evidence-based medicine is a combination of scientific evidence and results of statistical findings. It will provide information of the benefits, side effects in a scientific manner. The process of establishing evidence-based medicine, a well-designed, clinical trials is needed.

2. Amendment of FTA to Follow After EU-Japan Bilateral Agreement

The EU-Japan Mutual Recognition Agreement, put into force on 1 January 2002, focused in four product areas: telecommunications terminal equipment and radio equipment, electrical products, laboratory practices for chemicals and manufacturing practices for pharmaceutical.[37] The aim of the Mutual Recognition Agreement (hereinafter "MRA") was to facilitate market access and encourage international harmonization, while protecting consumer safety. Under the Sectoral Annex, the EU

[36] Ibid.
[37] EC – Japan Mutual Recognition Agreement (Sectoral Annex on Good Manufacturing Practice of Medicinal Products)

and Japan confirmed to work on Good Manufacturing Practice (hereinafter "GMP"), and discuss reduction of costs of the medicinal products in both parties, to facilitate further trade in the pharmaceutical sector.[38]

In contrast to the China-EU FTA, even though the TCM is one of the major trade concerns for both parties, it has never been addressed thoroughly. Currently, China doesn't have a good regulation on TCM and have no guidelines for quality control of the TCMs. However, the Chinese TCM exporters are concerned about the process of categorization of TCMs either as food or food supplements in Western countries. To improve standardization of TCMs in Western countries, it needs to have better transparency of TCMs and regulations to meet the needs of the consumer standard in both China and EU. The purpose of Sectoral Annex on GMP for medicinal products reads:

> "The term "Good Manufacturing Practice (GMP)" means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as

[38] The scope of medicinal products subject to the GMP Annex, based on the results of the preparatory work conducted jointed by the two parties.

required by the applicable marketing authorization or product specifications."

The Sectorial Annex clearly stated, the need for transparency, when authorizing medicinal products and quality control. It is also interesting that the term "medical products" is issued under the annex. TCM has the word "medicine" however, most of the TCM products are sold as food or food supplements. By having clear definition of the TCM, it will improve the international standard for TCM in the global market. Another advantage of implementing the Sectorial Review, is to ensure a better-quality control on TCM products. TCM in China does not have good quality control and are not regulated heavily. In china, Manufacturing process is poor, where there have been instances of some TCM products being contaminated with drugs, toxins or heavy metal. In the US, manufactures do not have the burden of proof to the FDA that most claims for TCM products are valid. However, if the products were a drug, they would have to provide proof. Applying Sectoral Annex on GMP for Medicinal Products won't solve the current obstacles of TCM in the EU market. Since the EU has a difficult regulatory hurdle for TCM products to be registered as medicine. But by applying the EU-Japan MRA Sectoral Annex on GMP, China-EU can also recognize the need for some sort of mechanism to enhance the status of TCM in the global market.

Therefore, EU-China FTA need to consider the importance of including TCM in their bilateral agreements, to further facilitate international trade. And implement EU-Japan FTA Sectorial Annex on GMP to improve free trade and standardization of TCM.

VI. Conclusion

This paper reviewed the TCM in Western culture, primarily focusing on the trade barriers of TCM in the EU, and its legal implications it had on the TCM market. The EU Directive of 2004/EC/24, unintentionally created many difficulties for TCMs registering in the EU, especially in satisfying the burden of providing proof of use, at least 30 years of use and 15 years in the EU. Also, different registration procedures made the process harder and more expensive for TCM producers. As a result of this, the new regulatory regime removed many over-the-counter drugs and TCM products that have failed to register in the EU.

Despite the rising demand of TCMs, the TCM industry is facing critical challenges in today's world. TCM doesn't have a reputable status in the Western society and emerging new drugs will make competition tougher. TCM practitioners and products need to accept the current obstacles and try to expand new footprints in the European market. In order to do that, China and the EU need to cooperate to discuss the future of TCM.

One approach is to improve standardization of TCM in the EU market. TCM in EU is sold as dietary supplement or food supplement. Consumers doesn't have a set standard whether TCM is medicine or a supplement. In order to improve standardization, it needs to go through clinical trials and switch to evident based medicine. Since many TCM

products are based on holistic approach and it doesn't have a clear evidence where the TCM recipes are came from. The second recommendation is to have China-EU FTA and implement Japan-EU MRA Sectoral Annex on GMP For Medicinal Products, to redefine TCM terminology. And by applying GMP, there will be better manufacturing process and quality control. Pending on the actions from China and EU, trade barriers of TCM may be lowered and with their combined efforts, TCM will bring about more trade opportunities in the future.

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Abstract (Korean)

국문초록

한의학은 중국에서 중요한 상징으로 자리 잡고 있다. 한의학은 전체론적 접근 방식에 의존하고 서양 의학과 비교하면 문화적 역량을 보여주고 있다. 또한 수세기 동안 연습 되어 왔으며 특히 유럽에서 관심을 얻기 시작했다. 한의학은 유럽에서 좋은 기반을 확립하였고 이것은 유럽에서 표준화, 연구 및 규제 개선의 촉매제가 되었다. 주목이 집중되는 와중에도 불구하고 한의학은 현재 유럽에서 많은 어려움에 직면해 있다. 예를 들어, 한의학 등록을 유럽 지출의 가장 큰 장애물로 삼은 유럽연합 2004/24/EC 의 지침에 따라 유럽으로의 한의학 수출은 더 어려워졌다. 현재 한의학은 안전 문제, 등록, 표시 등 여러 무역 장벽의 어려움을 겪고 있다. 이 논문은, 현재 유럽에 있는 한의학 시장의 무역 장벽을 법적 관점에서 분석하고 일본과 유럽연합의 상호인정협정 특징 도입이라는 방법과 개선된 평준화를 통하여 무역장벽 감소의 중요성을 시사한다.

주제어: 한의학, 유럽, 유럽연합 2004/24/EC, 무역장벽

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