WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

TAMA LAW: A Perspective Review on its Implementation in the Philippines

Bryan P. Labagnao, Dainnah Jericca D. Belbider, Eliza Dulce M. Fuentes, Euwan Miguel V. Manunod, Charisse Andrea A. Miclat, Rica Mae L. Regalado, Erwin M. Faller

Pharmacy Department, San Pedro College, Davao City, Philippines,8000
DOI: https://doi.org/10.55248/gengpi.2022.3.5.26

ABSTRACT

A law was passed in 1997 with the goal of enhancing the quality of medical services to the Filipinos by expanding and incorporating traditional and alternative health care into the national health care delivery system. The act is known as Republic Act No. 8423 or the "Traditional and Alternative Medicine Act (TAMA) of 1997." Over two decades old, the majority of the expected health benefits and policy implications of the act are still undefined. This perspective review aims to examine the progress of the act TAMA Law in the Philippines and identify the gaps and lapses with its implementation. In assessing the gathered literature about TAMA Law from various databases, it is organized based on Governance (Technical data for safety, legislation, administrative organization), Traditional Use and Scientific Validity, Human Resources (Education, Practitioners, Public Access to Information), Monitoring Process (Utilization, Provision, Quality Management, and Product Surveillance), and the tools for treatment (herbs, devices, medicine). Given the prevalence of traditional and alternative medicine in the Philippines, suggestions on stronger and more precise regulations for these products must be established to assure and guarantee the safety and efficiency of these products for consumers to have an additional source of health care.

Keywords: TAMA Law, Traditional and Alternative Medicine, Implementation

Introduction

TAMA (Traditional and Alternative Medicine Act) was passed in the Philippines in 1997 and is now over two decades old. However, most of the projected health benefits and policy effects are still unknown, according to Filipinos [1]. Because of the rapidly growing demand for traditional medicine, several governments have begun to include its regulation into their national policies. Traditional and complementary therapy are integrated into our country's health service under Republic Act No. 8423, "Traditional and Alternative Medicine Act (TAMA) of 1997." Even though the Philippine Institute of Traditional and Alternative Health Care (PITAHC), a primary government agency designed to promote complementary alternative therapy in the Philippines, the Food and Drug Administration (FDA) maintains regulatory authority over traditional medicine products [2].

The Philippines, being one of the countries with the most biologically diverse natural resources, has a strong stake in generating alternative treatments, particularly those produced from plants. The Food and Drug Administration (FDA) is the federal agency in charge of overseeing the manufacturing, marketing, and usage of several health products. Currently, the food supplement and herbal medicine industry may benefit from other countries that have well-developed regulatory systems for such items. More stringent government regulation is needed to handle the growth of unregistered items of varying quality in the interest of public safety. The ongoing movement among ASEAN countries to harmonize regulatory systems has increased this essential requirement. The Philippines should be able to offer local conference practices that encourage regional and national goals while also taking into account the interests of the traditional herbal sector and the Filipino people [3].

The World Health Organization defines complementary and alternative medicine as "a wide range of health-care therapies that are not part of the state's conventional or traditional medicine and are not completely integrated into the main health service."

Traditional and complementary therapies are used identically in certain localities. Traditional medicine has a rich history. It is the aggregate of all learnings, skills, and techniques based on concepts, values, and encounters unique towards other traditions, either intelligible or otherwise, that are employed in the management of health and reduce the risk, evaluation, and treatment of physical and mental disease [4].

The widespread use of traditional, complementary, and alternative medicine (TCAM) in the Philippines, including its provisioning of basic and secondary health care, indicates the sustainability of informal companies. According to the Department of Health, there is one TCAM health practitioner for every 300 Filipinos. The doctor-to-population ratio, on the other hand, ranges from 1 to over 26 000. The geographic distribution of physicians and health care institutions, as well as the ongoing mass emigration of professionals seeking greater wages and possibilities in other countries, make primary health care difficult. Because of their distinct historical and cultural heritage, the Philippines' uncomfortable cohabitation of biomedical and TCAM systems reflects the Filipinos' dual view of health based on scientific knowledge and holistic well-being. TCAM is defined by the World Health Organization (WHO) as a set of health techniques, understanding, and ideologies that include plant-based, animal-based, and mineral-

based medicines, spiritual therapies, manual methods, and strength training, all of which can be used alone or in combined effect to prevent, assess, and promote healing or retain health [1].

On the other hand, Western-based biological treatments are established on the germ theory of disease. Nonallopathic therapies are usually viewed with suspicion by Filipino health care practitioners. TCAM is sometimes compared to herb doctors (albularyos), therapeutic chiropractors (hilots), faith healers (espiritistas), and tribal mediums (shaman). Therein lies the source of conflict between two distinct health-care delivery paradigms [1]. Traditional medicine serves an alternative set of needs in wealthy countries. Individuals prefer more control over their health and choose natural products.

They use complementary and alternative medicine in a holistic approach to alleviate typical signs, enhance quality of life, and prevent illness and disease. Traditional medicine is an option provided by a well-functioning, people-centered, and integrated health system that balances therapeutic and preventive care in the best of all worlds [5].

Traditional medicine is considered to have existed in the Philippines for hundreds of years before the Spanish invasion. Traditional medicine is believed to have its origins in the practices of ethnocultural and indigenous Filipino people. The belief is that ethnic Chinese traditional medicine systems, local folklore, and experimentation with the use of medicinal resources have influenced the spectrum of traditional medicine in the Philippines. As a result of the long influence of Spanish colonization, the Philippines has integrated its ancestral beliefs with a modern Christian influence. Amulets were combined with prayers adapted from churches to ward off sickness, prevent natural calamities, and even protect against man-made conflict. Philippine faith healing, with its remarkable and controversial bare-handed, painless surgeries, is one of the most intriguing kinds of traditional medicine that has become a worldwide phenomenon (psychic surgery). The healers claim to operate on the patient's body, eliminating toxic blood and entrails, yet there is no evidence of a wound following the surgery. Skeptics have dismissed such instances as nothing more than a magician's sleight of hand, but local research suggests otherwise. Psychic surgery belongs to a realm of reality that isn't completely understood or acknowledged by modern science, but that does not mean it doesn't exist. Another Filipino healing technique is the recognition of energies emerging from the patient's body: when they are swept away by the hands, pain alleviation and even cure may occur [6].

The Philippine experience has yielded several policy lessons, insights, and conclusions, as well as an emphasis on the legal, theoretical, and philosophical components of public healthcare policy. The requirement for governments to make great health care inexpensive and accessible to the general populace underlines the importance of legislation, building consensus, innovations, and democratic will for TCAM to survive in developing nations in the long run.[1].

Methodology

This study reviews the implementation of the Philippines in approving the traditional but controversial practice and application of traditional, complementary, and alternative medicine (TCAM) over the past years. It does not generate hypotheses or compute statistical correlations but instead provides a detailed description of the situation and draws conclusions from the phenomena under consideration. This study is primarily based on a review of the literature [7].

The gathering of scholarly articles for reference was based on the databases such as Google Scholar, PubMed, and IJAR, searching terms like “TAMA Law in the Philippines,” “Traditional and Alternative Medicine in the Philippines,” and “TAMA law effectiveness in the Philippines” organizing the data in factors namely; Governance (Technical data for safety, legislation, administrative organization), Traditional Use and Scientific Validity, Human Resources (Education, Practitioners, Public Access to Information), Monitoring Process (Utilization, Provision, Quality Management, and Product Surveillance), and the tools for treatment (herbs, devices, medicine) [8].

The data used in the results and discussion of The TAMA LAW: A Perspective Review on its Implementation in the Philippines is organized into five categories specifically: Governance (Technical data for safety, legislation, administrative organization), Traditional Use and Scientific Validity, Human Resources (Education, Practitioners, Public Access to Information), Monitoring Process (Utilization, Provision, Quality Management, and Product Surveillance), and the tools for treatment (herbs, devices, medicine).

Governance (Technical data for safety, legislation, administrative organization):

The Philippines' traditional and alternative medicine legislation was passed into law, and it is already more than a decade old. However, most of the projected health advantages and policy results have yet to be observed, according to Filipinos. Traditional medicine (TM) is defined in the Philippines as the majority of knowledge in health care, expertise, and practice that people cannot precisely describe in a scientific approach. Still, its influence on sustaining health and quality of life has been acknowledged by society as reflecting their culture, origins, and social awareness. Traditional medicine is defined as follows: TheA variety of terminology is used, including homeopathic and/or natural remedies, herbal medicine (HM), traditionally used herbal products (TUHP), herbal supplements (HS), which include dietary supplements, and traditional herbal products (THP) (FS). regulatory rules in the Philippines are divided into categories based on the kind of product being regulated [8].

The Philippine Institute of Traditional and Alternative Health Care is a government-owned and controlled corporation affiliated with the Department of Health (DOH) that was established on December 7, 1997 by Republic Act No. 8423, also known as the Traditional and Alternative Medicine Act (TAMA) of 1997, which was authored by Senator Juan M. Flavier [10]. Moreover, legislation constituting the Philippine Institute of Traditional and Complementary Health Care was implemented. PITAHC is currently led by Director-General Annabelle Pabiona-De Guzman, MD, FPAFP, MHA, MA Med (UK), CESE, and is overseen by a Board of Trustees comprised of representatives from various government agencies, including the Department of

Science and Technology (DOST); Department of Environment and Natural Resources (DENR); Department of Agriculture (DA); Commission on Higher Education (CHED) and representatives from the following industries/sectors: a physician practicing Traditional and Complementary Medicine (T&CM); a member of a duly recognized academic institution engaged in T&CM research; a non-physician T&CM practitioner; a western physician, preferably a member of the Philippine Medical Association; one member from the natural food industry and one member from the environmental sector. The Secretary of Health presides over the board [9].

Traditional Use and Scientific Validity, Human Resources (Education, Practitioners, Public Access to Information)

For product registration, the Philippine FDA requires technical data safety and a manufacturer's Good Manufacturing Practice (GMP) certificate to assure the safety of TM and HS. Safety references are required for pre-marketing review. For TM, they may include monographs, pharmacopeias, and websites; for HS, they could include Physicians' Desk Reference, Codex, and websites. Toxicity screening is also required for premarketing approval. Registration of TUHP, on the other hand, requires the technical evidence for safety, including toxicity tests, must be submitted as well as a list of supporting references. However, there must be at least 5 decades of proven traditional usage experience. All of these products require the submission of technical data regarding efficacy or claimed usage in order to be registered. In the Philippines, pre-marketing review of TM and HS includes verification of raw material and end product effectiveness claims. TM should also go through clinical trials. Only a verification of raw material effectiveness claims is required for TUHP.

Relevant quality criteria as well as a GMP certificate should be submitted for product registration to guarantee the effectiveness of TM and HS. Prior to product marketing, the formula, raw materials, production procedures, and completed product specification are all evaluated. The stability study, water content determination, disintegration time, and microbiological count are all essential quality control metrics. The obligation for technical data submission for quality control also applies to TUHP [8].

Long-term consequences, efficacy in specific populations (e.g., youth, the seniors, pregnant women), and potential interactions with other drug products, according to Zarsuelo (2018), are still insufficient. Moreover, further studies about the environmental components that affect the efficacy of herbal products are required. Lastly, studies on the cost-effectiveness of herbal medications are also limited [10]. According to DOH Administrative Order 172-2004, herbal drugs must contain the fatal dose, pharmacological activities, quasi, sub-chronic and prolonged toxicities, medical research data, and biochemical tests (where relevant). Furthermore, examinations must be in operation to filter out any undesired substance from the source plant extract throughout the production process [11]. Yet, RA 8423 does not include requirements for developmental toxicity and carcinogenicity testing for herbal medications with traditional uses that are recognized or unidentified.

As a result, information on herbal medicines is still lacking and insufficient because data on long-term impacts policies, treatment outcomes on specific populations (e.g., kids, the elderly, pregnant women), and possible interactions with certain foods and medications are still lacking.

Human Resources (Education, Practitioners, Public Access to Information):

In partnership with relevant government and business institutions, PITAHC is mandated by Republic Act 8423, or the Traditional and Alternative Medicines Act of 1997, to support for and encourage the use of fully verified herbal supplements and natural health techniques. The Institute will collaborate with the Technical Skills Development Authority (TESDA), the Department of Education (DepEd), the Commission on Higher Education (CHED), and the Philippine Council for Health Research and Development (PCHRD) to develop regulations for the creation of short course educational and development resources, graduate, and postgraduate courses, as well as to form an interdisciplinary program development and implementation team under the TESDA framework. This unit will create databases for herbal medicine and alternative medicine in partnership with the Department of Science and Technology (DOST) and other Philippine universities.PITAHC is also responsible for educating the general public about traditional and complementary medicine material that may be deceptive or in violation of the law. The Food and Drug Administration is involved in the process of carrying out this activity. Guidelines in the form of tri-media facilities, as well as a list of natural goods that have been proved to be safe and effective, will be released and promoted on a regular basis. For both TM and HS,with complaint inquiries and product recalls, a framework for public input is in place. Post marketing control includes product surveillance [8].

Information is easily accessible with today's technologies. Information retrieval technologies have helped in the discovery and reuse of knowledge, allowing information to be sent around more quickly. Moreover, The Internet is one method by which information is transferred. Push and Pull technologies are one method of disseminating information. Both of these technologies are methods of client-server network communication [18, 19]. Moreover, the study "Herbal Medicine Information System Using Push and Pull Technology in Mobile Application " was conducted at Makati City, Philippines in which the researchers were able to come up with a conclusion that all of the requirements were met, user acceptability testing was conducted with target users and herbal medicine practitioners.PITAHC was adamant that content control be implemented to ensure that the herbal remedies information would be successful after the system was done.The functioning and usability of the produced mobile app's push and pull technologies were evaluated with the target audience. The accuracy of the data was also double-checked, and the study's herbal medication instructions were found to be comprehensive [20].

Therefore, we can say that after the past years, human resources, which includes Education, Practitioners, and Public Access to Information, is more convenient since the internet today is more stable. Moreover, different software has been developed over the years and has been successful in disseminating significant herbal information to the public.

Monitoring Process (Utilization, Provision, Quality Management, and Product Surveillance):

The post-marketing assessment of preventive medicine and health services includes monitoring of labeling, packaging, and advertising, as well as monitoring of adverse effects, post-marketing surveillance, sampling and laboratory testing, and inspection of the producer or distributor. Also encouraged is the use of self-regulation in product marketing campaigns. The Institute will work with TESDA, the Department of Education (DepEd), the Commission on Higher Education (CHED), and the Philippine Council for Health Research and Development (PCHRD) to develop guidelines, rules, and regulations for the development of learning and training materials for short courses, graduate and postgraduate courses, and create a division in its company headquarters to develop and implement these materials. This unit will create databases for herbal medicine and alternative medicine in partnership with the Department of Science and Technology (DOST) and other Philippine institutions. PITAHC is also responsible for educating the general public about traditional and complementary medicine material that may be deceptive or in violation of the law. This is achieved by working in collaboration with the FDA to issue and publish recommendations on a consistent basis in the form of tri-media facilities and a list of natural products that have been shown to be both safe and effective. [8].

In various nations, traditional and herbal medicines have been relegated to the status of foods or dietary supplements, which is the root of the vast majority of the issues that arise from their use. As a reason, there is no requirement for these herbal medications to have evidence of quality, effectiveness, or safety before they may be marketed [14]. Herbal medications, like conventional medicines, are issued a permit developed upon their safety, efficacy, and quality. They must be accompanied by thorough information including indications, warnings, product usage, drug adverse and side effects, storage guidelines, and compliance procedures as a rationale for drug safety. A pamphlet that comes with the product usually contains this information [15]. In order for traditional and alternative medicine to be widely accepted as a legitimate way for treating illnesses, it is necessary to guarantee the safety, effectiveness, and quality of traditional medications and procedures. In contrast to pharmacological medications and other contemporary therapies, traditional medicine's usage, distribution, and practice nevertheless lack strong and meticulous oversight. Moreover, the public's lack of access to a consolidated database of traditional medical items and practices is cause for worry. This database is critical for documenting traditional healing procedures for prospective benchmark and research studies, as well as presenting the community with precise and current facts about qualityitems.

According to WHO (2005), there are problems with herbal medication quality control: The quality of the raw materials that are utilized in the manufacturing of herbal medicines is directly related to the safety and effectiveness of the herbal medications. Variables that are not intrinsic to the source material, such as environmental conditions, cultivation and harvesting, field collecting, and post-harvest/collection transportation and storage, may have an effect on the material's quality. As a result, performing quality controls on herbal medicine raw materials is extremely challenging [16]. However, to surpass this difficulty, according to the TAMA law, the institute will be responsible for establishing standards and guidelines for the manufacture, quality control, and marketing of a variety of traditional and alternative health care materials and products in collaboration with the Bureau of Food and Drugs. This obligation was given to the institute. [17].

Tools for treatment (herbs, devices, medicine):

According to the Republic Act 8423, or the Traditional and Alternative Medicines Act of 1997, herbal medications are finished, labeled pharmaceutical formulations containing Active Pharmaceutical Ingredients (API), plant serial or subterranean fixings with other components, alone or mixed, in their natural state or as plant preparations [12].

Regarding safety and effectiveness, the whole value chain of Traditional & Complementary medications, including cultivation, collecting, processing, manufacturing, and research and development, must be controlled. There is also a rising recognition of the need of regulating the herbal value chain; nevertheless, it is unclear what, how, and to what extent this should be performed within the government. The herbal affairs are administered, the Ministry of Science, Technology, and Innovation, respectively. As a result, a related lack of adequate value chain regulation is reinforced by the absence of herbal policy coordination [22].

An act was passed that gave the Philippine Institute of Traditional and Complementary Health Care authority, provided it with more updated equipment and personnel management, established research centers and offices, modified parts of Republic Act No. 8423, and took resources for it. Its primary goal is to improve PITAHC's administrative and technical capabilities by modernizing its equipment, establishing its own testing laboratories and field offices, and expanding its people resources. Furthermore, this Act intends to provide a broader selection of health products and practices that are both safe and effective [13].

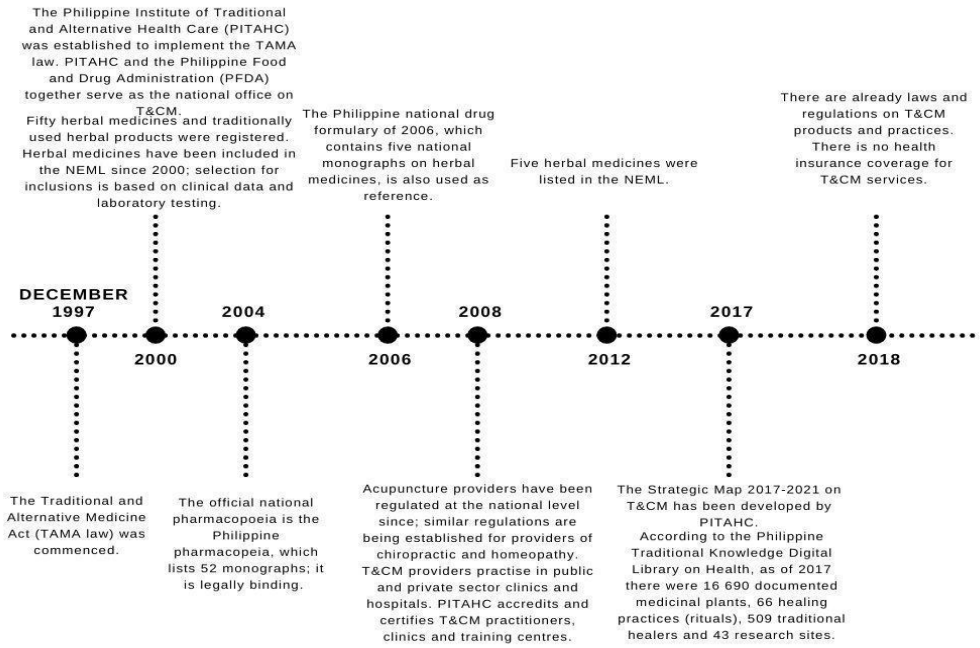

Figure 1. WHO global report on traditional and complementary medicine [21].

Conclusion

The Traditional and Alternative Medicine Act of 1997, or TAMA law, has achieved its purpose of recognizing the importance of traditional and alternative treatment in the Philippines over the years. Continuous efforts to reinforce its implementation in the community was strengthened by passing a number of initiatives, projects, and policies. Some aspects, however, require improvement. Despite the ubiquity in the Philippine market of traditional and alternative medicine, it is proposed that stronger and more precise guidelines for these products be created in order to ensure and protect the safety and effectiveness of these products so that customers have a further source of health care.

References:

1. Mendoza RL. Is it really medicine? The traditional and alternative medicine act and informal health economy in the Philippines. Asia Pac J Public Health. 2009 Jul;21(3):333-45. doi: 10.1177/1010539509336570. Epub 2009 Jun 5. PMID: 19502245.
2. Tolentino, F. (2021, January 7). Traditional medicine in the Philippines. Manila Bulletin. https://mb.com.ph/2021/01/07/traditional-medicine-in-the-philippines/
3. Robles, Y. R., Peña, I. G., Loquias, M. M., Salenga, R. L., Tan, K. C., & Ruamero, E. C. (n.d.). Regulatory issues on traditionally used herbal products, herbal medicines and food supplements in the Philippines. Aaspjournal.Org. Retrieved May 9, 2022, from https://www.aaspjournal.org/uploads/155/5951_pdf.pdf
4. World Health Organization. (2019). WHO global report on traditional and complementary medicine 2019. World Health Organization. Retrieved from https://tinyurl.com/yckrzxue
5. Zhang, D. Q. (2015). Traditional and complementary medicine in primary health care. Orient Blackswan. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK316267/
6. Bodeker, G., Burford, G., Grundy, C., Ong, C. K., & Shein, K. (2005). WHO global atlas of traditional, complementary and alternative medicine: Produced by the WHO Kobe centre: Text and map volumes. World Health Organization. Retrieved from https://tinyurl.com/4uuk3z2b
7. Park, J.-E., Yi, J., & Kwon, O. (2022). Twenty years of traditional and complementary medicine regulation and its impact in Malaysia: achievements and policy lessons. BMC Health Services Research, 22(1), 102. https://doi.org/10.1186/s12913-022-07497-2
8. Robles, Y. R., Peña, I. G., Loquias, M. M., Salenga, R. L., Tan, K. C., & Ruamero, E. C. (n.d.). *Regulatory issues on traditionally used herbal products, herbal medicines and food supplements in the Philippines*. Aaspjournal.Org. Retrieved May 10, 2022, from https://www.aaspjournal.org/uploads/155/5951_pdf.pdf
9. About PITAHC. (n.d.). Gov.Ph. Retrieved May 11, 2022, from https://pitahc.gov.ph/about-pitahc/
10. Zarsuelo, M.-A. M., Zordilla, Z. D., & Anacio, D. B. (2018). Review of Regulatory Policies on and Benefits of Herbal Medicine in the Philippines . Acta Medica Philippina, 52(5). https://doi.org/10.47895/amp.v52i5.334
11. Philippine Institute of Traditional and Alternative Health Care (PITAHC)-Department of Health. Strategic Plan 2017-2022 [Online]. 2017 December. Retrieved May 11, 2022, from http://pitahc.gov.ph/wp-content/uploads/2017/12/Final-Research-and-

Development- Strategic-Plan-2017-2022.pdf.

12. (N.d.-b). Wipo.Int. Retrieved May 11, 2022, from https://wipolex-res.wipo.int/edocs/lexdocs/laws/en/ph/ph050en.pdf
13. (N.d.-a). Gov.Ph. Retrieved May 11, 2022, from https://legacy.senate.gov.ph/lisdata/3083527778!.pdf
14. Ekor, M. (2014). The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. Frontiers in Pharmacology, 4, 177. https://doi.org/10.3389/fphar.2013.00177
15. David K Raynor; Rebecca Dickinson; Peter Knapp; Andrew F Long; Donald J Nicolson (2011). Buyer beware? Does the information provided with herbal products available over the counter enable safe use?. , 9(1), 94–0. doi:10.1186/1741-7015-9-94
16. (N.d.). Who.Int. Retrieved May 11, 2022, from https://apps.who.int/iris/bitstream/handle/10665/43229/9241593237.pdf
17. (N.d.). Stuartxchange.Ph. Retrieved May 11, 2022, from http://www.stuartxchange.ph/TAMA.html
18. D. Susan, E. Cutrell, J. Cadiz, G. Jancke, R. Sarin, and D. Robbins. "Stuff I've seen: a system for personal information retrieval and re-use." In ACM SIGIR Forum, vol. 49, no. 2, pp. 28-35. ACM, 2016.
19. G. Gousios, M. Pinzger, and AV. Deursen. "An exploratory study of the pull-based software development model". InProceedings of the 36th ACM International Conference on Software Engineering 2014 May 31 pp. 345-355.
20. M. J. C. Samonte, M. Therese P. Cadiz, B. M. R. Mabanag Camba and G. G. Esguerra, "Herbal Medicine Information System Using Push and Pull Technology in Mobile Application," TENCON 2018 - 2018 IEEE Region 10 Conference, 2018, pp. 2098-2103, doi: 10.1109/TENCON.2018.8650338.
21. World Health Organization. (2019). WHO global report on traditional and complementary medicine 2019. World Health Organization.
22. Park, JE., Yi, J. & Kwon, O. Twenty years of traditional and complementary medicine regulation and its impact in Malaysia: achievements and policy lessons. BMC Health Serv Res 22, 102 (2022). https://doi.org/10.1186/s12913-022-07497-2