RESEARCH ARTICLE

Regulatory issues on traditionally used herbal products, herbal medicines and food supplements in the Philippines

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Abstract

Comments and recommendations of different stakeholders on the existing policies on safety, traditional use, scientific validity, quality, registration process, monitoring, and public feedback for traditionally used herbal products, herbal medicines and food supplements were documented. While many agreed on the provisions of existing policies for herbal medicines and products, there exists discontent on the absence of stricter and more definitive guidelines for food supplements despite their abundance in the Philippine market. It was unanimously suggested that current policies must be revised in such a way that the consuming public must be ensured of its quality, safety and efficacy or authenticity of claims. Other issues that were extensively critiqued include the need for finer categorization of products, regulation of advertisements and an institution that will serve as a repository of information regarding these medicines and products.

Introduction

The Philippines, being identified as one of the countries with the most biodiversed natural resources, has an important stake in the development of its own alternative medicines, particularly those derived from plant sources. The Food and Drug Administration (FDA) is the government agency which has the regulatory power over the production, distribution and use of these health products. At present, the food supplement and herbal medicine

industry can learn from other countries with highly developed regulatory systems for such products. The proliferation of unregistered products of variable quality must be tackled by a more rigorous regulation of the government in the interest of public safety. This pressing need is even more compounded by the recent movement towards harmonizing regulatory processes among ASEAN countries. The Philippines must be prepared to bring to the regional forum those policies which protect the regional and national interests while being sensitive to the concerns of the local herbal industry and the Filipino people.

This study is aimed to describe the current status of the regulatory system in the Philippines; and, identify gaps and problems/ difficulties/weaknesses in the implementation of national laws (e.g. RA 8423 Traditional and Alternative Medicines Act, TAMA) and FDA regulations on traditionally used herbal products, herbal medicines and food supplements in consultation with various stakeholders. The alignment of FDA regulations with the provisions of TAMA is envisioned to strengthen the position of the local food supplement and herbal medicine industry in responding to the country's health needs.

Methods

This preliminary study was a descriptive qualitative design involving review of existing policies on traditionally-used herbal products, herbal medicines and food supplements, and an analysis of the strengths and weaknesses of these policies.

Key informant interviews of representatives from the FDA and Philippine Institute of Alternative Healthcare (PITAHC), and focus group discussions (FGDs) with various stakeholders (i.e. scientists, academicians, professional organizations, medical practitioners, consumer groups, etc.) were conducted. The interviews involved questions about their perspectives on the gaps and recommendations on how to improve the regulation of these products. The key informants and FGD participants were selected by theoretical sampling through prior discussion with PITAHC who suggested important stakeholders to be included in the study. A total of 9 FGDs were conducted from December 2009 to January 2010: 6 in Manila, 1 in Cebu City, and 2 in Davao City to represent Luzon, Visayas and Mindanao, respectively.

All key informant interviews and FGDs were initially transcribed verbatim using a template specific to the form used during the interview or FGD. These were then coded and displayed in matrices using Microsoft Word 2007. Content analysis was subsequently performed on the qualitative data generated.

Table 1 Gaps and recommendations on existing guidelines for herbal medicines, traditionally-used herbal products, and food supplements.

	Gaps	Recommendations
A. CRITERIA		
Product registration requires technical data for safety	• FDA is understaffed and is overloaded with products that need to be tested. • The criteria should be adapted for DS of herbal origin since their indirect claims satisfy the definition of herbal medicines. • Requirements for TM resemble those for conventional synthetic drugs. • DS have similar set of guidelines as that of TM.	• Manufacturers should state appropriate dose and usage of herbal products to avoid over dosage. • Data of clinical trials should be made transparent. • FDA should have separate guidelines or requirements *e.g. allergy testing, extent of systemic absorption,* for topical herbal products. • FDA should accredit institutions that will validate submitted technical data.

	Gaps	Recommendations
		• There should be close checking of claims of DS. The guidelines for them should be separate from those of food. • DS and herbal products should follow the same GMP requirement as that of herbal medicines, especially if the products are for commercial distribution.
Product registration includes GMP certificate	• There are no GMP guidelines specific for traditional medicines. Small manufacturing enterprises (SMEs) may have difficulties in complying with GMP standards set for pharmaceuticals. • Other alternative medicine providers, e.g. Chinese drugstores, are less regulated, which may have an impact on consumer safety.	• GMP guidelines should consider the situation of SMEs, but should not sacrifice product quality.
Pre-marketing evaluation requires references that support safety	• The current list of acceptable or valid references is not comprehensive or exhaustive.	• The references should be pre-approved by the FDA. • PITAHC should provide funding for research so that a database can be established and the data available therein could be used as reference. • Additional requirement for DS should be "minimal or absence of reported adverse effects".
Pre-marketing evaluation requires toxicity study	• There is lack of data or studies on adverse reactions and interaction of DS with conventional drugs. • There is currently no way to regulate unregistered products.	• FDA should conduct inspection of drugstores to police unregistered products in the market.
B. CRITERIA FOR TRADITIONAL USE		
It is defined as product with empirically long historical use.		
There should be traditional experience of long usage for at least five (5) decades.	• Fifty years is too short to assess long term effect of TUHP.	• The minimum requirement should be "75 years of usage".
C. CRITERIA FOR SCIENTIFIC VALIDITY		
Product registration requires technical data for efficacy (or claimed application for TUHP). Pre-marketing evaluation involves verification of claims of raw material and finished product efficacy.		• Minimum requirements for claims of TMDS should include at least chemical tests to prove the presence of constituents responsible for health claims; clinical trials may be omitted. • Anecdotal evidence should be an acceptable supporting data for TM. • Standard markers must be identified to support claims of herbal medicine. • A scientific committee within the PITAHC, with the involvement of representatives from Chamber of Health Industries in the Philippines (CHIPI), should be in place to approve standard protocols and research studies. • Evidence of efficacy required for registration of natural products should not be stricter as compared to those required for conventional medicines.

	Gaps	Recommendations
D. CRITERIA FOR QUALITY		
Product registration requires technical data for quality. Product registration includes GMP certificate.	• ELISA for aflatoxins may not be very sensitive test.	• Tests (e.g. for aflatoxins and pesticides) may not be limited to those specified in AO 172 and 184 • Test biomarker to establish purity. DS must also be GMP-certified.
There should be pre-marketing evaluation of formula, raw material, manufacturing process, and finished product specification.	• There is no standard way of testing homeopathic products	• Verification of the quality of the finished product alone should be adequate. • There should be separate criteria for raw materials and finished products. • Good Agricultural Practices for raw materials should be required when outsourcing raw plant materials.
E. REGISTRATION PROCESS AND REQUIREMENTS		
	• No separate center/unit for TM and HS in FDA. • Timeline for evaluation is variable in actuality.	• Invite guest evaluators with relevant technical background. • An alternative medicine practitioner or a certified herbalist should be part of the evaluation, instead of a medical doctor. • Timeline should be fixed and strictly implemented.
F. MONITORING PROCESS		
There is monitoring of labelling, packaging, advertisement and adverse effect. There is inspection of manufacturer and distributor.	• There are inadequate provisions in the Consumers Act that guarantees active participation of regulatory agencies like the FDA in the approval of commercial ads. • There is a passive reporting system.	• FDA should also monitor price. • Imported products should have English translation of texts on the labels. • FDA should pre-approve ads. • Explore more how the FDA and DTI can work more closely on this. • There should be more campaigns encouraging consumers to report adverse events through the use of IEC materials. • A technical committee should conduct the pre-evaluation of advertisements before forwarding them to ASC. • FDA should initiate a more inclusive consultation mechanism among stakeholders so that the guidelines on monitoring will be clear, acceptable and properly implemented.
G. GUIDELINES AND REQUIREMENTS FOR DOCUMENTATION		
There should be documentation of technical data on quality, safety and efficacy.	• There is no patent protection on herbal medicines/ herbal products and food supplement in the Philippines. • Documentation on healing effects/claims usually records only the negative effects.	• There should be a process patent for herbal products. • Documentation of effects should also capture positive feedback as well. • A Product Traceability System should be in place.
H. GUIDELINES AND REQUIREMENTS FOR PRODUCT LABELLING		
Product labels must bear minimum required information.	• Consumers find "no approved therapeutic claims" vague.	• Especially for DS, a product insert should be available. The language used must be appropriate for the intended audience.

	Gaps	Recommendations
	• The phrase "FDA-approved" on the label can be vague and misleading on the part of the consumers. • Physicians are not comfortable with prescribing DS bearing the caption "No Approved Therapeutic Claims". • Some labels put "No Approved Therapeutic Claims" but the text is printed in very small size. • Violators are not penalized.	• Translate "no approved therapeutic claims" to Filipino or native dialect. • Labelling requirements should be set per product category. • Labels should bear caution for high-risk users. • Labels should be translated to native language. • There is a need to set the labelling requirements for DS. • Label should instead state "Registered as Drug" or "Registered as food supplement" so that the public knows what level of requirements a product has met.
I. GUIDELINES AND REQUIREMENTS FOR ADVERTISING AND PROMOTION		
There is no prior approval of advertisements by the drug regulatory authority, but monitoring is conducted.	• No penalties for violators. • There is no way to monitor products sold by networking schemes. • There are often no technical persons in the Ads Standards Council. • Some ads have cure-all claims. • Multi-agency body that evaluates advertisements may become problematic because member agencies do not meet frequently.	• FDA should have major role in approving and regulating advertisements. • There is a need to establish technical/scientific body to pre-approve [tri- and quad-media] advertisements. • There should guidelines on how to ethically advertise herbal products. • Guidelines for advertising and promotion should be set per product category. • There should be a multi-sectoral body, composed of private and government sectors, technical group, and the industry, to screen and monitor advertisements and to formulate clear guidelines on how to advertise products.
J. GUIDELINES REGARDING PUBLIC ACCESS TO INFORMATION		
PITAHC is mandated by law to develop and implement a computerized information system on traditional and alternative medicine.	• This system is not in place. • Drugstores are not familiar with the real meaning of the phrase "No Approved Therapeutic Claims". • Public is unaware of difference in registration / technical requirements betweens TM and DS. • Public is unaware of PITAHC's mandate and its role in the implementation of TAMA.	• There should be public access to information regarding TM/DS. • PITAHC should constantly issue public advisories. • PITAHC's website should have information about TM and DS. • PITAHC should regularly update information. • PITAHC should become a functional institution.
K. GUIDELINES REGARDING PUBLIC FEEDBACK		
Post-marketing control includes system for product recall.	• There is currently a passive complaint system.	• There is a need to review the newly launched consumer advocacy for pharmaceuticals; if successful, should also be applied to DS. • Public feedback system should start in the drugstore level. • There should be more extensive campaigns and advertisements to empower the consumers for them to report any adverse reactions encountered with the use of herbal products. • For more effective post-marketing surveillance, distributor or manufacturer should have its own public feedback system to submit its reports to FDA/PITAHC. • The surveillance system for cosmetics may be applied to alternative medicines.

	Gaps	Recommendations
L. GUIDELINES REGARDING PRODUCT SURVEILLANCE		
There is monitoring of adverse events.	• There is under reporting of adverse events.	• There should be additional guidelines / evaluation program for product monitoring. • The law should require pharmacists to post announcements / public advisories. • ADR report forms should be made available from point of care/purchase. • There should be more massive campaign on ADR reporting. • Pharmacovigilance should also be applied to TM, DS, and homeopathic products.

Results and Discussion

Current status of the regulatory system: The Philippines defines Traditional Medicine (TM) as the totality of knowledge, skills and practice on health care that cannot be explicitly explained in a scientific framework but its impact in maintaining health and wellness has been recognized by the society to be reflective of their culture, history and social consciousness. It uses various terms such as herbal and/or traditional drug, herbal medicine (HM), traditionally used herbal products (TUHP) and herbal supplements (HS) which include food supplements (FS). The regulatory policies in the Philippines are categorized according to the type of product. Summary of the traditional and health supplement regulatory requirements in the Philippines is shown in Table 1.

Criteria for safety, traditional use, scientific validity and quality: To ensure the safety of TM and HS, the Philippine FDA requires the submission of technical data for safety and a Good Manufacturing Practice (GMP) certificate of the manufacturer for product registration. Pre-marketing evaluation requires references to support safety. These may include mono-graphs, pharmacopoeias and web-sites for TM; and, Physicians' Desk Reference, Codex and websites for HS. Toxicity studies are also compulsory for their pre-marketing evaluation. On the other hand, registration of TUHP requires also the submission of technical data for safety, including toxicity studies, and a list of references supporting it. However, there should be a documented traditional experience of use of at least 5 decades.

For all these products, submission of technical data for efficacy or claimed application is required for product registration. Pre-marketing evaluation of TM and HS in the Philippines involves verification of claims of raw material and finished product efficacy. Additionally, TM should undergo clinical trials. For TUHP, only a verification of claims of the raw material efficacy is needed.

In ensuring the product quality of TM and HS, technical data for quality and a GMP certificate should be submitted for product registration. Evaluation of formula, raw material, manufacturing processes, and finished product specification are conducted prior to product marketing. Results of the following quality control parameters are required: stability study, determination of water content, disintegration time and microbial count. The requirement for sub-mission of technical data for quality is also applicable for TUHP.

Registration and monitoring processes: Pre-marketing evaluation of TM and TUHP takes 6 months, while for HS, a period of 2-3 months is allotted. Both pre- and post-marketing evaluations are implemented to regulate TM, TUHP, and HS. Other

registration requirements applicable to TM, HS, and TUHP include certificate of free sales (CFS) and technical data for quality and safety. GMP certificate and letter of authorization are necessary for registration of TM and HS products, while technical data for efficacy are required for TM and TUHP.

Post-marketing evaluation of TM and HS includes monitoring of labeling, packaging, and advertisement, monitoring of adverse effect, post-marketing surveillance, sampling and laboratory test, and inspection of manufacturer and distributor. Self-regulation of product advertise-ments is also encouraged.

Public Access to Information, Public Feedback, and Product Surveillance: Republic Act 8423, or the Traditional and Alternative Medicines Act of 1997, mandates PITAHC to promote and advocate the use of appropriately-validated herbal medicines and alternative health modalities in coordination with concerned government and private agencies. The Institute shall collaborate with Technical Skills Development Authority (TESDA), Department of Education (DepEd), Commission on Higher Education (CHED), and Philippine Council for Health Research and Development (PCHRD) to formulate guidelines, rules and regulation for the development of learning and training materials for short courses and graduate and post-graduate courses, as well as establish a unit in its Central Office for the development and implementation of its computerized information system on traditional and alternative medicine. This unit shall establish in collaboration with Department of Science and Technology (DOST) and other Philippine universities databases for herbal medicine and alternative medicine. PITAHC shall also be responsible in informing the public about misleading or unlawful information on traditional and alternative medicines. This is done in collaboration with FDA through regular issuance and publication of guidelines in the form of tri-media facilities and a list of natural products certified safe and efficacious.

A system for public feedback is in place, acted upon by complaint investigation and product recall for both TM and HS. Product surveillance is also part of post-marketing control.

Policy Gaps and Stakeholders' Recommendations: The first gap identified was the absence of a common definition for TM and for HS acceptable to all stakeholders. Terminologies used for HS are food supplements, nutraceuticals, and dietary supplements (DS), the latter being agreed to be the most appropriate term for these. The definition of 'traditional use' being 'traditional exposure of long use of at least five decades' has been challenged. Some academics suggest a longer time requirement (e.g. 75 years of use) because the safety of a product should be assessed in consideration of some effects appearing only after more than one generation.

Reservations were expressed regarding the current capability of the FDA, many of them considering the agency as overloaded with all the products being tested and assessed. FDA could accredit institutions that will help in establishing and validating technical data of these products. Gaps in FDA regulations had also been identified. Technical data for safety for TM were deemed to resemble those required of conventional synthetic drugs. At the same time, the data requirements for HS should also be reviewed especially since their indirect claims satisfy the definition of HM. The guidelines for HS should be separated from those of food. Additional requirements should then be made for HS, such as minimal or absence of reported adverse effects. The list of admissible references for establishing safety of products should also be expanded.

It was pointed out that there are no GMP guidelines specific for traditional medicines. However, industry representatives mentioned that HS and other herbal products should follow the same GMP requirement applied to HM, especially that these products are produced commercially. Representatives from the local small- and medium-scale enterprises expressed that they may have difficulties implementing GMP standards for pharmaceuticals in their HS operations. It has been suggested that the FDA intensifies its conduct of outlet inspection in order to control the marketing of unregistered herbal products, which most likely have no proven safety and/or efficacy. There is also no separate center/unit at FDA that deals exclusively with TM and HS, prompting suggestions like inviting guest evaluators with technical background and practical experience with TM and HS. Despite the new FDA law (Republic Act 9711) being passed, there is no single unit dedicated to the screening, evaluation and processing of technical documents and other regulatory requirements for these group of products. They are either processed with applications for conventional medicines, or with applications for food items. The inclusion of such unit under the FDA is expected to streamline and expedite registration procedures to facilitate the release of product registration certificates. The composition of which may include experienced researchers on traditional medicines, FDA clerical staff, and practitioners of TM/HS with no competing interests. Alternative medicine practitioners or certified herbalists should be chosen to be part of evaluation teams, instead of medical doctors and conventional medicine practitioners.

As for the scientific validity criteria, the minimum requirements for establishing the claims of TM and HS should include at least chemical tests to prove the presence of constituents responsible for the claims made. In such case, clinical trials may be omitted. In the absence of historical documentation, anecdotal evidence was suggested to be considered as admissible supporting data for TM. Some stakeholders mentioned that evidence of efficacy required for registration of herbal products should not be as strict as the one applied with conventional medicines. A scientific committee within the PITAHC, in cooperation with the academe and industry, should be in place to establish and approve standard protocols used in conducting researches involving herbal products and in evaluating submitted data for product registration.

In terms of labelling and advertising, product inserts should be available especially for HS using appropriate language that is understood by lay people. Consumers find the auxiliary label "No Approved Therapeutic Claims" vague. The phrase "FDA-approved" on the label is often overemphasized as a marketing strategy, which can both be vague and misleading to the public. In most cases, the public is unaware of the difference in the registration and technical requirements between TM and HS. Label may be in instead state "Registered Traditional Medicine" or "Registered Herbal Supplement" so that the public will know what level of evidence in terms of safety and efficacy a certain product has met. There might be a need for setting labelling requirements per product category. Consumer groups pointed out that manufacturers should be explicit as much as possible on the appropriate dose and usage of herbal products to avoid overdosing. Labels should bear caution for high-risk users. There should also be platforms made available for greater public access to information regarding TM and HS (e.g. PITAHC's website, FDA public advisories, etc.). The FDA should have direct influence in approving the content and form of advertisements of such products.

Considering that FDA in the past took only a passive role in rectifying misleading released advertisements upon complaint of industry competitors and the public, the FDA needs now to establish a technical body to pre-approve advertisements which are endorsed to the Ads Standards Council of the Philippines (ASC) for approval of their release in media. This is very important most especially that there are aired advertisements which have 'cure-all' claims. Ideally, the body should be multi-sectorial, composed of private and government sectors, technical experts, and industry members. A more proactive mechanism should be made to replace the existing system wherein alleged false claims are addressed after complaints have been made. Penalties should be heavier and fully implemented. Above this, the FDA should endeavour in the formulation of guidelines on how to advertise herbal products. It could be that the guidelines for advertising and promotion will be set per product category. A list of permissible claims based on the technical experts review may be created.

At present, there are also clear guidelines on how to monitor HS sold by non-traditional schemes (i.e. networking companies and direct sales mechanism). A system should also be available for the public to confirm the claims of these products, as well as their safety. The adverse drug reaction reporting system involving the lay and health care professionals should also be reviewed since no substantial number of reports have been received ever since. There should be more extensive campaigns and advertisements to empower the consumers for them to report any adverse reactions encountered not only with conventional medicines but also with herbal products. For more effective post-marketing surveillance, distributors or manufacturers should have their own public feedback system that links reports to FDA or PITAHC.

Conclusion

Comments and recommendations of the different stakeholders on the existing policies on safety, traditional use, scientific validity, quality, registration process, monitoring, and public feedback for TUHP, HM and HS, indicate agreement to some existing policies and a wider discontent on the absence of stricter and more definitive guidelines for these products despite their abundance in the Philippine market. It was unanimously suggested that current policies for them must be revised in such a way that the consuming public must be ensured of their quality, safety and efficacy or authenticity of claims.

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