

Establishing a Blueprint for Nature-based Products Development and Conservation for the Philippines

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ABSTRACT

Background. Many of the leading causes of mortality and morbidity in the Philippines are controllable with nature-based products, either as agents of intervention, or prevention, as nutritional supplements, or for the control of side-effects of medications. The different R&D programs on nature-based products in the Philippines are usually conducted in isolation, or through silos. These often lead to products that are shortsighted, duplicate products, or products with minimal innovation, not readily applicable to population and environmental sustainability.

Objective. The study aimed to draft an internationally benchmarked and integrated blueprint for a population health- and environmental health-led nature-based product development and conservation for the Philippines.

Methods. The methodology consisted of review of literature; regional educational visits; and a series of consultative meetings with stakeholders.

Results. The study resulted in a stakeholder-validated blueprint which assigns the Philippine Institute of Traditional and Alternative Health Care (PITAHC) to lead the way for Filipinos to produce more nature-based products that are of international quality and attuned with local health needs. The blueprint has identified “9 Optimizations” in the realization of this aspiration, including an expanded role for PITAHC, a national database, an ethical researchers list, and to produce at least five commercial products and 20 intellectual property rights within 5 years with an estimated total investment of approximately PhP 816 M.

Key Words: conservation, nature-based products, patents, PITAHC

INTRODUCTION

Many of the leading causes of mortality and morbidity in the Philippines may be controlled by nature-based products as food and food supplements; as medicines; and as pesticides against disease vectors. Moreover, secondary metabolites from plants and microorganisms have been the foundation for several antiparasitic, antibacterial, antifungal, antiviral, and antineoplastic therapies.

The Philippines has a very rich biodiversity, serving as habitat for 70–80% of the world’s plant and animal species,

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and Filipino culture has a rich history of traditional medicine. The Philippines ranks fifth in the number of plant species and maintains 5% of the world's flora.¹ It is estimated that locally, 1,500 plant species have medicinal value, 200 of which have been identified with phytochemical content.² The National Integrated Research Program on Medicinal Plants (NIRPROMP) has identified 120 plant species as safe and promising for drug discovery.³ Furthermore, the Department of Health (DOH) in coordination with the NIRPROMP, has endorsed the use of 10 medicinal plants from the research results of the NIRPROMP, which after 25 years and PhP85 million, produced, among others, lagundi (*Vitex negundo*) syrup and tablet for cough and sambong (*Blumea balsamifera*) tablet for kidney stones. These two alone earned more than PhP50 million for the patent-licensee Pascual Laboratories, Inc. from 1997 to 2010.³

The total export value of Philippine nature-based products in 2011 was approximately US\$ 153 million while total import value for related products in the same year was approximately US\$ 198 million.⁴ Thus, nature-based products seem to be a good source of health and wellness products, internationally and locally.

OBJECTIVES

Generally, this study aimed to propose an internationally benchmarked and integrated blueprint for a population health- and environmental health-led nature-based product development and conservation for the Philippines. Specifically, this study aimed to: (1) identify the major stakeholders and players related to natural products development, (2) articulate intended national outcomes, and (3) clarify enduring roles and responsibilities of government agencies and other key stakeholders.

Conceptual framework of the study

The conceptual framework is presented in Figure 1. Nature-based products should be sensitive to the current health-seeking behavior of individuals and households.⁵ Products should be efficacious, safe, affordable, available, accessible, and acceptable to the target population at hand. The main stakeholders of nature-based products development could broadly be categorized as researchers from either academic or non-academic institutions, government agencies, industry and other private organizations, and the community, especially indigenous peoples. Indigenous peoples are usually the primary source of information regarding their endemic plants and respective uses, from which many new researches on nature-based products are derived.⁶ Eventually, the industry sector will then push these researches for mass production and distribution to the main target for most public health researches: the end-users. In this whole process, the indigenous peoples must be involved in such a way that their traditional knowledge is preserved and shared, and that they profit from the natural resources and traditional

knowledge they own.⁷ In section 32 of Republic Act 8371, the Indigenous Peoples' Rights Act of 1997, the Philippine government is committed to respect, protect, and develop ancestral domains and community intellectual rights such that cultural, intellectual, religious, and spiritual properties may not be taken from the indigenous communities without their free and prior informed consent, or in violation of their laws, traditions and customs.⁸

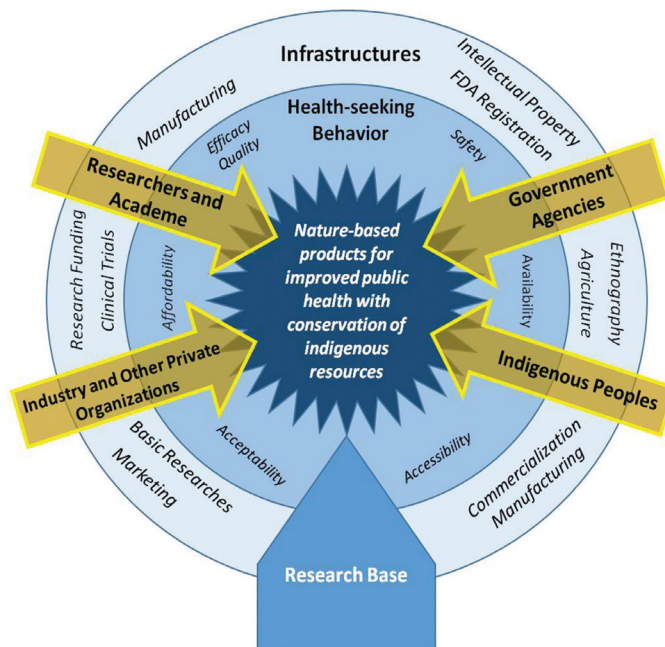


Figure 1. Proposed conceptual framework of nature-based products development and conservation in the Philippines.

Stakeholders' efforts for public health and sustainable use of indigenous resources must be aligned with each other to optimize scarce resources.⁹ Basic infrastructure should be present to encourage research. Infrastructure refers to both hardware and systems that lead to production. The government must be able to protect intellectual property rights, and to regulate the manufacture and distribution of nature-based products by Food and Drug Administration (FDA) registration.^{10,11} Funding from either the public or private sector must be available to support actual research implementation (from basic to translational research) or capacity building for researchers. Researchers should not only have the capacity to conduct laboratory or clinical research, they must also be able to undertake commercialization studies and market research studies to assess the feasibility of their potential nature-based products. Nature-based products benefit potential end-users by giving more alternatives to healthcare.¹²

Ideally, because nature-based products are currently perceived as inferior alternatives to western medicine, all infrastructures must be geared towards the improvement of health-seeking behavior for quality nature-based products. Such mechanisms should be in place to prove that quality

nature-based products elicit the expected effects (efficacy), with the least toxic effects possible (safety). These products must also be sold to patients who need and want them (acceptability), at a price that fits their purchasing capacities (affordability), in places that are qualified to store and distribute them to a larger number of people (availability and accessibility).

Significance of the study

Currently, many nature-based product R&D programs in the Philippines are usually conducted in silos. These programs often lead to products that are shortsighted; not readily applicable to population- and environmental-health; or worse, products that are duplicates to previous innovations or are of minimal innovativeness. From a societal perspective, these isolated R&D efforts are an inefficient use of the economic resources of a nation since these are asymmetrically advantageous to specific individuals or groups, but not to the public.

Countries such as India, Thailand, Malaysia, China, South Korea, and Japan have developed integrated programs, and have started to export their innovative products all over the world, even to the Philippines. The Philippines has the potential to leapfrog beyond these countries and lead in this area of research with its rich biodiversity and highly skilled population. This research shall inject environmental health conservation into the imperative for innovations so that the envisioned outputs will be holistic, and will result in economic progress that can be enjoyed by all Filipinos, including the poor and disadvantaged.

METHODS

This study obtained ethical clearance from the National Ethics Committee. This study involved a comprehensive review of literature, regional educational visits, and consultative meetings with stakeholders. The review of literature tackled local and international experiences in nature-based products R&D. Regional educational visits to various institutions in Taiwan, Malaysia, Japan, Thailand, and India were done to benchmark best practices. Results from the review of literature and regional educational visits were compiled into a draft blueprint. Selected local stakeholders were then invited to validate and to gather consensus on the proposed blueprint. Four stakeholder meetings were held in Angeles City, Manila City, Cebu City, and Davao City. Throughout the entire study, an advisory council which comprised of experts was consulted.

RESULTS AND DISCUSSION

1. On the definition of nature-based products and other related concepts

The authors have adopted the terminology of the United State Patent and Trademark Office (USPTO). According to the USPTO, “nature-based” refers to “those products derived

from natural sources that require closer scrutiny to determine whether they are an exception from being “products of nature”.¹³ Thus, nature-based products can include drugs, food or dietary supplements, traditionally-used herbal products (TUHPs), herbal medicines, traditional medicines, organic salts, and minerals.

2. Existing policies related to nature-based products development and conservation in the Philippines

The Philippines is one of a few Asian countries that have laws on traditional and alternative health care development.⁴ The Philippines has Republic Act (RA) 8423 of 1997, which is more commonly called the Traditional and Alternative Medicines Act.¹⁴ This law establishes and mandates the Philippine Institute of Traditional and Alternative Health Care (PITAHC) as an attached agency under the DOH, to oversee, coordinate, and facilitate the development of traditional and alternative health care and its integration to the current national health system. PITAHC’s responsibilities include conducting research, transferring technologies, formulating policy, and conducting public awareness campaigns and medical practitioner training programs. On the other hand, the Bureau of Food and Drug (BFAD, now the Food and Drug Administration or FDA) was created in 1963 to ensure the safety, efficacy, and quality of health products which include food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, radiation-emitting devices or equipment, and household or urban hazardous substances. In 2008, it was subsequently strengthened and expanded to include more centers, upgraded with more testing equipment and personnel, allowed to retain income, and upgraded the head from director to director-general and undersecretary.¹⁵

The law that protects intellectual property rights is RA 8293 or the Intellectual Property Code of 1998.¹⁶ Accordingly, any person or legal entity, including the government, can own intellectual property in form of patents or copyrights. The code states that any inventor or her/his assignee who is the first to file and be approved for patent application may own the patent. The person or institution who commissions the work shall own the patent, unless otherwise provided in the contract between the person who commissions the work and the employee.

The government may exploit the invention even without agreement of the owner if the reason for doing so is due to the interest of the public (i.e., national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government) or if the patent is anti-competition as assessed by the Intellectual Property Examiner. Moreover, currently, the government lacks the capacity to optimize the patent it seeks to break – from determining whether the invention serves public interests, to producing and distributing the invention, or to parallel importing the compound – all under the threat of legal action from the patent holder or its licensee.

Plant varieties, animal breeds, and biological processes to produce plants or animals are not patentable. This provision does not apply to microorganisms and non-biological and microbiological processes. However, the Intellectual Property Code is silent about the knowledge, practices, or resources owned by the indigenous communities which the Executive Order (EO) 247 resolves by requiring consent from indigenous groups for the access to their owned natural resource and profit sharing by those who use their natural resource.¹⁷

RA 9147 or the Wildlife Resources and Conservation Act grants the Department of Environment and Natural Resources (DENR) and the Department of Agriculture (DA) jurisdiction over the protection of wildlife, their habitat, and the minerals found therein.¹⁸ The Act seeks to protect endangered or rare species from extinction and to promote the sustainable use of the available natural resources for the benefit of the country. The Act promotes bioprospecting or the research, collection, and utilization of biological and genetic resources for purposes of applying the derived knowledge for commercial purposes if interested parties register with the DENR and DA.

3. Best practices from regional educational visits

There are several issues faced by the nature-based products industry of other Asian countries that are applicable to the Philippines. One important issue is funding. Private and public players dealing with nature-based product development must be guided by an agreed upon set of local/international standards whether it be in agriculture, in manufacturing, or laboratory testing. Aside from these players, whatever agency that is assigned responsibility over ensuring that players are at par with set standards will need funding. In Malaysia, India, and Taiwan, the government shoulder the cost of product development and pre-commercialization research.

Another important issue is the establishment of a lead agency. Several countries have agencies involved in their nature-based products sector which include the traditional and complementary medicine sector and the herbal products sector. Malaysia has shown the benefit of having one lead agency to coordinate all other agencies and their efforts, and a single body accountable for all development-related issues.

Sustainable supply of raw materials is very important to nature-based product development. Japan and India rely on local cultivation and chemical synthesis. Malaysia focuses on increasing farming of high-value medicinal plants. Taiwan is focused on biotechnology to produce their nature-based drugs. In Japan, India, and Taiwan the use of nature-based products is integrated into mainstream healthcare through the recognition of their use in their health insurances, thus, providing a financing mechanism for the producers and a reliable and sizeable demand for such products.

Another observation of a best practice is the extensive archiving of knowledge regarding traditional medicine,

or nature-based products researches, including large scale multistoried bio-banks. A few countries have had records that span centuries and millennia. Archives serve as a reference and source material for possible lead compounds or lead plant materials for a nature-based product. India has its traditional knowledge digital library (TKDL).

4. Current gaps in nature-based products research and development

The study team identified key issues on nature-based products development and conservation that the Philippines faces: in terms of idea generation, there is fear of plagiarism, insufficient funding, and the lack of sharing of research results; in terms of innovations, there are insufficient research funds for optimized extraction, purification, and manufacturing methods; DA and FDA lack capacity to monitor producers and suppliers; and the market is dominated by big companies and small unreliable manufacturers; and in terms of outcomes, there is a lack of products which can be commercialized and a lack of resource conservation mechanisms (Figures 1 and 2).

5. The way forward: 9 Optimizations

Based on the literature reviews and country visits, and as validated by key stakeholders in four round table discussions across the Philippines, the study group recommends that the country's nature-based products research should have the following vision so that in five years, the Philippines will be able to produce at least 5 commercial products and 20 patents, thus: (1) more nature-based products are commercially produced, (2) nature-based products produced are of quality, and (3) nature-based products produced are attune with local health needs.

There should be fast-tracking of the intellectual property rights application not only for nature-based products research and development, but also for all types of inventions and ideas at large. This will support and motivate innovators. For nature-based products research, PITAHC may create a National, and Regional Technical Working Groups (TWG) that will help the IPO and FDA review inventions applying for patents. PITAHC may also provide financial assistance for researchers to apply for patents.

Government funds for nature-based products should be managed by PITAHC. To ensure that government funds are maximized, PITAHC may hold the researcher accountable to results by using the intellectual property right as surety to the funding received. PITAHC must also be granted the authority to own the intellectual property rights, and subsequently transfer the research to another interested researcher, if the original researchers do not deliver results. But appropriate acknowledgement and royalties will be given to all researchers who contributed significantly along the progress of research.

Nature-based products may stem from indigenous communities' traditional knowledge, to be documented in ethnographic studies. Thus, PITAHC must ensure that

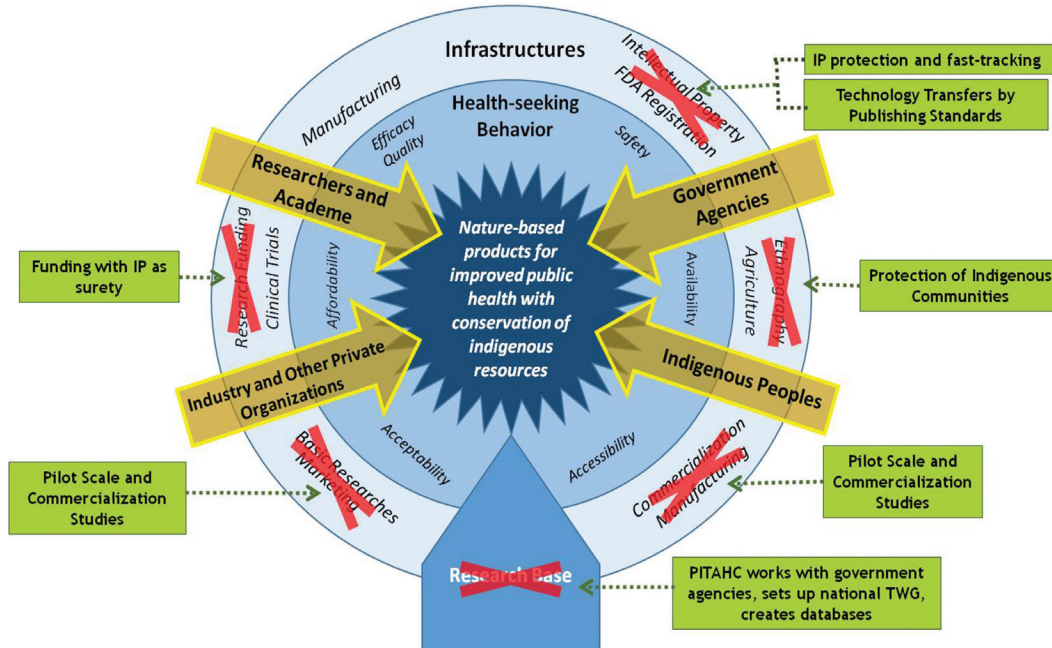


Figure 2. Target points of the proposed optimizations.

these communities should receive a share in the intellectual property. PITAHC may establish schemes through which the communities benefit, such as educational programs for the youth, and livelihood programs in the harvesting of the natural resources for a given nature-based product.

PITAHC should work closely with, and build the capacity of the FDA in the quality assurance of manufacturing nature-based products. PITAHC with the DA must also check whether the raw agricultural materials used are of acceptable quality. PITAHC may also set up an office for research integrity that will process complaints about intellectual property. This said office will review the validity of complaints and refer them to the proper authorities – such as seeking suspension or revocation of PRC licenses of erring individuals or filing patent infringement cases with the IPO.

Database of existing researches and researcher’s expertise can be useful for all researchers in general. This is to avoid duplication of existing research. This database to be created by PITAHC should ideally include all types of papers, from published ones to gray literature. PITAHC must also publish pilot scale and commercialization studies. PITAHC can convert its production plants for pilot scale runs and PITAHC may commission commercialization feasibility studies.

Last of the “optimizations” is the awareness and capacity building role of PITAHC. PITAHC must create educational modules and train researchers on patent application, medical doctors on the use of nature-based products for health service delivery, and consumers on the awareness of nature-based products as alternatives to western medicines. PITAHC should also identify, and

capacitate champions to propose and implement government initiatives or professional association initiatives on nature-based products R&D, training, certification, promotion, and practice (Table 1).

Scope of the optimizations

Given the current state of many players and funders in the realm of “herbal medicines,” the nine identified optimizations will be limited to nature-based products that have no approved therapeutic claims, while calling for more collaborations between PITAHC and PCHRD in pursuit of more herbal medicine discoveries (Figure 3).

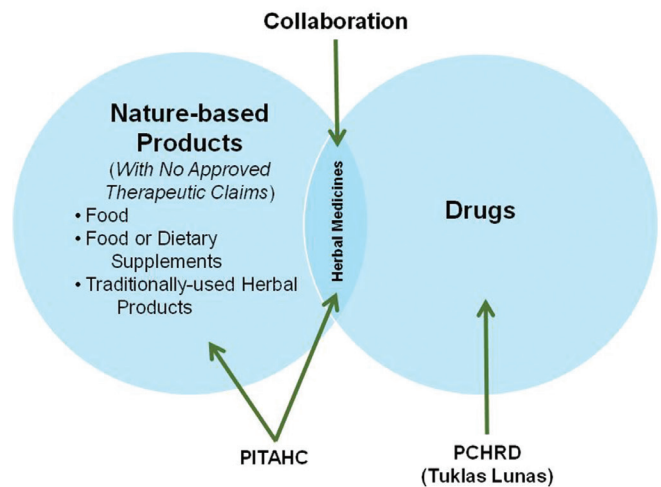


Figure 3. Venn diagram for the roles of the expanded PITAHC initiatives and PCHRD Tuklas Lunas Program that relate to the concepts of nature-based products.

Table 1. “9 Optimizations” and proposed implementation strategies

Optimization	Implementation strategy
1. Intellectual property (IP) rights protection and fast tracking assistance for nature-based products protection	National Technical Working Group (TWG) issues certification of nature-based products submitted to IPO PITAHC creates an IPO desk for nature-based products PITAHC provides funding for patent or Intellectual Property application for nature-based products
2. Provision of appropriate funding mechanism with Intellectual Property rights as surety	PITAHC provides appropriate funding mechanism surety: IP rights (patents, utility model, copyright, industrial design rights, plant varieties, trademarks, trade secrets, etc) PITAHC takes ownership of Intellectual Property rights if researchers do not deliver as per contract PITAHC to assign rights of possessed patents, Intellectual Property rights to new researchers
3. Dissemination of technology transfers by publishing standards for extraction, purification, manufacturing, quality assurance	PITAHC conducts/commissions researches on minimum standards for: <ul style="list-style-type: none"> • Ecologically friendly agriculture of raw materials • Extraction • Purification or isolation • Manufacturing • Quality assurance standards PITAHC disseminates standards PITAHC works with FDA on the conduct of QA in manufacturing and distribution PITAHC works with DA on the conduct of QA in agriculture of raw materials
4. Protection of indigenous communities' knowledge, and raw materials	PITAHC creates office to support indigenous peoples' communities which are sources of knowledge or raw materials and get benefit as: <ul style="list-style-type: none"> • Growers of raw materials • Shares of royalties
5. Working with FDA, DA, IPO, and Professional Regulatory Commission (PRC) on QA and ethical research	PITAHC creates office of research integrity to: <ul style="list-style-type: none"> • Receive complaints • Pursue complaints with PRC • Pursue complaints with IPO PITAHC disseminates list of unethical researchers
6. Setting up a National TWG	PITAHC sets up the TWG composed of the PITAHC Board + health economist + public health specialist + social anthropologist + pharmacist + finance/marketing expert Functions: <ul style="list-style-type: none"> • Sets national priorities • Reviews proposals for funding • Endorses proposals, rules, etc. for PITAHC Board's approval
7. Development of national database of Philippine nature-based products and research	PITAHC sets up repository of databases, including unpublished literature, clinical trials, researcher expertise, etc. PITAHC manages access to repository of databases
8. Publication of pilot scale and commercialization studies*	PITAHC converts its production plants for pilot scale runs PITAHC commissions commercialization feasibility studies PITAHC publishes results of pilot scale run results and commercialization feasibility studies
9. Awareness and capacity building (Patent search, MD appreciation, consumer appreciation)**	PITAHC creates and delivers certificate training modules on: <ul style="list-style-type: none"> • Patent search for inventors • Physician appreciation on nature-based products • Consumer awareness on nature-based products PITAHC identifies and capacitates champions to propose and implement government incentives on nature-based products R&D, training, certification, promotion, practice, and professional association

* This was added after the 3rd consultative meeting.

** This was added after the 4th consultative meeting.

CONCLUSIONS AND RECOMMENDATIONS

Relevant issues to the stakeholders of nature-based products include: (1) fear of plagiarism, (2) insufficient funding from the conduct of the research to manufacturing, (3) lack of capacity of the DA and FDA to monitor quality of producers and suppliers of raw materials and nature-based products, (4) market domination of big companies and proliferation of small unreliable manufacturers, (5) lack of nature-based products that can be commercialized, and (6) lack of conservation mechanisms for natural resources. To resolve or mitigate these six issues, the proponents have identified nine (9) stakeholder-validated strategies or “optimizations”. These “9 optimizations” are envisioned to help the country

to produce at least 5 commercial products and 20 patents, by allowing different specialized players to find synergies, specifically among researchers, farmers, manufacturers, and retailers, for a common goal, which is to develop nature-based products for population health improvements.

The study team estimated that the optimizations can be achieved for a cost of PhP 816 million; 22.2% of which shall be allocated to personnel expenses; 27.0% to maintenance, operating, and other expenses; 0.3% for capital outlay specifically for the database; 12.9% for commissioned researches; and 36.7% for marketing and awareness campaigns. The estimated PhP 816 million is within the rule of thumb in research and development, as successful businesses usually allocate 2-3% of their revenues to research and development.

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Statement of Authorship

All authors have approved the final version submitted.

Author Disclosure

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