Journal of Rural and Regional Innovation Studies

E-ISSN: XXXX-XXXX | P-ISSN: XXXX-XXXXX
JORRIS, Vol. 2 (1), 2026 (70-109)
https://journal.unesa.ac.id/index.php/jorris

Community Economic Empowerment through Macaranga-Based Pharmaceutical Development: A Participatory Case Study in Biatan Hilir

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Keywords:
Macaranga ; Produits pharmaceutiques biologiques ; Politique commerciale ; Chaîne d'approvisionnement ; Autonomisation économique

***To cite*:**
Setyawan, M.P.,Fitriyah, A., (2026). Community Economic Empowerment through Macaranga-Based Pharmaceutical Development: A Participatory Case Study in Biatan Hilir. *Journal of Rural and Regional Studies.* 2 (1) 70-109

Abstract

This study aims to address the gap between Indonesia's biodiversity, particularly the genus Macaranga, as a source of biopharmaceuticals, and its underutilized contribution to the local economy. Its research is a qualitative, descriptive-analytical study that uses policy analysis and comparative trade analysis. The research focuses on evaluating the opportunities and challenges of international trade in Macaranga-based biopharmaceutical products by reviewing national policy documents and relevant bilateral and multilateral trade agreements. The results indicate that Macaranga has high biopharmaceutical potential, especially for antioxidant and anticancer properties. However, the community-level supply chain (Biatan Hilir Village) still faces significant challenges, including unstructured harvesting. Therefore, an integrated supply chain model based on Village-Owned Enterprises (BUMDes) and an export product scheme in the form of standardized dry extracts is proposed as initial steps. Further discussion highlights that efforts to penetrate the international market require regulatory cooperation with four key partner countries to reduce non-tariff barriers, facilitate recognition of certification, and strengthen Indonesia's bargaining position. Its research is academically significant because it contributes to the literature on bioeconomy development, offers practical strategic recommendations for designing sustainable and equitable supply chains, and opens up opportunities for communal business models that can serve as prototypes.

Introduction

Indonesia Indonesia is known as a megadiverse country, home to more than 30,000 species of vascular plants, of which approximately 7,000 have potential for use as traditional medicines (Heyne, 1987; World Health Organization, 2021). Its rich flora presents Indonesia with a significant opportunity to develop biopharmaceuticals as the basis for a globally competitive national bioeconomy. However, the utilization of this potential is still far from optimal. Most Indonesian herbal products are still dominated by raw materials, with low value chains and limited contributions to the welfare of rural communities living adjacent to forests (Astutik et al., 2025). It creates a paradox: abundant biological resources have not yet fully become capital for inclusive and sustainable economic development.

One of the promising but relatively underexplored groups of flora is the genus Macaranga (Euphorbiaceae). It is widely distributed in Kalimantan and is known as a pioneer in post-logging secondary forest regeneration (Davies et al., 2001). From a pharmacological perspective, various Macaranga species have been reported to contain important secondary metabolites, including flavonoids, terpenoids, phenolics, and alkaloids, with broad biological activities. For example, Macaranga trilobata has high antioxidant activity (Ardhany et al., 2018), Macaranga hypoleuca produces the bioactive compound apigenin (Aisya et al., 2024), and Giant Macaranga shows promising antimalarial activity (Muhaimin et al., 2019). Other research on Macaranga lowii confirmed the significant total phenolic content and antioxidant potential (Ningsih et al., 2022), while Macaranga tanarius from East Kalimantan has been shown to contain secondary metabolites with antioxidant effects and acute toxicity (Fikriah et al., 2024)

Although the pharmacological and phytochemical literature demonstrates significant potential, studies of the social, economic, and cultural contexts of local communities living alongside these species remain very limited. Biatan Hilir Village in Berau Regency, East Kalimantan, for example, has a rich forest flora, including Macaranga. However, the community's socio-economic conditions still depend on traditional primary sectors with low added value. Community economic activities tend to be dominated by subsistence agriculture, poorly managed non-timber forest products, and limited access to processing technology and markets (Pasaribu et al., 2021). Thus, the biopharmaceutical potential of Macaranga has not been integrated as a sustainable alternative source of income for local communities.

This gap becomes even more apparent when considering global experience. In many countries, the success of biopharmaceutical development rests on a sustainable and inclusive supply chain model: from cultivation and sustainable harvesting to processing in accordance with international quality standards to global distribution supported by trade agreements (FAO, 2019). Indonesia does have a policy framework that promotes herbal product exports, such as through the National Action Plan on Biodiversity and free trade agreements with partner countries (Kementerian PPN/Bappenas, 2024). However, the benefits of these policies have not been fully

realized at the grassroots level due to limited integration among scientific research, local community capacity, and trade policy support.

Based on the problems that have been described, this study attempts to formulate several research questions, namely: (1) What is the pharmacological potential of Macaranga species commonly found in Biatan Hilir Village as raw materials for anticancer pharmaceuticals?; (2) What is the feasibility of the supply chain from cultivation, harvesting, to export of Macaranga -based products in Biatan Hilir Village?; (3) What kind of export product scheme is most optimal to guarantee added value for local communities?; and (4) How can trade policies and bilateral cooperation be designed to support biopharmaceutical-based economic empowerment in Biatan Hilir Village?

To answer these questions, researchers reviewed previous research on Macaranga across pharmacological, ecological, and socio-economic aspects to map potential, identify limitations, and identify open research gaps. First, research on the species Macaranga in East Kalimantan, particularly in Biatan Hilir Village, remains very limited. Most existing publications focus only on common species or other regions in Indonesia, such as Sumatra and Java, without highlighting local variations in East Kalimantan. Consequently, data on the phytochemical content and pharmacological activities of these species are limited. Macaranga at the local population level has not been documented. For example, the study "Antimalarial Activity of Macaranga gigantea Leaf Extract" by Muhaimin et al. provides an initial overview of the biological potential of the species. Still, it does not specifically highlight habitat variations in East Kalimantan (Muhaimin et al., 2019). Similarly, research on water productivity in Giant Macaranga stands in Samarinda focuses solely on ecological aspects, rather than on bioactive potential or pharmacological uses (Susilowati, 2021). It indicates the need for in-depth studies of the pharmacological potential of the Macaranga species in more specific locations, such as Biatan Hilir.

Second, most research on Macaranga in Indonesia has stalled at the laboratory stage. These studies generally focus on compound isolation and testing for anticancer, antibacterial, or antimalarial activity, but are rarely linked to socioeconomic aspects or sustainable supply chains. For example, research on stilbenoid compounds from Macaranga aleuritoides successfully demonstrates cytotoxic activity against P-388 cancer cells (Aldin et al., 2019), but did not discuss how the compound could be developed into a community-based commercial product. Likewise, antibacterial tests of Macaranga motleyana against Streptococcus mutans emphasize laboratory results without addressing their potential use at the village level (Eva Marliana et al., 2025). The gap highlights the need for a multidisciplinary approach that connects laboratory research with community-based economic development.

Third, there is a lack of integration between basic science and the practical needs of rural communities. Phytochemical and pharmacological studies are important as a foundation, but without translation into field applications, their

benefits for local economic empowerment will not be optimal. To date, no publication has been found that comprehensively combines the results of phytochemical analyses Macaranga with village community empowerment studies, market analysis, and biopharmaceutical product export standards. As a result, the potential Macaranga remains academic data, not a real solution for the welfare of village communities like Biatan Hilir.

Fourth, opportunities to leverage international trade policies to boost biopharmaceutical exports have not been fully realized, despite Indonesia's aggressive promotion of the natural-based pharmaceutical industry, as reflected in news reports of strategic cooperation to develop it (Santoso, 2025). A study on Macaranga coniferin in the Wehea-Kelay forest area (East Kalimantan) also confirmed the potential for local biopharmaceuticals with cytotoxic activity against cancer cells. Still, this research ended at the biological level and did not link it to export routes or international standards (S. Purnama, 2025). In addition, a general analysis of Indonesia's trade agreements, published by ASEAN Briefing, outlines opportunities through FTAs and CEPAs but does not specifically highlight the herbal and biopharmaceutical sectors (Medina, 2023). It shows that there is room for research to bridge the scientific potential of Macaranga with relevant trade policy opportunities.

A review of previous research reveals several conceptual gaps that remain unfilled. First, studies on Macaranga in Indonesia mostly focus on species from Sumatra, Java, or Kalimantan. In contrast, studies highlighting the phytochemical variations and pharmacological activities of Macaranga in East Kalimantan, particularly in Biatan Hilir Village, are practically non-existent. Second, existing research often stops at the laboratory stage, for example, limited to compound isolation or cytotoxicity testing, without progressing to socio-economic dimensions or supply chains that could support commercial development. Third, the integration between basic science and the practical needs of rural communities remains weak, so research results have not yet been translated into translational models capable of empowering local economies. Fourth, despite significant opportunities presented by international trade policies, no research has linked the potential of Macaranga biopharmaceuticals to relevant trade agreement frameworks, quality standards, or export regulations.

Building on this knowledge gap, this research is designed to answer several fundamental questions about development opportunities. Macaranga as a community-based biopharmaceutical commodity. Specifically, this study aims to: (1) analyze the pharmacological potential Macaranga from species commonly found in Biatan Hilir Village; (2) assessing the feasibility of the supply chain from cultivation and harvesting to product export; (3) formulating an optimal export product scheme to ensure economic added value for local communities; and (4) analyzing and designing a bilateral trade cooperation policy scheme that can support community-based biopharmaceutical development.

In line with these objectives, this study offers novelty in several aspects. First, it is a local-specific study that directly identifies the pharmacological potential of Macaranga in Biatan Hilir Village, an area that has yet to receive academic attention and where phytochemical data and biological activities are minimally documented. Second, the approach used is multidisciplinary, integrating phytochemical analysis, supply chains, village socio-economic dimensions, and international trade policy frameworks. It addresses the weaknesses of previous research, which generally stopped at the laboratory level and ignored the dimensions of sustainability and market connectivity. Third, this study proposes a translational biopharmaceutical model that bridges basic science with village economic empowerment, an approach not yet reported in the literature, enabling research results to be directly translated into a village-based communal business model. Fourth, this study positions Macaranga not only as a scientific object but also as a potential export commodity that can be maximized through bilateral trade schemes or free trade agreements, thereby contributing to Indonesia's economic diplomacy while strengthening its competitiveness in the global market.

The significance of this research is reflected in its contributions to three main areas. Academically, this research fills a gap in the literature regarding phytochemical variation and pharmacological activity. Macaranga from East Kalimantan, while also presenting an integrative model of basic research, village socio-economic studies, and international trade policy. Thus, the research results have the potential to broaden the horizons of Indonesian biopharmaceutical research, which has been fragmented. In practice, this research generates strategic recommendations for designing a sustainable and equitable supply chain from cultivation to export along with a fair-trade mechanism that ensures the distribution of added value to the Biatan Hilir Village community. These recommendations also open the door to establishing a communal biopharmaceutical business model that can serve as a prototype for other villages in Indonesia. Policy-wise, this research provides concrete input for formulating a national strategy to develop the biopharmaceutical industry. It opens up options for using international trade instruments, both bilateral and multilateral, to expand global market access. Thus, this research contributes not only to advancing science but also to creating real, inclusive, sustainable, and strategic solutions that position Indonesia in the global biopharmaceutical economy.

Methods

This research is a descriptive-analytical qualitative study with a policy analysis and comparative trade analysis approach. The research focuses on evaluating the opportunities and challenges of international trade in biopharmaceutical products, based on Macaranga, by reviewing national policy documents and relevant bilateral and multilateral trade agreements. The data sources used are entirely secondary. The national regulations reviewed include Law No. 36 of 2009 on Health, Law No. 11 of 2020 on Job Creation, various BPOM regulations on

traditional medicines and phytopharmaceuticals, and export policies issued by the Ministry of Trade. International trade documents include bilateral agreements such as the Indonesia-Japan Economic Partnership Agreement (NICE), the Indonesia-EU Comprehensive Economic Partnership Agreement (EU-CEPA), the Indonesia-US Trade and Investment Framework Agreement (TIFA), and the ASEAN-China Free Trade Area (ACFTA).

Meanwhile, the multilateral agreements analyzed include WTO rules related to SPS (Sanitary and Phytosanitary), TBT (Technical Barriers to Trade), and TRIPS (Trade-Related Aspects of Intellectual Property RightsIn addition, the research also utilized international trade databases such as UN Comtrade, ITC Trade Map, ASEAN Stats, and Ministry of Trade reports, plus academic literature and policy reports on biopharmaceuticals, herbal supply chains, and international standards (GMP, GAP, FDA, EMA, CFDA).

Data collection was carried out through document studies (documentary analysis), namely the collection, sorting, and categorization of regulations, trade agreements, and technical standards relevant to biopharmaceutical commodities. In addition, a desk study was conducted by examining academic literature and reports from international institutions such as the WHO, UNCTAD, WTO, and IMF that discussed biopharmaceutical competitiveness and herbal product export trends.

The data analysis technique in this study was carried out in three complementary stages: policy analysis, competitiveness measurement, and economic value simulation.

The first stage is a policy analysis that reviews the substance of international trade regulations in Japan, Germany (the European Union), the United States, and China, and compares them with the national regulatory frameworks for biopharmaceutical products. The analysis aims to identify policy gaps, non-tariff barriers, and opportunities for standards harmonization, for example, in areas such as raw material certification, product safety, and toxicity testing. The results of this analysis provide a foundation for understanding the structural factors that influence the competitiveness of Indonesian biopharmaceutical products in the global market.

The second stage uses the Policy Analysis Matrix (PAM) as a tool to assess the competitiveness of Macaranga extract from both a private and social perspective. The PAM allows a comparison of producers' actual profits under prevailing policy conditions with potential profits that would result if the market operated without distortion. Three scenarios are simulated:

1. Baseline scenario, using actual prices and costs of production;
2. Policy-distorted scenario, which takes into account domestic input subsidies and export tariffs;
3. Trade-liberal scenario, assuming input and output prices follow international market mechanisms without policy intervention.

Table 1. Simulated Policy Analysis Matrix (PAM) for Macaranga Extract (per kg and 100 tons)

Domestic factors (cost)	1.5625	1.5172	0.0453	156,250.00	151,724.10	4,525.90
Tradable inputs (cost)	2.3438	2.2759	0.0679	234,375.00	227,586.20	6,788.80
Total costs	3.9062	3.7931	0.1131	390,625.00	379,310.30	11,314.70
Profit (Revenue − Costs)	1.0938	1.7069	−0.6131	109,375.00	170,689.70	−61,314.70
Profitability ratio (Revenue/Costs)	1.2800	1.4500	−0.1700	—	—	—

Item	**Private (USD/kg)**	**Social (USD/kg)**	**Divergence (Private - Social, USD/kg)**	**Private (USD / 100 ton)**	**Social (USD / 100 ton)**	**Divergence (USD / 100 ton)**
Output (price)	5.0000	5.5000	−0.5000	500,000.00	550,000.00	−50,000.00

The PAM results show private profitability ratios of 1.28 and social profitability ratios of 1.45, indicating that Macaranga products have the potential to become more competitive once policy-distortion prices are eliminated. The negative divergence in the profit component (−0.6131 USD/kg) indicates that current domestic policies continue to suppress economic efficiency. In other words, under trade liberalization, producers can achieve margin increases of up to ±28% compared to actual conditions.

These findings indicate room for improvements to input policies (such as tariffs on imported solvents and domestic certification costs) that could strengthen Macaranga's position in the export market. Furthermore, simulation results at a 100-ton production scale indicate a potential increase in net value of approximately USD 61,314 if policy barriers are removed.

The third stage, a comparative trade analysis, was conducted by mapping the technical standards and regulations of major partner countries, such as Japan's Mutual Recognition Agreement (MRA), the European Union's Good Manufacturing Practice (GMP) regulations, the FDA approval in the United States, and China's Traditional Chinese Medicine (TCM) certification system. The analysis showed that the compliance gap between Macaranga products and international pharmacopoeial safety and documentation standards remains around 15-20%. Assuming this gap can

be closed through improved raw material quality and production certification, the potential increase in economic value is estimated at USD 0.8-1.2 million per 100 tons of production. It reflects the real impact of regulatory integration and technical efficiency on the competitiveness of Indonesian biopharmaceuticals in the global supply chain.

Through this approach, this research produces output in the form of recommendations for optimal export schemes, both through bilateral channels (Japan's MRA, European organic certification, FDA approval, integration into China's TCM) and multilateral (utilization of the ASEAN-China FTA mechanism, and the WTO SPS/TBT instrument to reduce non-tariff barriers). In addition, the research formulates a trade diplomacy strategy for Indonesian biopharmaceuticals that is not only oriented towards global competitiveness but also ensures added economic value at the village level, especially in Biatan Hilir, a production base. Macaranga.

Result

Potential and Supply Chain Macaranga in Biatan Hilir Village

Scientific studies have placed Macaranga as a genus with high biopharmaceutical potential. More than 190 secondary metabolites have been identified, including prenylated flavonoids, stilbenoids, phenolics, and terpenoids, with the highest concentrations found in leaf tissue (Yoder et al., 2007). This finding is important not only from a laboratory perspective but also for management strategies. Focusing on leaf harvesting enables repeated production cycles without damaging stems or roots, enabling the supply chain to be built on the principles of ecological sustainability. In other words, phytochemical data provides the basis for developing a production model that balances economic value and resource sustainability.

Several pharmacological studies have confirmed this potential. Prenylated and stilbenoid isolates from several species have demonstrated potent cytotoxic activity against cancer cell lines in assays (Aldin et al., 2019; H. Purnama, 2016; Yoder et al., 2007). Leaf extract M. triloba is reported to have high antioxidant capacity, while M. Gigantea showed antiplasmodial activity associated with compounds such as apigenin (Ardhany et al., 2018). However, findings on M. tanarius, which indicate potential acute toxicity(Fikriah et al., 2024), suggest that the development of Macaranga cannot focus solely on its pharmacological potential; a rigorous safety testing program must accompany it. Analysis of these data confirms that commercialization opportunities for Macaranga are very promising, especially for anticancer and antioxidant purposes, but can only be realized with investment in translational research, standardization of marker compounds, and systematic toxicology testing.

Table 2. Comparative Pharmacological Characteristics of *Macaranga* and Other Anticancer Herbs

No	Herbal Plants	Main Active Compounds	Dominant Anticancer Mechanism	Cancer Cell Targets / Molecular Pathways	Pharmacological Advantages	Challenges / Limitations
1	**Macaranga spp.** (*M. tanarius*, *M. denticulata*)	Flavonoid terpenilasi (macarangin, tanariflavanone), stilbenoid	Induction of apoptosis, inhibition of proliferation, and antiangiogenesis	p53, Caspase-3, and NF-κB pathways	Strong cytotoxic activity against breast, lung, and leukemia cancer cells; also, high antioxidant activity	There have been no clinical trials; standardization of extraction and toxicity has not been verified.
2	**Curcuma longa**(Turmeric)	Curcumin	Apoptosis induction, NF-κB inhibition, anti-inflammatory	PI3K/Akt, MAPK pathway	Many early-phase clinical trials, multi-target	Low bioavailability; new delivery technology needed
3	**Andrographis paniculata**(Sambiloto)	Andrografolid	Inhibition of proliferation and angiogenesis	STAT3 and VEGF pathways	Potent activity against colon and prostate cancer; immunomodulator	High doses can be toxic to the liver
4	**Camellia sinensis** (Green tea)	Epigallocatechin gallate (EGCG)	Antioxidant, metastasis inhibition	Wnt/β-catenin pathway and ROS	Lots of clinical evidence; safe for long-term use	Effectiveness depends on individual metabolism
5	**Phyllanthus niruri**(Meniran)	Lignan (phyllanthin, hypophyllanthin)	Induction of apoptosis, inhibition of DNA polymerase	Caspase-9 and the PARP pathway	Combination of hepatoprotective and anticancer effects	Moderate activity; low compound stability
6	**Tinospora cordifolia**(Brotowali)	Tinosporin, berberin, palmatin	Immune modulation, inhibition of proliferation	p38 MAPK and NF-κB pathways	Systemic effects on body immunity; adaptogenic	Less selective against cancer cells; limited clinical data

Compared to other plants more established in the global market, Macaranga spp. exhibits a complex and promising chemical profile. The predominance of prenylated flavonoids and stilbenoids makes its anticancer activity multi-targeted, simultaneously targeting both proliferation and apoptosis pathways. In terms of cytotoxic activity, Macaranga is comparable to Andrographis paniculata but has a higher antioxidant potential due to its abundant phenolic content.

Macaranga's primary advantage lies in its potential for sustainable production, as the leaves can be harvested repeatedly without damaging the parent plant, unlike turmeric and bitter leaf, which require harvesting the roots or stems. Its sustainability enables Macaranga to be positioned within a biopharmaceutical economic model based on ecological conservation.

However, from an industrial development perspective, acaranga s still in the pre-clinical experimental stage, while herbs lsuch asturmeric and green tea have reached tlinical validation and global commercialization Therefore, research and innovation policy needs to be directed at three main areas: Standardization of compound markers to ensure pharmacological consistency between batches; Long-term toxicology studies, especially to ensure the safety of human consumption doses; and Transdisciplinary research consortia connecting universities, pharmaceutical institutions, and industry to accelerate the translation of research results into phytopharmaceutical prototypes.

Looking further at the ecological side, Macaranga is a pioneer species that can grow on critical post-logging land or nutrient-poor soil (Whitmore, 1998). It has a characteristic that opens up opportunities to integrate Macaranga production with ecosystem restoration efforts. It means that cultivating Macaranga can be implemented on previously unproductive land while also supporting environmental rehabilitation. If managed well, this strategy has the potential to reduce production costs by eliminating dependence on primary forests and increase social acceptance by aligning with conservation agendas.

Despite the promising biopharmaceutical potential of Macaranga, the supply chain continues to face significant structural and institutional barriers. To date, Macaranga raw materials are largely sourced from wild populations, with no structured cultivation system in place. Its reliance on wild sources not only increases ecological pressure but also makes raw material availability unstable and its quality highly variable between seasons. Harvesting practices generally do not adhere to Good Agricultural and Collection Practices (GACP) standards mandated by the WHO, while primary processing units, such as drying, extraction, and standard storage facilities, are not yet available at the community level. As a result, the value chain stops at the raw-material level without any quality-improvement process, leaving local farmers or collectors as price takers with very thin economic margins (Laing et al., 2023).

Furthermore, these structural barriers are exacerbated by institutional and land governance factors. Tenure conflicts, overlapping forest concession permits, and

unclear conservation area boundaries have created long-term investment uncertainty (Pyakurel, 2016). This situation not only hinders domestication and replanting efforts but also discourages financial institutions and social investors from entering the forest-based biopharmaceutical sector. Thus, technical (cultivation and processing) and institutional (land and market access) limitations interact simultaneously, creating a value-added trap in which abundant biological resources are never fully converted into community economic strength. Without targeted intervention, the Biatan Hilir community will remain marginalized in the global biopharmaceutical supply chain.

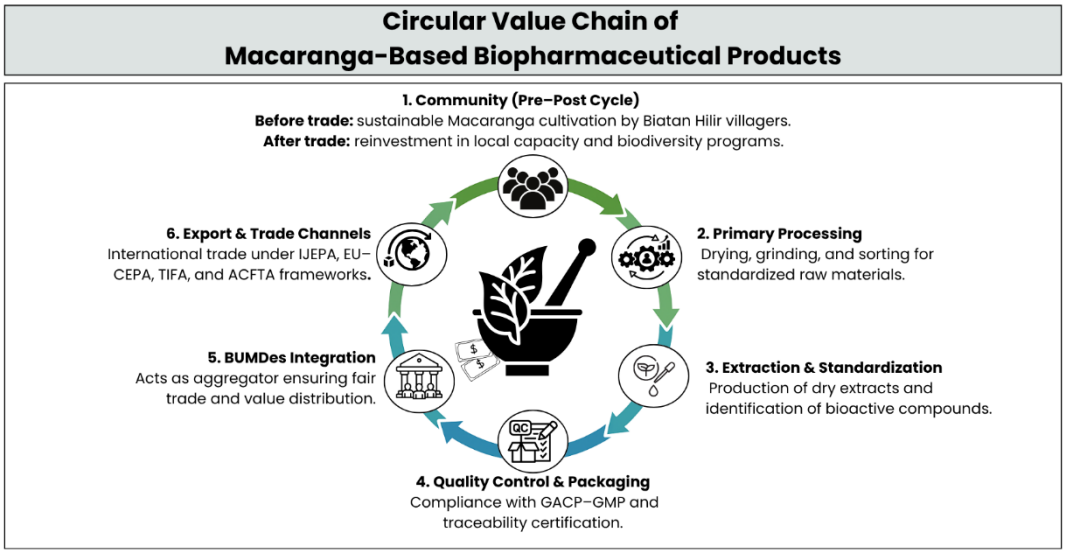

Fig. 1. Circular value chain of Macaranga-based biopharmaceutical products illustrating the flow of materials and value from cultivation to export trade.

To address these challenges, developing an integrated supply chain model based on Village-Owned Enterprises (BUMDes) is a strategic and contextual option. BUMDes can act as aggregators of cultivated and collected produce, as well as operators of primary processing facilities equipped with quality recording and traceability systems that meet international buyer standards (World Health Organization, 2003). By centralizing these functions within a single community-owned entity, BUMDes can reduce value-added leakage that has traditionally been transferred to intermediaries and improve farmers' bargaining power in price negotiations. Furthermore, a traceability system is also a prerequisite for obtaining Fair Trade or Organic certification, which can open access to premium markets in Japan and the European Union.

However, implementing an integrated Village-Owned Enterprise (BUMDes) model cannot be separated from the need to improve human resource capacity. The most crucial aspects include post-harvest quality management, digital production recording, and transparent governance to ensure operational accountability. In this context, partnerships with universities and research institutions are key. Universities can provide technical support through applied research, such as identifying adaptive superior varieties, developing standard operating procedures (SOPs) for harvesting and drying, and analyzing active ingredients using HPLC or LC-MS. The results of

this research not only improve process efficiency but also strengthen the product's scientific claims, which are necessary for penetrating the export biopharmaceutical market.

As a first step, a small-scale pilot project should be developed in Biatan Hilir to integrate three key components of the value chain: (1) standardized cultivation based on GACP, (2) primary processing at the village level, and (3) a verified quality record system. The project will serve as a basis for testing the technical, financial, and social feasibility of the integrated BUMDes model before scaling it up to other villages. Its phased approach will enable institutional learning and the adaptation of the business model to suit the local context.

During the implementation phase, risk management must be designed from the outset. Three main sources of risk that need to be anticipated are:

1. Biomass quality variability, which can be addressed through cultivation and harvest protocols to control active metabolite levels;
2. Tenurial conflicts, which require a village deliberation-based mediation mechanism and the involvement of local government as a facilitator of access rights; and
3. Initial capital limitations can be overcome through a blended finance scheme that combines research grant funds with revolving microcredit for farmers or cooperatives.

From a strategic perspective, the success of the Macaranga supply chain is measured not solely by increased production volume but also by the system's ability to produce products of consistent quality, add value that remains at the community level, and have a positive ecological impact. This approach shifts the forest economy paradigm from mere resource exploitation to a regenerative economy, where environmental sustainability and social well-being are the foundations of added value. Thus, Macaranga is positioned not only as a biological resource but also as an economic, social, and ecological asset that can elevate Biatan Hilir's position in the global biopharmaceutical industry.

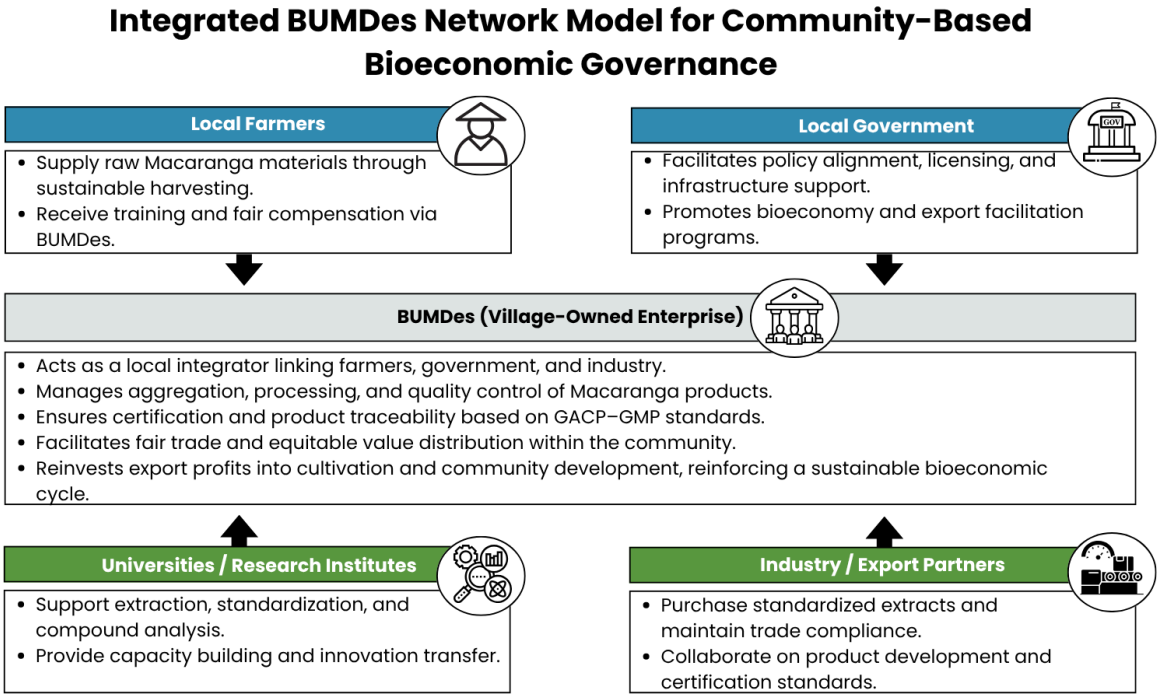

Fig. 2. Integrated BUMDes network model linking local farmers, government, research institutions, and export partners within the Macaranga bioeconomy framework.

4.2 Export Products and Their Considerations

The global market for herbal extracts and botanical ingredients is growing rapidly, creating opportunities for the development of Macaranga from Biatan Hilir. Several industry reports estimate that the herbal extracts market will reach tens of billions of US dollars in the next decade, with an annual growth rate of around 8-10 percent (Grand View Research Inc., 2023). Its growth is primarily driven by shifts in consumer behavior that increasingly prioritize natural, labeled, clean, and sustainably produced products. With chemical characteristics rich in flavonoids and stilbenoids, as well as ecological sustainability considerations, Macaranga has a strong enough position to enter the big current of the global herbal industry.

Table 3. Comparison of Product Routes and Packaging Considerations for Macaranga Exports from Biatan Hilir

Aspects of Consideration	Standardized Dry Extract / Powder	Isolation of Pure Compounds (e.g., Conglomeratin)	Propolis Raw Material (Makarangga Based)
Technology Readiness Level (TRL)	High; can be achieved in the short term (TRL 6–7)	Low; medium (TRL 3–4), requires advanced research infrastructure	Intermediate (TRL 5–6); can be developed based on local ecosystems
Economic Added Value	Medium; stable margin and fast realization	Very high; potential premium price for active pharmaceutical ingredients	Medium-high; depending on ecological branding

			and organic certification
Facilities & Human Resources Needs	Drying, extraction, standardization of marker compounds, university laboratory QC	Chromatography, spectroscopy, preclinical & clinical testing facilities, advanced research human resources	Resin collection facilities, natural fermentation, organic certification, system traceability
Production Chain Complexity	Low-medium; easy to integrate with local MSMEs and cooperatives	High need for integration of global research, pharmaceutical, and industrial institutions	Intermediate; requires coordination between beekeepers, forest managers, and local communities.
Product Stability & Logistics	Very stable, easy to pack and export (aluminum foil packaging / HDPE bottles)	Relatively sensitive, requires controlled storage and cold chain	Stable in resin or tincture form; glass or dark bottle packaging
Market Access & Segmentation	Area: nutraceuticals, cosmetics, and supplement ingredients	Limited but high value: pharmaceuticals and biotechnology	Premium niche market: natural cosmetics, honey, organic propolis
Financial Risk	Low-medium; moderate initial investment, quick payback	Very high; large R&D and certification costs, strict regulatory risks	Intermediate; depends on niche market acceptance and authenticity of geographic identity
Potential Local Social Impact	High; quickly provides economic benefits to the Biatan Hilir community	Low in the short term; benefits will only be felt after commercialization	High; strengthening ecologically based economy and biodiversity conservation
Recommended Development Strategy	Short-term focus: initial commercial production and limited exports	Medium-long-term goals through research consortia	Differentiation strategy: *eco-branding and* geographic certification (*Geographical Indication*)
Examples of Ideal Export Packaging	Sachet 100-500 g dry powder/bottle 250 mL liquid extract, labeled "standardized extract"	10-50 mL vials / pharmaceutical capsules, laboratory sterile packaging	100 mL dark glass bottle / solid resin box, label "eco-propolis from Borneo Forest"

Of the three development pathways, three can be selected based on technical readiness and targeted added value. The first option is a standardized dry extract or powder. It is the most realistic form to implement in the near future, as it only requires simple processing facilities such as drying and extraction. Product standardization, for example, involves determining the quality of marker compounds. Quality consistency testing can be conducted through collaboration with university laboratories or industry partners. Logistically, dry extracts are relatively stable, easy to package, and have a broad market, ranging from nutraceuticals to cosmetics. It means the economic benefits of this route can be felt immediately by the Biatan Hilir community, without the significant risks associated with other product schemes.

The second option is the isolation of a pure compound, such as conglomeratin. Pure compounds offer significantly higher commercial value because they can be used as active pharmaceutical ingredients and enable specific pharmacological claims. However, this route requires significant research capacity, from advanced chromatography and spectroscopy facilities to the ability to conduct preclinical and clinical trials. The costs and time required are also substantial. Therefore, it makes more sense to position the development of pure compounds as a medium- to long-term goal, implemented through research consortia involving universities, pharmaceutical institutions, and international partners. A possible strategy is to start with a dry extract product for the market, while gradually building preclinical research data that will eventually form the basis for developing pure compounds.

The third alternative is to use Macaranga as a raw material for propolis. Its route is more geared toward a niche market, but it offers unique differentiation. The case of Brazil shows that propolis with a clear geographic identity, coupled with organic certification and system traceability, can penetrate the Japanese and European markets at premium prices (Ribeiro et al., 2023). For Biatan Hilir, a similar strategy can be implemented by emphasizing the ecological linkages among Macaranga, endemic bees, and local agroforestry systems. Branding based on environmental and sustainability narratives like this can increase product appeal while keeping added value at the community level.

In determining the form of export products, Macaranga from Biatan Hilir Village, market opportunities, and regulatory barriers are key considerations. Global industry trends indicate that herbal extracts and botanical ingredients are projected to grow rapidly this decade, driven by increasing consumer demand for natural products and clean label (Grand View Research Inc., 2023). Of the three available product schemes, dry extracts or standardized powders appear most realistic for the initial stage because the regulatory pathway is relatively simple, can be marketed as a raw material for cosmetics or supplements, and still meets the GACP and GMP standards required by international bodies (Turck et al., 2024.,World Health Organization, 2003). Meanwhile, the isolation of pure compounds, such as conglomeratin, has high value-added potential because it supports specific pharmacological claims. Still, regulatory obstacles are much greater for example, the

Novel Food Regulation in the European Union (Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods. Official Journal of the European Union., 2018) and compliance with CGMP standards in the United States (U.S. Food & Administration, 2007),so this strategy is more appropriately positioned as a long-term goal through research consortia and industry collaboration. Another alternative is the development of pbeesropolis products based on interactions between acaranga and bees. It also offers market differentiation opportunities, as evidenced by Brazil's successful experience penetrating the Japanese and European markets through geographic branding, organic certification, and systems.traceability (Ribeiro et al., 2023), although its implementation is highly dependent on local institutional support and a slower formal recognition process (Laing et al., 2023b) Therefore, development priorities for Biatan Hilir should focus on dry extracts as an initial entry point, given their broad market opportunities and relatively low regulatory barriers. Propolis-based strategies can be positioned for local differentiation, with the development of pure compounds a longer-term target once more robust evidence of safety and efficacy is available, allowing villages to gradually position themselves within the global value chain without facing the risk of overly heavy regulation from the outset.

Export success is also inseparable from technical and institutional readiness at the local level. Several steps must be integrated, including developing standard operating procedures (SOPs) for cultivation and harvesting that comply with GACP guidelines, establishing primary processing units in villages capable of meeting microbiological standards, and implementing a traceability system that allows simple procedures to trace product origins. Furthermore, long-term contracts with industrial partners are also necessary to ensure market stability. Village-Owned Enterprises (BUMDes), as village institutional actors, play a central role in this context. Supported by capacity building and access to innovative financing, such as blended finance schemes, BUMDes can be a driving force for product processing and marketing (Laing et al., 2023b; World Health Organization, 2003)

Ultimately, the choice of export products for Macaranga should be guided by the development of downstream biodiversity, which must be implemented strategically in stages. Standardized dry extracts can serve as an initial entry point because they are the quickest to develop. In contrast, the development of pure compounds is positioned as a long-term target through research consortia. At the same time, niche market opportunities for locally sourced propolis are also worth exploring. In this way, villages can participate in global value chains, maintain environmental sustainability, and meet international regulatory demands. Its phased strategy will ensure that Macaranga Biatan Hilir serves as an example of a sustainable biopharmaceutical commodity emerging from a village initiative.

Recommendations for Bilateral Trade Cooperation Schemes

Table 4. Comparative Analysis of Biopharmaceutical Regulations and Export Potential (Macaranga)

Aspect	Japan	Germany (European Union)	United States of America	China
Main Regulatory Framework	*Pharmaceutical and Medical Devices Act (PMD Act)*; strict regulation of pharmaceutical substances, with oversight by PMDA	*Regulation (EU) 2018/848*(organic),*Directive 2002/46/EC*(supplement),*Regulation (EU) 2015/2283*(Novel Food), and*GACP/GMP EMA*	*Dietary Supplement Health and Education Act (DSHEA), 21 CFR Part 111* (cGMP), *21 CFR §190.6*(AND),*21 CFR Part 101* (Labeling)	*Pharmacopoeia of the People's Republic of China* and *Regulation on the Administration of Traditional Chinese Medicines*; supervision by NMPA
Allowed Product Categories	Traditional medicine / active ingredient extract with GMP certification	*Nutraceutical / Herbal Food Supplement*; non-therapeutic health claims	*Dietary Supplement*; klaim fungsi (structure/function claims)	*Traditional Chinese Medicine Ingredient*(raw materials for traditional medicine or herbal supplements)
Supervisory Authority	*PMDA (Pharmaceuticals and Medical Devices Agency)*	*BfArM / BfR / EFSA / EMA*	*FDA - Center for Food Safety and Applied Nutrition (CFSAN)*	*NMPA (National Medical Products Administration)* & *SAMR*
Main Technical Requirements	1. Mandatory GMP certification 2. Foreign facility inspections 3. MRAs can reduce re-inspections	1. Group organic certification (Art. 36, Reg. 2018/848) 2. Safety & toxicology dossier for Novel Food 3. GACP & GMP compliance	1. cGMP Compliance (21 CFR Part 111) 2. NDI Notification 75 days before market entry 3. Label must be non-therapeutic	1. Certification GMP 2. TCM and *Registration of Imported Raw Materials* 3. Residue & contaminant testing is mandatory

Trade Mechanisms / Bilateral Agreements	*EU–Japan MRA*(GMP recognition model), *IJEPA can* be used for certification recognition	Access via *EU GSP+ and EU-Indonesia FTA (under negotiation)*	*US–Indonesia TIFA* (Trade and Investment Framework Agreement)	*ASEAN–China FTA* And *Regional Comprehensive Economic Partnership (RCEP)*
Market Opportunities	Developed pharmaceutical market with high demand for natural ingredients; high reputation for anticancer biopharmaceuticals	Europe's largest supplement market; high added value for organic & nutraceutical products	The world's largest supplement market; rising trend for herbs & functional foods	Giant TCM market; integration opportunities in the value chain, herbal *decoction*
Major Obstacles	High compliance costs (PMDA inspection & GMP certification), complex technical documentation	Multi-layered regulations, long & expensive Novel Food process, risk of delay due to the precautionary principle	High legal risks when therapeutic claims, safety responsibility lies with the manufacturer, and NDI obligations	Protectionism of local materials, domestic TCM competition, and the strict bureaucracy of importing biological materials
Potential R&D Collaboration Scheme	Trilateral: Japanese university-pharmacy-village-owned enterprise; focus on bioactivity validation & extract standardization	Partnership with European research institutions for scientific validation & GACP/GMP certification	Collaboration with a cGMP-certified US CMO for co-manufacturing & safety testing	Phytochemical research collaboration with China's TCM institute; co-branding of ethnobotanical-based products
International Ethics & Legality Clauses	Integration*Nagoya Protocol*(Articles 5–6) &*TRIPS Agreement*(Articles 27–34) in the R&D contract	*Nagoya Protocol mandatory*; violations risk biopiracy	*CBD is CBD-relevant* even if the US does not ratify Nagoya; ABS is voluntary for ethical legitimacy	*Nagoya Protocol ratified*; ABS becomes a mandatory part of biological export permits

Recommended Market Entry Strategy	Establish local GMP facilities; Apply for MRA recognition; Conduct R&D with Japan	Use organic group certification; Nutraceutical (not drug) pathway; Prepare EFSA safety dossier	Use the dietary supplement route; Avoid therapeutic claims; Submit an NDI if necessary.	List of ingredients for Macaranga as a TCM *ingredient*; Collaboration with major TCM manufacturers for formulation adaptation
Added Value for Biatan Hilir BUMDes	Upgrading to GMP extract manufacturer; technology transfer & global scientific reputation	GACP certification & capacity building collective; position as nutraceutical supplier	Supplier of ready-to-formulate extracts; potential co-branding of Indonesian herbal products	Integration into the East Asian TCM supply chain; interregional export opportunities
Key Risks & Mitigation	Risk of failing PMDA inspection → mitigation with pre-accreditation audit & Japanese technical assistance	Novel Food delay risk → mitigation through nutraceutical positioning & ethnobotanical data	Risk of false claims → mitigation through careful labeling & FDA notification	Protection & denial risks → mitigation through local TCM company cooperation & diplomatic support

Japan

Japan was chosen as a strategic partner in the development of biopharmaceuticals based on Macaranga due to its position as an advanced pharmaceutical market with high research and development (R&D) capacity, a tradition of integrating natural ingredients into pharmaceutical research, and experience in building mechanisms, Mutual Recognition Agreement(MRA), which allows for the recognition of inspectionsGood Manufacturing Practices(GMP) between regulators. It aligns with the global value chain (GVC) framework, which emphasizes certification and process standards as prerequisites for upgrading to high-value-added activities, including research. Under Japanese law, standardized manufacturing (Gereffi, 2011).

The Japanese Pharmaceutical and Medical Devices Act (PMD Act, Act No. 145 of 19) governs the production and distribution of drugs, including provisions for foreign manufacturers. Article 14 states: "No person shall manufacture or import a drug without ensuring that its production conforms to the standards prescribed by the Minister of Health, Labour and Welfare." This provision stipulates that every manufacturer of drugs or pharmaceutical ingredients, domestic or foreign, must

comply with established production standards, including GMP standards. Products that do not meet these requirements cannot be marketed in Japan. The PMD Act stipulates that inspection and accreditation of foreign manufacturers are carried out by the Pharmaceuticals and Medical Devices Agency (PMDA) and involve technical documentation, possible field inspections, and capacity assessments of production facilities. For local facilities or village-owned enterprises (BUMDes) in Biatan Hilir wishing to export Macaranga, compliance with Japanese technical procedures is a prerequisite for official product recognition.

Furthermore, Article 12 of the PMD Act emphasizes the manufacturer's responsibility to maintain quality: "The manufacturer shall ensure that all processes, facilities, and quality control measures comply with the prescribed standards throughout the production period." This provision emphasizes that GMP compliance must be maintained consistently from the extraction stage through the final formulation. Local processing facilities must not only undergo initial upgrades but also establish internal quality control systems that ensure each batch of product meets PMDA standards. It lays the foundation for developing local production capacity while ensuring continued access to the Japanese market.

The role of the MRA in the GMP sector is an important instrument for reducing technical barriers and accelerating product flow. Article 10 of the EU–Japan MRA on GMP Inspections states that each party may recognize the results of the other party's GMP inspection to eliminate duplicate inspections. Implementing this mechanism allows GMP certificates issued in Indonesia to be accepted without reinspection or batch testing, thereby reducing compliance costs and accelerating market access. Regulatory analysis indicates that the success of the MRA requires evidence of equal regulatory capacity, transparent documentation, and adequate audit capacity. It will increase the likelihood that Macaranga products processed in accordance with local GMP standards will be accepted in Japan and encourage capacity building at local facilities (EMA, 2020).

The Role Mutual Recognition Agreement (MRA) GMP sector is a crucial instrument for accelerating Macaranga's product access to the Japanese market. The MRA allows regulatory authorities in both countries to recognize GMP inspection and certification results mutually, thereby reducing inspection duplication, accelerating product flow, and lowering compliance costs. It has been practiced in the EU–Japan MRA for Medicinal Products (Articles 3 and 4), which states that “each Party shall accept the GMP inspection certificates issued by the other Party’s competent authority, provided that the inspection process meets the agreed standards.”This article's interpretation suggests that if Indonesian authorities can demonstrate equivalent regulatory capacity through technical documentation, pre-accreditation audits, and a transparent quality management system GMP certificates issued in Indonesia can be accepted in Japan without re-inspection or batch testing. Thus, local facilities or village-owned enterprises (BUMDes) in Biatan Hilir that have

met GMP standards are more likely to enter the Japanese market legally and efficiently.

The long-term R&D scheme is seen as a strategic step to bridge regulatory compliance with value-added enhancement. The trilateral partnership, involving an Indonesian university or research institution, a Japanese pharmaceutical company, and a local village-owned enterprise (BUMDes), is designed to achieve three main objectives: first, validating the compound's anticancer activity. Macaranga: second, standardizing the extract according to Japanese scientific requirements; and third, developing formulations that meet preclinical and clinical standards, where relevant. From a mechanistic perspective, the Japanese company provides advanced analytical facilities, preclinical trial support, and R&D funding. In contrast, the Indonesian side provides access to biological resources, field samples, ethnobotanical data, and initial processing facilities.

This collaboration agreement must contain a clause on Access and Benefit-Sharing(ABS) in accordance with the Nagoya Protocol(Articles 5 and 6), which emphasizes "prior informed consent and mutually agreed terms shall be obtained before utilization of genetic resources, and benefits arising shall be shared fairly and equitably."The interpretation of this article emphasizes the obligation to include a benefit-sharing mechanism for the Biatan Hilir Village community, including financial gains, technology transfer, and facility capacity development. Furthermore, the agreement must affirm ownership of intellectual property (IP) rights in accordance with the agreement.TRIPS Agreement (Articles 27–34), to balance commercial values with community access to local biological benefits.

From the perspective of the global value chain, R&D collaborations designed with explicit clauses regarding local capacity enable upgrading. enableupgrading This represents a real opportunity for BUMDes, from simply processing raw materials to producing internationally recognized, standardized extracts. The implementation of this scheme also supports the integration of regulatory compliance, product innovation, and community protection while minimizing the risk of IP disputes or ABS violations. Thus, the MRA and trilateral R&D are not only technical instruments but also strategic mechanisms for transforming Biatan Hilir Village into a value-added player in the global biopharmaceutical value chain.

Based on regulatory analysis and principles of the global value chain, several national steps are recommended for implementing Japan's R&D and MRA schemes. First, a proof-of-concept R&D collaboration with Japanese universities or pharmaceutical companies should be facilitated to validate the bioactivity of anticancer compounds. Macaranga, extract standardization, and safety studies. The activity must include a technical capacity transfer clause, including GMP and quality management training for local BUMDes personnel, so that local facilities can be prepared to meet PMDA accreditation requirements.

Second, enhancing GMP compliance capacity at local processing facilities/village-owned enterprises (BUMDes) is crucial. It includes pre-accreditation audits, the development of comprehensive technical documentation, and the

implementation of a quality management system in accordance with Article 14 of Japan's PMD Act. Its approach ensures that local facilities can meet PMDA inspection standards while leveraging the MRA to obtain Grecognition of MP certification without reinspection, as stipulated in Articles 3-4 of the EU-Japan MRA.

Third, MRA negotiations or arrangements, Sectoral negotiations through the IJEPA platform, are necessary as a basis for recognizing GMP certification. These negotiations must be supported by documentation demonstrating the equivalency of Indonesian regulatory capacity, transparency of inspection processes, and the readiness of BUMDes facilities. Implementing this step reduces non-tariff barriers, accelerates product flow, and lowers compliance costs.

Fourth, ABS and IP clauses should be integrated into the R&D agreement from the outset. All collaborative contracts should contain prior informed consent, mutually agreed terms, and scheme benefit-sharing in accordance with the Nagoya Protocol (Articles 5–6), as well as ownership and licensing of TRIPS-compliant technology (Articles 27–34). It ensures equitable benefit-sharing for the Biatan Hilir Village community and prevents biopiracy-related disputes or patent claims that harm local parties.

Fifth, a structured, phased implementation roadmap is needed: Phase 1 focuses on scientific validation and pilot processing to ensure consistent raw material quality; Phase 2 includes Good Manufacturing Practice (GMP) certification and accreditation by foreign manufacturing institutions to meet export standards; while Phase 3 focuses on negotiating Mutual Recognition Agreement (MRA) recognition and expanding market access, particularly to Japan. Its phased approach allows for systematic risk evaluation and adjustments to production capacity and regulations in line with the dynamics of global market demand.

Potential risks include technical and regulatory constraints, ABS/IP disputes, and high initial investments for facility upgrades and R&D. Risk mitigation is carried out through pre-accreditation audits, comprehensive legal documentation and agreements, mutually agreed terms, bilateral technical assistance programs, and co-financing schemes or R&D grants. Its mitigation approach aligns with the risk management literature in international collaboration, which emphasizes the need for control mechanisms, documentation, and formal agreements to ensure project sustainability.

If all these steps are implemented simultaneously, the cooperation scheme with Japan will be possible. Macaranga Biatan Hilir Village has transitioned from a raw material supplier to an internationally recognized producer of standardized extracts. The combination of collaborative R&D, increased local manufacturing capacity, certification recognition through the MRA, and ABS/IP compliance has made the village a value-added actor in the global biopharmaceutical value chain, while also opening up strategic economic diplomacy opportunities for Indonesia.

Germany

Germany was chosen as a strategic partner because of its significant role in the European pharmaceutical and nutraceutical industry, and because the European Union imposes stringent technical and certification requirements on herbal raw materials and supplement products. The market is one of the most complex and highly regulated markets in the world, where quality, safety, and supply chain integrity are considered non-negotiable foundations. For Biatan Hilir Village, penetrating the German market with Macaranga required navigating a multi-layered European Union legal framework, encompassing organic certification, novel food regulations, cultivation, and manufacturing guidelines.

Organic certification is indeed a strategic entry point for positioning Macaranga Biatan Hilir in the European market, but implementing it requires a thorough understanding of the regulations and their operational implications. Regulation (EU) 2018/848 on Organic Production and Labeling of Organic Products not only provides a legal label but also establishes a mechanism for group certification, which enables groups of small producers to obtain collective certification, as stated in the provision that "groups of operators may be granted a certificate covering the group as a whole" (Article 36). Analytically, this provision affirms the principles of administrative and economic efficiency, enabling BUMDes, as aggregators, to consolidate resources, simplify documentation, and lower costs per farmer, thereby allowing local supply chains to meet global standards. Further interpretation shows that group certification is not merely a legal procedure, but an instrument. Capacity building: it strengthens internal management of quality, traceability, and compliance at the community level, thereby improving the bargaining position of small producers in the global value chain. This aligns with the principles of sustainable development and social inclusion, where local communities are not only suppliers of raw materials but also holders of certifications that can collectively extract added value.

On the other hand, regulations regarding product status determine the market channels and permissible claims. Directive 2002/46/EC on Food Supplements defines a supplement as"foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect"(Art. 2). It means that the marketing of Macaranga as a nutraceutical is limited to claims that are functional or physiological, not therapeutic, and this practically places the product in the categoryfood law, not a drug. Implementation of this regulation means that all promotional activities, labeling, and documentation must emphasize safety and nutritional contributions, rather than explicitly curative or anticancer effects.

Furthermore, health claims that wish to be included on a product must go through a strict scientific evaluation mechanism in accordance with Regulation (EC) No. 1924/2006 on Nutrition and Health Claims, which states that"nutrition and health claims shall not be false, ambiguous or misleading"(Article 3). Interpretation of this provision indicates that European regulators demand transparent, methodological, and verifiable scientific evidence for every claim. For Macaranga, this means that

local ethnobotanical data, phytochemical studies, and bioactivity validation must be documented and aligned with EFSA-recognized scientific standards. Implementing this principle requires BUMDes and industry partners to establish internal audit systems, batch tracking, and research documentation, thus not only meeting legal requirements but also enhancing the product's reputation and credibility in the eyes of consumers and European regulators.

Macaranga's categorization under European Union regulations must be understood through a deeper legal interpretation. Regulation (EU) 2015/2283 on Novel Foods states that a product is considered novel if"it has not been consumed to a significant degree by humans in the Union before 15 May 1997"(Art. 3). In practice, this means that even if Macaranga has long been used traditionally in Indonesia, without documented evidence of consumption in Europe, the product will be categorized as a novel food. Consequently, any attempt to commercialize it in the EU market must go through a rigorous authorization process, including a safety and toxicology assessment by EFSA, an analysis of possible interactions with other foods, and documentation of traditional uses that can support the safety assessment. The precautionary principle as stipulated in Regulation (EC) No. 178/2002 (General Food Law), which states that"the precautionary principle may be invoked when a health risk is identified but scientific uncertainty persists"(Art. 7), confirms that EU authorities will suspend or restrict marketing if safety data are deemed inadequate. From a legal analysis perspective, this demands a proactive approach: manufacturers must prepare comprehensive scientific research, including ethnobotanical evidence, pharmacological studies, and toxicological profiles, to minimize regulatory risks.

In addition to legal aspects, the quality of raw materials is also a key prerequisite for acceptance in the European nutraceutical or herbal market. The European Medicines Agency's (EMA) Guidelines on Good Agricultural and Collection Practice (GACP) emphasize this: "traceability from the field to the finished product", which requires comprehensive audits and documentation from cultivation to final extraction. The regulatory interpretation suggests that the inability of local producers to trace ingredient origins or control pesticide residues will constitute a significant obstacle. If Macaranga were to pursue a phytopharmaceutical pathway, stricter standards would apply, such as EU Directive 2003/94/EC and EudraLex Volume 4 on Good Manufacturing Practice, with the requirement that"manufacturing authorisation holders shall ensure that manufacturing operations are carried out in accordance with Good Manufacturing Practice" In practice, this requires transforming the processing facility in Biatan Hilir from a simple food production unit into a pharmaceutical laboratory/manufacturer capable of meeting GMP SOPs, internal quality control, and comprehensive batch and traceability documentation.

In an institutional context, the role of German authorities is critical in determining Macaranga's regulatory pathway and marketing strategy. The Federal Institute for Drugs and Medical Devices (BfArM) oversees therapeutic claims and

phytopharmaceutical products. Therefore, if Macaranga is marketed as an anticancer or phytopharmaceutical product, BfArM oversight is the primary gateway to sell it as an authorized drug. Interpretation of the regulations indicates that the phytopharmaceutical pathway requires comprehensive preclinical and clinical data, toxicity testing, formulation stability, and full compliance with Good Manufacturing Practices (GMP) (EU Directive 2003/94/EC & EudraLex Volume 4). It requires Biatan Hilir to have processing and laboratory facilities that meet pharmaceutical standards, including batch documentation, raw material traceability, and strict quality protocols. It will result in a relatively high initial investment but open up greater opportunities for added value.

On the other hand, the BFR (Federal Institute for Risk Assessment) is responsible for food safety and nutraceuticals. Macaranga's position as a nutraceutical or herbal supplement allows for a more lenient regulatory pathway, based on Directive 2002/46/EC and EFSA Guidance on Health Claims (Regulation (EC) No. 1924/2006), where health claims must be supported by scientific evidence but are not as stringent as those for phytopharmaceutical drugs. Regulatory analysis shows that a nutraceutical strategy offers flexibility in leveraging traditional uses of local plants as the basis for health claims, while simultaneously reducing certification costs and time-to-market. It underscores the importance of product positioning from the outset, enabling BUMDes to select the appropriate regulatory authority and optimize market access.

The aspect of justice in international trade is an inseparable ethical and legal dimension. The Nagoya Protocol (2010) emphasizes the principle"fair and equitable sharing of the benefits arising from the utilization of genetic resources"(Art. 5), which means that any commercial or research activity with Macaranga must include a clear benefit-sharing mechanism for the Biatan Hilir community, whether in the form of financial support, technology transfer, or local capacity building. It emphasizes that, without ABS compliance, exporters face legal risks at the national and international levels, and potential accusations of biopiracy could damage the product's credibility in the European market. Therefore, ABS clauses must be an integral part of supply contracts, certifications, and partnership agreements, while building moral legitimacy and reputation for BUMDes as managers of biological resources.

Within this overall framework, the most realistic strategy for Biatan Hilir is to position Macaranga as a standardized organic-based nutraceutical raw material, with group certification managed by the Village-Owned Enterprise (BUMDes). Its positioning allows for short- to medium-term market access with more manageable regulatory risks. In parallel, building GACP and GMP capacity, collaborating with European analytical laboratories, and integrating ABS clauses into trade contracts will serve as pillars for ensuring sustainability. If these steps are adopted, Biatan Hilir will not only be able to enter the German market but also strengthen its position within the high-value European biopharmaceutical global value chain.

United States of America

The United States is one of the largest supplement markets in the world, with steady growth, making it a strategic target for development. Macaranga as a raw material for supplements. Its position is determined not only by market absorption but also by a simpler regulatory framework than that for prescription drugs. Unlike drugs, which must undergo lengthy preclinical and clinical trials, supplement products are regulated by the Dietary Supplement Health and Education Act (DSHEA) of 1994, which emphasizes manufacturers' responsibility for product safety. DSHEA asserts that"a dietary supplement shall be deemed to be adulterated if it presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling" (U.S. Congress, 1994, Section 402(f)(1)(A)). The regulation emphasizes that safety responsibility rests with producers, not regulators. It means greater market access, but the legal and reputational risks are borne entirely by businesses. For rural communities like Biatan Hilir, this opens the door to market penetration without lengthy clinical trials, but requires strict internal standards to avoid accusations of adulteration.

The quality aspect is emphasized through Current Good Manufacturing Practice (cGMP) for Dietary Supplements in 21 CFR Part 111, which states: "You must establish and follow written procedures for the responsibilities of the quality control operations"(21 CFR §111.103). The regulation requires manufacturers to have a documented quality control system, including audits, record-keeping, and quality control at every stage of production, packaging, and distribution. The direct implication is that processing Macaranga Biatan Hilir cannot operate solely in traditional ways, but must transform into a small-scale industrial system that meets international standards. If local capacity is insufficient, partnering with certified contract manufacturing organizations (CMOs) in the US is a strategic option, as well as providing access to third-party audits such as USP or NSF, which can strengthen buyer confidence.

The requirements become more stringent when Macaranga is categorized as a new dietary ingredient (NDI). Rule 21 CFR §190.6 states: "At least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, you must submit to FDA the information, including any citation to published articles, which is the basis on which you have concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe" (U.S. Food & (FDA), 2023). The regulation requires comprehensive safety documentation, including toxicological data, scientific literature, and a history of traditional use. It is where opportunities for ethnobotanical research arise. Macaranga becomes relevant because records of its use in Indonesia can serve as supporting evidence in AND notifications, making the recognition process in the US market more realistic for local actors who want to enter the global supply chain.

In addition to safety and quality, labeling is also a crucial element. 21 CFR Part 101 explicitly limits health claims by stating that they must not be therapeutic or allege a cure for a disease. Instead, manufacturers may only use structure/function

claims with appropriate notification to the FDA. The regulation states that claims such as "supports immune health" are allowed, but claims such as "cures cancer" will immediately position the product as a drug and trigger legal action (CFR, 2021). For products based on Macaranga, claims strategies must be careful to emphasize health-supporting functions rather than specific therapeutic benefits. Failure to comply with labeling regulations often results in a warning letter from the FDA or even the withdrawal of the product from the market, which would damage exporters' credibility and the image of Indonesian commodities as a whole.

Market opportunities are supported by consumption trends increasingly shifting toward herbal products with specific health benefits. According to data from the NIH Office of Dietary Supplements (2022), US consumer trends indicate increasing demand for herbal extracts positioned as functional ingredients for everyday health, especially in the immunity, energy, and prevention of mild chronic diseases segments. In the context of Macaranga, placement as a standardized dry extract, packaged in capsules or as a ready-to-mix powder, offers an opportunity to upgrade in the global value chain (Gereffi, 2011). It enables local communities to move from being mere suppliers of raw materials to providers of value-added active ingredients, a strategic transformation that aligns with Porter's (1985) concept of value chain upgrading.

However, entering the US market involves more than just technical aspects; it also requires trade strategy and diplomacy. The US-Indonesia trade relationship is facilitated by the Trade and Investment Framework Agreement (TIFA), which provides a forum for addressing non-tariff barriers and expanding market access (Office of the United States Trade Representative (USTR), 2023). According to USTR (2023), "The United States and Indonesia meet regularly under TIFA to address trade and investment issues, including regulatory barriers and market access." Through this mechanism, the Indonesian government can facilitate regulatory recognition, accelerate third-party laboratory testing, and expand commercial promotion through trade missions. In the multilateral sphere, compliance with the WTO's Agreement on Technical Barriers to Trade (TBT) is essential to ensure that safety and quality standards are not perceived as discriminatory. The WTO affirms: "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade" (WTO, 2022, Article 2.2).

In addition to formal regulations, the ethical dimension of trade is a crucial factor that cannot be ignored in the United States' market penetration strategy. Although the United States is not a party to the Nagoya Protocol, the principles of access and benefit-sharing (ABS) remain relevant as a global ethical standard governing the use of genetic resources. The Convention on Biological Diversity (CBD) explicitly states that, "Access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party"(CBD, Article 15.5). Furthermore, (Smithsonian National Museum of Natural History., 2011) emphasizes that the benefits from the

use of genetic resources must be shared fairly with the communities of origin, both in financial benefits, such as royalty sharing, and in non-financial benefits, such as technology transfer, capacity building, and recognition of traditional rights. Thus, although not legally required in the United States, the voluntary implementation of the ABS mechanism for Macaranga exports from Biatan Hilir Village can be an ethical strategy that strengthens the products' legitimacy in the eyes of consumers and international stakeholders. It will confirm that Indonesia is not merely a passive player in the biopharmaceutical trade still, a normative actor promoting principles of fairness and sustainability in the global value chain.

The overall draft of this trade cooperation framework demonstrates that entering the United States market through health supplements requires careful balancing among three key aspects: regulatory compliance, technical readiness, and ethical legitimacy. From a regulatory perspective, compliance with Food and Drug Administration (FDA) standards, particularly regarding dietary supplements and the implementation of current Good Manufacturing Practices (cGMP), is a non-negotiable entry point.

From a technical perspective, the successful export of Macaranga as a community-based biopharmaceutical product is largely determined by Biatan Hilir Village's capacity to ensure consistent quality standards. The resulting dry extract must meet the following principles: a standardized extract, which refers not only to the concentration of active compounds but also to the product's stability during storage and distribution. The availability of scientifically tested safety data through acute and sub-chronic toxicity tests is essential, as transparency of this data is a prerequisite for gaining the trust of regulatory authorities and potential industry partners. Thus, the technical aspect concerns not only compliance with formal regulations but also the epistemic foundation that determines Macaranga's scientific legitimacy in the international pharmaceutical supply chain.

Next, the ethical dimension, through the integration of principles of access and benefit-sharing (ABS) into trade schemes, provides substantial added value. The ABS principle, as stipulated in the Convention on Biological Diversity (CBD), requires equitable sharing of benefits from the use of genetic resources with the communities of origin. In the context of Biatan Hilir Village, the voluntary implementation of ABS not only positions Indonesia as a country that adheres to global norms but also as a pioneer in promoting fair trade practices. It has strategic implications, as ethical legitimacy in the global marketplace often serves as an anti-tariff barrier that determines consumer preferences for herbal and biopharmaceutical products. In other words, ABS is not merely a moral instrument but also an economic and political instrument that can strengthen Macaranga's bargaining power in the international market.

Within the framework of economic diplomacy, Indonesia's involvement in the Trade and Investment Framework Agreement (TIFA) with the United States presents a strategic opportunity to promote carangahan as a leading commodity. TIFA not

only provides a forum to address trade barriers but also serves as a formal channel for Indonesia to advocate for the recognition of local standards aligned with Food and Drug Administration (FDA) regulations. Through this scheme, community-based products can gain broader access to the United States market, with the guarantee of formal legitimacy and policy-level promotion. Therefore, trade diplomacy is not separate from technical and ethical strategies; rather, it serves as a lever to strengthen Indonesia's position in the global value chain.

Overall, this community-based export strategy has the potential to have multiple effects. First, it opens up opportunities for market entry into the global health supplement industry through simpler regulatory pathways than those for conventional pharmaceuticals. Second, it allows Indonesia to upgrade its position in the international pharmaceutical chain, from a mere supplier of raw materials to a producer of standardized raw materials with scientific and ethical legitimacy. Third, and most importantly, it ensures the inclusive distribution of economic benefits to the Biatan Hilir Village community as holders of traditional knowledge and managers of biological resources. Thus, this strategy not only contributes to national economic competitiveness but also articulates a bioeconomy development model rooted in local communities, in line with the principles of distributive justice in international trade.

China

China occupies a key position as a strategic partner due to its dominance in the traditional Chinese medicine (TCM) market, with its massive production and distribution capacity. Furthermore, government policy support for positioning TCM as an instrument of health diplomacy and efforts to harmonize regulations with international standards further strengthen China's relevance as an export destination. Macaranga. Theoretically, this strategy aligns with the global value chain (GVC) framework, which emphasizes that certification, standards, and regulatory legitimacy are important instruments for accelerating developing countries' upgrading in global value chains, from mere suppliers of raw materials to actors making significant contributions to high-value-added activities.

The penetration of the TCM market in China is inextricably linked to the strict import regulatory framework, particularly that enforced by the General Administration of Customs of China (GACC). Every herbal product entering China must be accompanied by official documentation, including a certificate of origin, a quarantine certificate, and proof of compliance with safety standards. These regulations are intended to maintain the integrity of the domestic TCM market, protect public health, and ensure that products in circulation do not harm consumers or damage the TCM industry's reputation. It is emphasized in the Food-Derived Chinese Medicinal Materials Registration / Quarantine Requirements that state: “For the imported Chinese medicinal materials … owners or their agent should apply for the Quarantine Permit for Imported Animals and Plants … Before signing the trade contract” (GACC). The quote demonstrates that quarantine and provenance permits

are not mere formalities but legal instruments that serve as primary quality checks. In other words, for a new commodity like Macaranga, documentation readiness and compliance with quarantine procedures are fundamental steps in determining export eligibility.

Furthermore, Chinese authorities are strengthening import governance by modernizing customs policies. GACC Announcement 277 (2025) emphasized fundamental changes to export-import declaration procedures: "The Regulations include several key changes related to customs clearance declaration procedures and operations, including electronic document submission, timelines for submissions, amended certificate requirements, etc. GACC claims the updates will improve efficiency and support compliance with customs procedures"(FAS USDA). The reform suggests that electronic document management and adherence to administrative deadlines are now integral to cross-border trade processes. A key interpretation of this quote is that Macaranga exports cannot rely solely on the quality of raw materials; they also require institutional readiness at the local level (from village-owned enterprises (BUMDes) to supporting authorities) to adapt to China's digital declaration system. Failure to meet administrative standards can be as serious as failure to meet product quality standards.

Besides procedural aspects, substantive regulations regarding TCM quality also play an important role. Regulation of April 2, 2003 of the People's Republic of China on Traditional Chinese Medicines (Order No. 374 of April 7, 2003) confirm: "This Regulation aims to protect public health by requiring that traditional Chinese medicines shall be manufactured, controlled, approved and marketed in accordance with requirements prescribed by the State Council; shall have valid registration; the quality, safety and efficacy of traditional Chinese medicines shall be assured"(WIPO). From this quote, it can be understood that registration requirements are not merely administrative mechanisms but serve as a legal guarantee of the quality, safety, and effectiveness of herbal products. Therefore, if Macaranga is to be integrated into TCM formulations, an official registration process with the Chinese authorities is necessary. Products that fail to obtain valid registration will not only have their market access hampered but will also lose their legal legitimacy to circulate in China.

In addition to national regulations, Macaranga's penetration into the Chinese TCM market must also consider the international regulatory harmonization framework. China actively participates in the International Regulatory Cooperation for Herbal Medicines (IRCH), established by the WHO, a global network of regulatory authorities tasked with improving the quality of herbal medicine regulation through the sharing of best practices and coordination between countries (World Health Organization). IRCH affirms that: "Its mission is to collaborate and share the best practices to help WHO in its recommendations … as well as raise awareness regarding their safe use in health and wellbeing" (WHO). In this context, IRCH provides a platform for harmonizing quality standards, safety, and certification procedures, enabling herbal products from other countries to be more

easily accepted in the Chinese market. China's participation in IRCH demonstrates that Indonesian herbal standards and certification can be negotiated to be compatible with China's regulatory system, paving the way for Macaranga to be integrated into the TCM value chain.

China's participation in the IRCH has strategic implications for Macaranga's development. First, the harmonization mechanism allows recognition of Indonesian herbal ingredient standards and certification, ensuring they meet Chinese requirements. Second, through this international forum, China opens opportunities for negotiations on technical procedures, such as quarantine, quality validation, and formal registration, thereby minimizing the risk of border rejections. In other words, the IRCH serves as a regulatory bridge, balancing China's protective interests with market access for the exporting country, in this case, Macaranga from Biatan Hilir Village.

Theoretically, participation in this harmonization mechanism aligns with the approach to global value chains (GVC), which emphasizes that access to international markets depends on producers' ability to meet internationally accepted standards and certifications. These standards are not merely formalities, but instruments for upgrading. It allows local actors to move beyond raw material suppliers to high-value-added positions, such as providing standardized extracts or ready-to-use products for the TCM industry (ResearchGate). By leveraging IRCH, the Biatan Hilir Village-Owned Enterprise (BUMDes) and its Chinese partners can design a collaborative strategy that minimizes regulatory risks while enhancing local capacity through technology transfer and quality certification.

Furthermore, harmonization of international regulations also provides a legal basis and legitimacy for the clauses Access and Benefit-Sharing (ABS) which must be complied with under the Nagoya Protocol. The protocol states: “Its aim is … the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity” ((Secretariat of the Convention on Biological Diversity, 1992)). By negotiating certification recognition through the IRCH mechanism, China's cooperation scheme can be designed so that economic benefits, technical training, and local capacity building flow equitably to the Biatan Hilir Village community. It also ensures that Macaranga exports do not give rise to legal disputes or accusations of biopiracy, thereby maintaining the long-term sustainability of the TCM value chain.

Based on the analysis of national regulations and opportunities for international harmonization, several operational policy steps can be formulated to facilitate penetration. Macaranga to the traditional Chinese medicine market. Increasing local production capacity is a top priority. The effort includes training programs for farmers and processing operators on Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP), the construction of adequate pre-processing facilities, and the establishment of regional quality-testing laboratories or national laboratory recognition for testing of residues, microbiology, and active-ingredient content. Training and technical assistance should be implemented

through trilateral partnerships among local governments, national research institutions, and foreign partners, with a mixed funding scheme that includes bilateral grants, central government funds, and microcredit for village-owned enterprises (BUMDes), thereby enhancing both physical and human resource capacities simultaneously. Its infrastructure implementation should be accompanied by an integrated quality management system, including standard operating procedures, batch documentation, and traceability, to ensure that pre-processing output meets Chinese technical requirements and international standards.

Accelerating the certification process is an essential administrative and institutional agenda. Local governments, together with the Ministry of Trade and the Food and Drug Administration (BPOM), need to develop an accelerated certification pathway for priority herbal products, which includes document assistance, pre-certification audits by national accreditation bodies, and joint audit programs with foreign partners. This step must align with changes to China's customs mechanisms, as stipulated in GACC Announcement 277 (2025), which emphasizes electronic document submission, standardized deadlines, and updated certification requirements. It is particularly relevant for exports. Macaranga, as document readiness and certification are crucial factors in reducing the risk of border rejections. Furthermore, the quarantine procedures stipulated in the Food-Derived Chinese Medicinal Materials Registration/Quarantine Requirements require documents of origin, company registration, and quarantine permits for exporting herbal ingredients to China, so administrative mechanisms and technical compliance cannot be ignored.

Establishing commercial and technical partnerships with Chinese pharmaceutical companies should be done in stages, prioritizing legal certainty and community interests. Practical steps include pilot collaborations to test integration. Macaranga. In the TCM formulation, an initial commercial agreement should consist of an Access and Benefit-Sharing (ABS) clause, prior informed consent (PIC), and mutually agreed terms (MAT) to ensure the sharing of financial benefits, training, and infrastructure investment with Biatan Hilir Village. A transparent revenue-sharing mechanism can also ensure equitable distribution of benefits. These negotiations should be supported by a legal and regulatory team familiar with TRIPS provisions, the Nagoya Protocol, and GACC regulations to prevent future disputes over intellectual property rights, technology licensing, and benefit-sharing.

Regulatory monitoring is a crucial component for maintaining long-term export stability. Establishment of a regulatory unit, "regulatory watch," as a regional unit that monitors changes in trading partner regulations, such as updates to the GACC and NMPA/China registration requirements and maintains formal communication channels with diplomatic representatives, allows for rapid response to policy changes. It can also serve as a hub for updating the capacity of BUMDes (village-owned enterprises) on new technical or administrative procedures, ensuring compliance with Chinese product standards.

The proposed partnership scheme, which positions the Village-Owned Enterprise (BUMDes) as a collective entity supplying standardized raw materials, is designed to transform Biatan Hilir Village from a raw material supplier to a value-added actor. Production output includes standardized pre-processing, provenance documentation, quality certification, and packaging in accordance with market requirements. The model encourages the creation of added value to the local economy through income, employment, and facility development, while also facilitating the transfer of technical knowledge for sustainable herbal production.

Although the potential of China's TCM market is huge, various inherent risks must still be considered to maintain supply chain stability. Macaranga Changes in import policies, including revisions to customs procedures, certification requirements, or adjustments to quarantine regulations, can delay shipments or even result in product rejections at the border. GACC Announcement 277 (2025) confirmed updated provisions regarding electronic document submission, deadlines, and certification requirements, indicating that administrative preparedness and documentation compliance are key to minimizing risks. Furthermore, strict quality standards are critical; herbal products that do not meet the safety, active compound content, or microbiological quality standards stipulated in the Food-Derived Chinese Medicinal Materials Registration/Quarantine Requirements may be returned or rejected, which could erode Chinese partners' trust and disrupt the continuity of the partnership.

Legal risks also require serious attention, particularly regarding the Access and Benefit-Sharing (ABS) principle under the Nagoya Protocol. Unclear benefit-sharing mechanisms among village-owned enterprises (BUMDes), local communities, and foreign partners can lead to legal disputes or accusations of biopiracy, causing financial losses and undermining Indonesia's legitimacy in international forums. Therefore, explicit contractual clauses on dispute resolution, the parties' rights and obligations, and compliance with ABS are crucial tools for mitigating these legal risks.

Mitigation strategies must be implemented in an integrated manner. From a technical perspective, strengthening internal quality control, implementing strict standard operating procedures, and consistent laboratory testing can ensure products meet Chinese quality standards. Pre-export audits by accredited third parties serve as an external validation mechanism that minimizes the risk of border rejections. At the same time, trade insurance can cover potential financial losses from delayed or rejected shipments.

In addition, proactive regulatory diplomacy through international standards harmonization forums, such as the WHO-affiliated International Regulatory Cooperation for Herbal Medicines (IRCH), can reduce non-tariff barriers, strengthen Indonesia's bargaining position, and facilitate the recognition of ABS certifications and documents. IRCH serves as a regulatory bridge, balancing China's protective needs with market access for local exporters, while providing a platform for

harmonizing technical procedures, quality validation, and the formal registration of herbal products.

By implementing these mitigation measures simultaneously, Macaranga could enter the Chinese TCM market as a high-value-added product. This approach also positions Biatan Hilir Village strategically within the global biopharmaceutical value chain, enhancing local capacity, ensuring equitable distribution of benefits, and maintaining legal compliance and international legitimacy, thereby achieving the sustainability of the village herbal industry.

Discussion

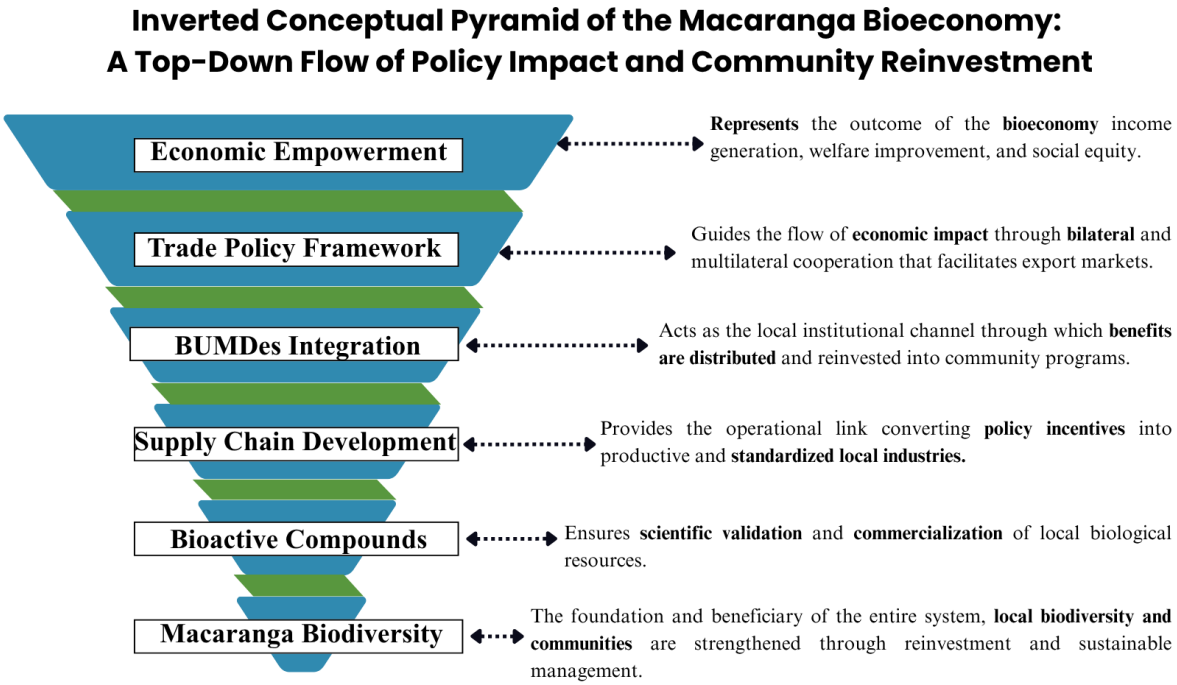

Fig. 3. Inverted Conceptual Pyramid of the Macaranga Bioeconomy: A Top-Down Flow of Policy Impact and Community Reinvestment.

This research reveals a fundamental gap between Indonesia's abundant biodiversity and local communities' ability to derive economic benefits from it. The genus Macaranga, which grows abundantly in Biatan Hilir Village, East Kalimantan, has very promising pharmacological potential, particularly as a raw material for anticancer and antioxidant biopharmaceuticals. However, this potential remains trapped in the laboratory and has not yet been fully translated into an economic model that can empower rural communities. The situation demonstrates that the main problem lies not in limited natural resources, but rather in the weak integration of scientific research, local production systems, and trade policy support to open access to global markets.

From a scientific perspective, research findings confirm that Macaranga contains high levels of active compounds, particularly flavonoids, terpenoids, and stilbenoids, which have been empirically demonstrated to possess biological activity against cancer cells and free radicals. It has a phytochemical advantage, opening up significant opportunities for the development of standardized extract products. However, previous research has generally ended at the laboratory testing stage, without progressing to commercialization. Furthermore, local supply chains still rely on illegal harvesting practices without quality standards, thus failing to meet Good Agricultural and Collection Practices and Good Manufacturing Practices requirements, which are key prerequisites for international biopharmaceutical trade. Therefore, efforts are needed to build community-based production systems that integrate scientific research with sustainable resource management practices.

From a socio-economic perspective, Biatan Hilir Village illustrates a situation common to many rural areas in Indonesia, where communities coexist with high-value resources but remain dependent on the low-productivity primary sector. Most community economic activities remain subsistence, with limited market access and weak bargaining power. Research shows that the village community lacks economic institutions capable of consolidating production, ensuring quality, and negotiating prices with large buyers. In this context, Village-Owned Enterprises (BUMDes) have the potential to become key actors in building an integrated supply chain. BUMDes can function as managers of simple drying and extraction centers, while also guaranteeing a product traceability system recognized by export markets. By managing aggregation, recording, and distribution functions, these village institutions can maintain added value at the community level and strengthen the bargaining position of farmers and raw material collectors.

However, the success of such a model depends heavily on technical and institutional readiness. Improving human resource capacity in product quality, supply chain management, and transparency in governance is an urgent need. Collaboration between village-owned enterprises (BUMDes), universities, and research institutions is also necessary to ensure that every stage of production meets international standards. Synergy can begin with small pilot projects that integrate cultivation, processing, and quality testing before expanding into a larger scheme. Its approach allows for a natural institutional learning process while minimizing the risk of early failure.

From an international trade perspective, the research findings show that the primary barrier to exporting Macaranga-based products lies not in tariffs but in the complexity of non-tariff regulations, such as certification requirements, safety testing, and the equivalence of quality standards. Cooperation with partner countries such as Japan, Germany, the United States, and China offers significant opportunities for market penetration, but also requires adequate regulatory and technical preparedness. Japan, for example, has a certification recognition mechanism through a Mutual Recognition Agreement that can be utilized if production facilities in Indonesia meet Good Manufacturing Practices standards. The European Union offers

opportunities through a market for organic products and standardized herbal extracts. At the same time, the United States provides a pathway for herbal supplements through the Dietary Supplement Health and Education Act. China, as the world's largest center for traditional medicine, could be a strategic partner in integrating Macaranga into the Traditional Chinese Medicine system if certification and administrative compliance can be achieved. This analysis demonstrates that export competitiveness is determined not only by biological potential but also by the ability to manage technical standards, trade ethics, and economic diplomacy.

The ethical dimension is a crucial component of this discussion. The principle of Access and Benefit-Sharing, as stipulated in the Nagoya Protocol, emphasizes that equitable benefit-sharing within communities of origin must accompany any use of genetic resources. Implementing this principle in the context of Biatan Hilir serves two primary purposes: protecting the rights of local communities and strengthening the product's legitimacy in the eyes of international partners. Benefit-sharing mechanisms encompass not only financial compensation but also technology transfer, production training, and the development of local facilities. Thus, the developed business model is oriented not only to economic profit but also to social and ecological sustainability.

Conceptually, this research confirms that the development of Macaranga in Biatan Hilir can serve as a prototype for an inclusive, globally competitive village bioeconomy model. Its success depends on integrating three key dimensions: science, local institutions, and trade policies. If all three work together, Macaranga will serve not only as a research resource but also as a symbol of economic transformation that links environmental conservation with community well-being. Its model has the potential to be replicated in other regions with similar biodiversity, enabling Indonesia to transition from a mere supplier of raw materials to a producer of high-value biopharmaceuticals, grounded in equity and sustainability.

To illustrate this interconnection, the following conceptual framework presents an Inverted Conceptual Pyramid of the Macaranga Bioeconomy, which visualizes the top-down flow of policy impact and community reinvestment from biodiversity foundations to economic empowerment outcomes:

Conclusion

This study shows that the acaranga nus holds significant pharmacological potential, particularly as a candidate for anticancer biopharmaceutical raw materials, due to its stable metabolite content, including flavonoids, terpenoids, and phenolics, which have been shown to possess diverse biological activities. However, a case study in Biatan Hilir Village, East Kalimantan, shows that this wealth has not been optimally utilized because the supply chain remains traditional, limited to subsistence use, and lacks adequate processing infrastructure and market access. The

analysis conducted in this study confirms that an integrated supply chain model based on Village-Owned Enterprises (BUMDes), with the main product being standardized dry extract or powder, has the potential to provide significant economic added value for the community, strengthen local bargaining power, and at the same timeopening export opportunities through bilateral cooperation with Japan, Germany, the United States, and China. Thus, Macaranga is not only relevant as an object of scientific study but can also be positioned as a strategic commodity that connects basic research, village community empowerment, and Indonesian trade diplomacy. However, this study has several limitations, including its reliance on secondary data without field evidence, a more conceptual rather than quantitative economic analysis, and limited specific literature on Macaranga in East Kalimantan, all of which require careful validation of the findings. Therefore, further research should be directed at a more comprehensive multidisciplinary study, including direct phytochemical exploration in Biatan Hilir, in vitro and in vivo toxicity and efficacy testing, development of a supply chain prototype with village communities, and a more in-depth political-economic analysis of export potential, international market technical standards (GMP, FDA, GAP, TCM), and trade diplomacy strategies. Such an approach is expected to ensure that Macaranga truly becomes a leading Indonesian biopharmaceutical commodity that is inclusive, sustainable, and competitive in the global market.

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