Research Needs in Philippine Pharmaceutical Sciences: A Qualitative Perspective from Regulatory and Clinical Research Sectors of the Pharmaceutical Industry

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ABSTRACT

Objective. This study aimed to identify problems and highlight opportunities for pharmaceutical sciences research in the Philippine pharmaceutical industry's regulatory and clinical research sectors that might have been previously overlooked or underrepresented. It identified current issues that can be addressed by research covering four areas of pharmaceutical sciences: drug design and discovery, pharmacokinetic/pharmacodynamic studies, formulation design and pharmaceutical technology, and regulatory science.

Methods. A descriptive qualitative approach was used in this study. Data collection was facilitated by key informant interviews (KII) using a standardized interview guide with open-ended questions to identify the pharmaceutical science research needs of the specific sectors. A purposive sampling method was employed, with five key informants (KIs), including the company vice president, director, and top-level managers from different local and multinational pharmaceutical companies. ATLAS.ti software was utilized to facilitate thematic synthesis for qualitative data analysis.

Results. Thirteen common themes were identified from the KIs, such as (1) incomplete development of therapeutic compounds, (2) sustainability of raw materials supply, (3) regulation of herbal medicines versus food supplements, (4) mapping disease priorities through the Philippine pharmaceutical roadmap, (5) government incentives and policies to support research, (6) technical personnel, (7) suboptimal regulatory process, approvals, and implementation, (8) gap in utilization of acquired knowledge on regulations, (9) regulatory governance, (10) passive regulatory action on counterfeit drugs, (11) PIC/S GMP version 14 adaption, (12) formulation optimization, and (13) active pharmaceutical ingredient (API) sourcing and regulation. Based on insights from the International Pharmaceutical Federation regarding anticipated hurdles in pharmaceutical sciences over the next 5-10 years, priority research needs were identified through KIs' input. Relevant action plans were developed, including the creation of research proposals to isolate, purify, and determine chemical structures of natural products, as well as analyzing recent Philippine Health Statistics to help assess the appropriateness of new drug releases for patient needs. Other action plans include forecasting future disease burdens in the

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country, performing toxicology studies (Health-Based Evaluation Levels/No Observed Adverse Effect Level or HBEL/NOAEL) for common generic drugs, and ensuring that research efforts are directed toward addressing the Philippine pharmaceutical regulatory and clinical research sector's most pressing needs practically and feasibly.

Conclusion. This study offers valuable insights into pharmaceutical sciences research and development initiatives within the regulatory and clinical research sectors in the Philippine pharmaceutical industry. These findings have the potential to catalyze transformative advancements in healthcare delivery and outcomes, positioning the Philippines for global excellence and competitiveness.

Keywords: pharmaceutical sciences, qualitative research, health policy, drug approval, thematic analysis

INTRODUCTION

Key components of achieving universal healthcare are the efficient production and distribution of high-quality, safe, effective, and affordable medicines.[1] Essentially, pharmaceutical science research is indispensable in each pharmaceutical industry sector, from drug discovery and development of new drugs and therapies to the delivery and repurposing of drugs in clinical settings.[2,3] This is because pharmaceutical sciences research provides the scientific foundation for understanding drug mechanisms, optimizing formulations, ensuring bioavailability and stability, minimizing adverse effects, and complying with regulatory standards. Hence, pharmaceutical sciences ultimately enable the development of medicines that are not only effective but also accessible and tailored to population health needs.

The Philippines is the Association of Southeast Asian Nations' (ASEAN) third-largest emerging pharmaceutical market. In 2022, the Department of Trade and Industry (DTI)'s plan to enhance the growth and development of the biopharmaceuticals industry in the Philippines gained the support of the Pharmaceutical and Healthcare Association of the Philippines. Estimated at ₱176 billion, the Philippine pharmaceutical market demonstrates a consistent growth rate of 8.3% annually, according to data science company IQVIA, formerly Quintiles and IMS Health, Inc.[4-6] These indicators underscore the country's expanding pharmaceutical and healthcare sectors, driven by both policy support and market potential.

Filipino households exhibit a prioritization of health, evident in the rise of out-of-pocket healthcare expenses from 47% to 54% of total health expenditures between 1994 and 2017.[5] Notably, 50.1% of households' healthcare budget is allocated to medicine procurement, regardless of income level, indicating a growing reliance on medication as a means to improve quality of life.[6] This heavy dependence on pharmaceutical products highlights the importance of continually identifying critical areas within the pharmaceutical industry that require attention, fostering targeted pharmaceutical sciences research to streamline operations and ensure the delivery of safe, effective, and affordable healthcare solutions to the population.

In 2016, the International Pharmaceutical Federation (FIP), representing 4 million pharmacists and pharmaceutical scientists globally through 137 member groups, identified key issues in the pharmaceutical sciences for the next 5-10 years. These issues include drug design and discovery, natural products, formulation design, regulatory science, and personalized medicine, each representing a critical area in the advancement of global healthcare. FIP, which collaborates with international organizations such as the World Health Organization (WHO), establishes global standards and policies to guide the pharmaceutical sciences toward innovation, safety, and efficacy.[3]

Drug design and discovery remain foundational to the development of novel therapeutics, especially in addressing emerging diseases and treatment-resistant conditions. This aligns with the Philippine pharmaceutical industry's need to enhance its capacity in early-stage drug development. Natural products, long used in traditional medicine, are increasingly being recognized for their potential in yielding bioactive compounds for modern drug development, a particularly relevant avenue for the Philippines, which has rich biodiversity yet underutilized natural resources in this field. Formulation design and pharmaceutical technology represent an area that is essential in ensuring the stability, bioavailability, and patient acceptability of medications, linking directly to the local industry's efforts to optimize generic and branded drug formulations. However, this study deliberately focuses on the regulatory and clinical research sectors, as these have been consistently identified as weak links in the Philippine pharmaceutical system compared to manufacturing or academic research and development. Bibliometric analyses of Philippine health research outputs reveal that most funded studies emphasize biomedical or basic sciences, while far fewer address regulatory science and clinical trial development.[7,8] This imbalance highlights the limited capacity in regulatory and clinical sectors, despite their crucial role in drug approval, quality assurance, and patient-centered outcomes. Regulatory science, which supports the creation of evidence-based policies and approval pathways, is crucial for improving the efficiency, transparency, and reliability of the Philippine regulatory system, areas highlighted as challenges in this study. Finally, personalized medicine, which involves the tailoring of medical treatment to individual genetic profiles, represents a longer-term goal that requires foundational work in areas like pharmacokinetics and pharmacodynamics, both of which are included in this research's scope. By aligning with these globally recognized priorities, this study contributes to both local relevance

and international discourse, highlighting opportunities for pharmaceutical science research to strengthen the Philippine pharmaceutical industry's regulatory and clinical research sectors.

Despite the rapid market growth and strong consumer demand for effective medicines, there remains a lack of strategic alignment between research outputs and the practical needs of the Philippine pharmaceutical industry. While global standards are being set, local implementation and innovation are often hindered by gaps in regulatory efficiency, resource allocation, and research prioritization. These gaps may contribute to missed opportunities for drug development, inefficient regulatory processes, and delayed access to quality medicines. Moreover, bibliometric reviews of the National Unified Health Research Agenda (NUHRA) and Philippine Council for Health Research and Development (PCHRD) project portfolios show a scarcity of regulatory-focused and clinical research publications compared to other pharmaceutical fields, reinforcing the need for deeper investigation of these sectors.[7,8] Without this information, researchers, policymakers, and industry leaders may struggle to collaborate effectively or direct resources where they are most impactful.

However, literature reviews reveal a significant research gap in assessing specific needs in pharmaceutical sciences research within various sectors of the Philippine pharmaceutical industry, including manufacturing, distribution, trading, regulatory, and clinical research. For instance, recent analyses have noted that while the Philippines has a rapidly growing pharmaceutical market, there is limited published evidence that systematically maps local research priorities to industry demands.[7,8] Comparative studies in other ASEAN countries, such as Thailand and Malaysia, demonstrate more structured national research agendas that link pharmaceutical science research with regulatory and clinical practice, underscoring the relative gap in the Philippine setting.[9-11] Hence, this study aimed to (1) identify and describe the key problems faced by the regulatory and clinical research sectors of the Philippine pharmaceutical industry; (2) determine priority areas for pharmaceutical sciences research in drug design and discovery, pharmacokinetic/pharmacodynamic studies, formulation design and pharmaceutical technology, and regulatory science; and (3) propose practical research directions that can address gaps between scientific outputs and industry or regulatory needs. These objectives were framed to provide a clear research question: "What are the priority pharmaceutical science research needs that can strengthen the regulatory and clinical research sectors in the Philippines?"

The information gained from this study would be critical in enabling industry stakeholders and researchers to determine research and service priorities where they can contribute to addressing industry needs for healthcare advancement. Likewise, stakeholders can uncover collaboration opportunities and partnerships for joint projects, fostering efficient problem-solving and knowledge exchange. Ultimately, the study could propel opportunities for translating scientific discoveries into practical applications, accelerating research and industry growth.

MATERIALS AND METHODS

The study utilized a descriptive phenomenological qualitative design to identify the pharmaceutical sciences research needs of the regulatory and clinical research sectors in the Philippines. Key informant interviews (KII) served as the method of inquiry using an interview guide with open-ended questions, validated by UPMREB. A purposive sampling method was employed, wherein the list of contact participants who worked in the manufacturing and regulatory pharmaceutical industry for at least 10 years was obtained from industry groups and the investigators' network. Approval from the UPM Research Ethics Board [UPMREB 2023-0559-01] was secured prior to the conduct of the study. Due to the limited availability of the participants, data saturation was not performed. Instead, key informants (KIs) were pre-selected according to their location and availability. KIs were selected from both multinational and local companies in order to capture the perspectives coming from different settings.

After sending out the invitation letters, which included the background of the study, an informed consent form (ICF), and the request for their acceptance via email, the participants were contacted to coordinate their available schedules for the interview. There were five KIIs with three experts from the local and two from the multinational settings. Participants included company vice president, director, and top-level managers from different pharmaceutical companies, well-positioned to speak about the topic or particular sector. The interviews were audio-recorded once their consent was obtained. Informed consent and confidentiality were embodied and observed throughout the study. These were conducted at the College of Pharmacy Conference Room, UP Manila, or avenue near the participants or via Zoom. These sites were preferred for the convenience of the participants, who were mostly busy with work and had limited time for travel, as well as for the researchers.

Transcription of the interviews was done manually. Unique alphanumeric codes were assigned to each KI, and any information that could reveal their identity was censored. Copies of the anonymized transcripts were shared with the respective KIs for validation and for any additional redactions. Audio recordings, transcripts, and identifiers were stored in password-protected files accessible only to the researchers.

An inductive thematic synthesis described by Thomas & Harden was conducted for qualitative data analysis using ATLAS.ti software (Scientific Software Development GmbH, Berlin, Germany).[12] Common themes were generated from the insights provided to summarize the industry's needs for pharmaceutical sciences research. Researchers reviewed, discussed, and reached an agreement

on the identified themes over several meetings. After that, priority research needs based on the Institute's resources and capacity were identified, and action plans were drawn to address the gaps identified in the study.

RESULTS

The analysis of KIIs from the regulatory and clinical research sectors revealed 13 significant themes of challenges in the pharmaceutical industry. These challenges were subsequently classified within the relevant focus areas identified by the FIP, such as Drug Design and Discovery, Regulatory Science, and Formulation Design and Pharmaceutical Technology (Figure 1). Notably, challenges related to Pharmacokinetic and Pharmacodynamic studies were not mentioned by the regulatory and clinical research sectors during the interviews. No key themes emerged under the pharmacokinetic/pharmacodynamic domain. The summary of challenges in these sectors is presented in Table 1.

Drug Design and Discovery

Incomplete Development of Therapeutic Compounds

The Philippines boasts a vibrant landscape of drug discovery activities, with promising initiatives in collaboration with the Department of Science and Technology (DOST). With the creation of the Harmonized National Research and Development Agenda (HNRDA) spearheaded by DOST, in consultation with government agencies and private research institutions, researchers are directed towards areas crucial for generating solutions that yield optimal economic and social benefits for the population. Section 2 of the HNRDA 2022-2028 details the priority areas under the Health Research and Development Agenda 2023-2028, including Drug Discovery and Development, specifically standardization and lead optimization of bioactive compounds.[13] However, as revealed through interviews with stakeholders from the regulatory and clinical research sectors, one of the prevailing themes emerges as the challenges associated

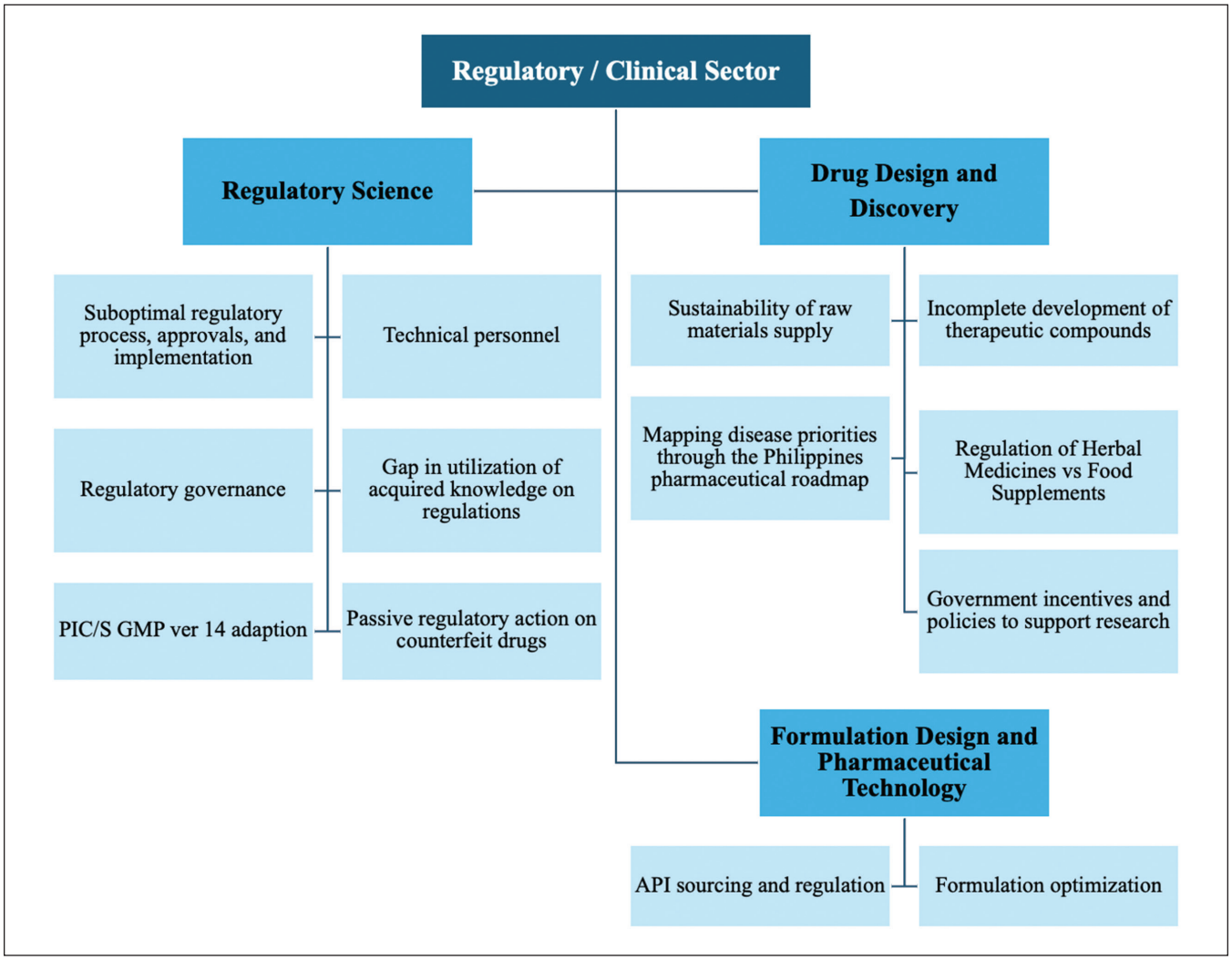

Figure 1. Summary of the main themes of the reported challenges.

with incomplete research studies hinder the progress of drug design and discovery.

The interviews reveal a common pattern where DOST's involvement is limited to basic research, swiftly and prematurely transitioning to marketing products, especially in the form of food supplements. The absence of chemical definition and isolation of active compounds limits understanding of structure-activity relationships and obstructs the progression to clinical trials, particularly phase one. The disproportionately low number or scarcity of active compound clinical trials in the Philippines, which limits the holistic understanding of drug safety and efficacy, is attributable to the insufficient groundwork in isolating, identifying, and knowing the active compounds. Furthermore, a nuanced challenge related to the transformation of raw materials into therapeutically effective and safe products was unveiled. It was acknowledged that mere access to raw materials is insufficient; the key lies in formulating a replicable process that ensures the safety and efficacy of the final product.

Collaboration between researchers and companies is hindered by the hesitancy of companies to invest due to perceived crude testing procedures and data, emphasizing the importance of promising and complete results for industry partnerships. Moreover, the lack of comprehensive information on innovative products from natural sources also raises skepticism among potential investors. Additionally, offering outdated formulations and registration documents to potential investors further complicates the situation, necessitating extra industry effort for compliance, underscoring the incomplete and obsolete data under DOST's purview.

Sustainability of Raw Materials Supply

KIs highlighted the critical nature of maintaining consistency in the supply of raw ingredients, stressing that it is not merely about having access to raw ingredients but ensuring their uniform quality over time. They explained that some companies proactively invested in farms to exercise control over the production of the active substance to provide uninterrupted access to quality raw ingredients. This investment addressed the variability in natural sources, illustrating the complexity of relying on naturally occurring raw materials for drug development. In most instances, the demand for a specific plant variety also underscores the meticulousness required in drug development. The challenges associated with sourcing the exact variety raise questions about the feasibility of consistency in large-scale production and ensuring uniformity across different batches. Moreover, the financial implications of addressing these challenges were also highlighted during the interviews.

Table 1. Summary of Challenges under the Main Themes that were Prominent in the KIIs

Focus Areas	Main Themes	Challenges
Drug Design and Discovery	Incomplete Development of Therapeutic Compounds	• Lack of chemical definition and isolation of active compounds • Transformation of raw materials into therapeutically effective and safe products • Insufficient clinical trials for active compounds with a rapid transition to marketing products as a food supplement • Lack of comprehensive information on innovative products • Companies' hesitancy to invest due to perceived crude testing procedures, outdated formulations, and registration documents
	Sustainability of Raw Materials Supply	• Ensuring stable and uniform quality of raw materials supply over time • Demand for a very specific plant variety in most instances • Significant financial investments are required
	Regulation of Herbal Medicines vs Food Supplements	• Technology transfer and non-exclusivity • Price discrepancy and business viability • Limited success in herbal medicine research and marketing • Misleading claims and safety concerns about food supplements • Gap between local and global standards and compliance • Absence of standardized guidelines for herbal medicine research
	Mapping Disease Priorities Through the Philippine Pharmaceutical Roadmap	• Lack of a clear pharmaceutical roadmap hinders efficient resource allocation • Misaligned priorities of the government have affected the availability of and access to drugs • Industry relies on outdated health information due to a lack of a comprehensive and up-to-date disease registry • Lack of a comprehensive local disease registry that supports the conduct of clinical trials in the Philippines
	Government Incentives and Policies to Support Research	• Lack of a supportive environment to sustain research beyond the pandemic (seed funding through research grants, post-commercialization support, and expedited approval processes) • No established national ethical regulations for patient honorarium in clinical trials

Table 1. Summary of Challenges under the Main Themes that were Prominent in the KIIs *(continued)*

Focus Areas	Main Themes	Challenges
Regulatory Science	Technical Personnel	• Absence of a dedicated honorarium or resources for the clinical trial technical review committee • Time constraints and work overload for multitasking professionals • Need for dedicated personnel for rigorous clinical trial reviews • Co-accountability of Contract Research Organizations (CRO) in conducting clinical trials • Lack of investment in building capabilities among technical personnel
	Suboptimal Regulatory Process, Approvals, and Implementation	• Prolonged approval timelines • Multi-site clinical trial complexities • Lack of a centralized approval body • Inefficient regulatory and ethical processes • Market approval challenges • Reliance pathway implementation • Lack of categorization for life-saving drugs • VAT-exempt medicine challenges • Extended approval time for product variations • Safety update approval delays • Transparency and dialogue issues, urgency, and collaboration • Increasing fees across regulatory bodies and the impact of understaffing • Disjointed application processes cause delays in clinical trials
	Gap in Utilization of Acquired Knowledge on Regulations	• Outdated regulatory guidelines and insufficient awareness of international standards • Concerns were expressed about correcting the Food and Drug Administration (FDA), fearing misinterpretation or overstepping boundaries • Numerous regulations, often with equivocal meanings or unclear terms • Lack of standardized interpretation, leading to diverse interpretations • Implementation overlap of repealed and current regulations creates confusion
	Regulatory Governance	• Call for the “whole of government” approach for the interconnectedness of regulatory decisions, not just the FDA
	Passive Regulatory Action on Counterfeit Drugs	• Call for stronger post-marketing surveillance to ensure a rigorous regulatory process (including online selling of drugs) • Lack of visibility on the review process quality
	Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practices (GMP) Version 14 Adoption	• Complexity in Contamination Control Strategy due to Health-based Evaluation Levels (HBEL) incorporation • Clinical-based computation of HBEL • Limited data on No Observed Adverse Effect Level (NOAEL) due to a lack of generic drug clinical trials • FDA's regulatory expectations for NOAEL data raise questions
Formulation Design and Pharmaceutical Technology	Formulation Optimization	• Challenges in the understanding and applications of pharmaceutical Quality by Design (QbD) approach • Need for education and training on big data handling and analysis
	Active Pharmaceutical Ingredient (API) Sourcing and Regulation	• Limited supply and a lack of API manufacturers in the country • Globally stringent international controls on API manufacturers • Comprehensive dossier required for generic product registration • Evolving regulatory controls require meticulous evaluation of the API source • Sharing the API manufacturer's contact information with regulatory bodies • Increased global regulation due to GMP and PIC/S GMP regulations • Supply chain impact due to API company closures and consolidations • Risk of product shortages due to major notifications and approvals when changing API suppliers • Consideration of substantial investments in API manufacturing in the country

Regulation of Herbal Medicines vs. Food Supplements

Distinctive challenges in herbal medicine development compared to food supplements were also highlighted. It includes regulatory challenges, technology transfer and non-exclusivity concerns, price discrepancy and business viability, limited success in herbal drug research and marketing, misleading claims and safety concerns of food supplements, global standards gap and compliance, and standardization and research guidelines.

Regulatory Challenges. Herbal medicines face stringent regulations, including clinical trials, therapeutic claims, and prescription possibilities, which subject them to Maximum Drug Retail Price (MDRP) control. In contrast, food supplements encounter fewer restrictions, lack clinical trials, therapeutic claims, and prescription requirements, and have no price control.

Technology Transfer and Non-Exclusivity. The non-exclusive requirement of the DOST for drug research data/licensing agreements emerged as a significant challenge. KIs expressed frustration with the non-exclusivity clause, which, while promoting open access, raised concerns about technology transfer. The interviews revealed hesitation among companies to engage in technology transfer due to fears of losing control over their research data, leading to potential conflicts in marketing. According to the KIs, the 5% gross sales royalty further complicates technology transfer, impacting the pursuit of certain research projects.

Price Discrepancy and Business Viability. The MDRP control for herbal medicines creates a pricing discrepancy, affecting business viability compared to food supplements. The additional costs associated with clinical trials and global standard compliance make herbal medicine research less attractive for investment. Moreover, the financial burden associated with drug development, including the need to invest in farms and adhere to price controls, was highlighted. KIs emphasized the millions required for development, marketing, and compliance with regulatory frameworks.

Limited Success in Herbal Drug Research and Marketing. The interviews reflected limited success in drug research and marketing. Only a few local drug research initiatives (e.g., herbal medicine Lagundi and Sambong) have been successfully marketed. KIs attributed this not merely to incomplete research findings but to contractual stipulations. The challenges in negotiating contracts, particularly exclusivity and royalty clauses, were identified as significant barriers to successful drug development.

Misleading Claims and Safety Concerns of Food Supplements. Interviews disclosed substantial concerns regarding deceptive claims in the marketing of food supplements. For instance, some studies, which are solely conducted *in vitro*, are presented to consumers as if they were clinical studies conducted in humans. Furthermore, a KI highlighted that nephrologists expressed distress over cases of acute renal failure in patients due to the improper usage of certain food supplements. Despite safety concerns and complaints, these products are not subjected to the same rigorous regulatory scrutiny as prescription drugs, prompting questions about the effectiveness of current regulatory practices.

Global Standards Gap and Compliance. The gap between local and global standards, illustrated by cases such as Lagundi's non-compliance with the European Medicines Agency and the United States Food and Drug Administration (US FDA), poses a significant hurdle for herbal medicines to enter the global market. Compliance with international standards, such as Good Clinical Practice (GCP) and Good Manufacturing Practices (GMP), remains challenging.

Standardization and Research Guidelines. The absence of standardized guidelines for herbal drug research was noted, emphasizing the need for clear considerations and requirements. Standardization is crucial for fostering an environment conducive to herbal medicine development that meets global standards.

Mapping Disease Priorities through the Philippine Pharmaceutical Roadmap

KIs stress a significant gap in Filipino clinical research priorities due to the lack of a clear pharmaceutical roadmap. They emphasize the need for strategic planning to identify and prioritize diseases, ensuring better government and private sector resource alignment. The absence of clarity hampers efficient resource allocation, potentially leading to redundant research efforts. This roadmap is crucial for attracting investments, guiding research, and boosting the Philippines' competitiveness in global clinical trials.

Concerns about the misalignment between the Department of Health (DOH) and the DOST in disease prioritization were raised. While DOH focuses on treatment, DOST's role in research and grants lacks coordination, hindering drug development. In contrast to other countries, the Philippines lacks a system where the government signals important molecules and guides industry focus based on data availability.

Another highlighted challenge is the absence of a comprehensive disease registry, limiting the identification of pressing health issues among Filipinos. Relying on republished data every five years exacerbates the challenge, hindering timely manufacturing, research, and drug development responses. Besides, a disease registry is crucial in presenting a unique Filipino profile in clinical trials. Without a registry, the Philippines struggles to define its competitive edge and to attract research on specific diseases that are prevalent among Filipinos.

Government Incentives and Policies to Support Research

The informants commend the government's efforts to support pharmaceutical and diagnostics companies during the pandemic, offering seed funding, post-commercialization assistance, and streamlined approval processes. However, concerns arise regarding the sustainability of these measures

post-pandemic, stressing the need for ongoing government support to drive long-term growth and innovation in drug development.

Interviews highlight challenges in clinical trials, particularly in Phase 3 and Phase 4, with waning interest in earlier phases due to inadequate incentives. The absence of guaranteed faster regulatory approvals, tax exemptions, and benefits for Filipino participants deters investment in Phase 1 and Phase 2 trials. A more comprehensive incentive framework is urged to attract diverse clinical trials.

Ethical considerations also surface, with no standardized regulations on honorarium for trial participants, leading to discrepancies among ethics committees. Clear guidelines are essential to ensure fair compensation and ethical standards across all clinical trials.

Regulatory Science

Technical Personnel

The KIs emphasized the financial challenges clinicians and the therapeutics committee members face when reviewing clinical trial papers. The absence of dedicated honorarium or resources makes it financially unsustainable for clinicians to allocate time to these tasks, especially when compared to revenue-generating clinical practices. The lack of financial sustainability is identified as a barrier to securing dedicated and trained individuals for reviewing clinical trials.

Additionally, multitasking professionals, including clinicians, find themselves in a challenging position due to time constraints and work overload. The interviews highlight the difficulty of attracting professionals to participate in clinical trial reviews when they are already engaged in multiple roles. The need for dedicated personnel is emphasized, as part-time contributions may not effectively meet the rigorous demands of reviewing clinical trial papers.

The interviews also touched on the role of Contract Research Organizations (CROs) in maintaining the conduct of clinical trials. There is a concern about how CROs, often seen as subcontractors, can be made co-accountable for conducting trials according to global regulatory standards. There is a need to not just complete trials within timelines but also ensure the quality of information and data, emphasizing the importance of global standards and regulatory guidelines.

Another critical aspect identified is the lack of investment in building capabilities among technical personnel. The KIs stress the importance of pushing beyond the comfort zone to upskill and enhance expertise, aligning with global standards of professionalism.

Encouraging schools to provide courses on emerging fields like pharmacoeconomics and HTA has also been identified as a challenge. The lack of resources and experts hinders the growth of these critical disciplines, affecting the readiness of the workforce to cope with evolving trends in the industry.

Suboptimal Regulatory Process, Approvals, and Implementation

Another overarching theme of the challenges within the regulatory and clinical research sectors in the Philippines on regulatory science is the issue of regulatory process, approvals, and implementation. Sub-themes were identified including Prolonged approval timelines, Multi-site clinical trial complexities, Lack of centralized approval body, Disjointed application processes in clinical trials, Inefficient regulatory and ethical processes, Market approval challenges, Reliance pathway implementation, Lack of categorization for life-saving drugs, VAT-exempt medicine challenges, Extended approval time for product variations, Safety update approval delays, Balancing regulation with urgency, Transparency and dialogue issues, Urgency and collaboration, Increasing fees across regulatory bodies, and Impact of understaffing.

Prolonged Approval Timelines. One of the predominant issues raised in the interviews is the prolonged timeline for initiating clinical trials in the Philippines. The process is described as significantly delayed, taking up to three years, with even six months considered fortunate. The delays primarily stem from the complex approval processes and the need to obtain separate approvals for each trial site, discouraging sponsors and making the Philippines less attractive for global clinical research endeavors.

Multi-site Clinical Trial Complexities. Streamlining processes and approvals poses a substantial challenge, especially in multi-site trials. Obtaining approvals for each site, coupled with differing compliance standards and findings, adds complexity and time, hindering efficient study initiation.

Lack of a Centralized Approval Body. Unlike some ASEAN countries, the Philippines' absence of a centralized approving body contributes to delays. Other nations with a single approval system demonstrate faster timelines, highlighting the need for a unified approach.

Disjointed Application Processes in Clinical Trials. The application for a Certificate of Medical Device Listing (CMDL) related to clinical trial supplies also notes specific challenges. The CMDL application process, introduced under Administrative Order 2018-002 by the Center for Device Regulation, Radiation Health, and Research (CDRRHR), is separate from the clinical trial regulations outlined in AO 2020-0010 of the DOH. The disjointed application processes cause delays in clinical trials, illustrating a regulatory gap and a lack of integration between divisions, further complicating the landscape.

Inefficient Regulatory and Ethical Processes. The separation of ethics and regulatory approvals further complicates matters. While attempts have been made to streamline through bodies like the Single Joint Research Ethics Board (SJREB)-DOH, challenges persist, indicating the need for a more integrated and efficient regulatory framework.

Market Approval Challenges. Delays in the approval of actual molecules for market use are acknowledged, prompting

the introduction of a reliance pathway to expedite essential reviews while ensuring compliance with FDA requirements.

Reliance Pathway Implementation. The reliance pathways, such as accepting approvals from reputable agencies like the US FDA and EU, are acknowledged as positive steps to focus on key aspects and expedite reviews. However, challenges persist despite the reliance pathway, including redundant reviews, a lack of categorization between life-saving drugs and generics, and unclear reasons for rejection.

Lack of Categorization for Life-Saving Drugs. The absence of categorization between life-saving drugs and generics, following a first-in-first-out approach, prevents faster access to essential medications and adds uncertainty to approval outcomes.

VAT-Exempt Medicine Challenges. The contradiction of granting Value-Added Tax (VAT) exemption while subjecting medicines to detailed examinations defeats the purpose of prioritization and adds complexity to Bureau of Customs procedures. VAT-exempt medicines face customs challenges, contradicting the priority status granted by the government. This impedes the streamlined flow of critical medications through customs. Section 12 of Republic Act No. 11534, also known as the "Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act," grants VAT exemption to specific health products, including medications for hypertension, cancer, mental illnesses, tuberculosis, kidney diseases, diabetes, high cholesterol, and COVID-19 medicines, and medical devices.[14] As per this legislation, the FDA is mandated to identify and relay the list of VAT-exempt health products to other implementing agencies such as the Bureau of Internal Revenue, Bureau of Customs, and Department of Trade and Industry.

Extended Approval Time for Product Variations. According to the KIs in the study, major and minor variations face a prolonged approval process of 2-4 years. The fast-changing global standards, especially in Europe, exacerbate the issue, resulting in additional costs, delays, and even potential environmental harm for the imported medicines in the country, for example, concerning the timely update of product information, such as changes in product inserts. A KI emphasizes the rapid pace of change in Europe, where product information is updated within the year. Thus, information applied for approval in Philippine regulations for variations becomes obsolete by the time it is approved (average 2-4 years), prompting companies to repackage, incurring added costs and environmental harm through increased packaging. Additionally, the delayed approval process leads to supply interruptions, impacting patients' dependence on consistent medication schedules, which is a critical condition. KIs question the rationale behind prolonged timelines, emphasizing the lack of pragmatism hindering progress and efficiency in the pharmaceutical sector.

Safety Update Approval Delays. A critical issue highlighted is the prolonged approval time for safety updates, taking up to a year. Resistance from the Philippine FDA to adopt faster international standards for safety updates, such as in Europe, where safety notifications are treated as information and are not subject to approval, was noted as a significant concern. The absence of urgency in safety notifications and the requirement for authorization before dissemination pose potential health risks to patients.

Balancing Regulation with Urgency. While regulatory processes are essential for ensuring safety and efficacy, balancing rigorous scrutiny and the urgency of medical needs is crucial. The interviews highlight instances where regulatory process delays have real-life consequences, especially during a health crisis. Striking the right balance is imperative for timely public health access to safe and effective healthcare interventions.

Transparency and Dialogue Issues. Unlike in other countries, dialogue is limited in Philippine regulatory agencies. Lack of transparency about rejection grounds creates hurdles for organizations seeking product approvals, limiting their capacity to resolve deficiencies effectively. Outright rejections without clear data requirements impede the re-application process, resulting in inefficiencies.

Urgency and Collaboration. The interviews shed light on the contrasting approaches during the COVID-19 pandemic, where urgency facilitated communication and collaboration. However, the post-pandemic scenario reveals a return to restrictive communication practices, hindering the flow of information crucial for disease management.

Increasing Fees across Regulatory Bodies. Another challenge emphasized is the rising fees in clinical research and across various facets of the FDA. The increased financial burden is a pressing concern, particularly when not accompanied by a corresponding improvement in service quality. This creates challenges for clients and sponsors, who may find it difficult to justify increased costs without noticeable enhancements in regulatory processes.

Impact of Understaffing. The challenges faced by regulatory bodies, attributing delays to understaffing, are also discussed. While recognizing the limitations and different levels of activity within regulatory agencies, concern is raised regarding the potential impact on service quality. This suggests a nuanced perspective that understands the constraints faced by regulatory bodies but also underscores the need to balance increased fees with improved services.

Gap in Utilization of Acquired Knowledge on Regulations

Another challenge highlighted is the outdated regulatory guidelines and insufficient awareness of international standards, exemplified by the lack of recognition for Pharmaceutical Inspection Co-operation Scheme (PIC/S) country approvals. An example is the emergence of new regulations in China, such as the National Medical Products Administration's accreditation equivalent to GMP. This showcases a critical gap as local regulators in the Philippines still demand traditional GMP certificates, impacting the acceptance

of equivalent documents and causing delays in approvals. Challenges associated with the FDA's request for unnecessary documents during the clinical trial application process were also highlighted. Issues include redundant requests for pre-clinical data already included in the investigational brochure, introducing inefficiencies and delays in the regulatory approval process. This lack of alignment between regulatory expectations and industry practices emphasizes the need for shared knowledge and mutual understanding.

Another critical issue is the limited familiarity with GCP components. The plea for regulatory agencies to align with industry knowledge on GCP and its guidance is evident. The lack of familiarity with crucial GCP guidance, such as E2A and E2B, raises concerns about effective communication and adherence to global best practices. According to KIs, the expectation is that regulatory inspectors should possess a deeper understanding of the processes involved and plead for improved knowledge through observation and learning. Amidst these concerns, the KIs express concerns about correcting the FDA, fearing misinterpretation or over-stepping boundaries, emphasizing the delicate balance between industry knowledge and regulatory collaboration.

Moreover, the KIs highlighted the overwhelming presence of numerous regulations, often with equivocal meanings or unclear terms. The lack of streamlining and standardized interpretation has created an environment where rules are subject to diverse interpretations. This complexity, compounded by the perception that the regulatory environment is still in its infancy, hinders industry progression and necessitates a catch-up with neighboring countries.

Another prevalent issue is the overlap and implementation of outdated regulations, which create confusion within the industry. The full implementation of the eServices Portal in 2020, while still relying on obsolete regulations to communicate with the FDA, exemplifies this challenge. Outdated regulations hinder the effectiveness of new digital platforms, causing overlapping issues. The coexistence of repealed and current regulations causes complications, leading to potential non-compliance.

Regulatory Governance

One of the KIs stressed the importance of a coordinated effort from the entire government rather than relying solely on the FDA. The call for the "whole of government" approach highlights the interconnectedness of regulatory decisions. The regulatory challenges go beyond FDA administration, requiring involvement from the DOH, Department of Trade and Industry, and DOST. The lack of coordination may lead to disjointed policies that impact the industry, exemplified by instances where FDA decisions are made without the involvement or understanding of other relevant bodies.

The challenges intensify when regulatory bodies, like the FDA, engage in international initiatives, such as becoming a member of PIC/S or seeking WHO recognition. The lack of awareness and involvement from other government agencies, especially DOST and DOH, raises concerns about the consequences on the local industry and the supply of essential health products. While the regulatory agency claims to conduct risk assessments, there is a lack of transparency in sharing these assessments with industry stakeholders. The interviewee questions the depth and extent of these assessments.

Passive Regulatory Action on Counterfeit Drugs

The KIs emphasize that despite their compliance with the registration process, they share the market with unregistered products, raising questions about the adequacy of existing regulations in controlling the entire pharmaceutical landscape. The call to strengthen post-marketing surveillance is rooted in the recognition that not all products in the market have undergone a rigorous regulatory process.

The interviews highlight the importance of directing more resources and attention to post-marketing activities, such as surveillance of products on the Internet and in pharmacies. The concern is that while the regulatory process assures the safety of registered drugs, it may not be adequate once products enter the market, particularly those not subjected to the same level of scrutiny. Additionally, a notable sentiment among the KIs is that the current regulatory focus, while potentially adequate for highly regulated drugs, may not be pragmatic or practical. There is a suggestion that the regulatory process, especially regarding timelines, might be overly stringent. The lack of visibility on the quality of the review process adds to the complexity, emphasizing the need for a more balanced and efficient approach.

PIC/S GMP PE 009 Version 14 Adoption

Another critical challenge within the pharmaceutical industry is the adoption of PIC/S GMP PE 009-14. The major hurdle identified is the intricacy surrounding the

Contamination Control Strategy (CCS). Specifically, incorporating HBEL has introduced complexities in determining contamination control measures. The HBEL, representing toxicological levels, plays a pivotal role in decisions regarding cleaning validation and the segregation or dedication of facilities.

The computation of HBEL, being clinical-based, adds to the challenge. Toxicologists engaged in clinical studies determine these levels, particularly for new products. The implication is that a lack of clinical trials for generic drugs leads to limited data on the NOAEL, a critical parameter in the HBEL computation.

The absence of NOAEL data for generic products becomes a significant challenge, as clinical trials are uncommon for generics. The FDA's regulatory expectations that this data be available for cleaning validation limits raise questions among local companies regarding where to source this essential information.

Regulatory expectations based on PIC/S GMP PE 009 Version 14 and the use of HBEL computations have a

cascading effect on facility design. Cleaning operations, room design, and overall facility structures must align with the stringent regulatory computations, posing challenges for companies to adapt swiftly.

Formulation Design and Pharmaceutical Technology

Formulation Optimization

The QbD approach in optimizing formulations and understanding the design space poses a significant challenge for local companies. The intimidating statistics and the unfamiliarity of local pharmaceutical companies with implementing research-driven QbD formulations and registering also add to the challenge. This gap needs to be addressed to align with evolving regulatory trends that increasingly require QbD compliance.

Another critical challenge identified is related to the handling and analysis of big data. One of the KIs expresses the need for education and training on effectively handling and analyzing big data. This challenge underlines the critical role of data analytics in decision-making. The importance of biowaivers and the timely release of monographs was also mentioned.

API Sourcing and Regulation

The foremost challenge articulated by the interviewees is the limited supply and lack of API manufacturers in the Philippines. This challenge is not confined to the local context but is part of a global phenomenon where international controls on API manufacturers are becoming more stringent. The international API market is facing heightened scrutiny, leading to stricter regulations. To register generic products, companies must submit complete drug master files for APIs. Unlike the past, where the focus was on formulation, the current regulatory landscape demands a comprehensive dossier, including detailed information on API sourcing, manufacturing, and impurities.

The KIs emphasize the evolving regulatory controls, where the source of APIs is meticulously evaluated. Submitting a complete API dossier becomes challenging, as not all API suppliers can provide such detailed information. The process involves sharing the API manufacturer's contact information directly with regulatory bodies, maintaining a portion of the information as confidential. This dynamic complicates the sourcing process, requiring effective communication and collaboration between regulatory authorities and suppliers.

The challenges extend to the increasing regulation of APIs globally, with the implementation of GMP and PIC/S GMP regulations. The stringent controls make it harder for companies to secure a stable and compliant supply of APIs, especially for generic products.

Another notable concern is the impact on the supply chain due to API company closures and consolidations, further exacerbated by the disruptions caused by the COVID-19 pandemic. The need for major notifications and approvals when changing API suppliers poses a risk of product shortages as the industry witnesses closures and consolidations among API manufacturers.

Substantial investments in API manufacturing are considered to overcome the challenges in API sourcing. However, this poses challenges, requiring significant budgets, research efforts, and a thoughtful assessment of return on investment. The complexities extend to factors beyond budget, involving the need for dedicated research teams and strategic business planning.

Among all the various challenges, the researchers identified priority research areas crucial for addressing the pharmaceutical industry's growing needs, as highlighted by the informants. Accordingly, an action plan has been formulated (Table 2) to propel pharmaceutical sciences research forward and meet the industry's demands.

DISCUSSION

The Philippines ranks fifth worldwide in plant species diversity, preserving 5% of the globe's flora. Notably, the country boasts significant species endemism, with at least 25 plant genera and 49% of terrestrial wildlife found exclusively within its borders. These abundant natural resources underscore the Philippines' dynamic environment for drug discovery initiatives. In line with this, the imperative to identify, isolate, purify, modify, and standardize compounds, especially from natural sources, is pivotal in advancing pharmaceutical research and development. These processes are essential for extracting active ingredients from natural sources, synthesizing new chemical entities, and ensuring the purity of pharmaceutical products.[15-18]

As highlighted by the KIs, the lack of chemical definition and isolation of active compounds leads to the pharmaceutical companies' hesitancy to invest. This issue is exacerbated by perceived crude testing procedures and outdated formulations of research presented before them, which hinder investment opportunities. These findings align with a study by Mauricio et al., which emphasizes companies' preference for investing in market-ready technologies.[19] However, beyond reiterating informant concerns, these results reveal a systemic gap: while natural resource richness positions the Philippines as a potential hub for drug discovery, weak translational infrastructure and underdeveloped regulatory–industry linkages stall progress. This reflects what has been described as the translational "valley of death" in pharmaceutical innovation, where discovery work does not flow into scalable development pathways.[20] In contrast, India's Council of Scientific and Industrial Research (CSIR) and Thailand's Government Pharmaceutical Organization (GPO) have built strong translational pipelines that combine natural products with clinical validation and manufacturing support, demonstrating the institutional scaffolding absent in the Philippine setting.[11,21,22] It is widely recognized in the

Table 2. Priority Research Areas and Action Plan

Focus Areas	Research Needs	Action Plans	Responsible Agency	Timeframe	Indicators of Success
Drug Design and Discovery	Identification, isolation, purification, modification, and standardization of compounds	• Isolation, purification, and elucidation of the chemical structure of natural products *(Health Research and Development Agenda 2023-2028 - Drug Discovery and Development - HNRDA 2022-2028)* • Evaluate the pharmacologic activities of novel compounds *(Health Research and Development Agenda 2023-2028 - Drug Discovery and Development - HNRDA 2022-2028)*	IPS-NIH	Yearly	Three (3) published articles on identification, isolation, purification, modification, and standardization of compounds
	Pharmaceutical Roadmap of Priority Diseases in the Philippines	• Research on the appropriateness of new drug product release on patient needs using the recent data from Philippine Health Statistics *(Health Research and Development Agenda 2023-2028 - Re-emerging and Emerging Diseases - HNRDA 2022-2028)* • Needs forecasting on conditions that may become main disease burdens in the country in collaboration with different experts and government agencies such as DOH, FDA, and industry groups / organizations (e.g., PHAP, PCPI) *(Health Research and Development Agenda 2023-2028 - Re-emerging and Emerging Diseases - HNRDA 2022-2028)*	IPS-NIH	By 2030	Published study on forecasted main disease burdens in the Philippines Published Pharmaceutical Roadmap of Priority Diseases in the Philippines
Regulatory Science	HBEL/NOAEL list for common generic products	• Propose toxicology studies (HBEL/NOAEL) on common generic drugs *(National Integrated Basic Research Agenda 2022-2028 - Likas Yaman sa Kalusugan (LIKAS) Agenda - HNRDA 2022-2028)*	IPS-NIH	By 2026 By 2028 By 2032	Created a Technical Working Group focusing on toxicological studies Twenty (20) HBEL/NOAEL studies initiated Published HBEL/NOAEL List for Common Generic Drugs
Formulation Design and Pharmaceutical Technology	Understanding and applications of pharmaceutical QbD approach	• Provide QbD training *(Health Research and Development Agenda 2023-2028 - Capacity Building Programs - HNRDA 2022-2028)*	IPS-NIH	By 2026 By 2027 By 2029	Created a Technical Working Group focusing on QbD Training Published QbD Training Module At least fifteen (15) researchers/ pharmaceutical scientists/ industrial pharmacists trained on QbD

academic and industry communities that there is a crisis in transferring basic scientific discoveries from the laboratory to practical applications and potential therapies for diseases.[20] The importance of private sector engagement in healthcare as adopters, funders, and research generators, particularly in resource-limited regions, cannot be overstated. Research shows that even in low- and middle-income countries like the Philippines, this engagement leads to tangible enhancements in intermediate health outcomes.[19] This highlights the opportunity for joint efforts between the public and private sectors to stimulate innovation, address healthcare challenges, and ultimately enhance global health results.

Understanding the chemical structures and pharmacological profiles of bioactive compounds enables the rational design and optimization of drug candidates with improved bioavailability, efficacy, and safety profiles.[23-25] Furthermore, standardization is vital to ensure batch-to-batch consistency and reproducibility, which are critical

for regulatory approval and clinical use.[26] This approach significantly broadens the spectrum of potential drug candidates, fostering a more diverse and resilient drug discovery pipeline.

Besides, KIs noted that the involvement of the DOST is predominantly confined to basic research, with a rapid and premature shift towards marketing products, particularly in food supplements. Thus far, only two herbal medicines, Lagundi and Sambong, have achieved notable success. Medical practitioners across various specialties in the Philippines have integrated *Vitex negundo* (Lagundi) for treating cough and mild asthma, and *Blumea balsamifera* (Sambong) as a chemolithiatic agent for kidney stones into their clinical practices. These herbal remedies have demonstrated scientific validation and commercial success.[27] According to DOH Administrative Order 172-2004, herbal medicines should include information regarding the bioassays (if applicable), non-mutagenicity, sub-chronic and chronic toxicity, lethal dose, pharmacological effects, and clinical trial outcomes for the final product.[28]

Dietary supplements developed through the collaborative efforts of the DOST and PCHRD's Tuklas Lunas program and currently available in the market include *Momordica charantia* (Ampalaya) tablet as a supplement for managing diabetes.[29] Bignay or *Antidesma bunius* capsule, recognized for its reported anti-inflammatory properties beneficial for lung disorders, and the Tawa-Tawa or *Euphorbia hirta* capsule, which serves as a remedy for dengue. Both Bignay and Tawa-Tawa supplements have attained technology readiness level (TRL) 9, with local utility model applications already submitted and FDA approval secured. Herbanext Laboratories, Inc. plans to initiate clinical trials for the Tawa-Tawa capsule to further its development into a pharmaceutical product intended as a complementary treatment for dengue, while the owner of the Bignay technology is open to engaging in licensing negotiations with potential distributors and manufacturers.[30,31]

On the other hand, Ulasimang Bato (also known as pansit-pansitan or pepper elder) has recently successfully completed pre-clinical and multiple phases of clinical trials stipulated by the FDA for medicinal formulations. These assessments have substantiated its safety and efficacy in addressing heightened uric acid levels linked with gout, characterized by painful joint inflammation. It is in the pre-commercialization phase (TRL 7).[32,33] Alongside Ulasimang Bato, other plant-based medicines awaiting commercial production and distribution include Yerba Buena (for pain relief post-operation, dysmenorrhea, childbirth, and circumcision), Tsaang Gubat (for anti-colic and relief from kabag), and Ampalaya (for anti-diabetic purposes).[32,34] Clinical trials I-III demonstrated that administering Yerba Buena and paracetamol orally yielded comparable analgesic efficacy, subsequently leading to its approval by the Philippine FDA.[35] The inclusion of the Tsaang Gubat tablet in the Philippine National Formulary ensued after conducting *in vitro, in vivo,* and Phase I-III clinical trials. Prospective research aims involve reformulating the current Tsaang Gubat medication for additional indications, understanding its molecular mechanism of action, and establishing strategies for plant preservation.[36]

The discussion of herbal medicines such as Lagundi, Sambong, and Ulasimang Bato also illustrates another systemic theme: the uneven trajectory from discovery to market. Informants noted the Department of Science and Technology's (DOST) premature push to commercialization, often in the form of dietary supplements, rather than building a robust, pharmaceutical-grade evidence base. This stands in contrast with Thailand's GPO model, which ties product development to the country's national essential medicines list, ensuring integration with clinical practice. Such comparisons suggest that the Philippine approach risks creating fragmented outcomes, where some products gain traction as supplements but fail to reach sustained pharmaceutical adoption.

Despite the report indicating that twenty-eight standardized herbal drugs had already been developed under the DOST's Comprehensive Drug Discovery Program or "Tuklas Lunas" Program, scheduled for pre-clinical and clinical assessments by mid-year of 2019, KIs expressed concerns about the limited number or scarcity of clinical trials focusing on active compounds in the Philippines during the recent interview in this study, last quarter of 2023.[37] To address these challenges and ensure the continued advancement of herbal medicine research in the Philippines, it is recommended that efforts be made to enhance the chemical characterization and isolation of active compounds. Additionally, updating research methodologies and refining testing procedures can improve the quality of data presented to pharmaceutical companies, increasing their confidence in investing in herbal medicine research and development. Addressing these issues and fostering collaboration between researchers, industry stakeholders, and regulatory authorities will promote sustainable development and utilization of herbal medicines for public health.

The issue of non-exclusive licensing provides another lens into systemic weaknesses. While originally intended to widen access, informants described how this approach disincentivized deep private sector investment. Regional experiences provide useful contrasts: Thailand's GPO balances exclusivity with public-interest licensing to sustain industry participation, while India's CSIR has leveraged exclusive licenses in early-stage products to attract committed investors before opening access.[11,21,22] The Philippine case shows the unintended consequences of blanket non-exclusivity: underinvestment, quality stagnation, and weak marketing uptake. These lessons suggest the need for differentiated licensing strategies calibrated to the maturity of the technology.

Another notable blind spot was the absence of pharmaco-kinetic/ pharmacodynamic (PK/PD) research themes among identified priorities. This omission may reflect informant expertise (regulatory and clinical stakeholders with limited

pharmacology backgrounds) or entrenched sectoral silos between clinical researchers and basic scientists. The lack of PK/PD perspectives has critical implications: without such data, dose optimization, therapeutic monitoring, and safety assessments remain underdeveloped, undermining drug development and regulatory decision-making. This underscores the need for cross-sector collaboration and training to bridge scientific divides.

The identified challenges in ensuring the sustainability of raw materials supply resonate with concerns raised by the FIP. In particular, the FIP emphasizes the need for a systematic approach to standardizing the cultivation of plant sources for natural products.[3] The FIP advocates for the increasing application of modern techniques in plant biology, agricultural sciences, genomics, molecular biology, and analytical and information sciences. By leveraging modern techniques in plant biology, agricultural sciences, genomics, molecular biology, and analytical sciences, countries can strengthen quality and sustainability. However, current Philippine efforts remain fragmented, relying on individual Tuklas Lunas projects rather than coordinated national strategies, unlike India's CSIR, which has established centralized metabolomics and genomics platforms to support standardization.[7,8,22,32] Furthermore, the FIP highlights the potential of metabolomics in evaluating the complex mixtures present in natural products. This aligns with the challenges faced by researchers in ensuring the uniformity and stability of active compounds, as discussed by KIs. Metabolomics offers a powerful tool for characterizing the chemical composition of natural products and assessing their quality and consistency over time. Additionally, the FIP suggests that genetic modification holds promise for creating new medicinal plants with enhanced properties. This innovative approach could potentially alleviate the challenges associated with sourcing specific plant varieties and ensuring consistency in large-scale production. Similarly, to fully capitalize on the advantages of herbal medicine research, it is imperative to address additional barriers and challenges that impede its development and commercialization. KIs have identified another significant challenge in advancing herbal medicine research: the non-exclusive licensing agreements imposed by the DOST, which was implemented due to the pharmaceutical solid industry's interest in herbal medicines like Lagundi and Sambong.[19] The openness for collaboration between the research team, the private sector, PCHRD, and NIRPROMP led to this. Before patents were granted, numerous companies were keen to invest in these herbal remedies. As a result, PCHRD introduced the non-exclusive licensing agreement to facilitate broader access to the technologies and accommodate this interest.

While non-exclusive licensing agreements offer advantages such as promoting knowledge sharing and collaboration, promoting widespread access to technology, and fostering competition, they also entail significant disadvantages that can impede the successful pharmaceutical adoption, commercialization, and market penetration of herbal medicine products.[21] Based on the interviews conducted in this study, licensees may hesitate to invest significant resources into research and development efforts when licensing agreements are non-exclusive for herbal medicines. Without the assurance of exclusivity, licensees fear that their competitors could easily replicate their efforts and benefit from the same technology without bearing the associated costs, such as those who will pursue marketing the product in food supplements. This lack of incentive could lead to underinvestment in the improvement and optimization of herbal medicine formulations, ultimately hindering innovation and limiting the competitiveness of the products in the market. Since multiple companies have access to the same technology, there may be less motivation to differentiate products through innovation or research and development. This could result in product quality stagnation and limited therapeutic efficacy advancements, ultimately hindering market growth and consumer adoption. Furthermore, non-exclusivity may diminish the motivation for licensees to invest in marketing and promotion efforts for herbal medicine products. Licensees may perceive limited returns on their marketing investments if competitors market similar products based on the same technology. Consequently, there may be less aggressive promotion of herbal medicine products, reducing awareness and acceptance among medical professionals and consumers.

To address these challenges, it is essential to carefully consider the implications of non-exclusivity and explore alternative licensing strategies that balance promoting innovation and ensuring commercial viability in the herbal medicine industry. In some instances, granting an exclusive license is the best approach, especially when the invention is in its early stages.[38] However, in other cases, adopting more open strategies, such as publication or offering non-exclusive licenses, is better. Engaging in dialogues with the DOST is vital to revisiting and potentially revising the non-exclusivity clause, considering the insights from the KIs that most of the research presented to them as potential adopters is still in its infancy. Moreover, providing incentives for successful commercialization can further encourage companies to invest in herbal medicine research, driving innovation and enhancing the development of herbal products. Another critical aspect of advancing herbal medicine research is ensuring transparent and mutually beneficial technology transfer processes between research institutions and companies. Facilitating forums where companies and researchers can openly discuss concerns related to technology transfer fosters a transparent and collaborative environment. These forums provide a platform for sharing best practices, addressing challenges, and establishing clear guidelines for technology transfer agreements. Barriers to technology transfer can be mitigated by promoting open communication and collaboration, enabling more efficient knowledge exchange, and accelerating the translation of research findings into commercial products.

Furthermore, the necessity for a pharmaceutical roadmap of priority diseases in the Philippines underscores the importance of strategic planning in healthcare to address the most pressing medical needs of the population. As the designated overall technical authority on health, the DOH is responsible for providing national policy direction and developing plans, standards, and guidelines on health, including pharmaceuticals.[39] This mandate necessitates the provision of a Pharmaceutical Roadmap by the DOH. However, upon checking the DOH website, the data presented, such as mortality and morbidity statistics, are outdated (covering 2014 reports), with the last update dating back to June 2016.[40,41] In contrast, the Philippine Statistics Authority website offers more current data, with updates available until 2023.[42]

Given the dynamic nature of the healthcare landscape, timely and accurate information is crucial for effective policy making and planning. A pharmaceutical roadmap could serve as a guiding framework for pharmaceutical companies, government agencies, policymakers, researchers, and healthcare providers to allocate resources effectively and prioritize research and development efforts toward tackling prevalent diseases and health challenges in the country, maximizing the impact of interventions and enhancing the overall effectiveness of healthcare delivery systems. By providing up-to-date data and analysis, the DOH can facilitate evidence-based decision-making, promote transparency, and ensure accountability in healthcare governance.

In response to this need, conducting research assessing the alignment of new drug product releases or the dominant available drugs in the country with the health needs of Filipino patients is fundamental for ensuring healthcare relevance and efficacy. By leveraging recent data from the Philippine Health Statistics, researchers can evaluate the appropriateness of the available drugs in addressing prevalent diseases and medical conditions in the country. This assessment includes analyzing disease prevalence, treatment gaps, patient demographics, and healthcare utilization patterns. Similarly, collaborating with diverse experts and government agencies, such as the DOH, FDA, and industry groups/organizations, is essential for forecasting needs on emerging disease burdens in the Philippines. By identifying potential disease hotspots and emerging health threats, stakeholders can develop targeted interventions, allocate resources preemptively, and implement preventive measures to mitigate the impact of future disease outbreaks. Moreover, by engaging stakeholders in the research process, the action plan promotes transparency, accountability, and inclusivity, ensuring that the needs and perspectives of all relevant stakeholders inform healthcare priorities. Ultimately, timely access to effective treatments can improve patient outcomes, reduce disease burden, and enhance the quality of life for individuals affected by prevalent diseases.

Another critical priority is to propose toxicology studies on commonly used generic drugs in alignment with the identified research needs highlighted by KIs relevant to PIC/S GMP version 14 PE 009, such as establishing HBEL/NOAEL lists for common generic products. This action plan holds significant importance as it goes beyond justifying cleaning limits. By conducting these studies and establishing HBELs, manufacturers can effectively assess and manage risks associated with cross-contamination in shared facilities. The Quality Risk Management process guided by HBELs ensures the adequacy of existing control measures. It helps determine additional measures needed, particularly for high-risk products.[43] This proactive approach enhances patient safety by minimizing the potential harm posed by cross-contamination of drugs, ultimately contributing to the quality and integrity of pharmaceutical manufacturing processes. The Philippine FDA Advisory No. 2023-0258 mandates automatic adoption of PIC/S GMP Guide revisions under Administrative Order No. 20120008, ensuring standardization and adherence to pharmaceutical manufacturing standards.[44] Effective January 15, 2023, strict compliance with PIC/S GMP Guide Version No. PE 009-14 is required in the country, emphasizing the commitment to quality and safety in medicinal product manufacturing.[44] Furthermore, in response to the challenge identified by KIs in understanding and applying the pharmaceutical QbD approach in formulation optimization, offering QbD training services will be beneficial.

On the identified challenges for technical personnel, particularly in the regulatory and clinical research sectors, our study results closely align with a separate investigation into clinical research in China, which identifies an insufficient number of qualified investigators in clinical research as one of their major challenges. The study underscores that research management staff, particularly study coordinators in hospitals, are often engaged on a part-time basis. Similar to multi-tasking professionals, they also feel overwhelmed by their workload. Inadequate training and preparation impede their ability to perform their duties effectively, further exacerbating the challenges faced by clinicians and other multitasking professionals when participating in clinical trial reviews.[45]

In light of the challenges under the suboptimal regulatory process, approvals, and implementation, the FDA acknowledges its slow registration process and attributes it to increased requirements, infrastructure issues, personnel shortages, and coordination difficulties among 'mother and baby' Certificate of Product Registration (CPR) certificate holders.[5] With a limited number of evaluators - 62 plantilla personnel in the FDA's drug registration unit, not all positions are occupied. Around 900 personnel, including regional offices, and a limited number of evaluators — approximately 60 for human drugs and two for Certificate of Listing of Identical Drug Product (CLIDP) registrations; there are 29,000 drug units registered or awaiting registration as of November 2018.[5] Besides, an FDA informant acknowledged the difficulty of finding personnel with technical expertise to work on drug registration application reviews.[5] Furthermore, large file sizes hinder electronic submissions, necessitating

manual data delivery, and the requirement for Bioequivalence (BE) testing of all oral preparations since 2013-2014 has worsened backlogs. Hence, efforts should be focused on addressing the human resource and infrastructure challenges faced by the FDA. Auspiciously, news was released this February 2024, that under President Ferdinand R. Marcos Jr.'s directive, the FDA plans to extend the duration of licenses to operate from two to five years and certificates of product registration from five to ten years.[46] Likewise, the FDA plans to cut the review and approval period for generic drug applications from 120 days to just 45 days, following the Facilitated Review Pathway.[46] Such a change would benefit the regulatory body and the industry, lessening the administrative workload associated with frequent renewals and potentially alleviating delays.

Based on the FDA Citizen's Charter 2022 (3rd edition, effective March 31, 2022), the approval process for minor variation applications would entail 60-180 working days (3-8 months), while major variation applications would require 180 working days (8 months).[47] Nonetheless, according to the KIs in the study, major and minor variations face a prolonged approval process of 2-4 years. Despite the FDA's response to the transparency and dialogue issues, which included the launch of regular "Kapihan" dialogue sessions to address industry issues, a no-contact policy during the registration process, and unclear grounds for rejection continued to impede collaboration and dialogue between regulatory agencies and stakeholders, and appear to be unresolved.[5]

Counterfeit drugs are a concerning issue, and their true extent remains uncertain, according to the FDA.[5] In 2018, Manila saw a significant seizure of counterfeit medicines worth $3 million. This event prompted the Philippine President at that time, Rodrigo R. Duterte, to take strict action against the facilities responsible for producing fake drugs.[48] According to a report by the United Nations, the Philippines has the highest number of counterfeit medicine cases in Southeast Asia from 2013 to 2017. The region witnessed a total of 460 cases involving the counterfeiting and unlawful distribution of pharmaceuticals. Among these, the Philippines accounted for 193 incidents, Thailand for 110, Indonesia for 93, and Vietnam for 49.[49] Research suggests that in less developed countries, there is a higher prevalence of counterfeit drugs and that the regulatory landscape in the Philippines appears to be stricter compared to those in other countries.[5,50] Nevertheless, despite the stringency of Philippine regulations, the multitude of problems and challenges cannot be disregarded and necessitate immediate comprehension and appropriate action. Taken together, these findings suggest that the barriers identified, hesitant industry engagement, premature commercialization, underperforming licensing strategies, blind spots in PK/PD, and fragmented standardization, are not isolated but systemic. They reflect an innovation ecosystem that lacks integrated governance, translational infrastructure, and sustained industry-academic-regulator collaboration. Addressing them requires not only technical fixes (e.g., better assays, improved toxicity studies) but also institutional reforms inspired by best practices in ASEAN and beyond.

CONCLUSION

This study on pharmaceutical sciences research needs in the Philippines' regulatory and clinical research sectors has identified pressing challenges and priorities requiring strategic intervention. From incomplete development of therapeutic compounds to regulatory gaps and formulation optimization, the landscape presents both complexities and opportunities. The researchers have outlined five research priorities aligned with FIP focus areas: (1) isolating and evaluating natural product compounds, (2) researching new drug release appropriateness and disease burden forecasting in the Philippines, (3) proposing toxicology studies on common generic drugs to compute for HBEL, and (4) providing QbD training. To translate these priorities into actionable outcomes, pointed recommendations are advanced for major stakeholders. For the FDA, strengthening regulatory science through clearer, harmonized guidelines and streamlined approval processes is essential to support NUHRA's priority on "health governance and regulation." For DOST, increasing investments in natural products research and clinical trials responds to NUHRA's focus on "drug discovery and development," ensuring that local compounds can progress into viable therapeutics. For CHED, embedding pharmaceutical sciences research, big data handling, and QbD in the academic curriculum addresses NUHRA's emphasis on "capacity building and human resource development." For the pharmaceutical industry, fostering collaboration in formulation design, active pharmaceutical ingredient (API) sourcing, and compliance with global standards will contribute to NUHRA's priority on "health technology development and innovation." By aligning these recommendations with NUHRA, this study positions itself not only as a diagnostic of current gaps but also as a roadmap for targeted action among stakeholders. Collaboration across regulatory agencies, government research bodies, academia, and industry will be crucial for sustainable progress. Ultimately, this study contributes to strengthening the pharmaceutical research ecosystem in the Philippines, ensuring that innovation and regulatory compliance translate into better access to safe, effective, and affordable medicines.

Study Limitations

The scope of this study was confined to assessing the pharmaceutical science research needs within the Philippine pharmaceutical regulatory and clinical research sectors. Therefore, the identified industry needs may not reflect a whole pharmaceutical and global perspective but rather the specific context of the sector and region under study. Purposive sampling was employed due to time constraints, potentially affecting the generalizability of the results. The

study takes into account the resources and capacity of the conducting institution to identify priority research needs and corresponding action plans, considering available expertise, infrastructure, and funding allocations that potentially limit its implementation. Moreover, success may hinge on cooperation and participation from various industry stakeholders, which cannot be guaranteed. Additionally, external factors such as regulatory changes, market dynamics, or technological advancements may influence the feasibility and implementation of proposed solutions, with potential impacts not fully accounted for in the study. Furthermore, responses may have been influenced by social desirability bias, potentially leading participants to provide answers that align with perceived expectations rather than candid reflections. The respondent profile was also relatively narrow, excluding technical and research staff who may hold valuable operational insights. The absence of data triangulation further limits the robustness of the findings, as conclusions were drawn primarily from a single set of qualitative inputs. Lastly, the qualitative scope was restricted to regulatory and clinical stakeholders, leaving out perspectives from other critical sectors such as manufacturing, distribution, and academic research and development.

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All authors certified fulfillment of ICMJE authorship criteria.

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