

Journal of STI Policy and Management

Publication details, including instructions for authors and subscription information: <http://www.stipmjournal.org/>

Potentials of Research Activities in Medicines at the Indonesian Institute of Sciences (LIPI)

Hadi Kardoyo, Mia Rahma Romadona, and Setyowiji Handoyo

Research Center for STI Policy and Management, Indonesian Institute of Sciences

Version of record first published: 15 July 2020

To cite this article: Kardoyo, H., Romadona, M.R., and Handoyo, S. (2020). Potentials of research activities in medicines at the Indonesian Institute of Sciences (LIPI). *Journal of STI Policy and Management*, 5(1), 51–71.

To link to this article: <http://dx.doi.org/10.14203/STIPM.2020.179>

ISSN 2540-9786 (Print); ISSN 2502-5996 (online)

Accreditation Number: 21/E/KPT/2018

Full terms and conditions of use: <https://creativecommons.org/licenses/by-nc-sa/4.0/>

You are free to:

- Share : copy and redistribute the material in any medium or format
- Adapt : remix, transform, and build upon the material
- The licensor cannot revoke these freedoms as long as you follow the license terms.

Under the following terms:

-  Attribution — You must give appropriate credit, provide a link to the license, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use.
-  NonCommercial — You may not use the material for commercial purposes.
-  ShareAlike — If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original.

No additional restrictions — You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits.

Notices:

- You do not have to comply with the license for elements of the material in the public domain or where your use is permitted by an applicable exception or limitation.
- No warranties are given. The license may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material.
- If you copy the dataset merely to extract the uncopyrightable data elements would not need permission to do so. However, if you republish the full dataset or using the copyrightable data layers require a permission from Research Center for STIPM, Indonesian Institute of Sciences.

**JOURNAL OF SCIENCE, TECHNOLOGY AND INNOVATION
POLICY AND MANAGEMENT (STIPM JOURNAL),
Volume 05, Issue 01, July 2020**

FOREWORD by EDITOR-in-CHIEF

We are very pleased to inform the readers that *Journal of Science, Technology, & Innovation Policy and Management (STIPM Journal)* Vol. 5, No. 1, July, 2020 is now ready for public reading and views.

STIPM Journal is an online research journal managed by the Research Center for Science, Technology, Innovation Policy and Management, Indonesian Institute of Sciences (P2KMI-LIPI). This journal in fact provides scientific information needed mostly by the research scholars. As a peer reviewed journal, STIPM provides free access to research thoughts, innovation, and original discoveries.

In this edition, the STIPM Journal contains six articles dealing with science, technology and innovation policy and management written by scholars from Japan and Indonesia.

The first article, entitled *Dynamics of Organisational Capability of Japanese Construction Firm towards Open and Service Innovation through PPP/PFI arrangement* was written by **Taeko Suehiro, Kumiko Miyazaki**. This study examines the influence of Public-Private Partnership (PPP)—or, more specifically, Private Finance Initiative (PFI)—arrangements in relation to open and service innovation in construction firms in Japan.

Second article was composed by **Pratiwi**, entitled *The Role of Local Community Associations as Intermediaries: A Multiple Case Study in a Rural Area*. This study investigates the role, capabilities, and the outcome of the engagement of local community associations as intermediaries in different sectors such as agriculture, food processing, and tourism product. This study describes the way innovation promotes rural development.

Erman Aminullah et al., present the third article, *Policy Role in Innovation Network: Case of Indonesian Food Processing Firms*. The objective of the study is to reveal internal and external factors that affect the use of network relations for innovation, with a focus on mapping the policy role in innovation networks. The study was undertaken through case analysis in four different firms in Indonesia.

The fourth article entitled *Potentials of Research Activities in Medicines at the Indonesian Institute of Sciences (LIPI)* was by **Hadi Kardoyo et al.** This article reveals the findings of research priority setting (RPS) in the field of medicine and health at the Indonesian Institute of Sciences (LIPI) in 2017. The RPS stage had been conducted with the Delphi Method and produced five major issues.

Next article entitled *What We Learn from Innovation Failure: A Review of Clean Water Postpaid Service in Remote Island Indonesia Using Sea Water Reverse Osmosis (SWRO) Technology* was presented by **Rendi Febrianda and Nur Laili**. Final article was compiled by **Syukri Yusuf Nasution and Yovita Isnasari** with the title *Valuation IP of Nano Technology to Make a Nano Tea Based on Mangosteen Peel as a New Product Development*. This article analyses the potential of nano technology in developing new

product, such as how much the potential of the turn over if the technology is used to produce a nano tea based on mangosteen peel, how much the royalty rate, and how is the positioning of the technology in in relation with legal aspects, technological readiness, market condition and finance.

In addition to all articles presented in this volume, we also would like to thank the authors, editors, and reviewers who have worked very hard in this edition. We hope that all articles featured in this edition are useful for the readers.

Jakarta, 16 July 2020

Editor-In-Chief

JOURNAL OF STI POLICY AND MANAGEMENT

Volume 5, Number 1, July 2020

LIST OF CONTENTS

Dynamics of Organisational Capability of Japanese Construction Firm towards Open and Service Innovation through PPP/PFI arrangement Taeko Suehiro and Kumiko Miyazaki	1–16
The Role of Local Community Associations as Intermediaries: A Multiple Case Study in a Rural Area Pratiwi	17–32
Policy Role in Innovation Network: Case of Indonesian food processing firms Erman Aminullah, Wati Hermawati, Trina Fizzanty, and Nur Laili	33–50
Potentials of Research Activities in Medicines at the Indonesian Institute of Sciences (LIPI) Hadi Kardoyo, Mia Rahma Romadona, and Setyowiji Handoyo	51–71
What We Learn from Innovation Failure: A Review of Clean Water Postpaid Service in Remote Island Indonesia Using Sea Water Reverse Osmosis (SWRO) Technology Rendi Febrianda and Nur Laili	73–82
Valuation IP of Nano Technology to Make a Nano Tea Based on Mangosteen Peel as a New Product Development Syukri Yusuf Nasution and Yovita Isnasari	83–93



Potentials of Research Activities in Medicines at the Indonesian Institute of Sciences (LIPI)

Hadi Kardoyo, Mia Rahma Romadona, and Setyowiji Handoyo

Research Center for STI Policy and Management, Indonesian Institute of Sciences

ARTICLE INFO

Article History:

Received : 01 October 2019

Revised : 07 June 2020

Accepted : 07 June 2020

Available online : 15 July 2020

Authorship Contribution:

Authors contribution is in line with the authorship order. First author is the main contributor.

Keywords:

Research priority setting,
Pharmaceutical industry,
Medicine research

ABSTRACT

This article reveals the findings of research priority setting (RPS) in the field of medicine and health at the Indonesian Institute of Sciences (LIPI) in 2017. This RPS has been conducted to address issues and explore potential research topics in LIPI in the area of drug and health industry. The RPS stage has been conducted with the Delphi Method and produced five major issues, namely 1) Structure of the pharmaceutical industry in Indonesia, 2) The role of government's R&D institutions and universities in the structure of the pharmaceutical industry, 3) Standardization and product supervision, and 4) Policies in the sectoral innovation system. Based on these major issues, LIPI has potential research topics that need to be developed. Those potential researches as contribution for the growth of pharmaceutical industry include: 1) research on discovery of "lead compounds", 2) research on combinations of chemical compounds in medicinal and health products, 3) social research related to public acceptance of medicinal products, 4) research on the potential of herbal medicines originating from "indigenous knowledge", 5) the need to develop a database of potential herbal medicinal ingredients, 6) development of formulations of finished drug products based on the expired patent utilization, 7) development of research for phytopharmaceutical products, 8) development of research on "reagents" to support research activities in the fields of health and medicine, 9) development of technological capabilities needed to support research activities in the fields of health and medical treatment, 10) development of research topics by referring to the ministry's pharmaceutical industry development road map and 11) research potential in R&D institutions and universities with reference to R&D and manufacturing scenario of APIs. Collaboration with industry becomes a critical aspect for LIPI in doing research in the area of medicine and health.

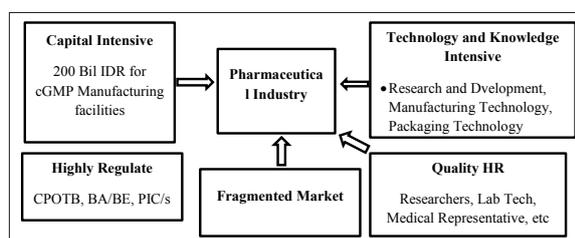
©2020 P2KMI-LIPI All rights reserved

* Corresponding Author.

E-mail: hadikardoyo@yahoo.com

I. INTRODUCTION

Indonesian Government Law No. 36/2009 concerning health states that drugs are materials or compounds of materials, including biological products used to affect or examine physiological systems or pathological conditions in terms of establishing the diagnosis, prevention, healing, recovery, and improvement in health for humans. In accordance with the law, medicines have an important role in supporting the quality of life. The production of medicines and medical devices must fulfill the guarantees and safety standards for the users.

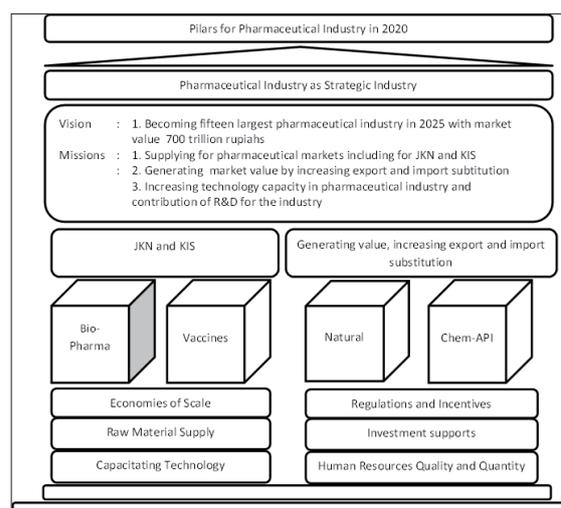


Source: Setiawan and Djohan (2016)

Figure 1. Characteristics of the Pharmaceutical Industry

The pharmaceutical industry has a number of characteristics such as capital intensive, highly regulated, hi-tech and knowledge-intensive, fragmented markets and requires high quality of multidisciplinary human resources (HR) (Setiawan & Djohan, 2016). Capital intensive describes a number of costs and risk to develop the business. Highly regulated means that medicinal and health products must comply with the standards as the products are directly related to the lives of the users. The process of producing medicines and medical devices must fulfill the standard of facilities, infrastructures and processes in the industry (CPOB, BA/BE, NIE, PIC/s). Moreover, fragmented market refers to the existing market share dominated by 4–6% of the companies. Technology and knowledge-intensive describes the needs of science and advanced-technology to support industrial activities. Moreover, specific and high-skilled HR capacities, such as researchers, laboratory technicians and medical representations, are also critical aspects to support industrial activities.

Several strategic issues are faced by the Indonesian pharmaceutical industry. Issues in national health insurance (JKN), innovation, competitiveness of the domestic pharmaceutical industry and the dynamics of the global economy are big challenges for the domestic pharmaceutical industry. Social health insurance and services such as health facilities as well as availability of medicines and medical devices still need more improvement. Innovation and competitiveness need to be developed to address the issue of raw material dependence. Availability of human resources and research funding is also a key to support the independence of the domestic pharmaceutical industry. The dynamics of the domestic market and the ability of the industry to penetrate the regional market become challenges for the pharmaceutical industry to compete in the global market.



Source: GP Farmasi (2016)

Figure 2. Four Pillars of Indonesian Pharmaceutical Industry in 2025

The pharmaceutical industry is designated to be one of the national strategic industries. Related to this, the pharmaceutical industry roadmap has been developed to support and accelerate the development of the domestic pharmaceutical industry. This roadmap, accordingly, is envisioned Indonesia as the 15th largest pharmaceutical producer in the world in 2025 with a market value of 700 trillion Indonesian Rupiahs (IDR). The mission is set out to fulfill the needs of medicine and national medicine, including JKN, contrib-

utes to the country's export markets and import substitution, and to develop pharmaceutical technology capability including R&D activities. The four pillars of industrial development strategies are set out in four categories of pharmaceutical industries, namely biopharmaceutical, vaccines, natural, and chemicals.

The Indonesian Institute of Sciences (LIPI) is the largest government's R&D institutions focusing on the development of studies including research on medicine. Research in the field of medicine and pharmacy is conducted at several research centers under the Deputy of Life Science (Research Center for Biology and Biotechnology), Deputy for Engineering (Research Center for Chemistry and Research Institute for Natural Materials Technology). Regarding the potential of development of the pharmaceutical industries, LIPI has developed a research program to contribute to the growth of the pharmaceutical industries.

Related to this, research priority setting (RPS) in the field of medicines and pharmaceutical is conducted to produce research priorities for LIPI in the future. The RPS project for the health and medicine is an assignment project from the top level management of LIPI and funded by DIPA 2017. This RPS is conducted to explore issues and potential research in the field of health and medicine that can be done by LIPI. LIPI has several deputies and research centers that can support the development activities of the health and pharmaceutical industry. This RPS was conducted to produce research topics carried out by LIPI in respond to the industrial needs. LIPI has strength in conducting basic research, however, collaboration with industries is needed to conduct applied research in the health and medicine fields. LIPI has strength in conducting basic research, however, collaboration with industry is needed to conduct applied research in the health and medicine fields. This RPS aims to develop guidelines for research activities in the field of medicine for 2017–2026.

II. ANALYTICAL FRAMEWORK

Determining research topics to become a project in an institution is an important part of the

activities of R&D institution. Various methods were developed as a tool to generate priority activities for an institution. RPS is a method for generating relevant research topics carried out at R&D institutions referring to the relevance and urgency of needs as well as considering other aspects such as the availability of human resources, funding, research facilities and risks.

Priority settings are mostly done on sectoral activities to determine activities at any given time. Priority settings, for example, were developed by stakeholders to determine activities or projects in the fields of energy, agriculture, health, and others. In the health sector, for example, World Health Organization (WHO) has developed priority settings to explore topics for activities that need to be carried out by taking into account several aspects. WHO (2016) states that priority-setting process is to select among different options for addressing the most important health projects with limited resources. The process of priority-setting is inherently political; it is a process where societal values and goals are considered, and resulting priorities reflect a compromise among stakeholders.

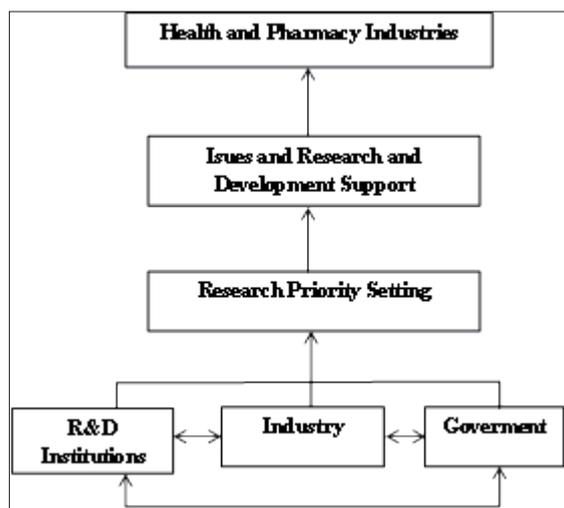
One of the RPS frameworks in health was developed by The Council on Health Research for Development (COHERD) (2000). RPS is an iterative and interactive process which includes several aspects such as priority setting exercises, elements of priority settings, criteria for priority settings, identifying broad priority areas and its implementation.

This study utilizes the research priority setting (RPS) stage, developed by COHERD (2000), in addressing issues and research potential to support the development of the pharmaceutical industry. The RPS set objectives to:

- a) Identify issues in research activities in the fields of medicine and health
- b) Determine the topic of R&D activities in the health and medicines that will be LIPI's priority in the next ten years (2017–2026).

The stage of the study is by conducting RPS and using the Delphi method. Delphi method, developed by Rand Corporation for the American Military in the 1950s, is a method to predict the

future based on expert consensus (Dalkey, 1969). This method involves expert council to identify issues and select research topics prioritizing the field of medicine. Brender, McNair, and NØhr (2000) described steps in Delphi that include brainstorming phase, evaluation phase, feedback, preparation, collection and analysis of the expert panel's rating of the individual topic.



Source: LIPI (2017)

Figure 3. Analytical Framework

Utilizing COHERD (2000), RPS is conducted through several stages as follows.

- 1) Identification of researchers, facilities and infrastructure, and developing issues in conducting research activities in R&D institutions and industries in the field of health and medicine. This stage is carried out to map researchers' competencies and to explore the topics of R&D activities in the field of health and medicine in LIPI. In addition, this stage is conducted to address issues and problems related to research activities in R&D institutions and industry. This stage will be done through a survey using a questionnaire to explore data and information from relevant stakeholders.
- 2) Selection of research topics is necessary for LIPI in the next ten years. This stage is carried out through brainstorming (generating ideas): screening ideas by experts on the topics of R&D activities in the field of medicine that LIPI needs to do in the next ten years by considering the level of importance

and relevance of the related competencies of LIPI. At this stage, experts are included to put forward their ideas in the format of research issues and topics. In addition, experts are also assigned to identify facilities and infrastructure needed by LIPI.

- 3) Assessment of the importance of research topics. The purpose of this stage is to rank the importance of R&D activities topics in the field of medicine by:
 - a) Assessing the list of topics obtained from stage 3, done by the expert board through the Delphi process by using predetermined assessment criteria.
 - b) Proposing topics of R&D activities from 20% of the most important topics in the field of health and medicine for the next ten years.

III. METHODOLOGY

Research methodology

This project focuses on the research centers at LIPI which have been conducting research activities in the area of health and medicine. This activity is to identify, both the human resources and the infrastructure needed by research centers. The study also explores specific research issues/topics to find out the future picture or condition of research activities in health and medicine through discussions with experts in related fields.

Method of data collection

This study utilizes primary and secondary data. Primary data were obtained through interviews, questionnaires and focus group discussions with experts in the fields of health and medicine. Meanwhile, secondary data collection was obtained through documents/literature inquiry related to health and medicine, with the following explanation.

- a) Document/literature inquiry. This stage is to obtain data and information related to the development of the latest health and medicine sectors, such as the development of the pharmaceutical industry, R&D activities, the dependence on imports of medicinal

materials and current pharmaceutical market conditions.

- b) In-depth interviews with stakeholders. This stage is to get a more detailed description of the development of research issues/topics for reference in determining references for determining the research priority that needs to be done by LIPI.
- c) Focus group discussions (FGD) with experts. FGD is conducted to get an overview of any research issues/topics related to health and medicine.
- d) Distribution of questionnaires to research centers at LIPI. This stage is conducted to address the issues/topics of research, competency of researchers, R&D facilities and infrastructure in each research center related to health and medicine.

Method of Data Processing and Analysis

The analytical method used in health and medicine RPS is based on each stage in the RPS. In the first stage, the situation analysis was done to describe the current conditions and the development of the health and medicine area. Whereas for the RPS stage, a descriptive analysis was conducted to address the issues, identification of research centers, researchers, facilities and infrastructure and screening of research ideas and R&D capabilities.

Research Area

This study was conducted by doing interviews and roundtable discussions with experts from PT Biofarma, Faculty of Medicine Gadjah Mada University, The National Agency of Drug and Food Control of Republic of Indonesia, and senior researchers of LIPI's (Research Center for Chemistry, Research Center for Biology, and Research Center for Biotechnology). The screening stage of research issues/topics and R&D capacities was conducted by surveys on selected LIPI's research centers including the Research Center for Chemistry, Research Center for Biology, Research Center for Biotechnology, Research Center for Appropriate Technology, Research Division for

Natural Product Technology, and Center for Plant Conservation Botanic Gardens.

Stage of the Study

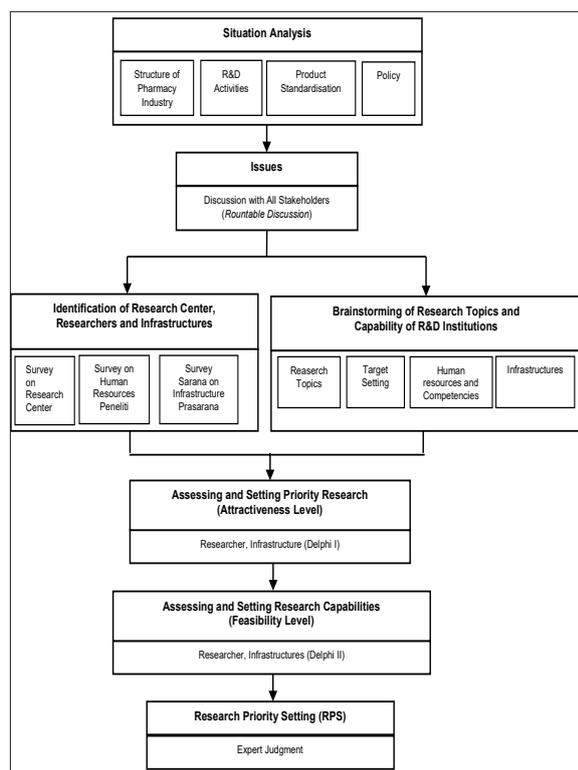
The RPS in health and medicine field is done by doing several stages ranging from analyzing the situation, addressing research issues/topics, and identifying research resources. RPS is a set of activities to determine which issues are most concerned to solve through research. The implementation of each stage of the RPS can be different regarding the objectives of each stage of the RPS as outlined in Figure 4. It is important to note that the method chosen must be able to assist researchers in achieving the objectives of the RPS. Ideally, the method selection is based on the latest empirical evidence. In addition, the research team needs certain methods for RPS. The research team also needs to adequately consider the role of the RPS team leader or facilitator. This stage involves stakeholder engagement and the expert board consisting of people with certain social and cultural backgrounds, values and preferences in RPS activities. Social dynamics and power relations between these individuals influence the pattern and results of RPS.

RPS can be used as a decision-making tool to improve organizational management and support decision making. However, RPS is also a research tool that aims to minimize bias in the research agenda, in this case, health and medicine researches.

There are at least two reasons for the need for the RPS in determining research issues/topics in health and medicine conducted by LIPI, namely:

- 1) Identifying overall gaps in the research agenda, namely the imbalance in the number of high-quality research projects carried out on certain topics with research topics based on individual behavioral interventions of researchers.
- 2) Construction of research questions, namely the imbalance in the amount of high-quality research that focuses on the contribution of science and technology development by contributing to solving problems in health and medicine.

Explanation of each stage of RPS is as follows.



Source: adopted from COHRED (2000)

Figure 4. Stages of Determining Priority Research (RPS)

Situation Analysis. This stage is an important step in the RPS as it will facilitate the achievement of the next stage. Situation analysis is conducted to collect data/information needed for RPS. This stage consists of collecting, organizing and mapping existing data. The data range from research data, statistical data, policies and programs in the fields of health and medicine.

The stage of identifying research issues according to stakeholders. This stage is done to address issues in the field of health and medicine. This activity is conducted by involving stakeholders through a roundtable discussion. The research team presents the results of the situation analysis in a roundtable discussion and this will be a basis for the stakeholders to provide input.

This stage identifies research centers, researchers, facilities and research infrastructures (Table 1). This stage will be conducted through a survey to the research centers of LIPI to collect data and information on the current situation of

the capacity and utilization of research in health and medicine such as publications, patents, facilities and infrastructure.

Screening research topics and R&D capabilities. A survey is conducted to address issues in the field of health and medicine by involving experts. The research topic assessment stage is supposed to be necessary for LIPI in the next five years (attractiveness level). This stage aims to identify what research needs to be done in the next five years to provide solutions for topics/issues/problems in the field of health and medicine. This stage has been conducted by involving the expert council, through brainstorming and Delphi I. Brainstorming activities are conducted to enrich the expert council's ideas on what research topics need to focus on the next five years based on the information identified in stage 4 by considering attractiveness and its relevance to the tasks and functions of LIPI. A list of research topics obtained from the screening of the above ideas are then assessed based on the level of importance by the expert council through the Delphi I. The 20% of research topics with the highest level of importance will be selected for research proposals for the next five years.

The stage of R&D capability assessment. This stage is intended to assess the capabilities of researchers, LIPI's R&D facilities, and infrastructure in implementing the selected research topic activities from the results of stage 5. This stage is done by preparing a list of proposed research topics, researcher data, facilities and infrastructure related to the research topic. The evaluation of LIPI's R&D capabilities to conduct each proposed research topic was done by the expert council through the Delphi II process. Experts will give a value between 1 (*very inappropriate*) to 10 (*very feasible*).

Research priority setting stage (RPS). Determination of research priorities for LIPI in the next five years is based on the level of research interests (*attractiveness*) and LIPI's R&D capabilities in conducting research (*feasibility*).

Stages 2, 5 and 6 were conducted by using the Delphi method to capture ideas and expert judgments in determining research topics in the field of health and medicine for the next five years

Table 1.
Stakeholders in the Research Issue Identification Stage

No	Name	Institution	Expertise/Status
1	Senior researcher	Center for Biomedical and Basic Technology of Health (Puslitbang BTDK)	Chairman of Center for Biomedical and Basic Technology of Health
2	Professional	GP Pharmacy	Chairman
3	Senior researcher	Faculty of Medicine, Gadjah Mada University	Pediatric Research Office, Department of Child Health
4	Senior researcher	Faculty of Medicine of Gadjah Mada University	Lecturer and researcher in Dept. of Pharmacology and Therapy
5	Professional	PT Bio Farma	Director of Research and Development Department
6	Senior researcher	PT Bio Farma	
7	Professional	The National Agency of Drug and Food Control of Republic of Indonesia (BPOM RI)	Vice manager of Evaluation of Therapeutic Products for Special Use, Directorate of Drug and Biological Product Assessment, The National Agency of Drug and Food Control of Republic of Indonesia
7	Professional	The National Agency of Drug and Food Control of Republic of Indonesia (BPOM RI)	Vice Manager of Clinical Trials, Directorate of Drug Assessment and Biology Products
9	Professional	The National Agency of Drug and Food Control of Republic of Indonesia (BPOM RI)	Vice Manager of Bahan Baku Obat (BBO)
10	Senior researcher	Research Center for Chemistry, LIPI	Researcher of Organic Chemistry
11	Senior researcher	Research Center for Biotechnology, LIPI	Field Coordinator of Research of Medicine
12	Senior researcher	Research Center for Biology	Natural Product Chemistry
13	Senior researcher	Research Center for Biology	Research Center for Biology

in LIPI. The research topics were explored based on experts' opinion, both those at LIPI and at the national level. In addition, roundtable discussion technique is to build consensus among stakeholders in identifying problems and finding.

Roundtable Discussion Stage

Roundtable discussion is conducted to build consensus, to identify problems, and to find solutions. Roundtable discussions are focused specifically on identifying existing or new research issues/topics in order to solve problems, find actions, and develop future research strategies.

A roundtable discussion with stakeholders (Table 2) provides opportunities for all experts in discussing issues and topics. According to Day, Morris, and Knight (1998), roundtables are discussion activities to address issues and aims to create a win-win situation. In the roundtable discussion, there will be no discussion leaders. Facilitators help the process and keep the discussion focused on the topic.

The Delphi Method

The Delphi method is a process for gathering opinions from a number of individuals in order to improve the quality of decision making. The application of this method is done through the distribution of questionnaires sequentially to the experts to find out the initial conditions of research resources, such as researcher, research facilities and infrastructure and the criteria that influence management in making a decision (Andrean, 2008; Wijaya, 2006).

Delphi has been selected as a method to conduct RPS based on the advantage of Delphi to cope with time and variety of expertise as well as participant in this project. Delphi method is also an effective method in allowing a group of individuals to deal with a complex problem (Linstone & Turoff, 2002). The advantages of Delphi are in term of a rapid consensus that it can be achieved with a wide range of expertise, the potential to gain large quantities of data, and to cope with a situation where data are lacking (healthknowledge.org, 2019).

Table 2.

Name of Roundtable Stakeholders Identification of Research Potential

No	Institution	Expertise
1	The National Agency of Drug and Food Control of Republic of Indonesia	Directorate of Traditional Medicines, Food Supplement & Cosmetic Evaluation
2	The National Agency of Drug and Food Control of Republic of Indonesia	Directorate of Pharmaceutical and Technology Development, The National Agency of Drug and Food Control of Republic of Indonesia
3	GP Pharmacy	
4	Ministry of Research, Technology and Higher Education of the Republic of Indonesia	Directorate of Pharmacy and Technology Development
5	National Development Planning Agency	Directorate of Community Health and Nutrition
6	Research Center for Biotechnology	Senior Researchers

On the other hand, this study also realizes the weakness of Delphi as it does not cope well with widely differing opinions or large changes in opinions, the facilitator's view may dominate in the analysis, differing opinions may not be sufficiently investigated, and the need of much effort to engage with participants to get their high motivation.

Generally, the involved experts (Table 3) are the ones whose expertise are in the subjects being studied. The experts do not know each other until they meet in the final stage of the Delphi method implementation (Gordon, 1994; Linstone & Turrof, 2002). Delphi does not require direct meetings (face to face), and this is useful for involving experts, users, resource controllers, or administrators who cannot come together.

Delphi allows experts to provide data and information individually and avoid domination by certain individuals. The implementation of the Delphi method in this RPS has been conducted by following stages: a) The first stage is distributing questionnaires that aim to explore health issues and problems by collecting information from expert groups related to issues/topics on health research and medicine and also the capabilities of research resources; b) The second stage is presentation of data and information from the stage 1. Broadly speaking, the Delphi method used in this study assesses the *level of attractiveness* and *feasibility* of the research issues/topics that have been identified. Attractiveness is a level of importance that shows how important the research topic is to be conducted, while the level of feasibility is the capability of LIPI in terms of human resources and infrastructures.

IV. RESULTS AND DISCUSSION

Results

- 1) Setting the objectives of RPS is to gain an understanding of the need for research priority setting and the objectives, scope, and description of output desired by LIPI.
- 2) Stakeholders involved in this research come from PT Biopharma, Ministry of Health, Ministry of Industry, The National Agency of Drug and Food Control of Republic of Indonesia, GP Pharmacy, Research Center for Biology, Research Center for Biotechnology, Research Center for Chemistry, Research Center for Oceanography, and Research Center for Natural Materials Technology. This stage is conducted by doing in-depth interviews with stakeholders to explore data and information related to issues and topics of research in the field of medicine.
- 3) Situation analysis aims to find the data/information needed and provides useful input in the research priority setting activities. This stage is to identify data/information, to organize data/information available and to conduct assessment of existing data. This stage is also mapping the researchers, R&D facilities and infrastructure owned by LIPI. Questionnaires were distributed to 19 senior researchers in the field of drug research.
- 4) The findings of this stage shows issues and research topics in the field of medicine as shown in Table 4.
- 5) Determining issues and topics that have been identified for research topics. This stage is conducted with roundtable discussion to

Table 3.

List of Expertise in Relation to the Issue and Research Topics in the Field of Medicine at LIPI

No.	Institution	Expertise	Status
1	Research Center for Biology	Natural Product Chemistry	Senior Researcher
2	Research Center for Biotechnology	Biotechnology	Senior Researcher
3	Research Center for Chemistry	Biochemistry	Senior Researcher
4	Research Center for Chemistry	Natural Chemistry	Senior Researcher
5	Research Center for Oceanography	Oceanography	Senior Researcher
6	Research Division for Natural Materials Technology	Technology Process in Chemistry and Environment	Senior Resercher
7	Center for Plant Conservation Botanic Gardens.	Botany	Senior Resercher

build consensus on related issues in the research of medicine and health by involved Biofarma, The National Agency of Drug and Food Control of Republic of Indonesia, Ministry of Health, Ministry of Industry, Research Coordinator from the field of Medicine, Research Center for Chemistry, Research Center Biology, Research Center for Biotechnology and Research Center for Oceanography. The findings show information on issues in health and medicine development stated in the Medium-Term National Development Plan (RPJMN).

- 6) This stage is followed by the process to determine the criteria for RPS in the next five years as solutions to the topic/issues in stage 5.
- 7) The expert team was selected with the assistance from LIPI's coordinator of health and medicine research and selected 5 experts in the field of medicine and are representatives of Research Center for Biology, Research Center for Biotechnology and Research Center for Chemistry.
- 8) The stage of Delphi consists of three FGDs by expert groups which aim to select the research agenda. This stage was conducted by involving the expert team at the following stages:
 - a) FGD I is brainstorming (generating ideas): filtering ideas by the expert team on what research topics need to be focused on in the next five years, taking into account the level of importance and relevance to the LIPI tasks. At this stage the experts are expected to put forward

their ideas in question format as presented in the questionnaire and the findings results as follows: Questionnaires were distributed for two weeks and the results showed that there were 12 research issues consisting of 11 main issues and 1 additional issue and there were 60 research topics (Tabel 4).

- b) FGD II: The next step is to ensure the findings from the screening of issues and research topics in the field of medicine, namely issues that are relevant for the next five year research at LIPI. The assessment process is done by the expert council giving a score of 1 to 10 (1 for very inappropriate and 10 for very feasible).
- c) FGD 3 is conducted to set research priority for the next five years (2017–2021) based on the level of interest in research topics (*attractiveness*) and LIPI R&D capabilities in conducting research (*feasibility*). The results of the assessment are displayed in two-dimensional graph (Table 5).

I. Issues related to the Role of R&D Activities in Innovation System

1) The Gap of the Innovation Process; The Valley of Death.

Valley of Death is the gap between the level of readiness of research outcome from government R&D institutions/universities and the industrial needs. Innovations targeted from R&D institutions/universities are far beyond the expectations. This phenomenon occurs generally due to the

Table 4.

Research Issues and Topics from the Stage of Screening Research Issues and Topics in the Field of Medicine

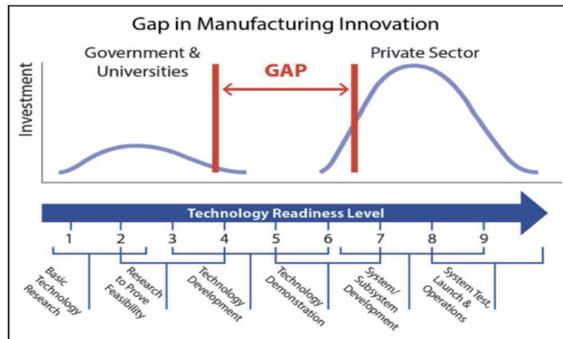
Research Issues	No. of Topic	Research Topics
1. Domestic research for “Markers” are still very low	1	Construction of bank extracts and library of active compounds from Indonesian medicinal plants
	2	Standardize the berberine content in Menispermaceae
	3	Building a “database” of secondary metabolites from Indonesia’s natural resources that are beneficial for health/pharmacy
	4	Building a “library” and “database” of NMR Spectrum secondary metabolites/ marker compounds from Indonesian natural resources that are beneficial for health/pharmacy
	5	Determination of marker compounds of traditional medicinal plants
	6	Standardize marker compounds in various herbal plant extracts to support the independence of medicinal raw materials
	7	“Herb scientification” as strengthening the standardization of active ingredients in Indonesian herbal products
	8	Stem cell research for the development of nutraceutical raw materials sources
	9	Development of marker compounds sourced from natural resources as candidates for drugs/raw materials for medicine
	10	Formulation and activity test of breadfruit leaf extract as a supplement for anti-diabetic
	11	Identification of marker compounds from Indonesian medicinal plants and scale-up
	12	The solution of medicinal plant marker compounds to support marker banks
	13	Isolation of asiaticoside from Gotu Kola herbs through bio-transformation with <i>Aspergillus</i> sp.
	14	Solation and production of piperine from Java chili
	15	Quantification of marker compounds on insulin leaves (yakon) which has spectroscopic antidiabetic activity
2. Lack of research on compounds combination	1	Combination of traditional medicine compounds to see the effect on the treatment process
	2	Standardize & isolate active compounds from syber marine biota for medicinal raw materials / active ingredients
	3	Development of green refinery biososaso extraction/isolation technology
	4	Formulation and test of quinine activity, artemisinin and quinine as candidates for anti-cancer drugs
	5	Formulation and activity test for breadfruit leaf extract as a candidate for anti-cardiovascular drugs
	6	Combination of traditional medicinal compounds to see pharmacological effects
	7	Test antioxidant activity and antidiabetes from a combination of catechin and mangosteen compounds in herbal preparations
	8	The formulation of OHT extracts of bay leaf extract (quercetin) and catechins as antidiabetic
3 Social research related to public acceptance of medicinal products	1	Formulation and activity test for <i>jamblang</i> leaf extract as a supplement for diabetes
	2	The development of the potential of local herbal medicines phytopharmaceutical products
4. There is still a lack of social research to explore the potential of herbal medicines sourced from local wisdom	1	Evaluation of ecological and socio-economic values of endangered medicinal plants in Indonesia
	2	Formulation and activity test of <i>sambang</i> blood leaves as a source of antioxidants

Research Issues	No. of Topic	Research Topics
5. The need to develop a potential catalog of herbal medicinal ingredients	1	Data collection of Nusantara forest medicinal plants
	2	Research on the use of Indonesian medicinal plants
	3	Isolation of active substances in local plants for antioxidant, antidiabetic and antimicrobial ingredients
	4	Development of potential herbal medicine catalog
6. Development of formulations of medicinal products from expired patents (expired patent utilization)	1	Development of product formulations from the expired patent
	2	Synthesis and pre-clinical testing of quinine derivatives as a candidate for anti-cancer drugs
	3	Formulation and test of quinine activity, artemisinin, and quinine as candidates for anti-cancer drugs
	4	Synthesis and clinical trials of dehydrolovastatin (lipstatin) as a candidate for anti-cholesterol drugs
	5	Formulation and activity test for <i>rambutan</i> skin extract as a source of antioxidants
7. Research development for phytopharmaceutical products	1	Development of standardized herbal medicine for tonics/aphrodisiacs
	2	Development of phytopharmaceutical to provide an alternative treatment for degenerative diseases and inflammation
	3	Development of phytopharmaceutical product research
	4	Development of standardized herbal medicines sourced from Indonesian medicinal plants for the development of the Indonesian phytopharmaceutical industry
	5	Development of natural ingredients extracts/active plants anti-HCU and HBV (anti-hepatitic and hepatitic B) as OHT (standardized herbal medicine)
	6	Development of <i>Syzygium cumini</i> leaf tablets as antidiabetic
8. Research development on reagents to support research activities in the fields of health and medicine	1	Hepatitis kit test
	2	TB Kit Test
	3	TB Kit Test
	4	TB Kit Test
	5	TB Kit Test
	6	HER-2 scoring kit for cancer application as a marker for prognosis and predictive therapy with trastuzumab
	7	The mutation detection and methylation kit of PTEN in cancer as a predictive marker of cancer therapy
9. Development of process technology to support research activities in the fields of health and medicine	1	Development of reagent for drug raw material researchers
	2	Development of research on drug reagents /raw materials, especially drug synthesis raw materials so as to support Indonesia's independence in the availability of reagents/medicinal raw materials
10. Development of research topics with reference to the pharmaceutical industry development roadmap from the ministry of health	1	Biodiversity for health
	2	Search for drugs for infectious and non-communicable diseases based on Indonesian microorganism resources
	3	Research supporting the pharmaceutical industry development roadmap
	4	Development of standardized extracts of soursop leaves which is rich in acetogenin
11. Research potential in R&D institutions and universities with reference to R&D and Manufacturing Scenario APIs	1	Development of API supporting industrial product development
	2	Research potential in R&D Institutions and Universities with reference to R&D and Manufacturing Scenario APIs
12. Additional Issues	1	Provision of research materials for algal-sterol as raw material for paracetamol and antimicrobial drugs
	2	Evaluation on wind endophytes for enzyme inhibitors, antibacterial, and antioxidants

Table 5.
Issues of Research Potential in the Field of Medicine

No	Potential Issues Research	The Explanation
1	Lack of research on “markers and lead compounds”	R&D institutions and universities need to develop research activities in “compound markers” and establish a marker bank. The National Agency of Drug and Food Control of Republic of Indonesia, for example, often has difficulty in getting marker compounds from within the country. Bringing these markers from abroad is costly and takes a relatively long time. In addition, the government needs to develop marker banks that function as catalogs of domestic drug compounds/the active pharmaceutical ingredients.
2	Lack of research on compounds combination	Some compounds will influence and lead to different treatment effect when the different compounds are combined. The research topic related to the combination of marker compounds is needed as a scientific guide for domestic manufacturers.
3	Social research related to public acceptance of medicinal products	The need to develop social research activities related to public acceptance of medicinal products and medical devices.
4	There is still a lack of social research to explore the potential of herbal medicines sourced from local wisdom	Indonesia has the potential to develop herbal medicinal products sourced from indigenous knowledge, such as betel leaves for the treatment of nosebleeds, leaves for femininity, mangosteen extract for stamina, etc. However, finished products from these ingredients are still low on the market. The wealth of Indonesian biodiversity has not been optimally utilized in developing the phytopharmaceutical industry. Basic research and applied research should be accelerated to support the progress of the domestic pharmaceutical industry.
5	The need to develop a potential catalog of herbal medicinal ingredients	Based on data from The National Agency of Drug and Food Control of Republic of Indonesia, more researches are needed to improve and add to the catalog of potential herbal medicinal raw materials from biodiversity.
6	Development of formulations of medicinal products from expired patents (expired patent utilization)	There is lack of research activities that reformulate expired patent. Expired patents utilization is generally carried out by industry. However, the activities on developing formulation of expired patents are still low in research activities in R&D institutions and universities.
7	Research development for phytopharmaceutical products	Indonesia is rich of potential of developing phytopharmaceutical products from biodiversity. Recorded from The National Agency of Drug and Food Control of Republic of Indonesia until 2017 only 16 phytopharmaceutical products were produced from domestic research activities. The government needs to accelerate research in government R&D institutions and universities, encourage collaboration between R&D institutions-universities-industries to develop phytopharmaceutical industry.
8	Research development on reagents to support research activities in the fields of health and medicine	Until now, 95% of the raw materials and reagents are imported. This has an effect on industrial competitiveness and domestic research activities. Government R&D and universities need to develop research topics in reagents development needed by pharmaceutical industry.
9	Development of technology process needed to support research activities in the fields of health and medicine	R&D activities in technology process is important to support medicine and health industry. Case study; technology development of the Artemisinin extraction process using Freon technology (HFC-134a) by Research Center for Chemistry of LIPI.
10	Research topics development should refer to the Ministry of Health's development roadmap	The Ministry of Health has set a roadmap for developing the pharmaceutical industry. Government R&D institution and universities need to produce research topics to support the consortiums in order to achieve Indonesian resiliency in drug raw materials.
11	Research potential in R&D institutions and universities with reference to R&D and Manufacturing Scenario for APIs	The development of research topics for government R&D institutions and universities needs to follow the R&D and manufacturing scenarios for APIs. The industry has developed a scenario for developing drug products by involving four pillars, namely biopharmacy, vaccines, natural and chemicals. The scenario of product development is divided into three periods up to 2025. Higher education R&D institutions need to refer to the scenario by conducting research activities such as developing active pharmaceutical ingredients (APIs) to support the domestic pharmaceutical industry.

funding gap in basic research which affects on the continuation of research activities towards innovation. Valley of death occurs in health and medicine research, especially for medicinal products. Research funding becomes a key regarding the readiness level (TRL) of R&D output.



Source: Sol (2015)

Figure 5. The Gap in Manufacturing Innovation

2) Technology Readiness Level (TRL) of government R&D institutions/universities has only reached level 1–4.

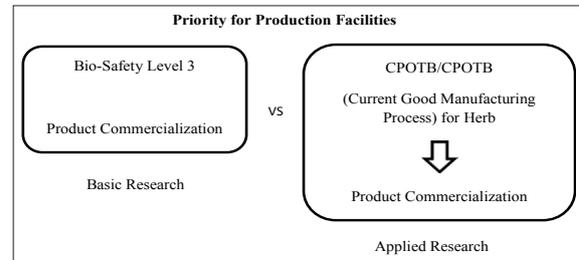
Research activities in government R&D institutions and universities, in general, have only reached TRL 1–4 (basic ideas, concept development, an experimental period of concept and process validated in the laboratory) as shown in Figure 6. Meanwhile, industries need research outputs with TRL 5–9 as displayed in Figure 6.

3) Funding gaps in basic research and product development/commercialization.

There are still gaps in financing basic research. The government needs to allocate more funding

for the basic research in health and medicines. This becomes a particular issue as the basic research requires high costs, but is lag behind the economic value projections.

4) Infrastructure availability of government R&D institutions.



Source: Agusta (2017)

Figure 7. Priorities for the Development of LIPI Health and Drug Research Facilities and Infrastructure

Research infrastructure in government R&D institutions is still lacking. Researchers in government R&D institutions/university often experience obstacles in conducting the stages of research in the field of medicine, due to the lack of medical and health research facilities and infrastructures. Research in the field of health and medicine in LIPI does not have clinical laboratories for clinical trials. Related to this, in 2018 LIPI committed to building infrastructure CPOTB/CPOB and a laboratory for certification of medicine research results, as shown in Figure 7.

TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9
Basic Idea	Concept	Experimental proof of concept	Process validated in a laboratory	Process validated on production equipment	Process capability validated on production equipment	Capability validated on economic runs	Capability validated over range of parts	Capability validated on full range of parts over long periods
Basic research		Preclinical research		Late preclinical research	Phase I trials	Phase II trials	Phase III trials	Phase IV trials
Research			Translation/Development			Commercialization		

Source: Mason, 2011

Figure 6. Technology Readiness Level (TRL) of Research Activities

Table 6.
Scenario Supply, R&D and Production of API (Active Pharmaceutical Ingredients)

API	Period		
	2015-2018	2019-2022	2023-2025
Biopharmaceuticals	EPO (Erythropoietin Growth)	Blood Fractionation (Albumin, Albumin Immunoglobulin, Faktor Vill, Faktor EX)	Monoclonal Anti Body (MAB)
	GCSF (Granulocyte-colony Stimulating Factor)	Enoxaparin (phlegm thinner), Growth Hormone, Interferon (Body protectors from sharing viruses)	
	Probiotic Insulin (for diabetes)	Trastuzumab (Monoclonal antibodies designed to work on the HER2 positive breast cancer target), insulin	
Vaccine	Dengue	DTaP (Diphtheria, Tetanus, acellular Pertussis)	HP (Human Papilloma Virus)
	MR (Mumps Rubell)	Hexavalent	Malaria
	HB (Hepatitis-B)	Men ACWY	New TB Recombinant
	Pentavalent (5 antigen vaccine)	New OPV	
	Sabin IPV (injection Polio Vaccine)	Pneumococcal (Vaksin Pneumonia) Rotavirus Thyphoid Vi-Coni	
Natural API	Dehidro-di-Isoeugenol (Nutmeg Seed Extract)	Glucosamine (for supplies produced in the body or extracted through crab or shrimp skin)	Andrographolide
	Curcumin (Contained in Curcuma for the liver)	Omega-3	Etyl-p-methoxy Sinamate (isolation of kencur (<i>Kaempferia galangal</i>) for skin protection
	Gingerol (Chemical Components in Ginger)	Resveratrol (antioxidant natural)	
	Phytantin (Meniran leaf extract)	Vinca alkaloid derivates	
	Piperin (Black Pepper Extraction)		
	Stevioside (Non-calorie sweetener)		
	Xanthohumol (components of essential oil typical of ginger) Zenderone		
Chemicals	Statin derivates (reduce cholesterol levels: Simvastatin, Atorvastatin, rosuvastatin)	Ascorbic Acid (vitamin C)	Cephalosporin (7-ACA)
	Pantoprazole		
	Clopidogrel		
	RV (Entecavir, Tenofovir)		
	Beta-Lactam (Amoxicillin)		
	Beta-Lactam (6-APA)		
	Glyceryl Guaiacolate (for cough medicine)		
	Pharmaceutical salt (NaCl Pharma-grade)		
	Paracetamol		
	Salicylamide		

Source: GP Farmasi (2016)

5) Research is conducted sporadically and in small scale.

LIPI has no research grand design in drug and health. Government's support regarding the performance of basic research will be important in supporting the development of the drug and health industry policies.

6) The skill capabilities of Indonesian researchers are high but need to specify the target.

Research in the field of medicine and health often still sets minimalist targets. Therefore, a clear target level is needed such as standardized herb medicines, phytopharmaceutical, candidates for drug and drug ingredients.

II. Issues related to Standardization and Product Supervision

1) Standardization and supervision of drug products from phytopharmaceutical; Lack of synergy between researchers/academicians and The National Agency of Drug and Food Control of Republic of Indonesia.

Regulatory control in the downstreaming of research results is an important part. Research in the field of medicine and health needs to involve The National Agency of Drug and Food Control of Republic of Indonesia. Therefore, the results correspond to the existing rules and can be registered. All the researchers in the field of health and medicine should comply with rules and regulations. The proper process will ensure accuracy of research results, hence it can be justified and standardized.

The case of *Arthemisia annua* research project in LIPI shows that joint project involving stakeholders has been quite successful from upstream to downstream, from plantation to extraction processes. LIPI, in this case, conducted this project in collaboration with pharmaceutical industry stakeholders (PT Indofarma). Another successful project is the development of breadfruit for phytopharmaceutical product by the Research Center for Chemistry LIPI.

III. Issues related to Link & Match and Policy in the Sectoral Innovation System (A-B-G)

1) Research collaboration and industry involvement.

Research should meet industrial needs so that from the initial stage research institution should develop network an communication with its users. From food and drug administration's point of view, researchers often lack coordination with industrial partners. This creates obstacles to continue research activities towards the production and commercialization process. Several stages of clinical trials that need to be completed are highly and become a major obstacle. This should be overcome by involving partners from the beginning of the research process.

2) Researchers in the fields of health and medicine need to update information and communication with stakeholders.

Some information related to the regulation of the WHO, The National Agency of Drug and Food Control of Republic of Indonesia and the Ministry of Health need to be considered by researchers. In many cases, researchers in R&D institutions and universities still do not know the information about the development of information and regulations regarding the research in health and medicines.

3) The duration of the customs clearance process for entering research materials (biosimilar).

Health and medicines researchers often encounter obstacles in material transfer such as importing research material from abroad. These constraints comes from the entry procedures from customs/excise. The custom often lack of facilities to treat research material. Addressing this issue, it is necessary for the custom to provide special lines or facilities for research material distinguished from other items.

4) Research acceleration.

The performance of research activities in the field of health and medicine plays an important role in supporting the domestic pharmaceutical industry. Research activities also need to refer to industrial

needs. Often, the research projects conducted by researchers in research institutions/universities are topics that already obsolete.

5) The gaps between industrial needs and R&D outputs.

Current health and medicine researchers in government R&D institutions/universities are often weak in setting the targets of research activities. In addition, researchers, especially in government R&D institutions/universities do not follow time to market for the research output needed by the industry. Researchers need to follow the pace of health and medicines research trends to meet industrial needs. Furthermore, researchers need to consider this phenomenon and to avoid obsolete research topics.

IV. RESEARCH POTENTIAL IN THE FIELD OF MEDICINE AND HEALTH

Situational analysis stage is to identify issues related to the development of pharmaceutical raw materials and active pharmaceutical ingredients. In addition, it also identifies how to produce several potential research topics that can be conducted by government R&D institutions/universities in order to support domestic pharmaceutical industry. Potential research topics include:

1) Domestic research results for “Marker” are still very low.

Government R&D institutions/universities need to develop research activities in compound markers. Besides, it is necessary to make a marker bank. The National Agency of Drug and Food Control of Republic of Indonesia, for example, often has difficulty in getting marker compounds from within the country. Bringing these markers from abroad is costly and takes a relatively long time. Furthermore, in developing marker research topics, government R&D institutions/universities need to develop marker banks and this also functions as catalogs of lead compounds.

2) Research topics in combination of compounds

Recently, there is a lack of research related to compound combinations. As an explanation, some compounds will influence and lead to different treatment effect when the different compounds are combined. will often produce different effects when the compounds are combined. The research topic related to the combination of marker compounds is needed as a scientific guide for domestic pharmaceutical industry to avoid producing adversely effects or hepatotoxic products.

3) Social research related to community acceptance of medicinal products

The government needs to develop social research activities related to public acceptance of medicinal products in Indonesia. The research area cover from research related to health/disease prevention, community acceptance of phytopharmaceutical/chemical/biological products and so on.

4) There is still a lack of social research to explore the potential of herbal medicines from local wisdom.

Indonesia has the potential to develop herbal medicinal products from local wisdom, such as betel leaves for the treatment of nosebleeds, mangosteen extract for stamina, and many more. However, finished products from these ingredients are still low on the market. The wealth of Indonesian biodiversity has not been optimally utilized in developing the phytopharmaceutical industry. Both basic and applied research needs to accelerate, so as to contribute to the development of domestic pharmaceutical industry.

5) The need to develop a catalog of potential herbal medicinal ingredients

Indonesia is rich potential of phytopharmaceutical industry based on biodiversity (Rosita, 2017). Based on data from The National Agency of Drug and Food Control of Republic of Indonesia, more research activities are needed to improve

the catalog of potential herbal medicinal raw materials from local herbal plants.

6) Development of formulations of medicinal product from expired patents (expired patent utilization)

Table 7.

List of Potential Utilization of Expired Patent of Medicinal Products

Top Biologic Drugs and Their Patent Expiration					
No	Drug	Year	No	Drug	Year
1	Neupogen (Anemia/ Amgen)	2013	8	Neulasta (Cancer/Amgen)	2015
2	Aranesp (Anemia/ Amgen)	2014	9	Enbrel (Arthritis/ Amgen)	2012
3	Myozyme (Pompe/ Genzyme)	2016	10	Fabrazyme (Fabry deases/ Genzyme)	2015
4	Herceptin (Breast cancer/ Roche)	2019	11	Avastin (Cancer/Roche)	2018
5	Rituxan (Arthritis/ Roche)	2018	12	Lucentis (Arthritis/ Roche)	2018
6	Erbix (Cancer/Eli Lily)	2017	13	Remicade (Arthritis/JNJ)	2014
7	Humira (Arthritis/ Abbot)	2016	14	Synagis (Respiratory/ AstraZenica)	18

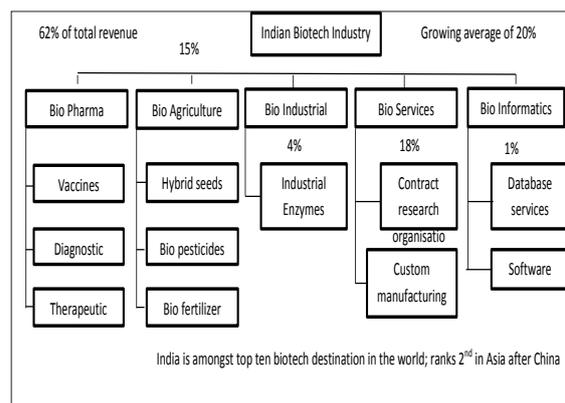
Source: Crasto (2017)

Opportunities exist over many expired patent medicines, but there are still few research activities that reformulate the drugs patents. This becomes potential and can be developed in drug reformulation research in Indonesia. The use of expired patents is generally done by industry, while the activities in developing formulations of expired patents are still low in research conducted by government R&D institutions and universities.

7) Research development for phytopharmaceutical products

The potential for developing phytopharmaceutical products in Indonesia is very large, however, Indonesia still has a long way to go in developing

its medicinal herbs products. Based on The National Agency of Drug and Food Control of Republic of Indonesia (2017), recently there are only 16 phytopharmaceutical products that were produced from domestic research activities. The government needs to give more support to government R&D institutions and universities and encourage collaboration between research institutions/universities and industries to develop herbal medicinal products.



Source: Bio-spectrum & Association of Biotechnology Led Enterprise (ABLE) Survey, (2010)

Figure 8. Selection of research topics deemed necessary for the next ten years LIPI (lessons from India)

8) Development of research on reagents to support research activities in the fields of health and medicine

Until now, 95% of the raw materials and reagents are imported. This has an effect on industrial competitiveness and domestic research activities. Government R&D institutions and universities need to develop research topics in developing reagents that play an important role in supporting research and development activities in raw material for domestic drug.

9) Development of technology capability to support research activities in the fields of health and medicine

R&D is needed in developing technology capabilities of process technology such as the capability to produce lead compounds needed in the health and medicine. A case of technology development of the Artemisinin extraction process using HFC-134a by Research Center for

Chemistry shows that increasing capability in process technology becomes one of important competencies for government R&D institution to support the growth of pharmaceutical industry.

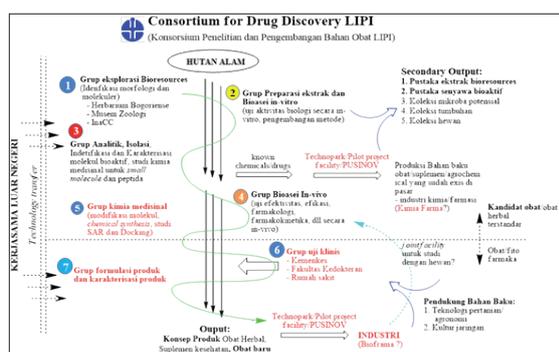
10) Development of research topics with reference to the pharmaceutical industry development roadmap of the Ministry of Health

The Ministry of Health has set up a roadmap for developing the pharmaceutical industry and it is expected to be a guidance for all stakeholders. Research activities are expected to refer to consortiums in conducting research. The objective is all stakeholders will be referring to the pharmaceutical industry development roadmap to achieve self reliancy in producing lead compounds, as shown in Table 8.

Table 8. Selection of necessary research topics for LIPI (The next ten years)

5 Consortiums	7 Working Groups
TB, Hepatitis B, Dengue, EPO, and Influenza	HPV, Stem Cell, Pneumococcus (pneumonia, lining inflammation, sepsis), malaria, rotavirus (diarrhea), HIV, and Policy

Source: Ministry of Health (2017) Forum Riset Vaksin Nasional (FRVN/FRLN) 2017.



Source: LIPI (2017)

Figure 9. The Consortium of Research and Development of LIPI Medicinal Ingredients

11) Research potential in R&D Institutions and Universities with reference to R&D and Manufacturing Scenario APIs

The development of research topics for government R&D institutions and universities needs to

follow the R&D and manufacturing scenarios originating from the industry. The industry has developed a scenario for developing medicine products by involving four pillars, namely biopharmacy, vaccines, natural and chemicals. This product development scenario is divided into 3 periods up to the year of 2025. Higher education R&D institutions need to refer to the scenario by conducting research activities such as developing active pharmaceutical ingredients (API) to support product development targets from the industrial sector (Table 8).

The assessment results on the issues and research topics in the medicine field by expert boards are as follows.

- 1) Building “Indonesian Bioresources Marker Compound Center” by considering that it is needed by domestic users, especially The National Agency of Drug and Food Control of Republik of Indonesia and health and medicine industry, especially herbal medicines. The following are the potential topics.
 - a) Lead compounds for infectious diseases derived from plants, microorganisms, and marine (marine biota)
 - b) Lead compounds for non-communicable diseases originating from plants, microorganisms and marine (marine biota)
 - c) Lead compounds from tropical forest plants
 - d) Lead compounds from animals
 - e) Lead compound of microbes
 - f) Lead compounds from marine biota
- 2) Developing standardization of herbal medicine (OHT) and phytopharmaceutical products. LIPI’s target for the next five years is to continue the results of active extract research and bring it into phytopharmaceutical and API products on the ten most popular diseases in Indonesia (infectious and non-infectious diseases). Research on OHT is very possible for LIPI.
- 3) Focusing R&D by referring to the pharmaceutical industry development roadmap from the Ministry of Health, and API manufacturing scenario with the following topics:

- a) Artemisinin from the *Artemisia annoa* plant has been researched and has the potential to be developed into an API product.
- b) DFA III, a cyclic disaccharide compound included in the category of functional food and produced through the enzymatic process of dahlia tubers using enzymes from microorganisms. This leads to the development of supplements/vitamins.
- c) Antibiotics are produced from research on microorganisms and are used as medicinal ingredients.
- d) Soft Coral as research conducted by the Research Center for Oceanography (P2O) can be developed into an API product. This topic still faces obstacles in the cultivation process.
- e) Research that utilizes microorganisms such as bacteria, actinomycetes and microalgae. These topics will contribute to the development of materials for APIs such as amoxicilin, and so on.

V. ANALYSIS OF FINDINGS

The stages of the RPS conducted at LIPI generate issues and research topics in the field of health and medicine for the next few years. There are three broad categories of issues from the results of the RPS conducted, namely 1) Issues in research and development activities by researchers on the elements of the innovation system, 2) Issues related to standardization and supervision of research products, and 3) Issues related to the relationship between R&D institutions and industry in conducting research activities in the field of health and medicine.

The first major issue is related to the level of TRL of the research results of R&D institutions that can be utilized by industry. So far, public has high expectations on research results that can be quickly utilized by industry. In the case of research activities in the field of health and medicine, the results of basic research have a long stage to become applied research. LIPI in this case has strength in basic research activities but has limitations in applied research activities.

Collaboration between R&D institutions and industry is expected to provide solution for the sustainability of basic and applied research demanded by industry.

In addition, coordination between all stakeholders in the health and medicine sectors needs to be strengthened to connect the competencies and capacities of each stakeholder in order to support the health and medicines industry development. The critical thing that must be resolved immediately is to close the gap between the research results of R&D institutions and industry's demand. The program of competency acceleration and research capacity in R&D institutions needs to be conducted to balance the needs of research results for industry. Communication and coordination between R&D institutions and industries need to be set up and become part of a research collaboration program between two parties.

RPS conducted by involving several relevant stakeholders has produced several topics several topics to develop by LIPI in supporting the health and drug industry activities. One of the major topics was the utilization of Indonesia's biodiversity to support the development of phytopharmaceutical industry. In addition, stakeholders expect that LIPI should focus on research activities to produce markers and also build a marker database in Indonesia. Furthermore, LIPI is also expected to continue conducting research on reagents production, research on herb products from local wisdom development, and related to combination of existing chemical compounds research. Other research topics are related to developing the potential and capacity of LIPI in supporting the health and drug industry growth.

VI. CONCLUSION

RPS conducted at LIPI in 2017 shows major issues related to institutional aspects in supporting the growth of domestic pharmaceutical industry. Several issues are related to:

- 1) The role of R&D activities in government R&D institutions and universities in the structure of the pharmaceutical industry
- 2) Product standardization and supervision

3) Links and match and policies in the sectoral innovation system (A-B-G)

The Delphi method used in the research has generated some potential research topics to consider by government R&D institutions/universities in supporting the roadmap for developing the national pharmaceutical industries. The research topics are related to:

- 1) Research and development of “Marker” compounds and development of “Bank Markers”
- 2) Research on combinations of chemical compounds in medicinal products and health
- 3) Social research related to communities acceptance toward medicinal products
- 4) Social research to explore the potential of herbal medicines derived from “local wisdom”
- 5) Development on potential herbal medicinal ingredients catalogue
- 6) Development on formulations of medicinal products sourced from expired patents (expired patent utilization)
- 7) Research and development on phytopharmaceutical products
- 8) Research and development on reagents to support research activities in the fields of health and medicine
- 9) Development on technological capabilities to support research activities in health and medicine fields
- 10) Development of research topics by referring to the pharmaceutical the pharmaceutical industry development roadmap of the Ministry of Health
- 11) Research potential in R&D institutions and universities by referring to R&D and manufacturing scenario APIs.

The RPS conducted at LIPI in 2017 produced several important issues related to the research activities in the field of health and medicine. The development of research competencies and infrastructure needs to be continuously developed in order to increase the capacity of government R&D institutions in supporting the health and

pharmaceutical industry. The acceleration program of research activities on several topics needs to be done to address industrial needs. In addition, this RPS also produce topics in accordance with the roadmap for developing APIs that need to be conducted by LIPI for the next few years.

ACKNOWLEDGMENT

We would like to thank the Research Center for Science Technology and Innovation Policy and Management (P2KMI)-LIPI for funding the RPS Project in the field of health and medicine in 2017.

REFERENCES

- Andrean, L. (2008). *Human resource planning using the delphi policy method and markov chain*. [Final Project Department of Industrial Engineering, Unika Atma Jaya, Jakarta].
- Agusta, A. (2017). Research Priorities Setting: in Health and Drug, presented in focus group discussion (FGD) Research Priority Setting Health and Drug, LIPI's Cibinong Science Center, 19 September 2017.
- Biospectrum-ABLE (Association of Biotechnology Led Enterprise (ABLE). (2010). The eighth survey of Indian biotech industry. Available at: http://ableindia.in/able_biospectrum_survey.php, retrieved on 15 May 2017.
- Brender, J., McNair, P., & Nøhr, C. (2000). Research needs and priorities for the next decade to implement the information society in health care: Outcome of a Delphi study. In Andersen, S. K., Brender, J., Kristensen, M., Nielsen, D. T., Nøhr, C., Vonsild, S. (Ed.), *Visioner for dansk forskning i sundhedsinformati: Kort, kompas og vejviser* (pp. 49–67). Aalborg Universitet. Rapport fra V-CHI.
- Crasto, A. M. (2017). *2010–2020 patent expiry*. New Drug Approvals.org. <https://newdrugapprovals.org/patentexpiry/2010-2020PatentExpiry>, accessed on 10 June 2017.
- Dalkey, N. (1969). An experimental study of group opinion: The delphi method. *Futures*, 1(5), 408–426. doi.org/10.1016/S0016-3287(69)80025-X.
- Day, G., Morris, E., & Knight, P. (1998). *Where do we go from here? A review of community participation methods*. Aberystwyth, United Kingdom: JIGSO.

- Gordon, T. J. (1994). The delphi method. In Gleen J. C. and Gordon, T. J. (ed). Future research methodology. Washington: The Millennium Project. Retrieved from <http://www.gerencia-mento.ufba.br/Downloads/delphi> (1), 1–33.
- GP Farmasi. (2016). New Paradigm in the Process of National Pharmacy Business Development to Achieve Pharmacy Business Independence in accordance with Nawa Cita. Presented at the *Penta Helix Seminar*, in the context of the 59th Anniversary of Padjadjaran University.
- Healthknowledge.org. (2019). The use of delphi methods. Accessed from <https://www.health-knowledge.org/public-health-textbook/research-methods/1c-health-care-evaluation-health-care-assessment/use-delphi-methods>.
- House of Lords (Science and Technology Committee). (2013). Regenerative medicine, Report. London: The Authority of the House of Lords. <https://publications.parliament.uk/pa/ld201314/ldselect/ldsctech/23/23.pdf>. Retrieved on 15 September 2019.
- Lembaga Ilmu Pengetahuan Indonesia (LIPI). (2017). Consorsium for drug dicoverly. Jakarta: LIPI.
- Linstone, H. A., & Turoff, M. (Eds.). (2002). *The delphi method: Techniques and applications*. Newark, NJ: New Jersey Institute of Technology. Accessed from <https://web.njit.edu/~turoff/pubs/delphibook/delphibook.pdf>.
- Ministry of Health. (2017). National research forum for vaccine development. Jakarta, August 29th–30th, 2017.
- Rosita. (2017). Development of herbal medicines in Indonesia. Directorate of Traditional Medicines Evaluation, Food Supplements and Cosmetics. Presented at the *Research Priority Setting Discussion*, LIPI Jakarta, September 7th, 2017.
- Setiawan, B. & Djohan, S. (2016). Innovation process for increasing competitiveness of the pharmaceutical industry. Presented at the *2016 National Hakteknas Commemoration*, DRN, Surakarta, August 9th, 2016.
- Sol, E. J. (2015). Samenwerking bij networked innovation eco-systemen. *NL-VL Symposium*, Rotterdam, 30 sept 2015. https://www.flandersinthenetherlands.be/sites/default/files/atoms/files/NL-VL%20ejsol%20sept%202015_0.pdf.
- Terwindt, F., Rajan, D., & Soucat, A. (2016). Priority-setting for national health policies, strategies and plans. In Schmets, G., Rajan, D., & Kadandale, S. (Ed), *Strategizing national health in the 21st century: A handbook*. Chapter 4. Geneva: World Health Organization. <https://www.who.int/publications/i/item/strategizing-national-health-in-the-21st-century-a-handbook>.
- The COHRED Working Group on Priority Setting. (2000). *Manual for research priority setting using the ENHR strategy*. Lausanne, Switzerland: The Council on Health Research for Development (COHRED). Available at https://www.cohred.org/publications/library-and-archive/a_manual_for_research_1_0/.
- Wijaya, E. (2006). Planning of number and composition human resource using the Markov chain approach. [Final Project of the Industrial Engineering Department, Unika Atma Jaya, Jakarta].