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Scenario Planning for Indonesian FDA In the Enforcement of GMP Guideline for Traditional Medicine 2021 Edition

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ABSTRACT

The continuity of a country's Drug NRA as a PIC/S member is determined by GMP Guideline that recognized in member country should equivalent with PIC/S GMP Guideline. GMP Guideline for TM / CPOTB currently enforced in Indonesia and harmonized with PIC/S is the 2021 edition. Indonesian FDA identified that there are significant gaps between GMP Guideline for TM 2021 edition compare to previous edition, as well as varied implementation capability in IOT and IEBA causing future uncertainties for Indonesian FDA in enforcing the guideline. To develop the strategy for Indonesian FDA to face future uncertainties, a scenario planning approach is utilized. The key focal issue of this research is how the Indonesian FDA enforced the implementation of the 2021 edition of the GMP Guidelines for TM to IOT and IEBA in the next 5 years. There are 13 driving forces that have been identified and 2 of them, which are free trade and government policy, identified as critical uncertainties. Scenarios are generated in 2x2 matrix that developed from critical uncertainties. Implications and options are defined for each scenario and challenge the Indonesian FDA to perform actions in order to plan strategies to face uncertainties in the future.

Keywords: CPOTB, GMP Guideline for TM 2021 Edition, Indonesian FDA, PIC/S, Scenario Planning

JEL Classification: H11, J18, L15

INTRODUCTION

Indonesia has the second-largest biodiversity in the world, after Brazil with its Amazon rainforest, which indicates by the high number of native medicinal plants. Because of that, although modern medicine is important, most Indonesian people, both in urban and rural areas, use traditional medicines (TM) to treat diseases (Elfahmi, 2014). Based on WHO Traditional Medicine Strategy 2014 – 2023, there are several key objectives from these strategies to strengthen the role of TM in keeping the health of population, one of them is to promote the safety, efficacy and quality of TM by extending the science base, and supply the guidance on regulatory and quality assurance standards. (World Health Organization, 2013). TM has become a national cultural heritage that has been used for generations. The tendency in society to consume TM as part of back to nature lifestyle and the high cost of modern medicines makes the demand for TM increase. The demand for medicinal plants in the world is projected to increase significantly. The world demand is estimated by the World Health Organization (WHO) to reach USD 5 trillion by 2050 (Salim, 2017).

In the current pandemic, encourages people to re-explore local wisdom and traditional knowledge in handling the COVID-19 pandemic, among others, by developing the use of traditional medicines. This condition creates the demand for TM is believed to have increased and gives hopes and business opportunities for the TM industries in Indonesia. According to President Director of PT Mustika Ratu Tbk, Bingar Egidius Situmorang "*Based on the analysis of Euromonitor (2020), the forecast sales of national TM in Indonesia could reach 23 trillion rupiah in 2025. Meanwhile, national TM sales have reached 13.8 trillion rupiah in 2020*" (Situmorang, 2021).

The increasing demand for TM in pandemic era is used by some irresponsible people to spread hoaxes and misleading information related to the use of TM. Many people claim that their products can prevent and even cure COVID-19 patients. This misinformation is clearly can harm the society. It is one of the responsibilities of the Indonesian FDA to control the development and circulation of TM quality products. The quality of traditional medicine in terms of safety, quality and efficacy must be ensured to achieve its intended use. Another problem that often arises related to TM products is the large number of TM products mixed with chemical drugs. In accordance with applicable regulations, TM are prohibited from using isolated or synthetic chemicals have medicinal properties, narcotics or psychotropics and protected animals or plants (Indonesian FDA, 2006).

The Drug and Food control system carried out by Indonesian FDA is a comprehensive process consisting of:

1. Standardization which is the function of preparing standards, regulations, and policies related to Drug and Food control.
2. Assessment (pre-market evaluation) is an evaluation of the product before obtaining a marketing authorization number and finally it can be produced and distributed to consumers.
3. Post-market control to see the consistency of safety, efficacy/benefit, quality, and product information, which is carried out by sampling the circulating Drug and Food products, inspection of production facilities and distribution of Drugs and Foods, monitoring of pharmacovigilance, and monitoring of labels/marking and advertising.
4. Laboratory testing. Products that are sampled based on risk are then tested through a laboratory to find out whether the Drugs and Foods have met the safety, efficacy/benefit, and quality standards.
5. Fifth, law enforcement in the field of drug and food control. Law enforcement is based on evidence from tests, examinations, and initial investigations. If the violation

is in the criminal realm, then the Drug and Food violation can be processed under criminal law.

(Indonesian FDA, 2020)

Based on Regulation of Minister of Health number 14 year 2021 on Standard of Business Activities and Products in the Implementation of Risk-Based Business Licensing of the Health Sector, TM can be produced in 4 categories of enterprises, namely:

1. TM Industry (IOT), is industry that manufactures all dosage forms of TM.
2. Natural Ingredient Extract Industry (IEBA), is industry that specializes in making natural ingredient extracts as the final product.
3. TM Small Enterprise (UKOT), is enterprise that manufacture all dosage forms of TM, except for tablet, effervescent, suppository and soft capsule.
4. TM Micro Enterprise (UMOT), is enterprise that only makes TM dosage forms in the form of param, tapel, pilis, topical liquid and chopped simplicia.

To ensure the quality of TM products in circulation, Indonesian FDA enforce regulations which requires manufacturers of pharmaceutical preparations (in Indonesia also known as drugs, medicinal ingredients, TM, health supplements / HS and cosmetics), some foods, and blood to take proactive steps to ensure that their products are safe, pure, and meet quality standards by implement Good Manufacturing Practice (GMP). It is also systems for ensuring that products are consistently manufactured and supervised according to quality standards (International Society for Pharmaceutical Engineering).

In the context of facing globalization, business actors must continue to improve their competitive capability in order to survive in an increasingly tight business environment. Competitiveness can have a big impact on a company's performance (Hikmatiyar, 2021). One of the ways to improve competitiveness is to meet standards and harmonization within an organization. Concerning to this matter, Indonesia represented by Indonesian FDA as a National Regulatory Authority (NRA), has been a member of The Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 2012. PIC/S, one of international organization that harmonizes GMP standards, is a non-binding, informal co-operation agreement between Drug NRA in the area of GMP for human or veterinary medical products. PIC/S has been active in the development and promotion of harmonized GMP standards and guidelines with PIC/S GMP Guideline as main instrument (PIC/S).

Even though PIC/S is not a trade agreement, PIC/S membership may facilitate the export of pharmaceuticals. Several PIC/S non-member authorities accept GMP Certificates from PIC/S member authorities. This means that PIC/S non-member authorities have a higher trust in medicines manufactured in PIC/S member authorities' countries. When a Drug NRA becomes PIC/S member authorities, there are also indirect benefits to their relevant industry, including as follows:

- Reduced duplication of inspections;
  If an industry in a PIC/S member country will export to another PIC/S member country, the importing country can trust the industry's GMP certificate so there is no need to inspect them anymore.
- Therefore, it becomes cost savings;
- Export facilitation and enhanced market access.

(PIC/S)

The continuity of a country's Drug NRA as a PIC/S member is determined by GMP Guideline that recognized in PIC/S member country should equivalent with the PIC/S GMP Guideline latest edition. Indonesia's membership in PIC/S does not only involve

medicinal products and raw material (active pharmaceutical ingredients / API), but also TM, so GMP Guidelines for TM also must be harmonized with the PIC/S GMP Guidelines. Based on Indonesian FDA Regulation number 25 year 2021 on the Implementation of GMP for TM, the guideline currently enforced in Indonesia and harmonized with PIC/S GMP Guideline is GMP Guideline for TM 2021 edition that recently issued in October 2021. There are 12 aspects and 4 annexes that regulates by GMP Guideline for TM 2021 edition.

There are several significant gaps between GMP Guideline for TM 2021 edition compare to previous edition. The result of self-assessment and gap analysis conducted by IOT and IEBA shows that they have varying gaps and level of capabilities in the implementation of the guideline. These conditions causing future uncertainties for Indonesian FDA in enforcing the implementation of GMP Guideline for TM 2021 edition. Indonesian FDA needs to develop strategies to enforce the implementation of GMP Guideline for TM 2021 edition to IOT and IEBA. To develop the strategy, a scenario planning approach is utilized. Propose strategies to Indonesian FDA by scenario planning approach to assist the agency have the capability to anticipate the plausible events in the future and promote the implementation plans in the enforcement of the implementation of GMP Guideline for TM 2021 edition to IOT and IEBA. In the process of scenarios development, this research explores driving factors, discover the critical uncertain factors to build scenario framework and prepare the readiness for Indonesian FDA in the enforcement of the implementation of GMP Guideline for TM 2021 edition to IOT and IEBA through the creation of implication, options as well as the early warning signals of each scenario.

LITERATURE REVIEW

Scenario Planning

Considering change is the only constant, an organization need to envisions what-if scenarios and expect that unpredictable events will happen to make responses in anticipating plausible futures. This activity, encapsulated with decision analysis, known as scenario planning. Scenario planning addresses both optimistic and pessimistic futures. Based on the scenario planning, the organization design strategic plan and activate it by the time optimistic or pessimistic scenarios that imagined start to arise. The objective of scenario planning is to design several specified and implement strategic plans. These plans make the organization more supple and effective than only have one master plan. The making process of scenario planning stimulates imagination and creation to set up finer future for an organization (Rothaermel, 2021).

Different from traditional strategic planning, which consider that there is usually a best respond to a strategic question, scenario planning occupies multiple possibilities. Different from contingency planning, which generally makes a single uncertainty as a focal point, scenario planning explores few uncertainties at the same time. And different from simulation modeling, which is severely numbers-driven, scenario planning uses subjective interpretation as well as objective analysis. Because of these, the scenario planning technique is notably useful in conditions where uncertainty and change are high, high-cost surprises have happened in the past, and the quality of strategic thinking or the supply of new opportunities is low (Garvin & Levesque, 2006).

Initially, modern scenario planning was developed and introduced by Herman Kahn and the RAND Corporation in 1950s that was conducted as part of military strategy research for the US Government (Lindgren. & Bandhold, 2009). Since then, there are many methods and approaches that have been introduced.

The typical viewpoint for most businesses is from the inside out. They begin by examining their own company, then move on to customers, competitors, structures, and technologies within their own industry. It is unusual for them to go deeper into the driving forces for the arena's adjustments. This strategy works as long as the approach's very narrow perspective is adequate. This perspective, on the other hand, is inadequate if the focus is on long-term product development in a complicated and continuously changing environment. The inside–out perspective makes it harder to foresee market changes that have not yet manifested themselves. To predict these changes, begin by examining the driving variables that may have an impact on what occurs in the arena and how it affects the organization's operations. Long-term trends in the arena are heavily influenced by external driving forces (Figure 1). As a result, trends in the surrounding world are a suitable beginning point for tracking. Scenario planning starts from the “outside-in” approach to recognize and prepare for external factors and uncertainties that will have a substantial impact on the company's decisions (Lindgren, M. & Bandhold, H., 2009).

PESTEL Analysis

External environment is the industry where the organization carry on their operation and the outside competitive forces that surrounded the organization. By analyzing the factors in organization’s external environment, they can mitigate threats and leverage opportunities. This research used PESTEL framework, which allows to scan, monitor, and evaluate changes and trends in the organization’s external environment. The PESTEL model groups the factors in the organization’s general environment into political segment, economic segment, sociocultural segment, technological segment, ecological segment and legal segment (Rothaermel, 2021). Organizations, for the most part, accept their surrounding environment as they are and adjust accordingly. High achievers cope with the difficulties of their external world by acting as internal supervisors. High performers establish competing priorities that are in line with their surrounding environment (Sakinah, 2021).

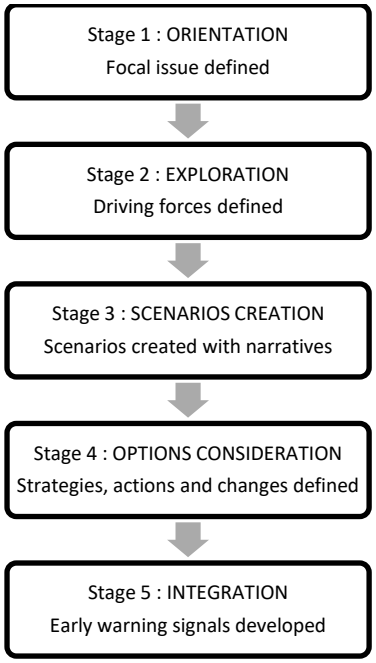
SWOT Analysis

The institutions must have particular type of resources and capabilities that combine to form core competencies in order to formulate and implement a strategy that improves the institutions’ chances of obtaining and maintaining competitive advantage. To live and thrive, the finest institutions carefully identify their core competencies, resources, and capabilities. Institutions must then decide how to manage and enhance internal strengths in order to respond to external challenges and opportunities. Institutions, in particular, conduct internal strength assessments and development in the context of external PESTEL forces (Rothaermel, 2021)

RESEARCH METHOD

This research applies scenario planning approach, developed by David A Garvin and Lynne C Levesque, that consist of 5 stages, namely Orientation, Exploration, Scenarios Creation, Option Consideration and Integration as shown in Figure 2.

Figure 1. Scenario Planning Stages



(Source: Garvin & Levesque, 2006)

The objective of Stage 1, namely Orientation, is to determine the focal issue and associated challenges, in clear statement from senior management of the key focal issue with specific time and place dimensions, through background interviews and other research. In Stage 2, which is Exploration, driving forces are defined through extensive research (by online, i.e., questionnaire, and offline interviews) to recognize and extend the understanding about the driving forces and critical uncertainties around the focal issue. Besides being recognize, the driving forces also then being analyze and ranked. Go to Stage 3, which is Scenarios Creation, done by two steps namely select the scenario framework and make the narratives. The scenario framework creates in the form of 2x2 matrix from the two most critical uncertainties, recognize its characteristics, causes and occurred events from present to future, then the narratives were built for each scenario. Furthermore, in Stage 4, which is Options Consideration, the implication of each scenario to the organization are developed through Focus Group Discussion (FGD). And the last stage, which is Stage 5, the early warning signals that could direct to possible future and the possibility of other scenarios emerge are created (Garvin & Levesque, 2006).

This research was conducted using qualitative analysis and data collection through literature review, interview, and FGD addressed to decision maker in Indonesian FDA and stakeholders (IOT, IEBA and Association of Indonesia Herbal and TM Business Actors and also primary and secondary data analysis. The interview was conducted to 16 interviewees which consist of 8 persons from IOT, 2 persons from IEBA, 1 person from association, 1 person as Indonesian FDA's expert of GMP Guideline for TM and 4 persons from Indonesian FDA. Moreover, to discover driving forces: topics and tendencies which might impact and form the key focal issue in fundamental ways, this research also uses PESTEL analysis to analyze external environment and SWOT analysis to analyze internal environment.

The five stages of scenario planning are interrelated processes. A stage is carried out by analyzing the results of the previous stage. It is crucial to emphasize that scenario development is ideally an iterative process. It is necessary to iterate at each stage,

checking that the contents are viable and making any necessary changes to ensure that they are. Iterations makes it possible to revisit and revise assumptions and decisions and tentative findings. It is important to remember that the goal of scenario planning is not to anticipate the probable future. Rather, the goal is to create and test strategic options in a number of plausible future scenarios. Preventatively performing this exercise—basically, preparing for different futures—improves an organization's ability to recognize, adapt to, and capitalize on changes in the industry over time (Monitor Company Group, L.P., 2007).

RESULTS

Stage 1: Orientation

The key focal issue in this research is how the Indonesian FDA enforced the implementation of the 2021 edition of the GMP Guidelines for TM to IOT and IEBA in the next 5 years. The 5-year timeframe was determined based on a literature study of the national strategy for developing the pharmaceutical industry to implement GMP in several African countries in collaboration with the United Nations, one of which is Ethiopia, where the strategy was prepared with a 5-year GMP roadmap (Government of Ethiopia, 2015)

Stage 2: Exploration

Several driving forces are identified during interview. The driving forces are as follows:

1. Government Policy
2. Free trade
3. Population
4. People purchasing power
5. Tax system
6. TM products pricing system
7. Back to nature, healthy and practicality lifestyles
8. Public knowledge on GMP for TM
9. Development of technology and digitalization
10. The availability of quality medicinal plant raw materials
11. Waste Management
12. Law enforcement related to the implementation of GMP Guidelines for TM 2021 edition
13. Issuance of Omnibus Law

In this study, the determination of critical uncertainties was carried out based on the results of interviews with interviewee. To determine the driving factors that become critical uncertainties, the level of impact and uncertainty is determined from the total score that given by interviewee and categorized into 3 level using an approach as in Table 1.

Table 1. Driving Force Categorization Approach

No.	Level	Score
1.	Low	0 – 2
2.	Medium	3 – 4
3.	High	> 4

(Source: Author’s analysis)

Using categorization approach as in Table 1, the driving forces are determined the level of impact and uncertainty as in Table 2. Based on the driving forces chosen by the

interviewee, can be concluded that the critical uncertainties for the key focal issue are government policy and free trade.

Table 2. Driving Forces Categorization

No.	Driving Forces	Impact		Uncertainty	
		Score	Level	Score	Level
1.	Government Policy	4	Medium	9	High
2.	Free trade	5	High	1	Low
3.	Population	0	Low	0	Low
4.	People purchasing power	2	Low	0	Low
5.	Tax system	1	Low	0	Low
6.	TM products pricing system	1	Low	0	Low
7.	Back to nature, healthy and practicality lifestyles	1	Low	0	Low
8.	Public knowledge on GMP for TM	0	Low	0	Low
9.	Development of technology and digitalization	3	Medium	1	Low
10.	The availability of quality medicinal plant raw materials	0	Low	1	Low
11.	Waste management	0	Low	0	Low
12.	Law enforcement related to the implementation of GMP Guidelines for TM 2021 edition	0	Low	2	Low
13.	Issuance of Omnibus Law	1	Low	2	Low

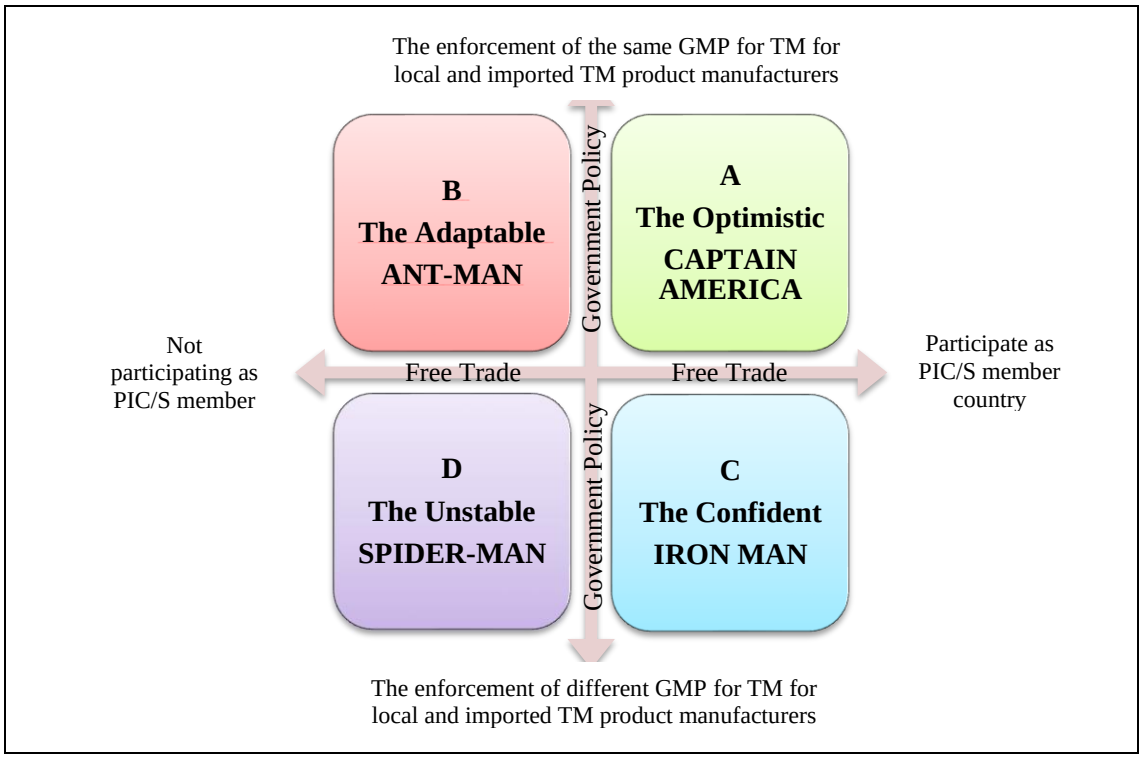
(Source: Author's analysis based on interview)

Stage 3: Scenarios Creation
Scenarios are built based on critical uncertainties, which are government policy and free trade, placed in a 2x2 matrix. The scenario matrix on the enforcement to IOT and IEBA to implement GMP Guideline for TM 2021 edition by Indonesian FDA can be seen in Figure 3. The name of scenario was taken based on the characters of Marvel Avengers' superhero.

Scenario A, The Optimistic Captain America, is a scenario for the Indonesian FDA which enforce the implementation of GMP Guideline for TM 2021 edition to both local and imported TM products. The application of GMP Guideline for TM 2021 edition to IOT and IEBA is a consequence of Indonesia's participation as a member of PIC/S, so that the GMP Guidelines for TM used in Indonesia must be harmonized. Scenario B, The Adaptable Ant-Man, is a scenario for Indonesian FDA which enforce the implementation of the same GMP Guideline for TM to both local and imported TM products, but unlike scenario A, in scenario B what is meant by the GMP Guidelines for TM is not the 2021 edition which is the result of harmonization with the PIC/S GMP Guidelines. By not participating as PIC/S member country, the GMP Guidelines for TM prepared by the Indonesian FDA can be adapted to the capabilities of IOT and IEBA. Scenario C, The Confident Iron Man, is a scenario for Indonesian FDA to enforce the implementation of GMP Guideline for TM 2021 edition to IOT and IEBA, but not for imported TM products. Moreover, as mentioned in Scenario A, the enforcement of GMP Guideline for TM 2021 edition to IOT and IEBA is a consequence of Indonesia's participation as a member of PIC/S. Scenario D, The Unstable Spider-Man, is a scenario for Indonesian FDA which does not enforce the implementation of GMP Guideline for TM 2021 edition, however enforce the implementation of the GMP Guidelines for TM which are only used in

Indonesia. In addition, the enforcement of the implementation of GMP for TM is not the same between local and imported TM products.

Figure 2. The scenario matrix on the enforcement of the implementation GMP Guideline for TM 2021 edition by Indonesian FDA to IOT and IEBA



(Source: Author's analysis)

Stage 4: Options Consideration
In this stage, an exploration of the implications of each scenario for the Indonesian FDA and the choices made by the agency to minimize the capability gap is carried out. The implications and options can be seen in Table 3.

Table 3. Implications and Options

Scenario A: The Optimistic Captain America	
Implications:	Options:
1. The number of exports of Indonesian TM products increased. 2. The number of IOT and IEBA that have GMP for TM Certificate or even the number of IOT / IEBA decreased.	1. Gives supports and incentives for IOT or IEBA that will carry out exports. 2. Create a GMP Guideline for TM 2021 edition enforcement plan through a structured approach.
3. There are objections from importers of TM products because they feel that it is difficult to fulfill the requirements of the GMP for TM Certificate to obtain a marketing authorization. 3. The quantity of imported TM products in Indonesian market declined.	3.1. Assessing the implementation of GMP on imported TM product manufacturers on the basis of GMP Guideline for TM 2021 edition 3.2. Provide incentives to imported TM products that can fulfill the requirement of GMP for TM certificate 4. Gives supports and incentives from upstream to downstream for IOT or IEBA that will carry out the development of TM.
Scenario B: The Adaptable Ant-Man	
Implications:	Options:

1. The exports quantity of Indonesian TM products declined.	1.1. Gives supports and incentives for IOT or IEBA that will carry out exports. 1.2. Conduct a benefit analysis of the participation of the Indonesian FDA as a member of the PIC/S.
2. There are objections from importers of TM products because they feel that it is difficult to fulfill the requirements of the GMP for TM Certificate to obtain a marketing authorization.	2.1. Assessing the implementation of GMP on imported TM product manufacturers on the basis of GMP Guideline for TM that apply only in Indonesia 2.2. Provide incentives to imported TM products that can fulfill the requirement of GMP for TM certificate
Scenario C: The Confident Iron Man	
Implications:	Options:
1. Many imported products circulating in the Indonesian market.	1.1. Strengthening the post-market control system. 1.2. Community empowerment through various communication, information and education activities.
2. The emergence of envy of local TM product manufacturers towards imported TM product manufacturers.	2. Gives supports and incentives for IOT or IEBA that will carry out the implementation of GMP Guideline for TM 2021 edition.
3. The number of IOT and IEBA that have GMP for TM Certificate or even the number of IOT / IEBA decreased.	3. Create a GMP Guideline for TM 2021 edition enforcement plan through a structured approach.
4. The number of exports of Indonesian TM products increased.	4. Gives supports and incentives for IOT or IEBA that will carry out exports.
Scenario D: The Unstable Spider-Man	
Implications:	Options:
1. Many imported products circulating in the Indonesian market.	1.1. Strengthening the post-market control system. 1.2. Community empowerment through various communication, information and education activities.
2. The exports quantity of Indonesian TM products declined.	2.3. Gives supports and incentives for IOT or IEBA that will carry out exports. 2.4. Conduct a benefit analysis of the participation of the Indonesian FDA as a member of the PIC/S.
3. The emergence of envy of local TM product manufacturers towards imported TM product manufacturers.	3. Gives supports and incentives for IOT or IEBA that will carry out the implementation of GMP for TM.
4. The credibility of the Indonesian FDA is at stake.	4. Establish good cooperation and collaboration with stakeholders to communicate and consult the policies made by Indonesian FDA.

(Source: Author's analysis)

Stage 5: Integration

Integration steps are carried out which include environmental or trend monitoring through an early warning system and the use of scenarios to guide strategic choices. To evaluate the effectiveness of strategic decisions as well as considering other important choices that available, the scenario is used. While the early warning signals are developed to indicate the likely emergence of one scenario rather than another. There are 5 indicators, as can be seen in Table 4, become the early warning signals for the scenarios.

Table 4. Scenario's Early Warning Signals

Driving Factors	Indicators	Scenarios			
		A	B	C	D
Government Policy	1. The result of policy effectiveness measurement	Inequality is ineffective	Inequality is ineffective	Inequality is effective	Inequality is effective
	2. Business actors that will object	IOT / IEBA	IOT / IEBA	TM product or raw material importer	TM product or raw material importer
Free Trade	3. The number of IOT and IEBA in Indonesia	IOT : ≥ 127 IEBA : ≥ 17	IOT : < 127 IEBA : < 17	IOT : ≥ 127 IEBA : ≥ 17	IOT : < 127 IEBA : < 17
	4. The result from capability mapping of IOT / IEBA in implementing GMP Guideline for TM 2021 edition	The number of IOT / IEBA who are capable to apply the guideline is more than those who are incapable	The number of IOT / IEBA who are incapable to apply the guideline is more than those who are capable	The number of IOT / IEBA who are capable to apply the guideline is more than those who are incapable	The number of IOT / IEBA who are incapable to apply the guideline is more than those who are capable
	5. The result from PIC/S membership cost-benefit analysis	Value of the benefit is bigger than cost	Value of the benefit is smaller than cost	Value of the benefit is bigger than cost	Value of the benefit is smaller than cost

(Source: Author's analysis)

DISCUSSION

The issue that become the background of the discussion is that there is a significant gap between GMP Guideline for TM 2021 edition with previous edition. This significant gap as a consequence as PIC/S member country and furthermore causes variations in the ability of IOT and IEBA in implementing the guidelines. With the spirit of opening as many opportunities as possible and increasing competitiveness for business actors, as well as creating Indonesia's independence in TM raw materials and products, it is necessary for Indonesian FDA to create a strategy that becomes a key focal issue, namely how the Indonesian FDA enforced the implementation of the 2021 edition of the GMP Guidelines for TM to IOT and IEBA in the next 5 years.

To collect qualitative data, this research using combination of interview, literature review and analysis, as well as FGD during the five stages of Garvin and Levesque's scenario planning. The interview was started with questionnaire and deepened with online or offline interview. The interview was conducted to 16 interviewees which consist of 8 persons from IOT, 2 persons from IEBA, 1 person from association, 1 person as Indonesian FDA's expert of GMP Guideline for TM, 1 person from Directorate of TM, HS and Cosmetics Standardization and 3 persons from Directorate of TM and HS Control. In the integration stage, FGD was conducted to get feedback on scenarios that have been developed and possible future events from users and other junior to chief and experienced GMP for TM inspectors in Indonesian FDA.

There are 13 driving forces that have been identified and 2 of them, which are free trade and government policy, identified as critical uncertainties as having the biggest impact and highest uncertainty. The critical uncertainty of government policy is described as a

policy related to the equal enforcement of GMP Guideline for TM 2021 edition among local and imported TM product manufacturers, while free trade is described as Indonesia's participation as PIC/S member country. Scenarios are generated in 2x2 matrix that developed from critical uncertainties and narrative was made for each scenario.

In the options consideration stage, implications and options of every scenario are explored and identified. In the Optimistic Captain America scenario, Indonesian FDA as PIC/S member country enforce the implementation of GMP Guideline for TM 2021 edition, and it is applied to both local and imported TM products. These conditions will make the implication of the Optimistic Captain America scenario are the number of exports of Indonesian TM products increased, the number of IOT and IEBA that have GMP for TM Certificate or even the number of IOT / IEBA decreased, there are objections from importers of TM products because they feel that it is difficult to fulfill the requirements of the GMP for Certificate to obtain a marketing authorization and the quantity of imported TM products in Indonesian market declined. To minimize the capability gaps, the options in this scenario are gives supports and incentives for IOT or IEBA that will carry out exports, create a GMP Guideline for TM 2021 edition enforcement plan through a structured approach consist of IOT and IEBA capability mapping, as well as gap analysis and intervention, assessing the implementation of GMP on imported TM product manufacturers on the basis of GMP Guideline for TM 2021 edition, provide incentives to imported TM products that can fulfill the requirement of GMP for TM certificate and gives supports and incentives from upstream to downstream for IOT or IEBA that will carry out the development of TM.

In the Adaptable Ant-Man scenario, Indonesian FDA enforce the implementation of the same GMP Guideline for TM to both local and imported TM products, but unlike scenario A, in scenario B what is meant by the GMP Guidelines for TM is not the 2021 edition. The implications of this scenario are the exports quantity of Indonesian TM products declined and there are objections from importers of TM products because they feel that it is difficult to fulfill the requirements of the GMP for Certificate to obtain a marketing authorization. While the options are gives supports and incentives for IOT or IEBA that will carry out exports, conduct a benefit analysis of the participation of the Indonesian FDA as a member of the PIC/S, assessing the implementation of GMP on imported TM product manufacturers on the basis of GMP Guideline for TM that apply only in Indonesia and provide incentives to imported TM products that can fulfill the requirement of GMP for TM certificate.

Moreover, in the Confident Iron Man scenario, Indonesian FDA becomes a member of the PIC/S, so it must enforce the implementation of the GMP Guidelines for TM 2021 edition to IOT and IEBA. However, the guideline only applies to IOT / IEBA. Several implications and options that could happen in Scenario A also could happen in this scenario, which are the number of IOT and IEBA that have GMP for TM Certificate or even the number of IOT / IEBA decreased and the number of exports of Indonesian TM products increased. Meanwhile other implications of this scenario are many imported products circulating in the Indonesian market and the emergence of envy of local TM product manufacturers towards imported TM product manufacturers. As for the options are strengthening the post-market control system, community empowerment through various communication, information and education activities, gives supports and incentives for IOT or IEBA that will carry out the implementation of GMP Guideline for TM 2021 edition.

In the last scenario, the Unstable Spider-Man, Indonesian FDA is not participated as member of the PIC/S, so it does not have to enforce the implementation of the GMP

Guidelines for TM 2021 edition to IOT and IEBA, and able to use local GMP for TM, but the guideline only applies to IOT / IEBA. Several implications and options that could happen in Scenario C and B also could happen in this scenario, which are many imported products circulating in the Indonesian market, the exports quantity of Indonesian TM products declined, the emergence of envy of local TM product manufacturers towards imported TM product manufacturers. While the other implication is the credibility of the Indonesian FDA is at stake, and the option are to establish good cooperation and collaboration with stakeholders to communicate and consult the policies made by Indonesian FDA.

There are 5 indicators that identified as early warning signals to indicate the emergence of a scenario. Evidence-based policymaking is becoming more prevalent as a method of policy evaluation. Impact studies, cost-benefit analysis, program assessment, and academic studies are examples of approaches that can be used to base policy decisions on scientific and empirical evidence (Widjanarko, 2021). Indonesian FDA needs to conduct policy effectiveness measurement toward the policy regarding the equality of the enforcement of GMP for TM among local and imported TM product and cost-benefit analysis to determine whether the goal on become PIC/S member country is achieved. The result of the measurement and analysis will become early warning signals. By doing policy effectiveness measurement, in the same time Indonesian FDA could finding out whether there are objections from IOT, IEBA or importers regarding the policy and at a time get a signal for the scenario.

In the last four years, the number of IOT are always increase or stable. There are 102 IOTs in 2017 (Ministry of Industry, 2017), 129 in 2018 (Ministry of Industry, 2018), 2019 (Hana, 2020) and 2020 (Rahayu, 2020), and 127 IOTs in 2021 (Indonesian FDA internal data, as of June 2021). Since there is large amount of resource required to implement GMP for TM (not only the 2021 edition), this is what causes IOT to decide to change their status to UKOT or even shift their business to other commodities. Organizational assets, knowledge, competencies, and processes are all examples of organizational resources. Real or tangible resources (financial or physical) are distinguished from intangible resources (knowledge, experience, and staff skills, firm reputation, brand names, and organizational procedures) (Bahri, 2019). For this reason, the number of IOT is become an indicator that the GMP Guideline for TM can be applied and Indonesia's continued participation in the PIC/S.

The last indicator is related to capability of IOT and IEBA to implement GMP Guideline for TM 2021 edition. The capability can be captured from mapping activities of TM production facilities in the framework of profiling related to the implementation of GMP for TM that have been carried out by Indonesian FDA since August 2021. Later, from the mapping results, IOT and IEBA will be grouped into clusters so that the ability to implement GMP Guideline for TM 2021 edition can be known.

CONCLUSION

The key focal issue this research is how the Indonesian FDA enforced the implementation of 2021 edition of the GMP Guidelines for TM to IOT and IEBA in the next 5 years. The uncertainties around the events in the future is explored using scenario planning so that the Indonesian FDA is prepared to face all the possibilities that may occur. Thirteen driving forces are further explored in terms of the magnitude of the impact and the high uncertainty effect to the key focal issue into critical uncertainties. The driving forces with the biggest impact is free trade and the highest uncertainty is government policy. Developed from critical uncertainties, four scenarios are built by a combination of government policy regarding the enforcement of the same or different GMP for TM for

local and imported TM product manufacturers and the free trade regarding Indonesia participation in PIC/S. The Optimistic Captain America is a scenario for the Indonesian FDA which enforce the implementation of GMP Guideline for TM 2021 edition to both local and imported TM products. The Adaptable Ant-Man is a scenario for Indonesian FDA which enforce the implementation of the same GMP Guideline for TM to both local and imported TM products, but unlike the first scenario, what is meant by the GMP Guidelines for TM in this scenario is not the 2021 edition. The Confident Iron Man, is a scenario for Indonesian FDA to enforce the implementation of GMP Guideline for TM 2021 edition to IOT and IEBA, but not for imported TM products. The last scenario, The Unstable Spider-Man, is a scenario for Indonesian FDA which does not enforce the implementation of GMP Guideline for TM 2021 edition, however enforce the implementation of the GMP Guidelines for TM which are only used in Indonesia. In addition, the enforcement of the implementation of GMP for TM is not the same between local and imported TM products. This research also developed implications of each scenario for the Indonesian FDA and the choices made by the agency to minimize the capability gap, as well as the early warning signals to indicate the likely emergence of one scenario rather than another.

LIMITATION

The limitation of this research are as follows:

1. The application of GMP Guideline for TM only in IOT and IEBA because based on Indonesian FDA Regulation number 14 year 2021 on GMP for TM Certification it is mandatory for them.
2. The GMP Guideline for TM that used in this research is the 2021 edition of GMP Guideline for TM.
3. Considering the importance of GMP in the production of TM, it is also important that the Indonesian FDA encourages IOT and IEBA to immediately implement the 2021 edition of the GMP Guideline for TM as soon as possible, so that the time frame used in scenario planning is limited to a period of 5 years.
4. With the research time constraint and small number of stakeholders involved in this research, the result of this research is the best scenario planning that researcher can design. It needs further comprehensive development, if required, to generate deeper result.

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DECLARATION OF CONFLICTING INTERESTS

The authors assert that there are no conflicts of interest during the implementation of this research.

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