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Investigation Report from the Industry-Government-Academia Round Table Discussion Project: Indonesian Pharmaceutical Market and Business Opportunities for Japanese Pharmaceutical Industry[1]

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1. Background

Since 2013, the Health Care Science Institute, a Public Interest Incorporated Foundation, has hosted annual symposiums called Industry-Government-Academia Symposiums to provide opportunities for those from industries, government and academia to have round table discussions on the latest important issues for the Japanese pharmaceutical and medical device industries. The theme of the 3rd Industry-Government-Academia Symposium in 2015 was to identify major difficulties commonly facing Japanese pharmaceutical companies that have been developing their business in emerging and developing countries. To advance the rather general discussion in the previous symposium by limiting focus to several selected countries and identifying country-specific major challenges confronted by Japanese companies in those countries, the 4th Industry-Government-Academia Symposium in 2016 had decided to be held with focus on ASEAN countries under the theme of "Access to Medicine Problems in ASEAN Countries and Business Opportunities for the Japanese Pharmaceutical Industry". This field study was conducted as one of a series of studies for that symposium.

Among ASEAN countries, Indonesia was chosen for the subject of this field study. Indonesia has a large pharmaceutical market as well as a good prospect of future growth. Aiming at the achievement of universal health coverage (UHC), it has introduced a new health care insurance system since January 2014. With the fourth largest population in the world of over 25 billion people, Indonesia is expected to have the largest UHC system in Asia at the completion of the transition, which is scheduled in 2019. As of September 2015, the rate of coverage is approximately 60.3% (Ministry of Health, Labor and Welfare, *Report on Conditions Overseas 2015*). Encouraged by the

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ongoing transition to UHC system, the Indonesian pharmaceutical market is receiving high expectations of future growth across the country and overseas. On the other hand, there are many uncertain elements about the future of the new health care insurance system and other health care policies. For these reasons, we considered it was worth investigating.

2. Objective

A main objective of this study is to identify the following: (1) the current status of the Indonesian pharmaceutical market that currently undergoes a transition to UHC system and its major high-priority challenges and (2) Japanese pharmaceutical firms' business opportunities that also contribute to increasing the access to medicine in Indonesia.

3. Method

The study was conducted through three phases: (1) preliminary study (2) field study and (3) additional study. As a preliminary study, we had meetings with those from the Ministry of Health, Labor and Welfare (MHLW), the Japanese Pharmaceutical Manufacturers Association (JPMA), and several Japanese pharmaceutical companies and consulting firm that have operated in Indonesia for years and thus been familiar with the recent situations of the Indonesian pharmaceutical market (see Table 1). The meetings were held during February and March 2016, prior to a field study.

Then, a field study on the Indonesian pharmaceutical market was conducted in Jakarta in April 2016. At the field survey, we visited Indonesian government sectors (the Ministry of Health and Badan POM), Indonesian pharmaceutical manufacturers associations, the Embassy of Japan in Jakarta, JETRO Jakarta and several Japanese pharmaceutical firms in Jakarta for interviews (see Table 1). One of the objectives of the field study was to directly ask those from the Indonesian government and industry about the government's major high-priority challenge to be solved. Such updated correct information should help Japanese firms capturing their business opportunities in Indonesia. The other objective of the field study is to verify the information about the recent situation of the Indonesian pharmaceutical market and its major challenges that we have collected through the preliminary study.

Finally, as an additional study, a seminar was held in May 2016 by inviting Prof. Hasbullah Thabrany (Chair, Centre for Health Economics and Policy Studies, Universities Indonesia) who has exerted himself for the transition to Indonesian UHC system. At the seminar, the latest situation of the transition and some related issues that had remained in doubt after the filed study were discussed.

4. Findings

1) Keywords for high-priority challenges faced by the Indonesian government in the pharmaceutical market and for Japanese companies' business opportunities

During the field study, we asked at the interviews with Indonesian government officials and those from Indonesian pharmaceutical manufacturers association which challenges faced by the government were of high priority to be solved. While the answers varied according to their positions, all the interviewees mentioned two keywords representing the government's high-priority challenges: unmet needs (not only unmet *medical* needs but also unmet *social/economic* needs) and capacity building.

Japanese firms' business opportunities then should increase if they correctly figure out where such unmet needs are and contribute to building necessary capacities (e.g., human, /physical/monetary resources) to tap those needs. That is, as depicted in Figure 1, investment and cooperation that are located in the intersection of the three circles of (1) high-priority unmet needs, (2) high-priority capacity building and (3) the feasibility from Japanese pharmaceutical companies, industry and/or government leads to a win-win relationship between Indonesia and Japan (see Figure 1). Regarding the feasibility from Japanese pharmaceutical companies and industry, the perspective of creating shared value (CSV) is important since otherwise it is difficult to maintain a long-term sustainable relationship.

2) Findings for individual issues

In what follows, we summarize findings for each individual issue that have often been discussed during the preliminary study in Japan or that have been pointed out during the field study in Jakarta.

(1) Issue 1: Quality of medicine (quality of manufacturing medicine, distributing medicine and manufactured medicine)

The quality of medicine (mainly, manufacturing medicine) had often been raised as an issue at hearings during the preliminary study in Japan. At the hearings, it has been pointed out that a quality assurance system sufficient to meet GMP requirements has not been developed at the vast majority of local manufacturers although several leadings manufactures have already successfully established it.

Given the information, we asked at the interviews during the field study whether Japanese companies, industry or the government can contribute to improving the quality of manufacturing medicine. The answer was that neither of those from the Indonesian pharmaceutical manufacturers associations or from government sectors is

concerned with it much. Badan POM is an Indonesian counterpart of Pharmaceuticals and Medical Drug Agency (PMDA) in Japan and thus responsible for establishing quality of manufacturing medicine. At the interview at Badan POM, they said that the quality of medicine is important. Moreover, they are concerned with how to maintain the quality of medicine when the national health insurance coverage increases in future. However, they said that they do not have any problem about the quality of medicine at this moment.

A possible reason why the findings from the preliminary study in Japan and the field study in Jakarta have been different is different views for the quality of medicine. For instance, the presence of cracks in pharmaceutical tablet is taken seriously in Japan but not very much in Indonesia. In fact, the top 5 to 10 local manufacturers have met international GMP requirements and thus had strong confidence in their quality of manufacturing medicine (and manufactured medicine) according to the interviews at an Indonesian pharmaceutical manufacturers association.

Discussion. These findings suggest that it may be true that Japanese pharmaceutical firms can contribute to improving the quality of manufacturing medicine in Indonesia but it is doubtful that this is their high-priority unmet need or helps their high-priority capacity building (see Figure 2). Therefore, a cooperation offer from the Japanese government or companies may not draw much attention from the Indonesian government or pharmaceutical industry if the corporation offer is merely for improving the quality of manufacturing medicine. Moreover, the difference in views for the quality of medicine between the two countries reflects their cultural differences. Therefore, they are likely to strongly resist being requested to have the Japanese standard of the quality of medicine such as no dirt on individual boxes.

Another possible reason why the findings from the preliminary study and the field study have been different is that there is little feedback of claim information about the quality of medicine to the Ministry of Health and Badan POM. This was pointed out by several government officials. Without feedback, the government cannot recognize correctly the current status of the quality of medicine and thereby the priority of the issue decreases.

Then, a question is whether it is true that there is no problem at all about the quality of medicine. According to the interviews with government officials, it seems (at least to us) that not a few problems exist at field level. However, unless such claim information is not fed back to government sectors, they may not able to take any measure

officially.

Discussion. An important question arising from this finding is how many human resources are allocated at field level who are responsible to feed claim information about the quality of medicine back to government authorities or whether any mechanism exists that helps them collecting claim information about the quality of medicine. For instance, it is difficult to find quality defects only from the appearance of medicines (including counterfeit medicines). Therefore, without doctors or pharmacists that are properly trained and highly motivated, it is difficult to detect quality defects from a high frequency of side effects or defective effects.

In Japan, government authorities systematically sample marketed medicines to check the quality. Also, Japanese pharmaceutical companies voluntarily save samples for each lot to monitor the quality for a certain period. In Japan, these systems ensure the quality of medicines. No such systems exist in Indonesia.

Given this, a possible contribution by the Japanese government or pharmaceutical industry is to help the Indonesian government authorities systematically collecting claim information, in developing human resources necessary for it and/or in developing a sampling system for their monitoring the quality of marketed medicines. Through it, the sensitivity of the Indonesian government and consumers to safety issues of medicines increases. In the future, this in turn will reduce the demand of defective medicines and raise the demand of high-quality medicines including Japanese ones.

(2) Issue 2: Local production and export

Several government officials pointed out that the priorities of local production and export are very high. Backgrounds underlying it include the Indonesian government's desire to generate local employment opportunities, to strengthen the local pharmaceutical industry as a defense industry, to raise it as a future export industry and to reduce ongoing current account deficits. While the government is anxious to increase export, it has structural trade deficits for pharmaceutical products.

Therefore, several government officials pointed out that any companies that create local job opportunities, build local production facilities and export their products are important to Indonesia and that the government likely continues to support those companies. Especially, the importance of local production from active pharmaceutical ingredients (APIs) to final products were stressed. Currently, APIs are imported from China and other countries and then processed in Indonesia. Therefore, the government

likely supports any firm that manufactures, not just processes, APIs, according to several government officials.

Discussion. According to this finding, both of local production and export by Japanese pharmaceutical companies are located in the intersection of the three circles as depicted in Figure 1. Moreover, cooperation offers from Japanese companies for increasing the quality of manufacturing medicine can also be located in the intersection of the three circles if it contributes to local production (especially, local APIs production) and export as well. In fact, our impression is that companies that have local production facilities and are active in increasing export may be advantageous.

On the other hand, firms that do not have local production facilities are presumably subject to strict application of foreign-owned enterprises restriction or the so-called "five-year rule" (a regulation of the completion of technology transfer from foreign-owned pharmaceutical manufacturers and the beginning of local production in 5 years) and thus become disadvantageous. Therefore, such companies are necessary to take another approach to contribute to local unmet needs and capacity building.

(3) Issue 3: Proper use of medicines

Several government officials stressed the importance of sharing the information about proper use of medicines. They pointed out that it is important to recognize at field level that proper use of medicines is essential to ensure the safe and effective use of medicines. Also, they emphasized that to do so, appropriate medication teaching is necessary. Accordingly, human resource development in this area is one of the capacity building of highest priority.

Discussion. A key to the Japanese government, industry and firms is how to contribute to this unmet need or capacity building regarding proper use of medicines. Although the development of human resources for proper use of medicine may not increase firms' sales immediately, they can lead to firms' products disease awareness in the medium and long run. Moreover, if those developed human resources gather the correct information about the quality of medicines and feed relevant claim information back from field levels, then the Indonesian government or the regulatory authorities may take more active measure to solve the issue.

(4) Issue 4: Regulations for foreign-owned enterprises on physical distributions

Capacity building in physical distributions used to be a high-priority issue. However,

several government officials pointed out that regarding ordinary physical distributions, necessary capacity building has already been completed by foreign-owned enterprises and local Indonesian enterprises.

On the other hand, several government officials pointed out that regarding special physical distributions such as those to remote islands or requiring certain temperature controls, further capacity building of low-cost and safe distributions is needed. That is, strong unmet needs still exist in this particular area.

Discussion. Based on these findings, it is reasonable that the Indonesian government has been tightening the regulations for foreign-owned enterprises on ordinary physical distributions. On the other hand, special distributions that is beyond ordinary distributions such as those for remote islands or requiring temperature controls are located in the intersection of high-priority unmet needs and high-priority capacity building as illustrated in Figure 1. Hence, here exist substantial business opportunities for Japanese companies.

(5) Issue 5: Halal certification

We investigated the current status and future prospects of Halal certification in Indonesia from multiple sources by asking those from the Ministry of Health and Badan POM and Prof. Thabrany from Universities Indonesia at interviews. All the answers at the interviews taken together, it is expected that in general, the Indonesian government strictly applies the Halal law to non-Halal products unless strong medical needs exist *and* no alternatives are available.

On the other hand, many Indonesian interviewees pointed out that in Indonesia, certain tolerance exists to consider both of the two aspects of religious reason and medical needs. Accordingly, some pointed out that if strong medical needs exist *and* no alternative are available, then the Halal law application becomes rather generous, although it depends also on the firm's bargaining power to regulatory authorities.

Discussion. Any Japanese manufacturer should have careful bargaining power that is sufficient to successfully account for the circumstance of strong medical needs and no available alternatives and convince regulatory authorities if he chooses not to have Halal certification on his product due to cost or technological considerations. On the other hand, once a Halal product becomes available at a low cost by a rival firm (especially, a local manufacturer), then the Halal law is highly likely strictly applied to the entire product category including similar products. In other words, any Halal certified

product not only differentiates itself from other similar products in the Indonesian market but is advantageous in other Islamic countries.

3) Implications for Japanese pharmaceutical companies

A main purpose of this investigation was to identify the current status of the Indonesian pharmaceutical market and business opportunities and challenges faced by Japanese companies in that market. From the findings, we derive the following five implications for Japanese companies that are applicable to other ASEAN countries in general.

First of all, Japanese firms should improve their ability to predict future trend of policies at a macro level by considering unmet social/medical/economic/ needs and capacity building from the view point of the government or regulation authorities of the country concerned. Good predictions increase their business opportunities. Note, however, that unmet needs change over time. And the same applies to capacity building. Once capacity building in one area is completed, then the priority of further capacity building in that area declines. Therefore, it is essential to carefully observe how the trends of unmet needs and capacity building change over time.

Secondly, while carefully observing the current status of high-priority unmet needs or capacity building and their possible changes, Japanese firms should plan their businesses strategically and implement them immediately. Note that those businesses should be not only feasible in the sense that necessary resources for the business is available in house but also profitable. For instance, the priority of capacity building in physical distributions used to be high. By now the capacity building in ordinary physical distributions has been completed but the priority of capacity building in special physical distributions such as those to remote islands or requiring temperature controls is still high. Other examples of areas in which further capacity building is still necessary include, for instance, local production and export (especially of APIs), human resource development and accumulation for proper use of medicines and medication teaching. With carefully observing external changes, Japanese companies should plan feasible businesses strategically and implement them immediately.

Third of all, in general, things are changing very rapidly in emerging countries. In those countries, in order not to miss constant changes, it is important to establish relationships with key opinion leaders (KOLs) by organizing within a company a unit that can commit to this task only. KOLs with whom to establish relationships include not only medical personnel but those from the government and academia that are engaged in designing health care systems or policies in the country concerned. In order

to let it concentrate on establishing such relationship and not get involved too much in management and other tasks, the unit should commit to this task only as much as it can.

The fourth implication is the importance of strategic use of capacities that have already been built both inside and outside companies. A company with own production facilities or own physical distribution networks is able to start a business such as OEM or contract business by using those resources. Moreover, resources outside companies including those having come to Japan under Economic Partnership Agreements are also important and should be used strategically.

Lastly, in order to adjust external environmental changes, information sharing that are mutual, continuous, active, multilayered and across organizations is essential. Especially, mutual information sharing such as obtaining information one wants to know by giving information the opponent wants to know is important. In fact, we were asked several times about the status of the Japanese pharmaceutical market at interviews during the field study in Jakarta. We were then able to obtain information we want to know by telling the interviewees what we knew. Also, we have recognized through the interviews the importance of information sharing that are continuous (not transient), active (not passive), multi-layered (having a relationship to not only medical personnel but those engaged in designing health care systems or policies) and across organizations (e.g., across ministries and/or regulatory authorities).

5. Future tasks

This time, an investigation of the Indonesian health care and pharmaceutical market was conducted by the Health Care Science Institute. As future tasks, continuous and multi-layered investigations by the Institute and other institutions are necessary. Moreover, such investigations can be conducted in other ASEAN countries as well. Doing so allows us to have truly continuous, multifaceted and multilayered investigations.

Table 1

Pre-hearing survey	Ministry of Health, Labor and Welfare, Japan Pharmaceutical Manufacturers Association, Japanese pharmaceutical firms operating in Indonesia, Ichikawa Pharma Consulting Office
Field survey（April, 2016）	－Indonesia government sectors ・Ministry of Health, National Agency of Drug and Food Control (Badan POM) －Indonesian pharmaceutical industry association ・IPMG (International Pharmaceutical Manufacturer Group) ・GPFI (Gabungan Perusahaan Farmasi Indonesia) －Embassy of Japan in Jakarta, JETRO Jakarta －Japanese pharmaceutical firms operating in Indonesia
Seminar in Tokyo	Prof. Hasbullah Thabrany (Chair, Centre for Health Economics and Policy Studies, Universities Indonesia)

Figure 1

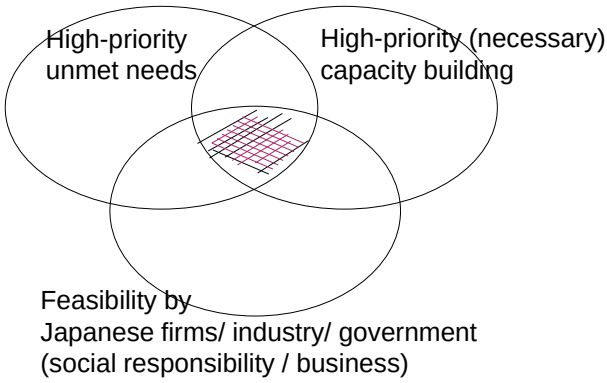

Figure 2