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Research Article

Qualitative Study on the Drug Availability for National Health Insurance (JKN) in Hypertensive Patients: the Perspective of the Tender Winner Manufacturer

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Abstract: Drug availability is a crucial part of patients healing, especially for chronic patient such as hypertension patients. Studies in the area of drug supply for JKN patients with hypertension was lacking. The objective of this study were to explore the causes of drug shortage through the perspective of the drug production and the hospital's realization process of Drug Needs Plan (RKO). We interviewed respondents from 7 manufacturers the winner of JKN drug tender, consisted of 2 government pharmaceutical manufacturers (BUMN), 2 international pharmaceutical manufacturers and the last 3 national private manufacturers. The involved informant were those who directly deal with the production process of JKN drug hypertension. The result of this research data collection was processed in content analysis.Result shown that the process between JKN drug and non-JKN drug production were similar. If the raw and the packaging materials were readily available, the manufacturer takes a month to produce the drug, otherwise the manufacturer takes three up to six months. The manufacturing process were done together in one production time. Before starting to produce drug, the manufacturer must collected several order form hospitals to fulfill one production time. The driving factors of JKN drug production were production of the same type of drug in one production time and high quantity of drug to be produced (high demand). The hurdle of JKN drug production short period between the number of production quantity and the production process, procurement beyond e-purchasing system, instability of foreign exchange rate, 2 years expired date regulation and availability of raw materials.In conclusion, according to respondents the quality of JKN and non-JKN drug were similar, there was no differences in the production process. The duration of production times depends on the raw materials availability in manufacturer was the major problem caused drug shortage in the hospital. The current process of selecting the tender winner manufacturer needs to be transformed into *multiple criteria decision analysis (*MCDA) and multi-winner supply system to guarantee the availability of drug.

Keywords: drug availability, hypertension, tender winner manufacturer.

INTRODUCTION

Since 2014, National Health Insurance (JKN) program has given huge benefits for people. During its four years, there have been so much benefit, JKN has given and several turbulance, JKN had to face included the drug supply problem for JKN patients. The drug supply is an important factor in the successful of therapy especially for patients with chronic diseases. JKN program, guarantees its patients to receive comprehensive health services from diagnostic, physical examination, until they receive prescribed medication (Kesehatan, 2014). The presidential regulation number 12 of 2013 about health insurance assigned that drug service and the patients' consumable medical suppies are guided by the list that was assigned by the minister (Manusia, 2013). This regulation obliges the health service provider to provide drug and consumable medical supply based on the applicable regulation.

In the context of drug supply chain, drug delivery starts from the manufacturer, distributors, and hospitals to the patients. In order to a good distribution systems, it involves the flow of capital, information and

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the drug product interaction. The manufacturer select supplier in regards to a predetermined criteria, along with produces and distributes drug to hospital through distributor. At the end of the supply chain, hospital will give the prescribed drug to the patient (Lu, 2011, Kritchanchai, 2012, Rachmania and Basri, 2013, Shou, 2013).

In JKN program, Government appointed the pharmaceutical manufacturer, thus the availability of drug in a hospital depends on supply from the particular manufacturer. The role of distributor only to distribute the drug from the manufacturer. In case of the manufacturer were having out of stock, at the end there will be a drug shortages in the hospital level. The drug shortages, will have immediate impact on drug resistance (Gu *et al.*,., 2011, Griffith *et al.*,., 2012).

An open tender system was employed by the Ministry of health (Kemenkes, 2014). Factors contribute to the winning of tender relies on the lowest price and high production capacity. This system needs to be fixed, considering all aspect which assure the availability. The Multiple Criteria Decision Analysis (MCDA) system has been developed to guarantee transparency, justice and the stakeholders involvement. This system can be used to make decision in the tender process that will be conducted (Drake *et al.*,., 2017).

Some factors that cause drug shortages in hospital can be explored through understanding on supply chain system. Those factors may arise from the manufacturer, distribution process and hospital. The causative factors arise from the manufacturer, i.e. including raw materials supply, modification of drug formula, production decision, manufacturer consolidation, manufacturer quality, production problem, globalization, reduction of employee, limitation of production capacity and disobedient. The causative factors that arise from distributor channel, including number of stocks; distribution, allocation, and quota limitation; challenge in transportation. The causative factors that arise from hospital, including supply-demand imbalance, drug selection, irrational use of drug; information, service and inventory system; and communication (Fox *et al.*,., 2009, Gu *et al.*,., 2011, Ventola, 2011, Griffith *et al.*,., 2012, Wangu and Osuga, 2014, Bogaert *et al.*,., 2015, Weerdt *et al.*,., 2015, Awad *et al.*,., 2016). .

To our knowledge, studies with regard in the area of drug supply for JKN hypertension patient was insufficient. Consequently, stake holder were facing difficulties to find evidence based solution to solve the problem of drug shortages. Thus, it is necessary to study the causes of drug shortages, through the perspective of drug tender winner manufacturer. The objective of the study was to elaborate the process of JKN drug production, production time, hospital realization process of Drug Needs Plan (RKO) and explore the driving and and obstacle factors of drug production.

METHODOLOGY

This study employed a qualitative design involving seven from sixteen winner drug manufactories of JKN hypertension drug tender. The respondents were employee of the pharmaceutical manufacturer whose directly related to the process of production. We asked how manufactories produce drug JKN, making coordinate with distribution and time to produce drug. The result of the deep interview presented in qualitative analysis was performed.

RESULT AND DISCUSSION

The result of the data collection showed that, prior to follow the tender process, the manufacturers did not have stock of drugs, even only a small number of stock. When raw materials and packaging were readily available, the production process will be finished in a shortest duration, i.e. 1 month. Otherwise, it will be finished in the duration of 3-6 months, due to waiting time for arrival of materials. In the beginning of the procurement year, the manufacturer took longer period of production due to stock in-availability. This statement is reinforced by the informant in the interview quote :

"Bisoprolol raw material takes 6 months from Germany. The filler and binder material take around 2-3 months" (P4).

"At least, it takes 3 months to the get raw materials and produce the e-purchasing order drug. Shipment of goods all over Java takes 3 days by land transportation" (P3).

" because the raw materials are imported, the process from ordering up to producing takes 3 months. For a new product, we got a little difficult to produce. For general description, it takes 3 months to produce the drug" (P3).

The consequences of this situatiion is the drug will be unavailable when the beginning of tender is announced. In these period, when there was a scenario a hospital were running out of stock of hypertension drug, the patients must wait the drug to be available or purchase drug from private pharmacy. The ministry of health are proposed to change the method of determining JKN drug tender winner, by doing Multi-winner and Multiple Decision Analysis (MCDA) (Drake *et al.*,., 2017). The *multi-winner* method will give guarantee that the manufacturer no need to be worried if they do not win since if they do not win the 1st order, they will be able to win the 2nd or 3rd order. The MCDA system gives assurance that the tender winner is not only the manufacturer with the lowest price but also the manufacturer with commitment to provide drug according to RKO. All aspects that assure

the drug availability, should be added to MCDA system for determining the tender winner manufacturer.

Production of drug was similar for JKN and non-JKN drugs. Both production process, utilize the same raw material, packaging, procedure, factory's room, quality control, quality assurance, machine and human resources. Only packaging were different for branded versus generic drug. In the last two years, Indonesia National Agency of Drug and Food Control (NADFC) required not to differentiate raw materials for generic and branded drug. Quality control was done in every step, to assure the quality of drug. Referring to interview from respondents, the quality of manufacturer produced JKN drug in adherence to the Good Manufacturing Process (CPOB), as it was reinforced by the respondents in the following interview quote:

"The production must be the same, same raw materials, same machine, same marketing authorization number, same human resources" (P5 and P6).

"There is no differences in materials, procedure, equipments and human resources. We are just different in sales price, even the marketing authorization numbers are same. We apply either release testing or not on them" (P4).

This situation is important because the enactment of selling price restriction in Self Estimated Price (HPS), makes JKN drug quality become challenging. The evidence showed the manufacturer guarantees that the drug they produce is always in accordance with the required standard and BPOM regulated the assurance of similarity of the quality of JKN and non-JKN drug (Makanan, 2012b). Distribution process takes 1-3 days, depends on the quantity of the required drug (Makanan, 2012a). If we calculate the 1 month production duration, plus at least 1 week shipping time to the distributor so it can be stated that drug supply for hospital takes at least 5 weeks to reach the central distributor.

A pharmaceutical manufacturer serves the hospitals, based on their demand which they request as needed. The pharmaceutical will collect the demand from various hospitals based on date of the demand then the production process soon to be started as the production quota have been reached. This production conduct might extend the production time. However, this conduct can be resolved by adding delivery plan variable when the hosipitals send RKO. This statement was reinforced by the informant in the interview quote :

"From the supply chain, we can get information about the amount of drug and the decided time. Sometimes the number of order is high while the raw materials is not available and our production capacity was calculated" (P2).

"If the stock of regular product is available, we can switch it for JKN product. There is no problem in drug delivery to a nearby region, but delivering drug to Maluku may spend 1 month, especially for delivery to remote cities" (P5).

The number of requested drug by government hospital for 3 months and uses APBD for the payment is an appeal for distributor. Because the large quantity and assurance of payment. These facts make distributor is inclined to choose hospitals with bigger order not only because the shipping cost will be more thrifty but also the administration process will be easier. Either the order quantity is small or large, it will take administrative file that is not much different. For this reason, the large quantity of order is more interesting to distributor. Seeing this all, then it is certain that the availability of JKN patient drug in government hospital is fulfilled.

Driving factors of JKN drug production were similarities of product and huge demand of drug to be produced. Whereas the obstacle factors will be faced by a manufacturer only produce drug for JKN; majorities of respondents implied the short duration from the announcement of tender winner to the production time. Other obstacles factors were purchasing out of e-purchasing systems, dollar value fluctuation, 2 years expired date regulation and supply of raw materials. This statement was reinforced by the informant in the interview quote :

"If the regular product is still available, we can divert the regular product for JKN product" (P5).

"Because the production quantity is huge, then the factory capacity will be used in a large amount, then fixed cost will be reduced" (P7).

"We are planning to build special line production, there will be special planning, it can be more efficient and no need to restore every time the batch is changed" (P6).

"The ability of private hospitals to buy in e-purchasing will threaten the drug taking from regular product, so that we have to follow that" (P2).

"The obstacle is the announcement of tender winner is too close to the showtimes" (P3).

According to the manufacturer, they will wait the tender winner announcement first, then produce the drug. The large quantities of demand push the manufacturer to join the tender since the manufacturer will be able to make every section of production efficient. Manufacturer will produce JKN drugs that is needed in big amount at the same time. The used time and equipment efficiency will stimulate the manufacturer to produce drug. The big amount of

demand needs big raw and packaging materials as well, and this fact can be used by manufacturer side for making offer to raw materials supplier so they can get bigger discount. (Kemenkes, 2014).

Manufacturer needs 1-3 months to produce drug and 2 weeks to distribute it to hospitals. Regulation about interval between tender winner announcement and deadline has been established which is 3 months, however the reality is the interval between tender winner announcement and the deadline is not more than 1 month. It needs commitment from The Ministry of Health to obey the set regulation. The tender winner information that is too close to deadline does not give enough time to the manufacturer to do production process (Ketikidis *et al.*,., 2010).

The dollar's high value will hamper the process of e-purchasing. The dollar fluctuation will affect production, due to 80% of drug's raw matrial have to be imported and it needs dollar. The rising of dollar exchange rate lead to manufacturer's inability in purchasing raw materials as planned in the early of tender. The effect is manufacturer can not produce madicine or just produce a little drug so they seem have fulfilled RKO. This problem can be solved by multi-winner system which the tender winner is not only one manufacturer with low HPS, but also there are several manufacturer with various HPS. The selection of those manufacturer using MCDA system which all aspects that guarantee the drug supply is considered in determining the tender winner manufacturer (Drake *et al.*,., 2017).

Drug's expired date that required for JKN drug which is at least 2 years, may threat the drug supply (Kemenkes, 2014). If the drug is included in fast moving goods, so the expired date is no need to be worried since the drug will be up but for slow moving drug, the expired date has to be considered. Generally, Hospital knows which drug that is fast or slow moving drug so that, 2 years expired date regulation does not have to be worried.

CONCLUSION

The manufacturer will need at least 1 month to produce drug but if it is not, the manufacturer will need 3-6 month. A pharmaceutical manufacturer accepts hospital's order, based on its demand that it sent as needed. Driving factors of drug availability from manufacturer side are similar product and big number of drug demands. The obstacle factors according to the manufacturer are manufacturer's ability to produce JKN drug only, too close tender winner information, out of e-purchasing purchase, high dollar value, 2 years expired date regulation and the raw materials supply.

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