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Good transportation practice to support good quality drugs for patient safety

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Abstract. In year 2012, Indonesian Food and Drugs Authority (BPOM) has issued the Regulation of BPOM No.HK03.1.34.11.12.7542 regarding the Technical Guidance of Good Distribution Practice (GDP). However the formal implementation only started this year by obliging all pharmaceutical distributors to be certified. GDP will maintain good quality drugs, which in the end good for patient safety. GDP needs transportation, and therefore Good Transportation Practice (GTP) become important. The aim of this research was to discuss the importance of GTP and how to manage it in order to keep good quality drugs. This research was a descriptive analysitical research with qualitative approach. It discussed the importance of good transportation practice not only as part of good distribution practice but also because it is needed. Data used in this research was secondary data obtained from literature review. Result and analysis showed that transportation of drugs shall need much more attention in order to keep the good quality drugs for patients safety. As conclusion not only pharmaceutical distributors needed certification, pharmaceutical transporter also needed certification.

Keywords: GDP, GTP, CDOB, Cara Transportasi Obat yang Baik

1. Introduction

1.1 Background

One of the role of pharmacists in drug dispensing as part of pharmaceutical care is to avoid medication error. Medication error is an error or failure in treatment process using drugs as medicine that may lead to harm to the patient. There were many causes that can lead to medication error. It can even start from the process of manufacturing the drugs, wrong formulation, wrong strength, contaminants, wrong packaging, until the process of prescribing the drugs, i.e. the incorrect medicine, incorrect dosage, irrational drugs, inappropriate drugs, underprescribing, overprescribing; dispensing of the drugs to the patient, i.e. wrong drugs, wrong formulation, wrong labelling; and administering the drugs by the patient, i.e. wrong route, wrong duration, wrong dose, wrong frequencies [1].

Besides those process, based on trading system applicable almost in every country, manufacturer cannot directly sell to end user. There were a supply chain procedure, whereby the manufacturer sold their products to distributor, the distributor sold the products to sub-distributor or wholesaler, and the sub-distributor or the wholesaler then sold the products to the retailer or drug store or pharmaceutical installation in hospital or pharmacy (in case of drugs) then finally the retailer or drug store or pharmaceutical installation in hospital or pharmacy sold them to the customer or patient as end-user [2] [3]. It is not only during the manufacturing process, or prescribing, or dispensing and administering the drugs medication error can happen. Medication error can also happen during the process of distribution of the drugs [4]. This meant that distribution also played an important role in supply chain of drugs.

The importance of distribution was not only because distribution was the next step of manufacturing before the drugs reached the patient; distribution was needed in order to keep the quality of the drugs, so that the drugs

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remained safe and had the same efficacy when the drugs were consumed by the patient. Distribution was also required to delivered the drugs on time for patient. Without time punctuality, patients may not be well treated [5]. This was why pharmaceutical management needs good distribution practices. One among several mechanism that make good distribution practices is the transportation. However transportation itself became important not only because of distribution system and activities as mentioned above, but transportation took place because there was a need to transfer drugs from one place to another different place, and the drugs shall reach the patients at a given time so that the drugs can be used for the benefit of the patients.

The importance of good distribution practices in Indonesia has just been recently enforced, even though the regulation of good distribution practices had existed since 2012. The regulation was issued by Indonesian Food and Drugs Authority (BPOM) under No.HK03.1.34.11.12.7542 regarding the Technical Guidance of Good Distribution Practice (GDP) (Pedoman Teknis Cara Distribusi Obat yang Baik) (PBPOMGDP) [6]. For the purpose of the enforcement of PBPOMGDP, in 2017 BPOM has issued another regulation. i.e. BPOM Regulation No.25 Year 2017 regarding the Procedures to Certify Good Distribution Practices (Tata Cara Sertifikasi Distribusi Obat yang Baik) (PBPOM25/17) [7].

1.2 Objective

The objective of this research was to find out and discuss the importance of good transportation practices in pharmaceutical supply chain management in order to keep good quality drugs.

2. Study references

2.1. Distribution management

Distribution is part of marketing mix. Distribution play the same important role with the products, promotions and pricing strategies. Distribution made the products reached the customer/ end user. Distribution helped customer to purchase a specific products from time to time and assisted the manufacturer to supply its product to the customer. Distribution process played an important role in moving the products from manufacturer to customer [9]. Along with the development in human needs, distribution became not only a mechanism to transfer products but also how to locate products accordingly with respect to type, volume, space, time to achieve the satisfaction of efficient demand that the products will be delivered according to the needs and requirements of the manufacturer and customer. Distribution was a channel for manufacturer, which became a route from which finished products go through intermediaries, known as distributors, sub-distributors, wholesalers, and retailers to reach the customer/ end user. The channel may involve movement of products from one place to another place or may be, in a specific condition, simply involving the transfer of title of the products without any movement at all [10].

In general, distribution channel involved the physical movement of products; transfer of ownership from manufacturer to distributor, from distributor to sub-distributor, from sub-distributor to whosaler, from wholesaler to retailer and principle to all enterprises that involved and participate in the channel; the flow of information with respect to the products, buyers and demand; promotion; payment; negotiation; order realization; and shipping, transportation and storage of the products. Through the distribution channel there was a possibility that the manufacturer did not have control anymore over the distributed products, because the distribution channel of the products was managed by an independent distribution company as intermediary. The width of a distribution channel will depend on the characteristics of the products, the availability of the products, competition, and customer's behaviour associated with the products. There may also a partition of the distribution channel depend on the type of the participants in the channels [11].

From the above explanation, we understand that there were manufacturers that totally submit the selling of their products in the hand of distribution companies. This meant that these manufacturers depended their sales income on the performances of the distribution companies. For these purposes, the manufacturers were required to transfer their knowledge of the products to the distribution companies. The distribution companies in the other hands required to absorb, acquire and then use the information obtained from the manufacturers to improve their services which at the end resulted in the increase of sales and profit of the manufacturers. Both manufacturers and distribution companies will benefit from the relationship [12]. To keep the products as they came from the manufacturers, the distribution companies required to do the same thing as the manufacturers did.

2.2. Management of transportation

As mentioned above, in general, distribution of products from manufacturers will require the physical movement of the products. This meant transportation become an important part of distribution, besides the storage of the products to be distributed. Transportation in view of financial management were another cost that must be calculated before the products can be sold in the market.

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If the distribution company that handle the transportation, either under its own name or through another third party, the transportation cost will be reflected in the fee of the distribution company that it will charge to the manufacturer. So in either way, transportation will determine the price of the products, as part of distribution channel contributed to marketing mix. In view of that management of transportation shall become important because at the end, when the products reached the customer/ end user, the products must satisfy the costumer expectation, that the products must be good, in time, cheap and with no error [13].

Transportation can took place on the land, water, air and inland waters. Each place will require different mode of transportation. There were at least 7 mode of transportation known until today. They were maritime transportation, rail transportation, air transportation, mail (courier), fixed transport installation, inland waters transportation and multimodal transportation [14] [15]. Under United Nations Economic Commission for Europe (UNECE) Codes for Types of Means of Transport, there were hundreds of modes of transportation that can be used for transportation of any kind of products elsewhere [16]. In international sales of goods, most of transportations of products were conducted by independent transportations. This meant that manufacturer and/ or distributor needed to outsource the delivery of products to "other" that may not have the same knowledge on handling the products that the manufacturer and/ or distributor had. Therefore manufacturer and/ or distributor were also required to share the information with respect to the handling of the products and made sure that this independent transporters will do as they were told or instructed. This mechanism in other hand will create cost to the independent transporters which at the end will again increase the cost of transportation for manufacturer. This was happened in Germany, europe [17].

3. Methodology

The scope of this research was to discuss about the importance of good transportation practice for pharmaceutical products in view of supply chain management in order to keep good quality drugs when the drugs reached the patients. Data used in this research were secondary data. Data were obtained through literature review. This research was a descriptive analytical research. Analysis in this research was made using qualitative approach.

4. Result and discussion

4.1 Good distribution practice

At the beginning, people only concerned on the process of manufacturing drugs and for such purposes, there existed a good manufacturing practice. However it was then people recognised that only good quality drugs that reached patients in time can provide good result in medication. The drugs must be available when they were needed, in a good quality. Supply chain management made it possible [3]. Supply chain management process was a complex process. It started from international level, where private and public sector imported drugs from multinational enterprises. It can also begin from national manufacturers that purchase the active ingredients from international suppliers. The importers and national manufacturers will then sell the drugs all over the territory of the nation, which involved a local distribution company that had enough networking to supply to all private pharmacies, hospitals, government institutions that dealt with selling drugs to community, either through healthcare professionals such as physicians or directly to the drug stores [18]. So actually in each and every process as mentioned above, there was a process of distributing drugs in a wider sense. Distribution was not the only function that was taken care by a wholesale distribution company only. Distribution was a process of distributing products, i.e. drugs from manufacturers to end users, i.e. the patients.

Under WHO good distribution practice for pharmaceutical products (WHOGDP), there were seventeen items that must be taken into attention for the implementation of good distribution practice. They were organization and management, personnel, quality system, premises, warehousing and storage, vehicles and equipment, shipment containers and container labelling, dispatch and receipt, transportation and products in transit, documentation, repackaging and relabeling, complaints, recalls, returned products, counterfeit pharmaceutical products, importation, contract activities and self-inspection [6]. The good distribution practice itself was defined as a part of quality assurance which ensure that drugs and pharmaceutical products are consistently stored, transported and handled under suitable conditions as required by the marketing authorization or product specification [6] [19]. Discussion for the need of good distribution Practice has been conducted many times by WHO, since the first draft prepared for comment in 2004 [20]. It was then continued in 2009 [21], which resulted in form of WHOGDP in 2010 [6].

Besides WHO, European Commission (EC) in 2013 also introduced Guidelines on Good Distribution Practice of

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medicinal products for human use based on Article 84 and Article 85.b.(3) of Directive 2001/83/EC (EC Guidelines). The EC Guidelines laid down appropriate tools to assist wholesale distributor not only in doing their activities but also to protect falsified medicine from entering legal supply chain. There were at least 9 items that wholesale distributor must have. They were quality management, personnel, premises and equipment, documentation, operations, complaints, returns, suspected falsified medicinal products and medicinal product recalls, outsourced activities, self-inspections, transportation and specific provision for brookers [22].

Health Products Regulatory Authority (HPRA) of Ireland in 2017 has also issued Guide to Good Distribution Practice of Medicinal Products for Human Use. The Guideline provided necessary components for wholesalers to comply with, which comprised of quality management, personnel, premises and equipment, documentation, operations, complaints, returns, suspected falsified medicinal products, medicinal products recalls, outsourced activities, self-inspections, transportation and brokers [23]. Health Science Authority of Singapore in august 2015 issued Guidance Notes on Distribution Practice. The Guidance provided requirements of personnel, premises and equipment, stock handling, stock control and deliveries, product complaints, product recall, returned products, counterfeit products, self-inspection, contract activities, handling of active pharmaceutical ingredient or intermediates [24]. Organisation of Pharmaceutical Producers of India (OPPI) made Guidelines on Good Distribution Practices for Pharmaceuticals Products in 2013. The Guidelines provided requirements of organisation and management, personnel, quality system, premises, warehousing and storage, temperature, environment, and storage control, transportation, shipment containers and labeling, dispatch and receipt, documentations, complaints, recalls and returns, spurious pharmaceutical products, importation, contract activities and self-inspection [25]. Indonesia has also incorporated the importance of transportation in PBPOMGDP in chapter vii [7].

4.2The need of good transportation practice

Those guidelines of good distribution practice made transportation as one of the important elements or requirements. However as explained before, the function of transportation can be independent from the function of distribution, considering the place to where the distributed products, in this case drugs, will be delivered. Especially in international transaction, which may include export-import of drugs across nations and across ocean, many modes of transportation will be required. These meant an independent transporter may be required by distribution company.

To accommodate the so important of transportation, NHS in 2015 issued Clinical Transport of Medicines SOP. The SOP included the transport within hospitals, transport of medicines between health services premises, transport of medicines from the pharmacy department by authorised transport, transportation by taxis, transport of medicines by Designated Community Practitioners is covered in the Standard Operating Procedure for community based practitioners and transport of Controlled Drugs - Returning controlled drugs to the pharmacy [26]. Even WHO has provided model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products [27]. Canadian Health Products and Food Branch Inspectorate has also made Guidelines for Temperature Control of Drug Products during Storage and Transportation [28].

Several considerations that were discussed of what may happen during transportation (and storage) and distribution of drugs, were products mixed-up, deterioration of the quality of the drugs, discoloration of formulation, microbial contamination, label mutilation, loss of drugs integrity and abnormal delay that may effect the quality of the drugs [29]. Therefore as mentioned before, NHS, WHO and Canadian Health Products and Food Branch Inspectorate issued guidelines on storage temperature during transportation. This will protect not only the temperature but also humidity, vibration (shock impact), handling the unusual delay and environment conditions. This will require the validation of the drugs before dispatch, during the transportation and after receipt of the drugs. For such purpose all equipment required must be calibrated after a certain period of time. To maintain the validity of the drugs there should be an adequate training for the personnel, good documentations, good labeling and good process. The process will include the use of the best mode of transportation, the duration and transit, closure, air condition and air flow of the container as the storage facility, and the endurance and resistance of the storage and vehicle to impact [29]. All of this will need. not only good mechanics but also well-trained pharmacist. Despite the existence of pharmacist for good distribution practice, another pharmacist will be needed for good transportation practice. This is because the distribution company did not always have the transportation business attached to it. An independent transportation company that functioned as transportation company for distribution of drugs shall have and implemented good transportation practice.

Indonesia, as a thousand island country with multimodal transportation, really needed a strong transportations method in order for drugs to reach the remote areas all over Indonesia. Not all distribution companies had the capacities and capabilities to do so. Independent transporters may be required to cover several areas. For

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such purposes good transportation practice will be absolutely needed in Indonesia, in order to have good quality drugs when the drugs reached the patient on time.

5. Conclusion

The research concluded that it is time to consider the requirement to have good transportation practice. Facts showed that distribution company did not necessarily have enough transportation vehicles to cover up its distribution activities and capability to enter into specific area that drugs were certainly required. Especially in Indonesia with thousand islands. Facts also proved that there were many independent transportation companies that did deliver drugs across countries. For such purpose good transportation practice was indeed needed. Patient safety was all the reason behind it.

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