

# Quality Risk Management In Infusation Product Distribution Using Failure Mode And Effect Analysis (FMEA) And Analytical Hierarchy Process (AHP) Methods

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## **Abstract.**

*This study aims to determine the causes of product leaks so as to minimize the risks of product quality degradation. The research method used is descriptive qualitative research method, data collection techniques used are observation, interviews and documentation. The collected data is then analyzed to obtain useful information to solve a problem in research. The process of testing the validity and reliability in this study uses a triangulation process. In this study, to measure Quality Risk Management, FMEA is used as a tool to measure or identify the source or cause of a quality problem. The next method to solve problems or risks in Quality Risk Management is AHP. The results of the study can be concluded that, Quality Risk Management in the distribution of Infusion products. The risk with the highest RPN value is the risk of damaged goods in the distribution flow of releasing goods from the warehouse to the expedition of PT. BSP which causes a leak in the softbag packaging. These risks are then analyzed to find the best alternative for handling them. Determine alternative handling of Quality Risk Management in the distribution of Infusion products at PT. BSP using the AHP method. Based on calculations using Expert Choice 11 software, the priority criteria are time and handling effectiveness which has the highest pairwise comparison value is the alternative of adding product handling information labels on cardboard packaging.*

**Keywords:** *Quality risk management, Capital, Failure Mode and Effect Analysis (FMEA) , Analytical Hierarchy Process (AHP).*

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## **I. INTRODUCTION**

The Ministry of Health continues to strive to improve the competitiveness of the domestic pharmaceutical industry, one of which is by providing convenience for business actors in accessing quality and affordable local medicines through an online system or e-catalog [1]. This is in synergy with one of the goals of pharmaceutical procurement, which is to make it easier for humans to get their rights to be able to access medicines. Distribution of pharmaceutical preparations is an activity of distributing both drugs and medicinal ingredients in accordance with the requirements in order to maintain the quality of the pharmaceutical preparations that are distributed [2]. Handling of pharmaceutical products is certainly not the same as the Basics of Risk Management used in business aspects, both on aspects of finance, manufacturing, insurance, job security, public health, and pharmacovigilance by organizations that regulate these industries. The majority of risks in pharmaceutical product supply chain

operations are internal risks caused by inappropriate processes, human resources, and management functions that can be managed by an appropriate mitigation strategy [3]. To protect patients in terms of the quality, safety and effectiveness of medicines, the International Medicines Regulatory Authorities (MRAs) recommend that the pharmaceutical industry adopt a risk-based approach to maintain the life cycle of pharmaceutical products [4].

The processes included in quality risk management are Hazards (source of disaster/loss) that can affect the quality characteristics of drugs; the level of the hazard; and sub-processes of critical quality [3]. PT. BSP is a national-scale distributor of health care, consumer products and raw materials which was founded in 1994, which has forty four branches throughout Indonesia. PT. BSP is the sole distributor for drugs produced by PT. SF. In addition to producing medicines for both humans and animals, PT. SF also manufactures liquid or Infusion products. Based on information from the Infusion Promotion Team of PT. SF, Infusion product of PT. SF has better quality compared to competing products, namely international standard softbag packaging so that the packaging is not easily broken and leaks, keeps droplets constant until they run out according to the dose given, product name labels are printed directly on the packaging (not stickers) , and transparent softbag packaging so that it can be seen immediately if there is a chemical reaction. Leakage of Infusion products cannot be directly identified because each softbag package is re-wrapped by plastic so that if there is a leaking product, the liquid will be accommodated first in the plastic packaging and will only seep if the plastic packaging is also broken.

A leak will only be known if the hospital has unpacked the carton or master box to give it to the patient. Leaks can also occur due to mishandling during distribution such as when moving goods or improper storage (too stacked). The risks faced by actors in the pharmaceutical industry are internal and external risks. Internal risk occurs due to the company's processes, human resources, and management functions that can be managed with the appropriate strategy. Meanwhile, external risks are more difficult to manage and have a significant impact on the stability of the pharmaceutical product business condition. Any risk that affects the supply chain of pharmaceutical products, will not only waste resources but will also threaten the lives of patients with drug limitations. The assessment and implementation of strategies to control risks in the pharmaceutical supply chain is an essential aspect of the health care system [5]. Quality Risk Management is one of the regulations issued by The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), an organization that has the authority to regulate technical aspects of the pharmaceutical industry. ICH's mission is to achieve worldwide harmonization to ensure that the distribution of medicines is safe, effective and of high quality.

One of the regulations issued by ICH is Quality Risk Management which is included in Quality Guidelines No. 9 or also called Q9. The Quality Guidelines aim to

achieve harmonization in the quality area which is an important milestone in an organization, especially in the pharmaceutical sector. “Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.” ICH (2005). In general, the process of Quality Risk Management according to ICH (2005) is shown in the following diagram:

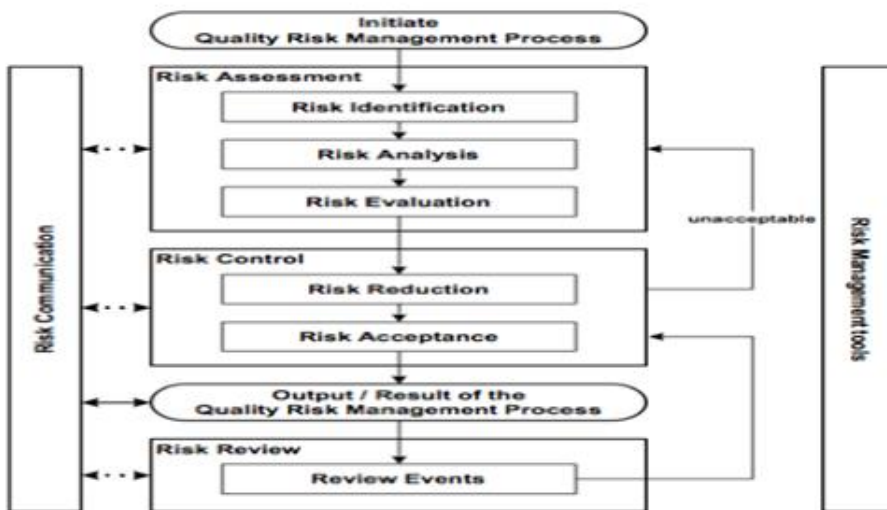


Fig 1. Quality Risk Management Process

Source: ICH Guideline (2005)

Based on the description above, it is necessary to investigate the cause of the leakage of the product so as to minimize the risks of the occurrence of poor quality products, especially in Infusion products at PT. BSP, researchers are interested in conducting research with the title "**Quality Risk Management In Infusion Product Distribution Using Failure Mode And Effect Analysis (FMEA) and Analytical Hierarchy Process (AHP) Methods**".

## II. METHODS

The research method used in this research is descriptive qualitative analysis. The sampling technique used in this research is purposive sampling, which is a technique in which the researcher determines the specific characteristics according to the research needs. Sources of data or informants in this study are the Warehouse Supervisor, the Returns Controller, the Ethical Supervisor, and the Salesman at PT. BSP Bandung branch. In this study, the data collection techniques used were observation, interviews and documentation. The process of testing the validity and reliability in this study uses a triangulation process. Based on the triangulation process that has been carried out, it can be concluded that the data from this study is valid and reliable. In this study, to measure quality risk management, researchers used FMEA as

a tool to measure or identify the source or cause of a quality problem. After getting the highest RPN value, the next step to get alternative improvements that can be done by the company is to use the AHP method.

The next method to solve problems or risks in Quality Risk Management is AHP. The steps in the AHP method according to (Limbong, et al 2020), are: 1) Defining the problem, determining the solution and compiling a hierarchy of the problems encountered; 2) Determine priority by making comparisons of pairs and representing the relative importance of elements; 3) Consider the comparison of pairs to obtain priority or synthesis; 4) Measuring consistency; 5) Calculating Consistency Index (CI) with the formula  $CI = (\lambda \max - n) / (n - 1)$ , where  $n$  is the number of elements; 6) Calculating Consistency Ratio (CR) with the formula  $CR = CI / RC$ , with  $CI$  = Consistency Index,  $RC$  = Random Consistency Index; 7) Check the consistency of the hierarchy.

### III. RESULT AND DISCUSSION

PT. BSP is a company engaged in the distribution of pharmaceutical products or also known as Pharmaceutical Wholesalers (PBF) which distributes its products to pharmacies and hospitals that have permits in accordance with the laws and regulations. PT. BSP is the sole distributor for medicinal products manufactured by PT. SF, one of which is a liquid product or Infusion. In carrying out its operations, PT. BSP is obliged to follow the regulations from the government which are contained in the good and good distribution method (CDOB) to ensure the quality of the product until it reaches the end consumers (patients) and to prevent any misuse of the distributed drugs. Pharmaceutical products or drugs must reach the patient's hands in good and safe conditions so that the contents are not damaged so that treatment is needed. Specifically, one way to maintain the quality of pharmaceutical products is to implement Quality Risk Management, a regulation issued by The International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) in 2005 which aims to provide guidelines for decision-making based on risks to mitigate risks to the quality of pharmaceutical products. Maintaining product quality does not only provide a sense of security for consumers but also to maintain the stability of the pharmaceutical product business condition.

The first stage of the Quality Risk Management process is the Risks Assessment. In this process, identify and assign values to each risk that may occur in the distribution process of Infusion products. The steps taken to determine the value or weight of each risk are: risk identification, risk analysis and risk evaluation. In carrying out risk identification, it is necessary to do in detail each business activity carried out by the company. This supports research conducted by system [6] which states that the risk event identification technique is carried out by trend analysis or historical (past) analysis and company projections in the future As the Return Controller of PT. BSP

conducts risk analysis on Infusion Product Distribution. Based on the results of risk analysis, a risk rating is carried out on the effects or impacts of a risk. For the first distribution channel, namely the receipt of goods from the factory PT. SF, the impact of damaged goods with leaky packaging has a high risk rating. According to the Warehouse Supervisor of PT. BSP, the quality of the softbag packaging also causes the packaging to leak easily. The consequences of leaking goods also have a moderate level, namely the goods cannot be sold and returned to the factory.

If one of the labels is damaged, then the information about the product can still be seen on the other side so that based on the assessment of the possibility and consequences of the damaged label getting a Low Risk risk rating. The process of analyzing risk in the distribution flow of Infusion products at PT. BSP is in accordance with research conducted by [7] which states that risk can arise anywhere and anytime, if it is not analyzed beforehand, it cannot control the existing risks and can disrupt the company's performance. The next stage in the Risk Assessment is Risk Evaluation. At this stage the results of the Risk Analysis are reviewed to determine which risks are a priority for PT. BSP in handling. Based on an interview with the Warehouse Supervisor of PT. Priority BSP is a risk that has a minimum weight of moderate probability of occurrence and a minimum weight of moderate consequence. The results of the Risk Evaluation of the Distribution Flow of Receiving Goods, the risk whose handling is a priority is the risk of leaking goods due to mishandling. This risk is a priority because of the possibility that it occurs quite often and can cause losses to the company both in terms of material and time. The existence of goods that leaked during delivery from the factory PT. Sanbe Farma can see if there are cardboard packaging that is wet due to seepage from leaking products. When there is seepage, the carton packaging will be dismantled by the Warehouse Helper for further sorting which products are leaking softbag packaging.

If the product is leaking, it will be returned to the factory. The next risk that becomes a priority is the occurrence of differences in goods between physical goods and shipping documents. The existence of human error and the limited delivery fleet caused the delivery to be carried out in stages. With the difference in goods arriving, warehouse officers must immediately conduct a search to the factory to find out the cause of the difference in goods so that the goods that arrive are in accordance with the allocation of needs to fulfill customer orders. Based on the results of the Risk Evaluation for the distribution flow of Infusion product storage at PT. BSP, the priority risk is damaged products, either leaking or crystallizing due to mishandling when stored in the warehouse. There is a leaky package because the cardboard packaging is too piled up when stored. The warehouse capacity that does not match the number of goods that arrive causes the carton packaging to be stacked to maximize storage space so that pressure occurs on the softbag packaging which causes the goods to leak. For infusion fluids that occur crystallization also needs to be given priority treatment because the product storage area is still too cold because the air conditioning in the

warehouse area is central. Both the damaged packaging and the crystallized liquid made the goods unable to be sold and had to be returned to the factory. BSP which is the first priority is the type of goods prepared that are not in accordance with customer orders.

This risk is prone to occur due to the Warehouse Helper's error factor in preparing the wrong item to take the product caused by similar packaging of goods. As a result of this risk, if it reaches the customer, the product cannot be accepted and given to the patient because the type and content is different from the product ordered or needed. The next risk given priority handling is the error in preparing the order quantity. This error can occur because the Warehouse Helper misreads the order amount on the Delivery Order slip. As a result of such errors can lead to a particular warehouse department and a loss of trust from customers. Based on the results of the Risk Evaluation of the Distribution Flow of Goods Expenditure, the risk that becomes a priority in the distribution flow of the release of goods from the warehouse to the expedition of PT. BSP is leaky goods caused by handling errors such as goods that are too slammed when moving from the warehouse to the expedition area and delivery cars and goods that are too stacked when stored in the expedition loading area and in the delivery car. If damaged goods occur in the form of leaky packaging when the customer has received it, a return process will be carried out to PT. BSP. According to information from Sales Supervisor PT. BSP, there are several customers (hospitals) that have regulations if there is only one package that leaks, then all orders that come along with the leaked goods will be returned because it is considered a production failure and for fast moving goods. In the hospital will soon be replaced with products from competitors.

The process of implementing Risk Evaluation in the distribution flow of Infusion products at PT. BSP is run by supporting research from [8] which states that "The purpose of risk evaluation is to assist in making decisions based on the results of risk analysis about which risks require treatment and priorities for treatment implementation. Decisions must take into account the wider context of risk and include consideration of the risk tolerance borne by other parties (other than the organization) that are beneficial. The next stage in Quality Risk Management is Risk Control. At this stage, the risks that have been identified, analyzed and evaluated are then measured whether these risks will be accepted or eliminated. In Quality Risk Management, there are two steps taken in Risk Control, namely Risk Reduction where acceptable risks are eliminated and risks that require acceptable handling or Risk Acceptance. In the Risk Reduction stage, the risk in the distribution flow of Infusion products at the PT. BSP that can still be handled so that the possibility of occurrence is minimal is eliminated in order to focus more on dealing with risks that are likely to occur and have an impact on the company's business processes. The risk is decided to be reduced or reduced by ensuring beforehand that the risk can be handled as long as the business process is carried out in accordance with the Standard Operation Procedure (SOP). Based on Risk

Reduction in the Warehouse Distribution Flow of PT. BSP, the reduced risk is the risk that has the weight of the possibility of a rare occurrence because if the probability of occurrence is small, it will not have an impact or consequence for the company. In the distribution flow of goods receipt from the factory PT. Sanbe Farma, the reduced risk is the risk of damaged goods in the form of information labels regarding the product being lost due to erosion.

Based on the author's observations, the label on the packaging is quite safe because each softbag package is re-coated by plastic so that if friction occurs due to the buildup of cardboard packaging, it will not directly scratch the label printed on the softbag packaging. Implementation of Risk Reduction at PT. BSP supports research conducted by [9] which states that the form of risk reduction can be in the form of reducing the possibility of a risk occurring, reducing the losses caused when the risk occurs, and reducing both. The next step in the Risk Control stage is Risk Acceptance. Risks that are assessed to have an impact on the company are accepted by the relevant sections or departments so that prevention and treatment can be carried out. The risks that have been identified, analyzed and evaluated at the Risk Assessment stage are then selected to become risks that are accepted by the company. The risk criteria that are accepted for further follow-up are selected based on the probability of occurrence and the impact on both the company and the customer. Based on Risk Acceptance in the Warehouse Distribution Flow of PT. BS, the risk that is accepted is a risk that has a risk rating of High Risk and Extreme Risk. According to the risk analysis matrix table, if the result of the risk rating is High Risk, then the risk requires attention from senior management, while for Extreme Risk, immediate action is required.

The risk that is accepted in the distribution flow of receiving goods from the PT. Sanbe Farma is the risk of damaged goods in the form of leaky softbag packaging and the difference in goods being sent from the PT. Sanbe Farma. Both of these risks have a risk rating of High Risk, which means that management's attention is required. All risks from each distribution channel received are a concern for PT. BSP, especially the warehouse department, should immediately be given continuous preventive measures so that these risks can be handled before they become problems that will harm the company materially and disrupt business processes at PT. BSP. Moreover, it can reduce customer confidence in the quality of products from PT. BSP. This supports research conducted by [10] which states that "These dominant risks must receive special attention from competent parties who are responsible for the occurrence of risks so that mitigation actions can be taken in order to reduce the negative impacts caused by the risk. ". After conducting Risk Assessment and Risk Control, the next step in Quality Risk Management in the distribution of Infusion products is Risk Review. At this stage, the results of the Risk Control are reviewed whether the risks that are eliminated or accepted are in accordance with the objectives of the company or related departments. The Risk Review aims to ensure that in the distribution flow of the Infusion product the risk that has been reduced at the Risk

Reduction stage becomes a risk that often occurs and has an impact on the company while the risk received or Risk Acceptance never occurs. The controlling party in the implementation of Quality Risk Management, namely the Warehouse Supervisor at PT. BSP is obliged to control and monitor that the handling of these risks is carried out consistently and can review if there are new risks that were not previously identified in this study. This is supported by research conducted by [11], which states that "Quality risk management must ensure that supplier risk management is an on-going activity, not one time action." The last stage in the Quality Risk Management process is Risk Communication.

Risk management can run effectively and efficiently if all parties related to the distribution of Infusion products at PT. BSP gets clear information on how to avoid and handle a risk that may occur in the company. In addition to conveying information, Risk Communication is also a process of exchanging opinions in order to identify risks and their causes from various aspects and then look for ways to handle them. Related parties who must obtain information and be asked for their opinion to handle quality risks in the distribution of Infusion products at PT. BSP is Warehouse Supervisor, Warehouse Administration, Warehouse Helper, Return Controller, Sales Supervisor, Salesman, Expedition Helper, Driver, Loper and external parties such as the Infusion Marketing Team of PT. Sanbe Farma and customers from PT. BSP. A series of communications conducted by PT. BSP supports the Guidance for Industry statement in [12] which states that "Risk communication is the sharing of information about risk and risk management between the decision makers and other stakeholders. The output/result of the quality risk management should be appropriately communicated and documented". This is confirmed by research by [6] which states that information and communication are dimensions that play a role in helping to ensure that the reports provided by the company are complete, verified, and validated. In addition, information and communication functions to assist the company in responding if there are irregularities that violate regulations. After several dimensions are implemented, the company needs to carry out monitoring, evaluation, and development so that the integrated system is in accordance with the company's goals [13].

### **3.1 Measuring Quality Risk Management on Infusion Product Distribution at PT. Bina San Prima by Using FMEA Method**

Quality Risk Management can be measured by a method and tools to get accurate risk measurement results. Based on the Quality Risk Management Guideline issued by ICH, the methods that can be used to measure Quality Risk Management are Basic Risk Management Facilitation Methods, FMEA, Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP), Preliminary Hazard Analysis (PHA), Risk Ranking and Filtering and Supporting Statistical Tools. In this study the authors chose to use the FMEA method. Steps in FMEA such as process review, brainstorming and making a list of the impact of each error (severity)



have been carried out at the Risk Assessment stage. Furthermore, the data needed for the FMEA method is to identify the level of probability and the level of possible detection of a risk (detection). The next step is to assign a value on a scale of 1-10 for each severity, occurrence and detection so that the Risk Priority Number (RPN) value can be obtained by multiplying the severity, occurrence and detection values ( $S \times O \times D$ ). The FMEA method uses the results of the Risk Control so that the RPN that is calculated is only the accepted risk by adding data regarding the risk management controls that have been carried out to get the value from the detection. Based on the FMEA Process in the Warehouse Distribution Flow of PT. BSP, the highest RPN value is the risk of damaged goods in the distribution flow of goods release from the warehouse to the expedition with a total value of 160.

These results are obtained from the multiplication of the severity value for the occurrence of leaky packaging of 4 points or Minor based on the description has criteria for production flow or process the company's business is quite disrupted and causes time losses of more than one hour to 3 hours, financial losses of more than 3% to 5% and disappointment from customers. With the leaked goods that reach the customer, the leaked goods will be returned with a process in the warehouse for 1 to 3 hours starting from receiving the leaked goods from Sales, checking the batch number on the goods with the original sales invoice and if it is appropriate it will entered into the system to issue a return invoice. The existence of leaked and returned goods also reduces sales achievement and leads to disappointment from customers because the goods ordered cannot be given to customers. Furthermore, the occurrence value is 5 points or possible failure rates from 1 to 400 with a description of the possibility of stacked goods and other handling errors being moderate or generally related to previous processes which sometimes fail but not in large numbers. Then for the detection value of the risk of damaged goods in the distribution flow of releasing goods to the expedition, it gets a value of 8 points where the possibility of detecting the risk is in the form of checking the carton packaging whether there is liquid seeping or not, there is very little chance that the detection description does not prevent the risk but detects 50 % after the risk occurs [14].

The next highest RPN value is the risk of damaged goods in the form of leaky softbag packaging in the distribution channel for receiving goods from the factory by 90 points. For the highest RPN value in the third place is the risk of damaged goods in the form of leaking softbag packaging in the distribution flow of goods storage in the warehouse by 64 points. The difference in the RPN value for the same type of risk is caused by the detection value which has a fairly high difference. The detection value for damaged goods in the form of leaky softbag packaging in the distribution channel for receiving goods from the factory is 6 points or low because even though there are goods that leak in one carton package, the liquid does not immediately seep in the carton packaging because each softbag is re-wrapped with plastic packaging so that the liquid leaks will be accommodated in the plastic. Furthermore, the detection value for

the risk of damaged goods in the form of leaky softbag packaging in the distribution channel for storing goods in the warehouse gets a value of 4 points or high enough which is described as having a great opportunity to detect the risk before it occurs.

When the carton packaging of goods is stored in the warehouse, if there is an order from a customer with a soft bag unit, the carton packaging will be dismantled and it can be immediately identified if there are leaked goods [15]. The risk of the highest RPN value in the FMEA method is the same as the result of the Risk Analysis, namely the risk of damaged goods in the form of leaking packaging in the distribution flow for releasing goods from the warehouse to the expedition department of PT. Bina San Prima with the results of the Extreme Risk risk rating. Based on the results of the FMEA calculation and Risk Analysis, it was agreed that from the risk of damaged goods in the distribution flow of releasing goods from the warehouse to the expedition of PT. BSP will determine the most appropriate risk handler using the Analytical Hierarchy Process (AHP) method. This supports the research conducted by which states that after knowing the potential effects of failure, potential cause of failure, and detection or current control of each priority risk, the next step is to determine the mitigation strategy. Mitigation strategies are determined to address risks in accordance with the priority risks obtained from each risk factor [16].

### **3.2 Determining Alternative Handling Quality Risk Management in the Distribution of Infusion Products at PT. BSP Using the AHP Method**

The AHP method is used in various studies to solve a problem by creating a hierarchical structure consisting of the goals of the problem to be solved or the next goals to determine what criteria to solve the problem and the last is to determine alternatives that can be used to solve the problem [17]. In this study, the purpose of the problem to be solved is to reduce the risk of leakage of softbag packaging during the process of releasing goods from the warehouse to the PT.BSP expedition so that customers get goods with good quality. Furthermore, to determine the repair criteria in solving the problem of the risk of leaking goods. The criteria for time effectiveness are intended so that in dealing with the risk of damaged goods in the form of leaky softbag packaging, it does not take a lot of time so that the distribution of Infusion products to customers is delayed. Furthermore, for the cost effectiveness criteria, it is hoped that the handling of the risk of damaged goods will not increase the company's operational expenses or reduce sales of Infusion products and the last criterion, namely the effectiveness of the workforce, is intended so that risk handling does not involve a lot of labor so that other work can still be carried out and does not have an impact on adding company operating costs [18].

The next step is to determine alternative options to deal with the risk of leaking Infusion packaging. Based on the results of interviews with alternative sources that can be used is to sort goods by unpacking all carton packaging, both those that have just arrived from the factory or those that have been stored in the warehouse. The next alternative is to add information about the handling of goods on cardboard packaging,

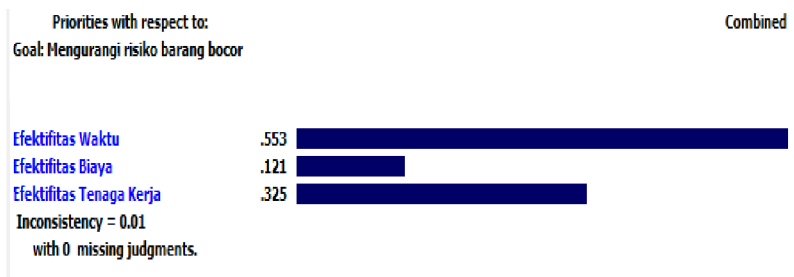
namely information on maximum accumulation, warnings not to slam goods, correct position for storing goods and provisions for storage room temperature [19]. The carton packaging of Infusion products currently does not include this information, which causes frequent mishandling of goods which causes the goods to be damaged. The softbag packaging used is considered to have poor quality, namely packaging that is not elastic or rigid so that if it gets pressure it will leak [20]. Cardboard packaging is also considered too thin so that it cannot withstand piles or impacts that can affect the condition of the softbag packaging inside the carton. The alternative to this problem is to replace softbag and cardboard packaging with better quality. The last alternative is to control orders from customers so that they match the needs and storage capacity in the customer's warehouse to avoid stockpiling of goods [21]. Based on the objectives, criteria and alternatives mentioned above, the hierarchical scheme of handling leaked goods to the release of goods from the warehouse to the expedition of PT. BSP is as follows:



**Fig 2.** Skema Hierarki Risiko Barang Bocor

*Source : PT. BSP, 2020 (data reprocessed)*

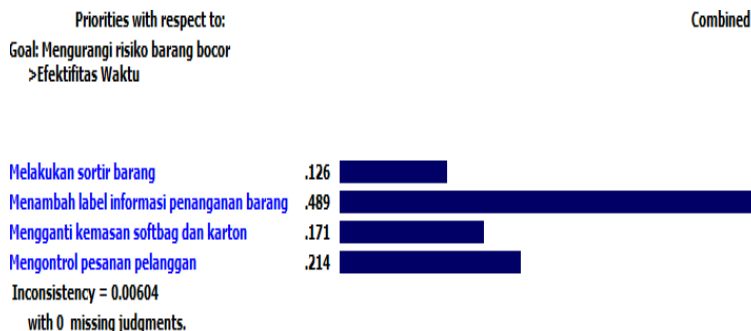
To determine the results of the Analytical Hierarchy Process (AHP) using the Expert Choice 11 software. The first stage in the AHP method is to determine the priority criteria determined based on interviews and questionnaires to five respondents, namely the leaders and employees of PT. BSP. The results of the priority criteria by making pairwise comparisons against the goal of reducing the risk of leaking goods are as follows:



**Fig 3.** Pairwise Numerical Priority Results

Source: *Software Expert Choice 11, 2020*

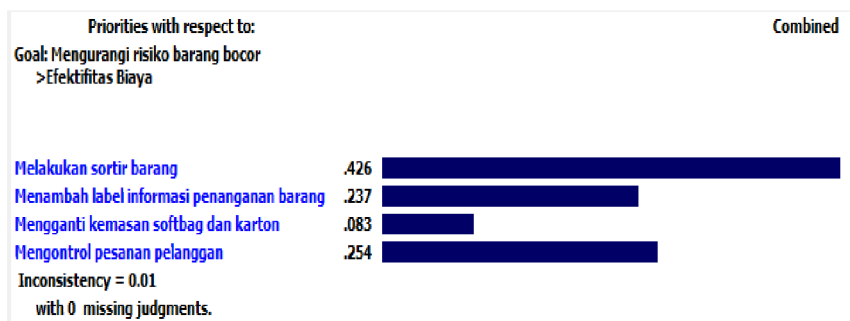
Based on the picture above, the results of processing the questionnaire data show that the time effectiveness criteria get a value of 0.553, cost effectiveness gets a value of 0.121 and the labor effectiveness criteria gets a value of 0.325. Based on the results of these values, the priority criteria are time effectiveness, then labor effectiveness and the last is cost effectiveness. The results of the pairwise comparison get an Inconsistency value of 0.01 or declared consistent because it has a value of less than 0.1. The next step is to do a pairwise comparison on each criterion with the alternative choices that have been determined. The results of the pairwise comparison between the alternatives with the Time Effectiveness criteria are as follows:



**Fig 4.** Pairwise Comparison Results Time Effectiveness Criteria

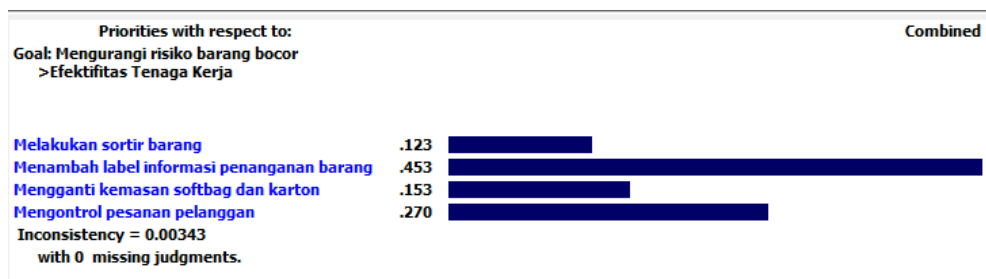
Source: *Software Expert Choice 11, 2020*

Based on the results of the pairwise comparison calculation for the Time Effectiveness criteria, the alternative that is chosen is to add a label regarding the information on handling goods on the Infusion carton packaging with a value of 0.489. According to information from sources, the presence of a goods handling label on cardboard packaging can provide information to all parties who handle the goods, thereby reducing the risk of damaged goods due to mishandling. The results of the calculation of the pairwise comparison are also stated to be consistent with the Inconsistency value of 0.00604. The next step is to find out the alternative choices on the Cost Effectiveness criteria by calculating pairwise comparisons with the following results:



**Fig 5.** Pairwise Comparison Results Cost Effectiveness Criteria  
*Source: Software Expert Choice 11, 2020*

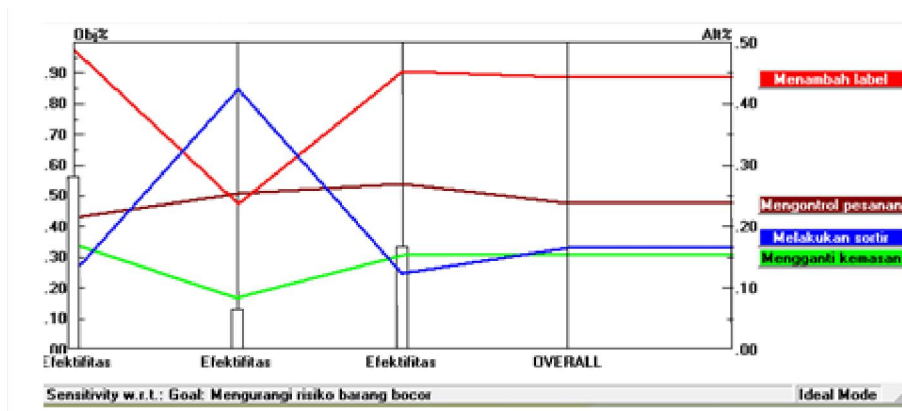
Based on the results of the alternative pairwise comparison calculation on Cost Effectiveness, the alternative that is the main choice in reducing the risk of damaged goods is to sort the goods before they are sent to customers with a value of 0.426. Although it will take quite a lot of time and labor but this alternative does not cost much compared to replacing softbag and carton packaging or controlling customer orders which can risk reduced sales. The results of the calculation of the pairwise comparison on the Cost Effectiveness criteria are stated to be consistent with the Inconsistency value of 0.01. The next step is to calculate alternative pairwise comparisons against the Labor Effectiveness criteria with the following calculation results



**Fig 6.** Pairwise Comparison Results of Labor Effectiveness Criteria  
*Source: Software Expert Choice 11, 2020*

Based on the results of the pairwise comparison calculation above, the alternative chosen to reduce the risk of leaking goods with the criteria of Labor Effectiveness is to add an information label on the handling of goods on the carton packaging of the Infusion product with a value of 0.453. The calculation results are declared consistent with an Inconsistency value of 0.00343.

The final step in AHP is to determine the chosen alternative to deal with the risk of damaged goods in the form of leaky softbag packaging in the distribution flow of goods release in the warehouse that already meets the criteria of Time Effectiveness, Cost Effectiveness and Labor Effectiveness with the calculation results in the Expert Choice 11 application as follows:



**Fig 7.**Results of Analytical Hierarchy Process

*Source: Software Expert Choice 11, 2020*

Based on the diagram above, the results of the AHP calculation indicate the alternative that should be chosen by PT. BSP is to provide information regarding the handling of goods on cardboard packaging of Infusion products. With the information listed on each carton of Infusion products, every party who handles Infusion products from the factory PT. Sanbe Farma, PT.BSP's warehouse and expedition officers and PT.BSP's customers can carry out handling in accordance with the provisions listed so as to avoid accumulation of goods, slamming packaging and storage at inappropriate temperatures which can cause damaged goods which have an impact on the quality of the product. Infusion products distributed by PT. BSP. To include an information label on product handling, PT. BSP must coordinate with the Purchasing department of PT. Sanbe Farma so that relevant departments can order cardboard packaging that has information labels on it.

**IV. CONCLUSION**

Based on the results of research and discussion on Quality Risk Management in the distribution of Infusion products at PT.BSP, it can be concluded as follows:

1. Quality Risk Management in the distribution of Infusion products consists of: a) Risk Assessment on the distribution of Infusion products including Risk Identification, Risk Analysis, and Risk Evaluation, and b) Risk Control on the distribution of Infusion products at PT. BSP includes Risk Reduction, Risk Acceptance, Risk Review and Risk Communication.
2. Measuring Quality Risk Management in the distribution of Infusion products using the FMEA method aims to determine the Risk Priority Number (RPN) derived from the calculation of the impact of risk (severity) multiplied by the probability of the occurrence of risk (occurrence) and multiplied again by detecting the possibility of risk (detection) or  $S \times O \times D$ . The risk with the highest RPN value is the risk of damaged goods in the distribution flow for releasing goods from the warehouse to PT.BSP expeditions which causes leaks

in the softbag packaging. These risks are then analyzed to find the best alternative for handling them.

3. Determine alternative handling of Quality Risk Management in the distribution of Infusion products at PT. BSP using the Analytical Hierarchy Process AHP method. Based on calculations using Expert Choice 11 software, the priority criteria are time and handling effectiveness which has the highest pairwise comparison value is the alternative of adding product handling information labels on cardboard packaging.

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