ABSTRACT

EVALUATION OF IMPLEMENTATION OF GOOD DISTRIBUTION PRACTICE (GDP) GUIDELINES BY PHARMACEUTICAL DISTRIBUTORS WITH CIPP APPROACH

(STUDY IN PHARMACEUTICAL WHOLESALERS IN BALI PROVINCE)

GDP is a drug distribution method that aims to ensure quality along the distribution line following the requirements and intended use. The principle of GDP is the overall monitoring and control of distribution activities through an effective and traceable quality system. To determine compliance with drug distribution facilities in applying aspects of GDP, it is necessary to evaluate the application of the GDP guidelines. This research method is a quantitative research method with a descriptive analysis. The sampling technique used was purposive sampling. The sample of this study is pharmaceutical wholesaler in Bali Province which meets the following inclusion criteria, namely (1) Central pharmaceutical wholesalers, (2) None-pharmaceutical wholesaler tender, (3) Does not have a GDP certificate, and (4) Willing to be a respondent. Based on these criteria a sample of 14 pharmaceutical wholesalers was obtained. Evaluation results, the percentage of effectiveness for context variables is 88%, the percentage of effectiveness for input variables is 67%, the percentage of effectiveness for process variables is 44%, and the percentage of effectiveness for product variables is 79%. Based on the research results, the following conclusions can be drawn: (1) Context variables effectively support the application of GDP guidelines by pharmaceutical wholesalers in Bali Province, (2) Input, process, and product variables are ineffective in supporting the application of GDP guidelines by pharmaceutical wholesalers. GDP aspects that are not effective in its application include quality management aspects (56%), Organization, Management and Personnel (68%), Buildings and equipment (78%), Operations (55%), Self Inspection (57%), Complaints, Medicine Returns, Allegedly False and Withdrawal (45%), Transportation (26%), Distribution facilities under contract (25%), Documentation (40%), and aspects of drug quality assurance (79%).

Keyword: GDP, Pharmaceutical Wholesaler, Bali