CHAPTER VIII

CONCLUSION AND RECOMMENDATIONS

8.1 Conclusion

The Safety Monitoring Programme (SMP), Thailand's new drug 'safety monitoring system, aims to perform new drug safety profiles for Thailand. There has been an increasing number of new drugs in Thailand and only a few studies have explored this particular issue. This study was therefore aimed to perform situational analysis of new drug Safety Monitoring Programme in Thailand and identify safety indicators of the SMP system through the structure, process and outcome model. Various methods including documentation analysis, modified Delphi method, semi-structure interviews, and a case study strategy were used for analyzing the SMP system. Coxibs and Statins were the case study drugs to explain how structure, process affected the safety of new drug in the SMP. The data collections were intensively performed about 14 months, from June 2004 to August 2005.

The results revealed that there were essential elements in the SMP influencing the quality of safety profile of new drug. Policy, law, regulation and guideline were critical to safety profiles which affecting structure and process components such as information system, organization and ADR management system at both national and local level. The safety indicators of the SMP were identified by the 3-round Modified Delphi method. Seventy-one indicators were identified in the first round, 40 indicators in the second and 19 indicators in the final round. The assessment of the SMP through the 19 core safety indicators found that there were 6 existent elements of 9 structure indicators, 1 existent element of 6 process indicators and 2 of 4 outcome indicators. From these findings, the amendment of law, regulation and national policy should be strengthened to better the effectiveness of the SMP system. The safety indicators should be further developed and continuing used and improved.

8.2 Recommendations

8.2.1 Recommendations for Actions

1. Based on the results, the Ministry of Public Health, especially the Thai FDA, should concern more on the SMP system especially at the policy level. It might be essential to adjust the law, regulation and national policy to better the effectiveness of the SMP system since the effectiveness system in other countries were enacted by laws.

2. To strengthen new drug safety monitoring mechanisms both at national and at local level, all responsible organizations in the Thai FDA should put the efforts to build up the expertise in this area. Personnel responsible for tasks in the SMP system should be provided opportunity for advanced and ongoing training. The most needed knowledge and skills are those in new drug information system of which would support for all safety issues not only new drugs. The effectiveness of the SMP system will be achieved not only in the immediate future but also in the long run.

3. Designing for sharing database of new drugs among organization is vital to the Thai FDA. With this establishing, the Thai FDA could perform the activities in more advanced manners.

4. Warning letter to communicate the risk of drug might be useful for the Thai FDA to use as a feedback or communicating tool to all stakeholders especially to the ADR reporters both hospital and company.

8.2.2 Recommendations for Further Study

Since this is the first study on safety indicators of the SMP system in Thailand, further studies on these indicators are needed.

1. The safety indicators should be developed as a practical evaluation tool of the SMP system and be continuing used and improved. Rating scale might be further developed and applied to these indicators.

2.   Sensitivity and specificity of the indicators should be studied to investigate the applications of this tool.

3. Focus group of stakeholders in the SMP might be useful to justify the issues in the core indicators and also obtain the feedbacks of practical aspects

4. It was suggested that there is a need in studying of unlabelled ADR of which is the actual goal of the ADR detection of the SMP. Furthermore, the indicator of time to detect the ADR of new drug may be need to be explored since this indicator is used in various countries to identify risk of new drugs.

In addition, the structure-process-outcome model was suitable for the complicate and dynamic system as in the SMP, so it could be applied to other complex issues too.