



Post - Marketing Surveillance Program on Pesticide Formulation Used in Public Health

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ABSTRACT

Post-marketing surveillance program on pesticide formulation used in public health in Thailand is annually cooperated between the agencies within the Ministry of Public Health such as the Department of Medical Sciences (DMSc), Food and Drug Administration (FDA) and Provincial Public Health Institute (PPHI). The program covering analysis of pesticide active ingredient to support enforcement. The enforcement actions would be taken against non-compliance of regulations under the Hazardous Substances Act B.E.2535 (1992) (3rd Amendment B.E.2551). For the year 2009-2010 surveillance program were cooperated between the DMSc and the FDA. It was found that 17.8 % of samples were non-compliance, due to the content of active ingredients were exceeded the acceptable deviation from the labeling. There are various sample form and active ingredients, which cypermethrin is of majority. Good management of the program would be beneficial to the safety of consumer in using pesticide products.

Key word : post-marketing surveillance program, pesticide formulation, public health

INTRODUCTION

In Thailand, pesticides are regulated under the Hazardous Substances Act B.E. 2535 (1992) (3rd Amendment B.E. 2551). It is an umbrella Act that controls pesticides use in both public health and agriculture. Pesticide formulations used in public health means pesticide products for household use and disease control purpose. Registration and licensing on pesticides for using in public health are regulated by the Thai Food and Drug Administration (FDA) with supporting test results from the Department of Medical Sciences (DMSc), Ministry of Public Health. In order to ensure that pesticide formulation used in public health marketed in Thailand would not be non-compliance, particularly concerns regarding counterfeits, adulterated and substandard products, post market surveillance program by cooperation between FDA and DMSc has been established since 1992. The program is planned annually under agreement between FDA and DMSc. Various criteria for the surveillance program to be concerned such as chemical type of active ingredient, physical state which may affect the exposure potential, main use of pesticides e.g. insecticide, larvicide, rodenticide. Other factors, such as high volume of consumed products and complaint from public, are also interesting to be covered in post-marketing surveillance program.

OBJECTIVE

A post-marketing surveillance program on pesticide formulation used in public health in Thailand would be good management in order to minimize poor quality products in the market.

ACTIVITIES & RESULTS

Due to decentralization of the public health care system, there has been deep concerns regarding vector management at the Local Administrative Levels. The regional laboratories of the DMSc located in various parts of Thailand have adequate laboratory facilities for the analysis of some pesticide.

Post-marketing surveillance program on pesticide formulation used in public health, cooperation between the DMSc and FDA consists of

- Annual plan and agreement between DMSc and FDA
- FDA submit sample to be analysed by DMSc
- Quantitative analysis of samples using standard method (eg. CIPAC, WHO, USEPA, AOAC) or in-house validated method with routine quality control (eg. control chart of duplicate analysis / injection, recovery and blank analysis)
- DMSc report the test result to FDA
- Legal enforcement



Figure 1 : Determination of active ingredients by GC and HPLC

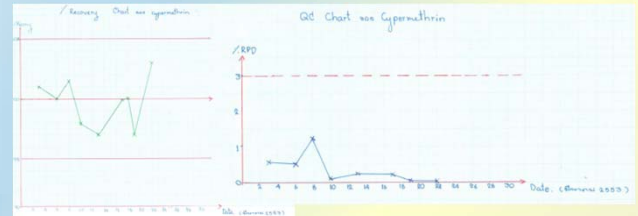
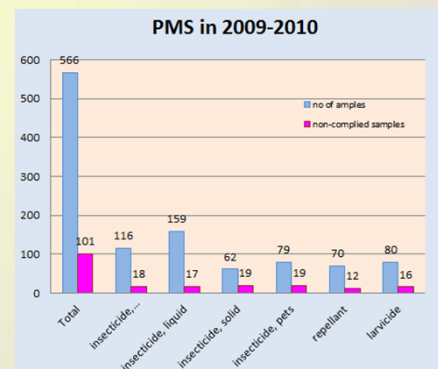


Figure 2 : Quality control chart

Enforcement actions taken against non-compliance of regulations under the Act are carried out, i.e. inform the manufacturer to declare depends on the evidence of the case and approved by the legal case consideration committee following the notification under the Act and make decision for either admonition, fine or imprisonment.

For the fiscal year 2009-2010, the results showed that

- Non-complied samples of 17.8% (101 from 566 samples) due to the content of active ingredient are higher or lower than the acceptable deviation from labeling.
- Product form : spray, lotion, pet shampoo, mosquito coils, larvicide sand, bait
- Main use : insecticides (73%), repellent (12.3%) and larvicide (14.1%)
- Frequent found active ingredients : cypermethrin, DEET, permethrin, temphos, deltamethrin, d-allethrin, tetramethrin, prallethrin, cyhalothrin, piperonyl butoxide
- Non-complied sample :



SUMMARY

Post - marketing surveillance program on pesticide formulation used in public health in Thailand is planned annually upon agreement between agencies within the Ministry of Public Health such as the DMSc, Thai FDA and PPHI in order to ensure the safety of consumers. For fiscal year 2009-2010, the majority type of sample are insecticides liquid, which contains active ingredient e.g. cypermethrin, DEET, permethrin and allethrin isomers.

Good management for surveillance program including good collaboration among the relevant parties to minimise duplicate of work, harmonize regulatory requirements and procedures as well as optimize and share the use of available resources could minimize the non-compliance products which resulting in safety to the consumers.

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