10th ACCSQ PPWG Meeting

The Post-Marketing Alert System for Defective or Unsafe Medicinal Products, Cosmetic Products, Traditional Medicines And Health Supplements

Update on the Malaysia-Singapore Pilot Scheme

Introduction

1. The 8th ACCSQ-PPWG Meeting agreed to assign Singapore and Malaysia as the lead countries to look into a Post-Marketing Alert (PMA) System for defective and unsafe pharmaceutical / medicinal products in ASEAN. This is related to roadmap measure item 49 "Formalise a post-marketing alert system for defective and unsafe pharmaceutical / medicinal products" by 31 December 2005 under the ASEAN Healthcare Sector Integration Initiatives. This PMA system could then be considered for adoption as a model for the ASEAN PMA system for voluntary sharing of information relating to healthcare products. Flexibility was considered in the proposed system for extension to other healthcare product sectors such as traditional medicines and health supplements and also the cosmetics sector.

2. The Malaysia-Singapore Second Technical Meeting on the 4th and 5th April 2005 agreed to adopt the PMA system as discussed in this paper as a Malaysia-Singapore pilot scheme and this was launched with immediate effect.

Objectives

3. The objectives of the Post-Marketing Alert (PMA) System are:

    a. To establish an efficient and effective system of alert on post-marketing issues affecting the safety and quality of healthcare products

    b. To enhance the pharmacovigilance capabilities of the two agencies through mutual exchange of drug safety data.

Scope

4. The scope of the PMA System would include exchange of information and regulatory actions or measures on:

    a. Products for which registration has been cancelled / suspended / withdrawn based on a safety issue

b. Products recalled from the market due to quality defects with serious public health implications and also known to be exported to other countries

c. Products found to be adulterated

d. Significant label changes involving safety that are initiated by the regulators especially for traditional medicines

e. New restrictions to usage

f. Exchange of the following which are produced and issued by the local regulatory authorities:

    i. Dear Healthcare Professional Letter
    ii. Media releases issues related to drug safety
    iii. Adverse Drug Reaction bulletin publication

g. Adverse Event reporting of cosmetic products, specifically fatal or life threatening serious adverse reactions or non-serious adverse reactions that occur at high incidence.

Process and Communication

5. Each country should nominate a country PMA System focal point or coordinator. It is recommended that this should be the Director or Head of the respective ASEAN Drug Regulatory Authorities (DRAs). A local DRA central coordinator will be appointed to operationalise the system.

6. Based on the scope of the PMA System, an ASEAN Member Country will send (email or fax) an alert notification to other Member Countries using the agreed standardised form for reporting. The timeline requirement for notification will be subject to individual Member Country's professional judgement and discretion, to allow for reporting timeline flexibility.

7. A Member Country on receiving an alert notification may then wish, if it is of their interest, to follow-up with the original Member Country for further information, clarification or necessary regulatory action on an individual basis.

Standardised Form for Reporting

8. There is a need to standardise the format for reporting and information exchange. The proposed format for information exchange is found as Form A. The form should be completed in English.

(Note: Form A is a new proposed format for information exchange, which is the product of combining the previous two forms i.e. Annex A Form (Quality Defects) and Annex B Form (Pharmacovigilance) that were presented at the 10PPWG Meeting. Using one standard format for both quality defects and pharmacovigilance will help to simplify & streamline the process for information exchange.)

9. There is also a need to list the definitions and terminologies used e.g. definitions of defective products, recalls and withdrawals. A proposed glossary of terminologies and definitions used by member states are listed for reference as a country-specific Annex document. A recommended country-specific glossary template is attached as Annex A. This list can be further updated as and when required.
   (Note: Due to different countries having different terminologies and definitions, it would be clearer if each Member Countries reflect their terminologies and definitions used into their own country-specific glossary document.)

Pilot Scheme

10. Under the pilot scheme for the period April to August 2005, there were eight notification alerts exchange:

    a. Alert Notification for Quality Defect – 1 case on product recall on a traditional medicinal product

    b. Pharmacovigilance Alerts – 7 cases

        - DHPL (Dear Healthcare Professionals Letter) on the voluntary withdrawal of a COX-II selective inhibitor product
        - DHPL on COX-II selective and nonselective NSAIDs
        - DHPL on elevated blood glucose meter readings with a peritoneal dialysis solution product and specific brands of glucometers
        - Press release on adulteration of traditional medicinal products
        - Labelling changes for a traditional medicinal product to include statement on increased bleeding tendencies
        - Labelling changes for an anti-obesity product arising from ADR reports of vaginal bleeding

- Labelling changes on a Health Supplement product to include statements on possible allergic reactions after use

11. Both countries found the PMA system workable and the sharing of information useful and beneficial. No major problems were encountered during the pilot scheme.

Recommendation

12. The proposed PMA System is submitted for PPWG consideration and in-principle endorsement. Member Countries are requested to submit their inputs and comments to the lead countries within one month after the Meeting to finalise the PMA System.
(Afternote: "The 10PPWG Meeting agreed to adopt in principle the establishment of a PMA System in the region, subject to modification and revision of the format. In this regard, the Meeting requested Member Countries to submit their inputs by 31 December 2005 to Singapore so that the format can be modified for submission at the next PPWG Meeting. The Meeting also agreed that Member Countries exchange information on any issues related to unsafe and defective pharmaceutical products.")

13. Member Countries may submit the names and contact details of their respective PMA focal point or coordinator if they wish to join the PMA System.

Prepared by Malaysia and Singapore
Dated 18 August 2005
Revised 13 October 2005

References:

a. Pharmaceutical Inspection Co-operation Scheme (PIC/S) SOP on "Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects", reference PI 010-1 dated 24 Jun 02

b. The European Agency for the Evaluation of Medicinal Products (EMEA) Committee for Proprietary Medicinal Products (CPMP) "Revised Note for Guidance on the Rapid Alert System (RAS) and Non-Urgent Information System (NUIS) in Human Pharmacovigilance" Reference CPMP/PhVWP/005/96, Rev.1 London, dated 29 Jul 99

c. A Guide Manual for the Industry: Adverse Event Reporting of Cosmetic Products (June 05)

d. Paper on Post-Marketing Surveillance/Safety Evaluation of Cosmetic Products (Dec 03)