MINISTRY OF HEALTH
DRUG ADMINISTRATION

No: 2224/QLD-TT
Ref: ADR reporting

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Hanoi, Mar. 11, 2009

Respectfully to: - Manufacturers, Distributors in Vietnam
- Foreign companies licensed for business operations in medicines and medicinal starting materials in Vietnam

On Jul. 10, 2006, Drug Administration issued an official letter No. 4331/QLD-TT on guideline of implementation of Adverse drug reaction (ADR) reporting which has been applied for manufacturers, distributors in Vietnam, foreign companies licensed for business operations in medicines and medicinal starting materials in Vietnam.

After 2 years of development, implementation according to Guideline of official letter 4331/QLD-TT occured some inadequacy. According to Guideline, scope of urgent report includes: (1) Serious ADRs occurring in the Vietnam territory, (2) Unexpected ADRs occurring both in the Vietnam territory and foreign countries. However, the quantity of unexpected ADR reports occurring in foreign countries is so numerous, up to tens of thousands of reports each year. The collecting, sending and receiving reports from overseas sources, especially in reporting of unexpected ADRs within 10 working days causes the overload not only for reporting companies but also for 2 ADR monitoring centers in Hanoi and HCMC.

Based on actual situation, in order that ADR reporting is highly possible, Drug Administration adjusts the scope and timing for urgent report in Guideline on ADR reporting which has been applied for manufacturers, distributors in Vietnam, foreign companies licensed for business operations in medicines and medicinal starting materials in Vietnam (Revised guideline on ADR reporting is enclosed with this official letter).

Drug Administration informs the company to acknowledge and comply.

VICE CHIEF OF DRUG ADMINISTRATION
(signed and stamped)

Nguyen Viet Hung

GUIDELINES ON REPORTING, MONITORING ADVERSE DRUG REACTIONS

applied for manufacturers, distributors in Vietnam, foreign companies licensed for business operations in medicines and medicinal starting materials in Vietnam

1/ Legal basis

Point b, item 4, article 51 of the Pharmaceutical Law has stipulated that: "During drug circulation, manufacturers and distributors should monitor and report to the head of entities and the competent pharmaceutical regulatory authorities about adverse reactions of medicines manufactured, distributed by themselves".

2/ Objective

Aim to monitor drug safety during circulation in order to ensure to use drug safely and reasonably.

3/ Some concepts

3.1. ***Adverse Drug Reactions (ADRs):*** are undesirable effects which are noxious to health, and which can occur at normal doses.

3.2. Serious *adverse drug reactions (serious ADRs):* are adverse reactions that might lead to the following results:

+ Death
+ Life-threatening
+ Hospitalization or prolonged hospitalization
+ Permanent or severe disability
+ Birth defect/malformation

and ADRs that might cause the same results.

3.3. ***Unexpected ADRs:*** are adverse reactions having symptoms, severe degree and frequency are inconsistent with information on the prescription or drug label.

4/ Guidelines on reporting

4.1. **In case of requiring Urgent reports:**

- Scope:

+ Serious ADRs occur in the Vietnam territory
+ Unexpected ADRs occur both in the Vietnam territory

- *Reporting timing:*

  Units must report within 10 working days from the department that is responsible for monitoring ADR of the units received the information

Report is implemented according to ***reporting form No.1***

4.2. In case of requiring Periodic report

- *Scope:*

  + ADRs do not belong to scope of urgent report occuring the Vietnam territory
  + ADRs occur in foreign countries

- *Reporting timing:*

  Units to collect suspected ADR that do not belong to urgent reports of each medicine manufactured, registered, distributed in one year (from 1 January to 31 December of year). Units must report one time every year, latest by 25 January of next year.

  For each report which discribes suspected ADRs in details and related information, units must keep as archives, manage and show to the competent regulatory authorities upon request within 15 working days.

Report is implemented according ***reporting form No. 2***

4.3. Information relating to drug safety:

In case the drug safety changes which results in changes on drug management such as: need to update information on label, use restriction, drug recall, withdraw of registration numbers,…, units need to inform authorities (Drug administration – Ministry of Health in Vietnam) within 3 working days since units receive information.

4.4. Location of receiving reports

Reports are sent officially by post, only accepted to send via fax or email in case of very urgent case (original copies must be sent via post). Reports can be sent one of the 2 addresses:

Center for monitoring ADRs in the North
Drug Administration of Vietnam
138A Giang Vo – Ba Dinh – Ha Noi
Tel.: 043 – 8235 812 Fax: 043 – 8234758

Center for monitoring ADRs in the South
(located in Sub Institute for Quality Control in HCMC)
200 Co Bac – District 1 – HCMC
Tel.: 08 – 38 373 332 Fax: 08 – 38367 900