

MINISTRY OF HEALTH
DRUG ADMINISTRATION
OF VIETNAM

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: 6749/QLD-CL

Hanoi, May 4th 2013

Suspend the use of Quinvaxem in EPI

EMERGENCY

- To: - Provincial Health departments;
- Provincial Preventive medical centers;
- Expanded Program of Immunization (EPI) management board;
- Representative Office of Berna Biotech Korea Corporation in Vietnam (35 Nguyen Hue str., District No. 1, HCM City)

Pursuant to current pharmaceutical regulation;

Pursuant to conclusion of Advisory Committee of using vaccines and biological meeting dated 27/4/2013

To assure safety of user, Drug Administration of Vietnam announce:

1. Suspend using Quinvaxem vaccine in Expanded Program of Immunization (EPI) (Vaccine of 5 components: DTwP – HepB – Hib in liquid form), Registration No.: QLVX-0604-12, produced by Berna Biotech Korea Corporation.

2. Representative Office of Berna Biotech Korea Corporation in Vietnam cooperate with importation and supply enterprises in order to:

+ Send announce to all vaccine supply and using agents for suspending the use of vaccine Quinvaxem inj (Vaccine of 5 components: DTwP – HepB – Hib in liquid form), Registration No.: QLVX-0604-12, produced by Berna Biotech Korea Corporation); request all agents to store vaccine at required storage condition stated in label of vaccines.

+ Report to Drug Administration of Vietnam and General Department of Preventive Medicine on exportation, supply and distribution of vaccine Quinvaxem inj before 15/5/2013

3. Provincial Health departments, Expanded Program of Immunization (EPI) management board and Provincial Preventive medical centers announce to all vaccine supply and using agents for suspending the use of vaccine Quinvaxem inj, to store vaccine at required storage condition stated in label of vaccines and check, monitor agents to perform this announce.

Drug Administration announce to the said units to proceed immediately./.

Recipients:

- As above;
- Minister Nguyễn Thị Kim Tiên (to report);
- Deputy Ministers (to report);
- Inspectorate of Ministry of Health (to cooperate);
- General Department of Preventive Medicine (to cooperate);
- National Institute for Control of Vaccine and Biological;
- National Institute of Hygiene and Epidemiology;
- Pasteur Institute;
- Army Medical Department – Ministry of National defense;
- Medical department – Ministry of Public Security;
- Medical department – Ministry of Transportation;
- DAV's departments, DAV's website;
- Archived: VT, CL (02 copies).

DEPUTY DIRECTOR

(Signed)

Nguyễn Việt Hùng