

USP Drug Quality and Information Program (USP DQI) Activities on Avian Influenza in Southeast Asia (September 2007 – March 2008)

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AIMEBA Activity Code 1 – Preparedness and Planning

OBJECTIVES

- ◆ Obtain comprehensive information on all suppliers and distributors of oseltamivir in the region to support a preparedness to outbreak scenario in Southeast Asia
- ◆ Establish oseltamivir quality monitoring program in the region
- ◆ Maintain the quality of stockpiled and circulated oseltamivir in the Mekong Sub-region (Core funds)

ACCOMPLISHMENTS

1. Mapping all oseltamivir suppliers and distributors in the region – **COMPLETED** in Thailand.

(In collaboration with PSyRIC under ANEQAM** activities)*

* Pharmaceutical System Research and Intelligence Center
** Asian Network of Excellence in Quality Assurance of Medicines

◆ Information collected

- ✓ Oseltamivir product or API manufacturers
- ✓ Production capacity
- ✓ Brand/generic names
- ✓ Prices and procurement mechanism
- ✓ Registration requirements
- ✓ Distributors
- ✓ Quantity available on the market
- ✓ Stockpile (where, how many, from what time it began)

◆ Report ready for dissemination

2. Obtained formal permission from MOH of Lao PDR for sampling of stockpiled and circulated oseltamivir products.

(In collaboration with WHO/Laos)

3. Developed protocol for the survey of the quality of oseltamivir products stockpiling and circulating in selected Southeast Asia countries (Laos, Cambodia, Vietnam, Thailand).

- ◆ Broad screening for quality of stockpiled and circulated oseltamivir using basic testing methods – minimum number of units/sample (5-10 tablets of each lot/batch) will be collected.
- ◆ Additional sampling of questionable/doubtful samples for confirmation testing using pharmacopeial specifications – 30-40 units/sample will be required.
- ◆ Marketing surveillance will be established.

ONGOING ACTIVITIES

Laos

- ◆ Sampling of stockpiled and circulated oseltamivir products by Food and Drug Quality Control Center (FDQCC)
 - ✓ 16 Hospitals – Central and Provincial
 - ✓ WHO stockpile
- ◆ Analysis of collected samples using basic testing methods – physical/visual examination, simplified disintegration, and thin layer chromatography (TLC) – Global Pharma Health Fund (GPHF) Minilab® testing manual – by FDQCC

Thailand, Cambodia, Vietnam

- ◆ Discussion on sampling, testing, and obtaining formal permission from country MOH or Drug Regulatory Authority for sampling of oseltamivir products in progress
- ◆ Refresher workshop for Minilab users including QC of oseltamivir in Thailand

CHALLENGES ENCOUNTERED

- ◆ Difficult to convince officials that stockpiled and circulated oseltamivir products can lose their potency before the expiration date and, therefore, should be tested periodically to ensure that the quality of the drugs meets the requirements
- ◆ Delayed publication of *Osetamivir Phosphate* and *Osetamivir Capsule* monographs for official use (absence of related compound A *Reference Standard* – at the process of synthesis)

ACTIVITIES USING CORE AI FUNDS

Development of guidelines, in collaboration with WHO and relevant partners, on how to maintain the quality of oseltamivir from acquisition to use – in progress

- ◆ For government regulatory authorities, procurement and distribution agencies, NGOs, national communicable diseases control programs, QC labs and field staff
- ◆ Will be important tool for training on oseltamivir QA/QC