SEA-CD-152
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Regional Production of Oseltamivir: Review of the Current Situation

Report of an Informal Meeting
New Delhi, India, 30-31 March 2006

WHO Project: ICP CSR 001

World Health Organization
Regional Office for South-East Asia
New Delhi

July 2006

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1. Background

The South-East Asia Region of the World Health Organization (WHO/ SEAR) covers 11 countries with a total population of over 1.5 billion persons, representing one quarter of the global population.

The countries in WHO/SEAR are vulnerable to avian influenza (AI). Thailand, Indonesia, Myanmar and India have reported AI outbreaks in poultry, while Thailand and Indonesia have reported human cases. More recently, the disease has spread among poultry and wild birds in a number of countries in Europe, Africa and the Middle East.

However, the epicentre of the outbreak remains in Asia where the disease appears to have become endemic in poultry in some countries.

The spread of avian influenza is indeed rapid. Since 2003, AI outbreaks in birds have occurred in more than 50 countries with 9 countries reporting human cases. More than 200 million chickens have died or been culled since 2003. So far, 193 humans have been infected by the virus, with 109 deaths.

Epidemics do not respect national boundaries and can therefore rapidly spread to many countries causing morbidity and mortality as well as interruptions and loss in trade, travel and tourism. As long as the outbreaks in poultry persist, the threat of human infections and the possibility of an influenza pandemic will remain.

Vaccines and antiviral drugs have been the mainstay of prevention and control of several viral infections. At present, vaccine against the AI H5N1 virus is not available. Some experts believe that early and strategic use of antivirals such as oseltamivir, along with social distancing, could pre-empt an outbreak of AI at source.

Antiviral drugs against human influenza A viruses of subtype H1, H2 and H3 are not effective against H5 subtype. However, the antiviral oseltamivir is currently seen as the most efficacious drug which can be taken orally for treatment of human avian influenza. It is therefore important to have adequate stockpiles of antivirals at both regional and national levels.

Against this background, a meeting was organized by WHO on March 30- 31, 2006, in New Delhi to discuss regional production of oseltamivir. The meeting was attended by representatives from the Ministries of Health (MoH) of Bangladesh, India and Thailand and pharmaceutical companies currently manufacturing oseltamivir with potential to manufacture the drug within the Region, technical experts and WHO staff. (The programme and list of participants are given in Annexes 1 and 2.)

Dr Shiv Lal (India) and Dr Supamit Chunsuttiwat (Thailand) were elected as Chairman and Co-Chairman respectively and Mr Binay Das (Bangladesh) as Rapporteur of the meeting.

The general objective of the meeting was:

- To exchange information on the production of oseltamivir in the Region in the context of a possible influenza pandemic.

The specific objectives were:

- To review the situation of avian influenza and influenza pandemic preparedness in the WHO/SEA Region;
- To provide a forum for discussion among pharmaceutical industry representatives and Ministry of Health officials of selected countries on the role of oseltamivir, as a part of pandemic preparedness and response;
- To find a way forward for regional production of oseltamivir.

The opening address at the meeting was delivered by the Acting Regional Director, WHO/SEARO, who indicated that the countries in the Region are vulnerable to the influenza virus of which the spread could be very rapid and that as long as the outbreaks in poultry existed the threat of a pandemic will remain. She added that the current manufacturing capacity in the Region cannot meet its own demand as the manufacturing process is complex and lengthy and the lead time for production could be up to one year. Countries in the Region who had placed orders in October 2005 could expect to receive their supply only by December 2006 from the sole supplier.

The Region fortunately has many pharmaceutical companies who can manufacture the drug, thus increasing the likelihood of its availability.

What needs to be done is to foster and strengthen partnerships. In this case, public-private partnerships are indeed important to ensure coordinated efforts of all stakeholders.

The meeting is therefore unique and important in that it brings together pharmaceutical companies, government representatives and WHO staff to discuss the issues relating to the production capacity of oseltamivir to meet the needs of the Region.

2. Avian and pandemic influenza – an overview of the global and regional situation and strategies

A presentation on the global and regional AI situation and regional strategies was made by WHO staff. It was explained that AI is mainly a disease of animals, particularly birds, and that humans are rarely infected. However, it was noted that the virus is highly unstable and a pandemic virus is likely to pose a challenge as populations will lack immunity. The history of pandemics in the last century was described. The present concerns surrounding the H5N1 virus centre around the current unprecedented outbreaks in poultry.

The host range has expanded from birds to other animals like tigers, cats and dogs and the H5N1 virus is now endemic in some countries in Asia. Apart from Australia and the Americas, all continents are now affected and spread is rapid. The need for outbreak control in poultry, establishing surveillance at grass-roots level and preventing exposure of humans are important in minimizing mortality and morbidity.

The three key strategies that WHO recommends to prepare for a pandemic are:

(1) Decrease the risk of a pandemic virus

(2) Pandemic preparedness which will include preparing national pandemic plans and research into developing a pandemic vaccine

(3) Rapid response and containment

Work is required at all levels for operationalizing and implementing the national plans. WHO needs to develop exercises to simulate a real event and there is a need for rehearsals to further strengthen national capacity.

The regional plan addresses cross-cutting issues and the key steps that are needed for planning and preparing for a pandemic. Two areas were highlighted: (i) stockpiling – how to organize delivery; and (ii) quarantine - the practicalities of achieving this taking legal and ethical issues into account.

WHO's role also includes resource mobilization to help countries in their planning and providing technical assistance when required. The importance of NPPPs and preparing for a pandemic were reiterated. There is a window of opportunity to act, which is now. The need to train physicians and making the national pandemic preparedness plans (NPPPs) implementable were stressed.

3. National influenza pandemic preparedness plans – country experiences

Representatives of Ministries of Health made presentations on the status of their pandemic preparedness. These presentations highlighted certain ongoing initiatives/good practice examples that could be adopted by other countries. For example, (i) the compensation scheme to farmers in India; (ii) ongoing community-based volunteer scheme in Thailand and designation at provincial and district levels of medical officers as 'Mr Bird Flu'; and (iii) Rapid Response Teams (RRTs) in India and Thailand. They also highlighted the importance of testing their plans. Thailand is currently developing table-top and field exercises to test their pandemic preparedness plans at all levels. The importance of resource mobilization was emphasized not only for human health sector but also for the animal health sector.

Bangladesh

Bangladesh with its 143.8 million population is bordered on three sides by India, Myanmar on the south-east and the Bay of Bengal on the south. Although Bangladesh has a good health infrastructure the health services are stretched.

There have been no H5N1 outbreaks in poultry or humans although the country is in close proximity to H5N1-infected countries. Other issues that make Bangladesh vulnerable are:

- Large cross-border movement between India, Myanmar and Bangladesh
- People carrying poultry with them
- Illegal/informal trade of poultry and poultry products
- Migratory birds – about 244 species visit Bangladesh
- More than 40 temporary habitats for migratory birds
- Vast wetlands along with 710 km of the coastal belt and several islands which are popular habitats of migratory birds
- High human population density and close living quarters between humans and birds raise potential for virus transmission
- Bangladesh has the third largest duck population in Asia
- Backyard poultry – poor bio security
- Live-bird markets – these are largely unregulated and slaughtering is carried out alongside the sale of live poultry

Bangladesh has a national AI multisectoral task force whose members include representatives of relevant ministries, directorates, professional bodies, NGOs and the private sector. There is also a technical committee at the Directorate level in the Health and Livestock Departments.

Activities are ongoing to prepare for a pandemic and to strengthen services; however, there are still a number of gaps. In terms of stockpiling, oseltamivir has been procured from WHO. Procurement of 50 000 capsules is in progress.

One pharmaceutical company has started producing oseltamivir and the government should ensure its quality through laboratory testing.

India

India has a joint monitoring group chaired by the Director-General of Health Services (DGHS) which comprises a number of agencies such as

state governments, department of animal husbandry and WHO. This group keeps a watchful eye on the situation. There is in addition a committee to develop the national pandemic preparedness plan which is chaired by the Director, National Institute of Communicable Diseases (NICD). When cases were reported from neighbouring countries, India developed a contingency plan based on WHO guidelines. Experience from dealing with the SARS outbreak helped in this process. Actions focus on surveillance of human cases; early detection and management; and decreased social disruption and economic loss.

The NICD has been designated as the nodal agency for human cases while the animal husbandry department is the nodal agency for animal disease. The Ministry of Health and Family Welfare (MoHFW) is the nodal Ministry. There is also in place a high-level taskforce chaired by the Health Secretary. Rapid response teams (RRTs) are in operation and comprise clinicians, epidemiologists, laboratory personnel and a veterinarian. In terms of stockpiling oseltamivir, India has received 70 000 treatment courses from Hetero, 30 000 from Roche and 2000 from WHO who also provided the paediatric formulation during the recent outbreaks.

10 000 sets of personal protective equipment (PPE) are available for managing human cases. The Department of Animal Husbandry will procure PPE for their use. The Ministry of Home Affairs will provide airlifting services to the RRTs.

Concerns felt at the field level include:

- Difficulties using PPE in humid conditions
- Migratory birds in some areas
- Quarantine
- Role of media
- Safe disposal of poultry droppings
- Compensation

An interdisciplinary integrated approach is the key.

Indonesia

An update on the avian influenza situation was provided and four key actions were being undertaken:

- Strengthening the early warning system
- Rapid containment operations
- Building capacity
- Coordinating global science and research to better understand the epidemiology

An avian influenza command post has been set up in the Communicable Disease Control section of the Ministry of Health (MoH). This comprises national experts sub-divided into working groups with WHO representation.

The NPPP has been drafted and FAO is having an input into the agricultural component of the plan. US $15.4 million have been raised for human health and this is being used for personal protective equipment (PPE) and stockpiling of oseltamivir. There is a great need for capacity building. There is a plan to develop polymerase chain reaction (PCR) diagnostic capability and training in specimen collection and transportation. Under-reporting is suspected and testing is only being done of inpatients. Guidelines are being developed for hospital response teams. There are plans to upgrade lab facilities to BSL 3. There is also a need to conduct simulation exercises.

The government intends to procure oseltamivir through its two pharmaceutical companies.

Thailand

The situation was described with its three waves of AI outbreaks in two years. The government has approved two plans: (I) Avian Influenza; and (II) Pandemic Influenza Preparedness. The MoPH and Ministry of Agriculture (MoA) are responsible for implementing the plans. Activities include surveillance and rapid response teams with daily situation monitoring and updates. There is one team per district working with provincial-and central-level teams.

Thailand operates a village health volunteer scheme whereby volunteers assist in public health activities which include surveillance in the case of AI. There is also a designated 'Mr Bird Flu' who oversees AI activities at sub- national level.

The Government Pharmaceutical Organization of Thailand (GPO) has undertaken the following activities:

- Pre-formulation studies
- Purchased 5 kg of API from Hetero for stability testing on a pilot scale
- In possession of 100 kg of API from Hetero for emergency use in the event of an outbreak
- There are no intellectual property rights (IPR) issues and no patent of Tamiflu in Thailand
- In the process of conducting bioequivalence studies

Concerns were expressed about the uncertainties which make it difficult for private manufacturers to produce a stockpile of drugs.

4. Oseltamivir and its role in avian influenza

A presentation was made by Prof. Ranjit Roy Chaudhury, WHO Temporary Adviser, who informed the group that he had observed an increase in knowledge about oseltamivir over the past few months.

Humans are being infected with H5N1 which is normally a disease of birds. There is adequate information on influenza A and B in humans but little available about avian influenza. Some of the available information on oseltamivir is based mainly on its use in influenza A and B in humans, with extrapolation to humans with H5N1.

Oseltamivir is a neuraminidase inhibitor and it acts by preventing new viral particles from being released by the infected cells by blocking the action of neuraminidase. This is the only drug available for use in avian influenza and is currently produced by one manufacturer. The other antivirals used in influenza include amantadine and rimantidine which are classed as M2 inhibitors; other potential drugs include zanamivir (given by inhalation route) and permavir, which are also neuraminidase inhibitors. Irrational use of amantidine and rimantidine have led to a high level of transmissible resistance.

Certain key aspects of oseltamivir were highlighted:

Dose: treatment needs to be given within 48 hours of symptom onset. No studies have been carried out on a higher or lower dose than the currently recommended dosage schedule.

Bioavailability: the drug is converted into a carboxylate and its bioavailability is 80%.

Efficacy: if given within 48 hours of detection of symptoms the efficacy is 90%. However, according to unpublished data, the efficacy is only 50–60% if given much later. There is a knowledge gap in terms of effectiveness and time of administration of oseltamivir. Experience from Turkey revealed survival in those given oseltamivir within 36 hours of symptom onset.

Administration of oseltamivir within 36 hours of symptom onset was therefore recommended.

Side-effects: the common ones include abdominal pain, diarrhoea, nausea, headache and vomiting. Less common include: bronchitis, insomnia and vertigo. Research is ongoing into the causes and effects of childhood deaths including possible drug-related suicides.

Risk in pregnancy: data available are from animal studies. So far oseltamivir has not shown embryo toxicity or teratogenicity, nor does it affect organogenesis. It is excreted in the breast milk like zanamivir.

Resistance: data from Japan revealed 0.5% resistance. At the moment, resistance is low but possible. The low frequency in communities is likely due to low level transmission of resistant variants.

Stability: the drug is stable for up to five years from the time of production but there are plans for testing at 8 and 11 years.

Probenecid: this agent increases the levels of oseltamivir in blood, so it might be a good way of decreasing the required dose, side-effects and cost. However, due to patient variability, it has not been possible to show an increase in oseltamivir levels with probenecid. This is therefore a potential area for research.

Indications: oseltamivir should be given as early as possible. The challenge lies in getting the drug to those in need within the recommended 48 hours (or 36 hours). Reference was made to the adoption of schemes in countries that may allow for this, e.g. the village health volunteer (VHV) scheme in Thailand. Good public health surveillance is crucial to early detection and response.

In terms of whom to give the drug: all those in contact with poultry; household contacts; health care workers in contact with infected material. The point about essential staff was raised, e.g. should it be given to policemen; if so, when? This will be a national decision and most countries have opted to administer it to health care workers (HCWs) who come into contact with patients. In contrast the policy in the UK is to give HCWs only when they develop symptoms and they will be given it on a priority basis.

In summary, adequate quantities of oseltamivir will be required. More work is needed to learn more about this drug and its use. Although the production capacity may be adequate, it is the delivery to those who need it at the most peripheral levels that is the challenge.

5. Public-private partnerships in regional production of oseltamivir

What is the value of public-private partnerships? The AI pandemic could be a catastrophe beyond the coping capacity of the private sector alone. The response involves surveillance programmes, resource mobilization and distribution, awareness raising, planning for the production of required products for interventions. However, the overall responsibility for ensuring the health and welfare of citizens still remains with the State for which society or the tax payer foots the bill. There are certain areas where the private sector is more efficient and is accountable for its actions and investments and has strengths in manufacturing and delivering goods in a more cost-effective manner. The role of the private sector is to manufacture and deliver oseltamivir of the specified quality in adequate quantities and at the right time.

Shikimic acid, isolated from the Chinese star anise, the natural material used in making oseltamivir by the current manufacturer, is

available mostly from China and Viet Nam. Shikimic acid can also be produced from Cinchona bark.

The prices of oseltamivir are quoted from US$ 2.5 (India, Bangladesh and Thailand) to US$ 6-10 (US, UK) per capsule of 75 mg.

Issues regarding oseltamivir

- Acquiring adequate quantities of oseltamivir for its availability, accessibility, affordability and distribution within 48 hours
- Appearance of drug resistance in some cases
- Effectiveness in humans as a prophylactic yet untested; little data available on right dosage, frequency of administration and duration of treatment. Longer treatment may be required for highly virulent strains
- The process is not as complex or difficult as projected
- The price will come down with more players and better availability of raw material
- The patent protection issue needs to be dealt with on a case-by-case, country-to-country basis, although to date, the current supplier has not raised any issue against any generic manufacturer.

Governments' role

- To ensure the national plan is ready along with diagnostic testing facilities; and it has access to immediate requirements of oseltamivir for chemoprophylaxis and treatment
- To work with companies to plan production, stockpiling and distribution
- To ensure rational use
- If patent issues become a reality, consider articles 30 and 31 of TRIPS and DOHA agreement para 6.

Private sector's role

- To ensure that a viable, cost-effective process and technology are available for producing the drug at short notice
- To work out the capacity available or what can be set up in defined time frames
- To obtain all necessary clearances for domestic use and exports
- To initiate R&D to optimize the production process, improve the quality and shelf life and develop alternate routes for production
- To identify new sources of raw material
- To look at cheaper drugs such as amantadine and rimantidine
- To develop new delivery systems of zanamivir and similar drugs to improve their bioavailability and half lives to make them more orally active.

The following section summarizes the statements made by the representatives from the pharmaceutical companies present at the meeting regarding their viewpoints about the potential for production, capacity and price. (see Annex 3).

Eskayef, Bangladesh

This company has produced a booklet on bird flu for doctors and has conducted a poster campaign, seminars and symposia on avian influenza. They are in possession of 1000 doses of oseltamivir and stated that they have a production capacity of 5 million capsules per month.

Beximco, Bangladesh

They have produced both the API and the finished formulation. They launched oseltamivir with the brand name Oseflu (75 mg capsule) and are also in the process of making the liquid formulation. The company has donated 100 doses to the Government of Myanmar. They have 500 treatment doses and have raw material for producing 1 million doses in a month. They are working with MoH and will contribute doses according to the government's requirement. They can sell the product through pharmacies and through doctors' prescriptions. However, they have decided not to

supply to pharmacies to discourage irrational use of the drug. They have decided to take advice from the government and will keep supplies at 16 distribution points. The company will give doctors a hotline card so that they can inform when they have seen a case and therefore request supplies of the drug. Every export goes through the Drug Administration.

Cipla, India

They are manufacturing from the API as well as the finished formulation and they have been approved by the Drug Controller's office. They have a stockpile of 20 000 courses and a manufacturing capacity of 100 000 courses per week. They have engaged in an information campaign for physicians.

Natco, India

Their capacity is 1000 kg per month of API and they can produce 1 million capsules per day and pack 1 million blister packs per day.

Ranbaxy, India

This is the largest pharmaceutical company in India in terms of revenues. They have readily available API and have the approval to market API in India. They can also export this product. They have submitted a toxicity study and have now been given approval to conduct a bioequivalence study.

Strides Arco Lab, India

This is a very young pharmaceutical company with headquarters in Bangalore. There is no retail marketing in India. Their capacity is 7 000 000 capsules per month which can be doubled or trebled if demand arises. They plan to export to countries where there are no patent issues and licensing is under process.

Indo Farma & Kimia Farma, Indonesia

There were no representatives from these companies but details about them were provided by a WHO staff member from Indonesia who was present at the meeting (Annex 3).

GPO, Thailand

Government Pharmaceutical Organization is a state enterprise under Ministry of Public Health. The capacity of GPO in the production of oseltamivir is around 400 000 capsules per day. GPO now have 100 kg of API available for emergency use.

Besides these companies, according to information available, Roche has granted 15 sub-licences: 2 in China; 1 in India (Hetero); and 12 in European countries.

It was clear that countries were in the process of implementing their NPPPs. There was capacity within the Region for the manufacture and scale up of production of oseltamivir. The advantages and limitations of oseltamivir in its use against H5N1 were highlighted. There appeared to be a role for public-private partnership in the prevention and control of a potential pandemic.

6. Next steps for WHO

(1) Develop guidelines on rational use of oseltamivir. Explore the available evidence on oseltamivir as treatment/prophylactic; dosage; frequency. Consider operational research to document experience with oseltamivir use in current outbreaks.

(2) Take the lead for regional stockpiling and implement the guidelines for stockpiling of oseltamivir at regional level.

(3) Share information gleaned from this meeting with governments in the Region and consider organizing a regional meeting to discuss the issues surrounding oseltamivir.

(4) Encourage public-private partnerships.

(5) Develop proposals with relevant sectors for resource mobilization, a part of which could be used for purchasing a regional stockpile.

(6) Support studies and undertake research to forecast the likelihood of a pandemic based on available data from previous pandemics in addition to data from recent outbreaks.

(7) Arrange a follow-up meeting to discuss new evidence, new production capacities with pharmaceutical companies and progress with action points.

7. Closing session

The WHO Deputy Regional Director thanked the participants for their presentations which were most valuable. She said that WHO-SEARO would disseminate the outcome of this important meeting to Member countries. She also thanked the representatives of pharmaceutical companies for their participation and for their willingness to make oseltamivir available to countries whenever needed.

Annex 1

Programme

Day 01 – Thursday, 30 March 2006

0830 hrs	Registration
0900 – 0920 hrs	Inaugural address by Acting Regional Director
0920 – 0925 hrs	Objectives of the meeting
0925 – 0930 hrs	Announcements
0930 – 0940 hrs	Group photograph
0940 – 1000 hrs	Tea/coffee break
	Session – 1
1000 – 1045 hrs	Avian and pandemic influenza: Overview of the global and regional situation and strategies (SEARO)
10 45 – 1115 hrs	Oseltamivir and its role in avian influenza – Prof. Ranjit Roy Chaudhury
1115 – 1230 hrs	National influenza pandemic preparedness plans Country presentation: • Bangladesh • India
1230 – 1330 hrs	Lunch
1330 – 1430 hrs	Country presentations (contd.) • Indonesia • Thailand
	Session – 2
1430 – 1515 hrs	Regional production of oseltamivir – Statements by manufacturers
1515 – 1530 hrs	Tea/coffee break
1530 – 1700 hrs	General discussion

Day 02 – Friday, 31 March 2006

Session – 3

0830 – 1015 hrs	Public–private partnership in regional production of oseltamivir: Concept and practice – Dr M.D. Nair
1015 – 1030 hrs	Tea-coffee break
1100 hrs	Closing session

Annex 2

List of participants

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Annex 3

Statements from manufacturers on their production capacity and pricing of oseltamivir

No.	Pharmaceutical manufacturers	Ability to manufacture API	Finished product	Stock available	Manufacturing capacity (capsules per month)	Time frame to enhance production	Price per capsule (USD)	Ability to export
1	Eskayef Bangladesh Ltd.	No	Yes	1000 doses	5 million	3 mths	< 2 (less for the Govt)	Yes
2	Beximco Pharmaceutical Ltd. Bangladesh	Yes (trial production completed)	Yes	5000 doses (200 000 more by mid-April)	7 million	3 mths	1.8 (less for the Govt)	Yes
3	Cipla Ltd, India	Yes	Yes	20 000 doses	4 million		2.5 (less for the Govt)	Yes
4	Natco Pharma, India	Yes	Yes	75 000 after license	30 million	1-2 mths	1.7 (negotiable)	Yes
5	Ranbaxy Laboratories Ltd. India	Yes	Yes	API 250kg/mth up to 1 tonne	15 million	3 mths	1.5 for 2006	Yes
6	Strides Arcolab Ltd. India	Yes	Yes	50 kg	7 million	6-8 Weeks	1.5	Yes
7	Indo Farma, Indonesia	No	Yes	N/A	6 million	N/A	2.0	
8	Kimia Farma Indonesia	No	Yes	N/A		N/A	2.0	
9	Govt. Pharmaceutical Organization, Thailand	No	Yes	2000 doses 100 kg API	5 million	Dec 2006	1.8	Yes