



***Preparing for and responding to influenza pandemics:  
roles and responsibilities of Roche***

***Revised May 2013***

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## **Introduction**

The purpose of this document is to articulate in an open and transparent manner the roles and responsibilities of Roche and other stakeholders during pre-pandemic and pandemic time periods. The audience for this document includes international agencies, governments, the business community, and any other person or organisation involved with an interest in pandemic preparedness.

The document was first written and made publicly available in January 2008 and has been updated subsequently.

It is important to note that the revision of this document in no way reflects any material changes to how Roche views or articulates what it believes to be its role in the multi-agency response to a pandemic. Rather, Roche has taken the opportunity to reflect on its experiences from the 21<sup>st</sup> century's first global pandemic.

## **Executive summary**

### **Overview**

Pandemic influenza must be viewed not just as a government public health emergency but as a global problem with a potentially serious impact on human health and well-being, the global economy and social infrastructure.

Global pandemic preparedness is a critical element for the protection of global society and its economy. Influenza pandemics have occurred approximately every thirty years. There were three pandemics in the 20<sup>th</sup> century, the last of which originated in Hong Kong in 1968-1969 and resulted in 800,000 deaths.

On June 11<sup>th</sup> 2009, the WHO raised the alert to phase six, and the 21<sup>st</sup> century's first pandemic was declared and officially ended on the 10<sup>th</sup> August 2010.

95 governments worldwide have purchased or ordered pandemic Tamiflu<sup>®</sup> (oseltamivir) stockpiles, which cumulatively is sufficient to treat only ~5% of the world's population.

### **Roche's role**

As the manufacturer of Tamiflu, an oral antiviral (not a vaccine) active in the prevention and treatment of all influenza viruses, including swine influenza A (H1N1) and avian influenza A (H5N1), Roche has an important role in pandemic preparedness.

The company recognises that healthcare is a shared responsibility and that medicines are only one component of healthcare. However, we believe that our primary role is the research, development and registration of innovative medicines for serious illnesses including influenza.

Roche will undertake specific activities in the pre-pandemic and pandemic phases. These include:

- Ensuring we have a supply chain which can be modified to a defined extent in response to surges in demand
- Securely delivering Tamiflu which meets stringent quality standards
- Acting in a socially responsible manner by:
  - contributing to WHO stockpiles
  - ensuring that emerging economies have access to Tamiflu through its Tamiflu Reserves Programme (TRPs)
  - tiered pricing for developed and emerging economies
  - financial solution that provide flexibility in accessing Tamiflu
  - holding no patents for Tamiflu in Least Developed Countries (LDCs)
- Prioritising orders effectively and following defined business practices in the event of scarce supplies of Tamiflu. Roche will fill orders in the following priority:
  - 1) Delivery of the Rapid Response Stockpile to the WHO
  - 2) Global health interest in consultation international agencies such as the WHO

- 3) Government and corporate orders already placed
  - 4) New orders from governments
- Working collaboratively with non-governmental organisations and industry associations
  - Advising governments on how Tamiflu fits within their own national pandemic preparedness plans.

Roche is committed to executing these activities to the very best of its abilities.

However, it is also important that Roche is transparent about the roles that do **not** fall under its responsibility. These include:

- Manufacturing and stockpiling high levels of Tamiflu in the absence of firm orders. Governments must recognise reliance on 'surge' capacity is unrealistic to efficiently handle a future pandemic. Hence, governments, in accordance with WHO recommendations, should have sufficient antiviral stockpiles in place.
- Taking on the role of government in health care delivery. Once Tamiflu has been delivered to governments it is their responsibility to ensure that the infrastructure exists to deliver it to patients. Should governments wish to involve Roche capabilities, they can ask the company to assist. It is also governments' responsibility to educate citizens on measures they should take (e.g. social distancing) to prevent the spread of the virus
- Determining which countries become recipients of Tamiflu from the WHO stockpiles. This is the responsibility of the WHO
- Undertaking the global co-ordination of surveillance and tracking the development of the virus. This is also the role of the WHO and other bodies such as the Centre for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC) and national laboratories.

## **Roche's role**

### **1) Ensuring a sustainable manufacturing supply**

#### ***Pre-pandemic***

As the manufacturer of Tamiflu, Roche's responsibility is to ensure that production of Tamiflu meets the demand for the management of seasonal influenza and for pandemic stockpiling orders.

In addition, Roche has provided manufacturing sub-licenses to generic manufacturers in several countries – allowing them to produce generic versions of oseltamivir to further increase the global availability of the drug for pandemic use.

However, it should be noted that over-production is not sustainable from a business perspective and production output will be modified to meet real demand.

#### ***Pandemic***

Upon the declaration of a pandemic by the WHO, Roche will upscale the complex manufacturing process. This has a defined maximum output over time.

This expanded production capacity, allows Roche to increase the amount of orders it can satisfy. However, in countries where Roche does not hold patents, governments are free to pursue the production of oseltamivir through generic manufacturers if they feel this is in the best interests of their country.

## 2) Filling orders for stockpiles

During an influenza pandemic, and despite our increased production capabilities, resources are likely to be in short supply. For this reason, Roche, in line with WHO recommendations, has advocated advance stockpiling of antivirals by governments as a pandemic preparedness measure.

However, it is recognised that not all governments would respond to this advice and intelligence suggested that ahead of the Pandemic (H1N1) 2009, global stockpiles of antivirals secured by governments was enough to treat only ~5% of the world's population.

In recognition of this and to support governments, Roche has a series of protocols which outline how it would allocate limited supplies of Tamiflu during a pandemic.

### Objective

Roche has determined that its policy for allocating Tamiflu during a pandemic should be consistent with the WHO publication, *Ethical considerations in developing a public health response to pandemic influenza*, which states that “resources should be used to provide the maximum possible health benefit”.

### Principles

As a global company and recognising the role Tamiflu will play in the event of a pandemic, Roche's policy regarding the allocation of Tamiflu during a pandemic is guided by the following key principles:

- Maximizing the health benefit to society during a pandemic, by supporting WHO's and national governments' containment, treatment and transmission reduction efforts
- Balancing the needs of society, employees and Roche's shareholders
- Basing decisions on the strength and integrity of the scientific and medical information available
- Communicating Roche's approach in a transparent manner and providing a transparent delivery schedule
- Maintaining a dialogue with WHO and other international agencies regarding the areas and populations in need of antiviral allocation.

## **Policy for the allocation of Tamiflu**

It is these objectives and principles – as well as input which Roche has sought from a variety of stakeholders representing different interests including ethicists, physicians, government and non-governmental organisations, policymakers and the private sector – which underpin the company’s policy for Tamiflu allocation.

The policy, which applies to the extent permitted under local emergency legislation affecting Roche’s manufacturing and supply capabilities, is outlined below and is aligned with the WHO’s pandemic alert levels.

### *Phase 3 – Focus on pandemic preparedness and prevention*

- WHO stockpiles established for rapid containment and for management of current outbreaks as a preventative measure
- Governments will be prioritised over the private sector
- Any further orders will be scheduled on a “first come, first served” basis.

### *Phase 4 – Focus on implementation of pandemic containment measures*

- Delivery of WHO rapid response stockpile
- Fulfillment of existing pandemic orders, from both governments and other groups
- Increase rapid response effort for containment in collaboration with WHO and other international agencies
- It is important to note that at this point Roche will prioritise new WHO and government orders over those from other groups.

### *Phase 5/6 – Containment measures have failed*

- Roche will continue to seek the input of international agencies such as WHO as well as other advisors to ensure the allocation of Tamiflu “ provides maximum possible health benefit”
- In the absence of international input and advice, and where clear priorities for allocation cannot be developed and agreed upon, Roche will consider the “first come, first served” principle for scheduling government orders (a letter of intent or firm order determines the date of the first in a schedule of deliveries)
- However, Roche retains the right to prioritise some orders if the spread of the virus provides a clear indication that there is public health need to deliver to one country before another i.e. epidemiological evidence or concentration of the outbreak would indicate that one country may be in greater need than another.

It is also important to note that:

- While Roche will take responsibility for the delivery of orders to governments, Roche cannot take responsibility for the distribution of Tamiflu in country. This will be the responsibility of the competent health authorities
- To ensure an efficient supply chain, Roche will agree a date for delivery of the first installment of the order for Tamiflu once a firm letter of intent has been received from an ordering government. A contract must be signed shortly afterwards to secure the delivery date for the remainder of the order. Roche will not provide any one country all of their Tamiflu order at once which could cause delays for other countries to also receive the first installment of their order.
- Roche will supply Tamiflu to all governments placing an order. The company will not discriminate, by refusing to allocate Tamiflu, against citizens of specific countries based on the economic, political or social record of their government
- Roche will not release information about which governments have placed orders. It is for those governments to make public their purchase of Tamiflu.

Roche adhered to this policy throughout its response to Pandemic (H1N1) 2009.

### **3) WHO Stockpile**

#### ***Pandemic***

It is important to note that while Roche will ensure it meets its stated obligations to deliver stockpiles to the WHO, the decision on which country will be offered access to the stockpiles rests with WHO. Roche is also unable to take responsibility for the subsequent delivery of Tamiflu to patients in the countries receiving treatment stockpile. This also rests with the WHO and the national governments involved.

### **4) Tamiflu pricing policy**

Roche is committed to combining and balancing its pursuit of innovation with corporate social responsibility.

In relation to pandemic preparedness, the company will act in a socially responsible manner by helping the world's poorest countries through differential pricing. Roche has offered Tamiflu at a reduced price for government orders, with further reduced pricing offered to developing countries, since stockpiling began in 2004.

In July 2009 and in response to Pandemic (H1N1) 2009, Roche launched its Tamiflu Reserve Programme (TRP) to ensure Tamiflu is available to governments and patients in developing nations. This is for use when the WHO has declared an influenza pandemic, or for the management of a novel influenza strain defined by WHO that has significant and current pandemic potential.

Under the TRP programme which is available to GAVI<sup>1</sup> countries (excluding India<sup>2</sup>), Roche will produce and store Tamiflu pandemic stockpiles for specified emerging

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<sup>1</sup> The Global Alliance for Vaccines and Immunisation is a global health partnership representing stakeholders in immunisation from both private and public sectors: developing world and donor governments, private sector philanthropists, the financial community, developed and developing country vaccine manufacturers, research and technical institutes, civil society organisations and multilateral organisations.

countries at a significantly reduced price with the cost spread over a number of years. Roche will then ship the stockpile to the governments of countries involved when an influenza pandemic has been announced, or in the event of a public health emergency, upon request from a government. The countries can exercise their option to purchase the product at any time.

Roche will not raise its prices during a pandemic unless an increased cost for raw materials, contract manufacturing, transportation or applicable taxes and duties are raised forcing it to do so.

## **5) Data collection on real-life utilisation of Tamiflu**

### ***Pre-pandemic***

Roche has performed and supported a number of clinical research programmes since the initial approval of Tamiflu.

Roche wishes to ensure appropriate use of Tamiflu and provide valuable insight into real-life use.

### ***Pandemic***

Roche will share any data gathered that will help international organisations and national governments respond to the public health threat posed by the outbreak.

It should, however, be understood that although Roche has a pharmacovigilance process for Tamiflu during a pandemic, the role of monitoring the development and spread of a pandemic is best carried out by supra-national organisations and co-ordinated by the WHO. It is not the role of Roche to co-ordinate global surveillance.

## **6) Company pandemic preparedness**

Roche has a company pandemic preparedness plan to enable it to fulfill its obligations in a pandemic. This plan includes prioritising products and services to be maintained during a pandemic such as the supply of previously specified life-saving medicines, but also identifying medical and non-medical interventions to minimize the risk of spread of the virus in the workplace, and the provision of Tamiflu to Roche employees and their families during a pandemic.

## **Conclusion**

This position paper describes Roche's roles, responsibilities and contributions, both in a pre-pandemic and a pandemic setting, and addresses the expectations of the global community.

Responsibility for pandemic preparedness has to be shared between governments and international agencies/non governmental organisations (NGOs) as well as manufacturers of antivirals and vaccines.

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<sup>2</sup> India is not included in the programme as a sub-licence for the production of generic oseltamivir was granted to the Indian company Hetero by Roche in 2005.

While Roche is not in a position to lead this response it acknowledges the key role it has to play as a partner in it.

**In this respect, Roche calls upon all stakeholders involved to understand their responsibility, to work together cohesively to further refine and develop future pandemic preparedness plans.**

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