Statement by Dr Keiji Fukuda on behalf of WHO at the Council of Europe hearing on pandemic (H1N1) 2009

Context

WHO is pleased to take part in this hearing, and thanks the Council of Europe for taking this initiative. The H1N1 influenza pandemic has created immensely complicated challenges for countries as well as the global community. At the same time, rising to this challenge has created an unprecedented level of global cooperation and coordination among countries in confronting a fast moving threat in this increasingly linked and globalized world. There is much to learn about how the world can improve its handling of such events and a need to separate fact from rhetoric. Again, we welcome this opportunity.

I would like to place the current experience in a historical and scientific context. The World Health Organization (WHO) is a specialized agency of the United Nations with 193 Member States. The WHO implements the global health policies decided upon by these countries and provides technical support to the countries. WHO takes very seriously its role of helping all countries to protect and improve the health of their populations. The response to the H1N1 pandemic is just one example.

In 1946, when plans for establishing the WHO were being discussed, one of the first actions agreed upon was the creation of a worldwide network of laboratories to monitor influenza viruses. That network became operational two years before WHO itself began its work.

There were good reasons for this sense of priority and urgency. First, influenza viruses mutate constantly and are notoriously unpredictable. Second, influenza was known to cause both seasonal epidemics of disease, and on occasion, much larger global outbreaks of disease, known as pandemics. Influenza pandemics occur when a new influenza virus appears and spreads around the world in populations which previously have not been exposed to the virus. History has shown that influenza pandemics can range enormously in their impact but that it is impossible to accurately predict the eventual impact at the beginning. What is seen early may be very different from what has been experienced by the end. The 1918 influenza pandemic, which killed an estimated 50 million people worldwide, started with relatively mild waves of illness and then evolved into the most severe influenza pandemic in history.

Preparedness

Over decades, WHO has worked with its Member States and partners to strengthen global defences against influenza as well as other major health threats. Such efforts include the strengthening of laboratories, epidemiological investigations, clinical care and communications, as well as the building of new capacities such as the International Health Regulations, to which I will return later. One result has been to significantly strengthen the broad global and national foundations essential for detecting, assessing, and responding to many health threats and not only influenza.

The WHO network of influenza laboratories, first conceived in 1946, now encompasses 139 national laboratories in 101 countries which collectively work together under the coordination of WHO. This network provides rapid warning and expert scientific assessment as well as the information essential for keeping influenza vaccines updated.

This system did not catch the very start of the 1957 and 1968 pandemics, but did quickly confirm, for both pandemics, that explosive outbreaks of respiratory disease in Asia were caused by novel influenza viruses. This allowed WHO, in both instances, to alert the world to prepare for the international spread of a pandemic.

In 1918, vaccines were not an option. For both the 1957 and 1968 pandemics, vaccines were produced round-the-clock but arrived too late. Worldwide, the 1957 pandemic caused more than 2 million deaths while the pandemic of 1968 caused around 1 million deaths. Although

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both were less severe in comparison to 1918, by any other measurement, such numbers of preventable deaths are large and unacceptable. Terms such as "severe" and "mild" are relative when it comes to pandemics.

WHO issued its first influenza pandemic preparedness plan in 1999, two years after a serious outbreak of avian H5N1 influenza in Hong Kong, SAR. This document was part of an intensified effort to help countries prepare for future pandemics and was updated in 2005 and again in 2009. These public documents, which form a historical record and provide recommendations to countries, were based upon the collective input of public health and scientific experts from around the world. The documents are built around the idea of phases, including a pandemic phase, and provide recommended actions to be taken by countries and WHO depending on the real world situation.

The 2009 version provides an example of the effort that went into these plans. The work began in 2007 and involved contributions from more than 135 public health scientists from 48 countries. An invitation to countries for additional comments on a draft document resulted in more than 600 replies. This work was completed in February of 2009 and published in April of that year.

The H1N1 Pandemic

In April 2009, WHO was informed of human infections caused by a new H1N1 virus. The report was of immediate concern because the genes contained in the virus were from animal influenza viruses, definitively establishing this virus as very different from the usual seasonal human influenza viruses. Further laboratory testing confirmed that existing antibodies to the current human H1N1 viruses did not react to the new H1N1 virus further underscoring the potential of the new virus to cause a pandemic. But the most important information was when investigations indicated that this new virus was causing community outbreaks with person to person spread. In Mexico, early outbreaks included deaths and severe respiratory illnesses requiring ventilators among previously healthy young people.

WHO took decisive actions in accordance with the International Health Regulations but did not announce the start of a pandemic until 11 June 2009 when the updated pandemic criteria were met. The new virus spread with unprecedented speed, reaching 120 countries and territories in about 8 weeks, and now has been reported from virtually all countries.

The H1N1 pandemic is not the same as seasonal influenza and differs in major respects. Large outbreaks occurred outside the usual season for influenza. The virus caused a striking and unusual pattern of severe illness and deaths in younger people, with many deaths caused by viral pneumonia, an especially aggressive form of pneumonia. This pattern is not typically seen during seasonal influenza.

The pandemic is not over, but to date, more than 14,000 laboratory confirmed deaths have been reported. We often see the number of deaths compared with figures from seasonal influenza. The is comparing apples with oranges. Deaths from seasonal influenza are based on statistical models. Deaths from the pandemic have been confirmed one by one through laboratory tests and unquestionably are much lower than the true number. It usually takes about 1 to two years after the end of a pandemic to get more realistic estimates of deaths using statistical modelling.

International Health Regulations and its Emergency Committee

I now want to focus on the International Health Regulations or IHR as they are often called, and the Emergency Committee. Revised in 2005, the IHR provide the world with an orderly, rules-based framework for detecting, assessing, reporting, declaring and responding to public health emergencies of international concern. They also provide the world with a system of checks and balances to ensure that no one, including the WHO Director-General, has unfettered power when making decisions.

When a possible public health emergency of international concern occurs, the IHR calls for the establishment of an Emergency Committee to advise the WHO Director-General. The Committee's membership is drawn from a larger roster, also established under the IHR, of people who are selected from around the world on the basis of their individual technical expertise.

The Emergency Committee met multiple times to advise the WHO Director-General on phase changes as well as temporary recommendations. When the Emergency Committee met to discuss a possible move to a declaration of a pandemic, the Emergency Committee meeting additionally included members who represented Australia, Canada, Chile, Japan, Mexico, Spain, UK, and the USA, eight countries that experienced widespread outbreaks at the time. These national representatives were present to ensure full consideration of the views and possible reservations of the countries expected to bear the initial brunt of economic and social repercussions.

On 11 June 2009, the Committee and all national representatives advised the Director-General that all criteria required for declaring an influenza pandemic had been met. The decision was unanimous.

Pharmaceutical Industry

Recently, accusations have been made that policies and recommendations of WHO were influenced by the pharmaceutical industry. Providing independent advice to Member States is a very important function of the WHO that is taken seriously. WHO guards against the influence of any improper interests.

Let me state clearly for the record. The influenza pandemic policies and responses recommended and taken by WHO were not improperly influenced by the pharmaceutical industry.

WHO recognizes that global cooperation with a range of partners, including the private sector, is essential for optimally addressing the public health challenges of today and tomorrow. Numerous safeguards are in place to manage conflicts of interest or perceived conflicts of interest among members of WHO advisory groups and expert committees. Expert advisers provide a signed declaration of interests to WHO detailing any professional or financial matters that could affect the impartiality of their advice. WHO takes allegations of conflicts of interest seriously and is confident of the integrity and scientific validity of its decision-making during this influenza pandemic. An explanation of how WHO uses advisory bodies in responding to the influenza pandemic was made publicly available on the WHO web site on 3 December 2009.

Closing

In closing, I would like to reiterate the most basic point. This current influenza pandemic is a scientifically well-documented event in which the emergence and spread of a new influenza virus has caused an unusual epidemiological pattern of disease throughout the world. This is not an arbitrary matter of word-smithing, definitions or polemics. The labelling of the pandemic as "fake" is to ignore recent history and science and to trivialize the deaths of over 14,000 people and the many additional serious illnesses experienced by others.

As we go forward, the world will continue to face many difficult health challenges. The resources to face them are limited, especially among developing countries, and finding ways to do this better is the shared responsibility of Member States and organizations, such as the Parliamentary Assembly of the Council of Europe, as well as WHO. Thank you.