



WORLD HEALTH ORGANIZATION

Summary of SAGE Recommendations on stockpiling H5N1 influenza vaccine and establishing a mechanism for providing access to a pandemic vaccine for developing countries without influenza vaccine manufacturing capacity

SAGE Meeting, 17 and 18 April 2007, Geneva, Switzerland

The WHO Director General requested SAGE¹ to advise whether WHO should constitute an international stockpile of H5N1 influenza vaccine and establish purchasing mechanisms to obtain influenza pandemic vaccine for resource constrained countries to use after WHO has declared the onset of an influenza pandemic.

The WHO's global survey "*Mapping the Landscape*" on the current use and possible future uptake of seasonal trivalent influenza vaccine requested countries to indicate if they would require financial assistance for the purchase of pandemic vaccine. The analysis of the survey showed that an estimated 350 million doses of monovalent pandemic vaccine would need to be financed by the international community for those low and middle income countries without influenza vaccine production that participated in the survey².

SAGE was presented with a summary of available scientific evidence, which suggests that some of the current H5N1 vaccine prototypes induce potentially protective immune responses in ferrets against viruses from other H5N1 clades and therefore might offer homologous and heterologous protection in people. SAGE was also presented with an overview on the key regulatory issues relevant to stockpiling of H5N1 vaccine. SAGE considered the potential risks linked to the use of stockpiled H5N1 vaccines, including potential adverse effects and indicated a need to study the use of such vaccine in children 6-23 months of age. SAGE was also informed of the necessity of a stability testing program to monitor potency of the vaccines throughout the stockpiling period. SAGE recommended that, if stockpiled H5N1 influenza vaccine were used in the pre-pandemic period, data on safety and immunogenicity would need to be collected. SAGE was also assured that regulatory considerations relevant to an international stockpile of H5N1 influenza vaccines have been identified, and are subject to ongoing development by WHO and its Member States, in consultation with regulatory authorities and the vaccine industry.

SAGE acknowledged the concerns of countries with human cases of H5N1 infection, or their neighbours, that such infections pose a potential threat to the national public health security of such countries.

SAGE noted that an H5N1 stockpile could potentially prevent deaths and possibly slow the spread of H5N1 in combination with other measures at the early stages of human to human transmission. SAGE agreed to recommend to the Director General that there was sufficient evidence for WHO to create a stockpile H5N1 influenza vaccine for countries without influenza vaccine production capacity or ability to purchase stockpiles of H5N1 vaccines. The stockpile could be used for attempting to contain limited early outbreaks of human to human transmission of H5N1 virus, or to immunize essential personnel in countries affected by a potential pandemic, thus preventing deaths and helping maintenance of functional health systems and other crucial national infrastructures.

¹ Strategic Advisory Groups of Experts was established 1999 to provide guidance to Director General of the WHO on the work of the Organization and its Department of Immunization, Vaccines and Biologicals

² Based on the preliminary analysis of data provided by 59 countries that indicated a required quantity of influenza pandemic vaccine and specified a need for financial assistance to purchase them. An additional 28 countries indicated that they would require financial support to purchase influenza pandemic vaccine but did not specify the required number of doses.

SAGE noted that WHO needs to proceed at the same time as developing stockpile to develop the operational guidelines that would govern the management and release, of the stockpiled H5N1 influenza vaccine in addition to defining appropriate methods for monitoring the use and evaluating outcomes. SAGE further recommended a feasibility study on the management and use of the stockpile.

SAGE also agreed to recommend to the Director General that WHO should establish mechanisms for ensuring access to pandemic vaccine, should a pandemic be declared by the Director General, for distribution to developing countries, without influenza vaccine production capacity or resources to purchase such vaccines. This support would provide greater equity in accessing pandemic vaccine and it would also assist countries in their ability to slow the spread of a pandemic in conjunction with the use of other measures.

Finally the SAGE reiterated the value to all countries of reassessing the cost/benefit of using seasonal influenza vaccine in their immunization programs for disease reduction. Increasing demand and utilization of seasonal influenza vaccines will lead to increases in manufacturing capacity that will then be applicable to pandemic vaccine production.