

## Pandemic flu: building the case to prime now

**LONDON, UK----12<sup>th</sup> March 2009----ExpertREACT.** Latest research from strategic consultancy VacZine Analytics<sup>(R)</sup> suggests that the expert community is leaning towards the idea of priming the population now against a possible influenza pandemic. The concept referred to as pre-emptive or “early” immunological priming, is faced with obstacles, but it appears not as many as those linked with current pandemic vaccine strategies.

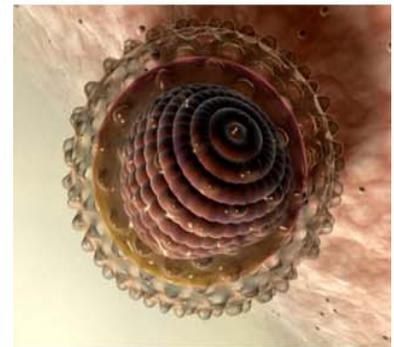
Many experts believe that the next influenza pandemic is imminent and poses a continual threat to global human health. According to latest research **(1)** experts remain concerned about the current avian influenza strain H5N1 (and subclades) which has spread rapidly in bird populations in SE Asia. Although the number of cases since 2003 is relatively low at just over 400 **(2)**, the case fatality rate is high (~60%) and the number of countries reporting H5N1 human cases is growing. H5N1 human cases have not been reported in large Western nations with Turkey and Egypt being closest to the European continent.

Seasonal influenza, which is distinct from pandemic influenza, causes many deaths each year. Because certain elements of the influenza virus are pliable, the pathogen can rapidly change characteristics, especially its transmissibility. Experts state that there is a statistical chance that a simultaneous infection of a human influenza virus and avian H5N1 could cause genetic reassortment forming a new virus. This virus could be spread more rapidly between humans initiating a pandemic. With H5N1 there are arguments that this event may never happen because a number of years have passed since its first human cases and no dramatic changes have occurred. However, because the threat is so extreme experts take the view it cannot simply be ignored.

Vaccines and antivirals along with other containment measures are now the cornerstone of pandemic preparedness plans in all major nations. In the US, for example, the Department of Health and Human Services (HHS) during the Bush administration has received budget authority since 2004 of nearly \$8 billion dollars to prepare for a pandemic. Approximately \$4 bn has been allocated to vaccines in order to increase production capacity, build stockpiles and invest in cell-based expression systems **(3)**. For stockpiles in particular, some countries have amassed H5N1 antigen in order to be released on declaration of a pandemic for immediate vaccination. Although it is not known what influenza strain will cause a pandemic, the vaccine is hoped to provide some protection in the lag period before a more specific vaccine is produced (8-9 months later). In the US, the major French vaccine company, Sanofi Pasteur, was the first to receive a FDA license in 2007 for a pandemic vaccine along with support from the U.S. National Institutes for Allergy and Infectious Diseases (NIAID) **(4)**. Sanofi's whole vaccine elicits an immune response with two doses but is considered “not the most practical vaccine” because of its large antigen amount (90mcg) and relatively low safety database at time of approval restriction to 18 to 64 yrs. In Europe, other major manufacturers such as GSK Biologicals, Baxter Vaccines and Novartis have also pushed forward the pandemic vaccine agenda.

In addition to stockpiling H5N1 vaccines, countries have also made advance supply agreements with manufacturers to produce pandemic specific vaccine once a pandemic is declared. Normally the arrangement is to cover as much of the population as possible with certain groups e.g. children, elderly and critical “front-line” occupations being prioritized. Countries have also notably stockpiled antivirals such as Tamiflu (oseltamavir) for strategic and/or widespread use. Upon closer inspection advance supply agreement strategies, like H5N1 stockpiling have potential weaknesses. These are mainly linked to the possible safety risk of rapidly vaccinating the population with an uncharacterized vaccine, especially if it contains an adjuvant. There is also the concern that, assuming a pandemic vaccine can be made, logistically will countries be able to execute a program in a state of heightened national disruption? Moreover, although experts agree that from scientific point of view, vaccination to protect against a pandemic is sound concept it is still debated of how to best compare pandemic vaccines from different manufacturers and prove their immunogenicity will be protective in the “absence of real disease”. There are many “unanswered scientific questions”.

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As part of this new research experts were asked whether they would support vaccinating certain elements of the population with a pre-pandemic vaccine now, possibly H5N1. Many arguments for and against were raised. It appears early immunological priming does have obstacles but similarly avoids some of the issues being associated with H5N1 stockpiling and advance supply agreements. Furthermore, an emerging body of scientific data suggests that “early” immunological priming gives long-term memory which can be boosted many years later with potentially valuable cross-protective immunity.

Overall, **VacZine Analytics**<sup>(R)</sup> believes that one of the main lessons from this new research is that the best outcomes often occur when we think and act ahead of time. “Early priming” is a concept that should be discussed and explored further but will always be about a government’s and individual’s perception of risk.

**References:**

- 1) **MarketVIEW** and **DiseaseINFOPACK: Pandemic influenza** (CAT No: VAMV004 and VADIP010), published by VacZine Analytics, March 2009
- 2) World Health Organization (WHO). Website. Available at: [http://www.who.int/csr/disease/avian\\_influenza/country/cases\\_table\\_2009\\_02\\_27/en/index.html](http://www.who.int/csr/disease/avian_influenza/country/cases_table_2009_02_27/en/index.html) Accessed March 2009
- 3) Levitt MO. US Department of Health and Human Services (HHS). Pandemic Planning Update VI. January 8, 2009. Available at: <http://www.pandemicflu.gov/plan/pdf/panflureport6.pdf> Accessed January 2009
- 4) Sanofi Pasteur Corporate Press Release. FDA Licenses First U.S. Vaccine for Humans Against Avian Influenza, April 17<sup>th</sup> 2007. Available at: [http://198.73.159.214/sanofi-pasteur2/ImageServlet?imageCode=23011&siteCode=SP\\_CORP](http://198.73.159.214/sanofi-pasteur2/ImageServlet?imageCode=23011&siteCode=SP_CORP). Accessed March 2009

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**About VacZine Analytics**<sup>(R)</sup>:

VacZine Analytics is a new strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines.

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