Feasibility of Production of Human AI Vaccine
in AI vaccine Manufacturers in China

Distinguished delegates, ladies and gentlemen,
Good morning!

It is my pleasure, on behalf of the Ministry of Agriculture, China, to attend this meeting; I appreciate the opportunity offered by WHO, FAO and OIE.

Avian influenza (AI) is the common challenge to all the countries in the world. Stringent global cooperation in control of avian influenza is in favors common interests of all countries. Avian influenza spreading does not only affect the economy and social development of a country, but also seriously harms people’s health and lives. Or even threatens regional and global safety and stability. The present international epidemic situation indicates that the global Avian influenza spreading is speeding up. Human cases are persistently increasing and deaths are continuously rising. Pandemic is unpredictable.

Facing potential risk of global pandemic influenza and shortage of human influenza vaccine producing capacity, WHO and other international organizations are undertaking assessment of the feasibility of production of human vaccines in veterinary vaccine facilities. This is of great significance for response to the potential pandemic. On behalf of the MOA, China, I would like to introduce development of AI vaccines for poultry in China and the feasibility of producing human AI vaccines in veterinary vaccine facilities.

1. Research & development of AI vaccines for poultry in China

China National Avian Influenza Reference Laboratory developed reassortant avian influenza virus vaccine, inactivated \((\text{H}_5\text{N}_1 \text{ Subtype, Re-1 strain})\) by reverse genetic, avian influenza recombinant newcastle disease virus bivalent vaccine, live \((rL-\text{H}_5 \text{ Strain})\) by gene assortment technology. Animal test showed two vaccines had 100% protection rate. Both vaccines had been produced in batches. The recombinant inactivated AI vaccine \(\text{H}_5\text{N}_1 \text{ (Re strain)}\) has been applied in big scale in China and Vietnam. It played important role in prevention and control of AI outbreaks. Moreover, \(\text{H}_5\) AI gene modified subunit vaccine has developed by the National AI Reference Laboratory, with relatively good safety and stability.

2. Production of AI vaccine

8 enterprises approved by the Ministry of Agriculture for producing AI vaccines for poultry. These vaccines include: avian influenza vaccine, inactivated \((\text{H}_5 \text{ Subtype, N28 Strain})\), reassortant avian influenza virus vaccine, inactivated \((\text{H}_5\text{N}_1 \text{ Subtype, Re-1 strain})\), avian influenza recombinant fowlpox virus vaccine,
Live (H5 Subtype) and avian influenza recombinant newcastle disease virus bivalent vaccine, live (rL-H5 Strain), with an annual capacity of 46 billion doses, including 21 billion doses of inactivated and 25 billion doses live vaccine. The domestic demands for AI vaccine are about 25 billion doses. With a surplus capacity of 21 billion doses, this can be exported to other countries. 500 million doses of vaccines have been exported to Mongolia, DPR Korea, Vietnam, and Egypt since October 2005.

3. Feasibility analysis on production of human AI vaccine in AI vaccine facilities for poultry in China

3.1 The China National AI Reference Laboratory had begun AI research from early 1980s. They made progress in AI immunology and vaccine development.

- They have the advantage in seed virus selection. The information data bank of China AIV strains has been established, and it can basically meet the requirements of continuous upgrading or renewal of human vaccine strains. In case of pandemic, the most antigenically related seed virus would be selected very soon.
- They have the most advanced technology for research and development of human AI vaccine. The reverse genetically operating technique which can effectively reduce virus’ pathogenicity is used for vaccine development. Subunit vaccine has been developed. It is possible to produce most safe and stable human AI vaccine.

3.2 China’s AI vaccine production capacity can be adapted to the requirements for production of human AI vaccine. Approved 8 enterprises specific for poultry AI vaccines with a capacity of 46 billion doses, which can meet requirements for domestic poultry vaccination. In addition, there are other 35 veterinary bioproducts enterprises have passed GMP certification. When necessary, they can be allowed to produce AI vaccines, and the AI vaccine production capacity can be increased greatly. WHO has recommended that the production capacity of 2~3 billion doses be transformed to produce human AI vaccine without affecting domestic market demand.

3.3 Modification of AI vaccine enterprises can meet requirement for production of human AI vaccines. The Chinese Veterinary drug GMP was formulated in reference to the US and EU GMP standards and is essentially identical to human medicine GMP requirement. The production technologies for veterinary AI vaccine and those for human AI vaccine are same in many aspects, and the most difference is that high level purification process is added in production of human vaccines. If the veterinary vaccine enterprises introduce high level purification process, they should meet the management requirement for production of human vaccines.

Preliminary analysis shows that AI vaccine research and development
institutions and the AI vaccine production enterprises have the ability for research development and production of human AI vaccines.

4. Recommendations

4.1 We welcome WHO’s assessment to AI vaccine facilities for poultry in China. Ministry of Agriculture is willing to work together with the concerned ministries in the country, WHO and other international organizations to fully demonstrate the differences between poultry and human AI vaccines with regard to GMP, production technique, to train the employees with the veterinary vaccine enterprises and to conduct necessary technical reforms so as to meet human vaccine production requirements.

4.2 Based on the assessment, one of three ways can be chosen.

- China veterinary vaccine enterprises are subjected to necessary reforms and produce human AI vaccines after obtaining license issued by the state Food and Drug Administration, in order to provide vaccine stockpile in response AI pandemics.

- China’s veterinary vaccine enterprises are subjected to necessary reforms and after obtaining the licenses issued by the State Food and Drug Administration and under WHO Coordination, produce human AI vaccines for the demanding countries.

- China’s National AI Reference laboratory and veterinary vaccine enterprises cooperation with foreign enterprise and produce AI vaccines in the foreign countries.

Wish the meeting a great success.
Thank you.