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

Gu Hong
Ministry of Agriculture of P. R. China
AI -- common challenge to the all countries

Global cooperation in control of AI is in favors common interests of all countries

The international epidemic situation indicates that the global AI spreading is speeding up. Human cases are persistently increasing and deaths are continuously rising

Pandemic is unpredictable
● It is of great significance for response to the potential pandemic that WHO and other international organizations are undertaking assessment of the feasibility of production of human vaccines in veterinary vaccine facilities.

● 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 (H5N1 Subtype, Re-1 strain) by reverse genetic and reassortant

- Avian influenza recombinant Newcastle disease virus bivalent vaccine, live (rL-H5 Strain) by gene recombinant technology
Animal test showed two vaccines had 100% protection rate.

Both vaccines had been produced in batches.
Reassortant avian influenza virus vaccine, inactivated (H5N1 Subtype, Re-1 strain)

- has been applied in big scale in China and Vietnam.
- played important role in prevention and control of AI outbreaks
H5 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 MoA for producing AI vaccines for poultry. These vaccines include:

- Avian influenza vaccine, inactivated (H5 Subtype, N28 Strain)
- Reassortant avian influenza virus vaccine, inactivated (H5N1 Subtype, Re-1 strain)
- Avian influenza recombinant fowlpox virus vaccine, Live (H5 Subtype)
- Avian influenza recombinant Newcastle disease virus bivalent vaccine, live (rL-H5 Strain)
Annual capacity of AI Vaccine for poultry is 46 billion doses
- 21 billion doses --- inactivated
- 25 billion doses --- live vaccine.

- About 25 billion doses --- domestic demands
- About 21 billion doses --- surplus capacity can be exported to other countries

- 500 million doses --- 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 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’ pathogencity 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
-- can meet requirements for domestic poultry vaccination.

there are other 35 veterinary bioproducts enterprises have passed GMP certification.
-- can be allowed to produce AI vaccines
-- 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

- formulated in reference to the US and EU GMP standards

- 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.

- 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.
4.0 Recommendations
4.1 We welcome WHO’s assessment to AI vaccine facilities for poultry in China.

- MoA 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 choiced.

- China veterinary vaccine enterprises are subjected to necessary reforms and produce human AI vaccines after obtaining license issued by the SFDA, 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 SFDA 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!

Thanks!