Veterinary vaccine capacity for human pandemic vaccine?

Presentation to WHO

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Geneva April 27th 2006
IFAH’s COMMITMENT

- The Animal Health Industry is committed to protecting both human and animal health.
- In the event of a human health crisis arising out of an influenza pandemic, the Animal Health Industry will work with human health authorities to help in the most appropriate manner the circumstances dictate.
- The Animal Health Industry has substantial vaccine resources that include R&D capabilities and the ability to manufacture using a variety of technologies.
- IFAH will need to balance the need for committing some its companies’ capacity for producing human vaccines to protect people in the event of a pandemic with the continuing requirement for manufacturing poultry vaccines.
Vaccine availability from international companies

- Billions of doses have been used over the past 10 years
- Each year several hundreds of millions doses, OIE compliant, are used
- The vaccines are licensed in the countries
- Vaccines: inactivated (H5N2, H5N6, H5N9, H7N1, H7N7, H9N2) and recombinant H5
- IFAH supports the OIE requirements for AI vaccines
- Capacity is more than sufficient to meet the present demand
- An increase in demand could be met, but for a sudden and massive increase, adequate lead-time is necessary, and thus strategic stocks/vaccine or antigen banks are essential
Standards in Veterinary Vaccine production

- GMP requirements for human and veterinary vaccine production facilities are comparable.
- Requirements for antigen production in eggs and cells for human and veterinary vaccine production are comparable.
- IFAH represents the international companies, which comply with GMP and OIE requirements.
- IFAH offers accredited facilities and processes, which are compliant with OIE requirements.
What will happen in case of a pandemic?

- More cases in people
- Disturbed egg supply
- New outbreaks poultry

Pandemic virus
Egg production, the veterinary issues

- Many vaccines for poultry and other species are produced on eggs
- Continuous supply of vaccines is essential for protecting poultry for continuous egg supply for vaccine production for humans
- In case of a pandemic:
  - demand for AI poultry vaccines will surge
  - egg supply might be limited
- Considerable differences in DSP between animal and human vaccine production
- IFAH conclusion: egg-based influenza antigen from the veterinary sector for human influenza vaccine production will not mitigate substantially the potential shortage of human vaccine
Cell-based antigens: issues

- Large scale cell-culture facilities are available in the animal health industry
- Cells, media and production technology need to be transferred from the human manufacturers to veterinary companies
- Transfer of technology takes time and effort
- Technology may be protected by Intellectual Property (IP) rights
- If antigen supply can be increased, what are the consequences for the DSP (antigen purification) capacity?
Particular concerns

• Liability relating to human vaccines cannot be accepted by veterinary companies which would need extraordinary liability protection in the event they participate in the manufacture of human vaccines.

• In case of AI outbreak, disease control measures might stop egg supply or animal experiments.

• Continuation of egg supply, transport of eggs, animal experiments, need to be ensured in national and international contingency plans for control of a pandemic or AI outbreak in poultry.

• Cell-culture: technology transfer, regulatory consequences?

• Technology transfer brings IP issues.
The way forward

• In case of a pandemic the veterinary and human vaccine producers need more capacity
• Compliance with national and international standards (OIE, WHO) need to be maintained
• Regional availability and location of manufacturing facilities should not be an issue, it’s availability that counts
• Prevention and control of a pandemic is a task for the whole world
• Funds need to be made available to the industry to increase vaccine production capacity and to create a steady purchase of strategic stocks/banks and emergency vaccines, human and veterinary
Conclusions

- Availability of human vaccines is essential
- IFAH will do the utmost to assist in solving capacity
- Increased capacity may come from cell-culture and not from egg-culture technology
- Funding of capacity and purchase of emergency vaccines, veterinary and human
- IFAH will do the utmost to play its part to protect human and animal health
Thank you for your attention