Two Avian Flu Vaccines for Birds Okayed in Europe

BY JONATHAN GARDNER
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The European Medicines Agency has approved the first two avian influenza vaccines for birds that the agency says will reduce mortality and virus excretion in poultry exposed to the disease.

The European Medicines Agency (EMEA) gave a positive opinion to Nobilis Influenza H5N2 from Intervet International BV, a subsidiary of Netherlands-based Akzo Nobel BV, and Poulvac FluFend H5N3 RG from Fort Dodge Animal Health, a division of U.S.-based Wyeth.

Both are inactive, adjuvanted avian influenza vaccines administered by injection. Nobilis is for use in chickens, and Poulvac is intended for use in chickens and Pekin ducks.

The agency's Committee for Medicinal Products for Veterinary Use approved the vaccines under "exceptional circumstances," anticipating a period of high risk for infection in the autumn and winter. The committee decided that the benefit of using the vaccines outweighed the risks but will review the vaccines annually.

Under the approval, EMEA also requires enhanced safety monitoring by the two manufacturers.

London-based EMEA is a division of the European Union that offers pharmaceutical manufacturers a way to obtain a single approval for the 25 EU countries. A positive opinion from EMEA is forwarded to the European Commission for single marketing approval.

Many experts believe reducing the number of H5N1 infections in birds may be the best path to preventing a pandemic outbreak in humans.

The density of both humans and poultry in the world, coupled with trade, travel, and a history of avian influenza virus strains that mutate into forms that spread easily among humans, means "all the ingredients are in place for the occurrence of another pandemic," said Dr. Didier Houssin, interministry delegate for the fight against avian influenza in the French Ministry of Health, Paris.

The vaccines were approved under 'exceptional circumstances,' after a committee decided that the benefits outweighed the risks.

"Prevention of human contamination should also be the first line of defense against a potential human pandemic," Dr. Houssin told the First International Conference on Avian Influenza in Humans.

Among the strategies countries should consider is the vaccination of poultry, although he warned that this step may not always prevent avian influenza from entering a country. "Measures taken at the country level are not sufficient, because wild birds know no or almost no frontiers," Dr. Houssin said. ■

Clinical Trial Finds Good Response to Avian Flu Vaccine

GlaxoSmithKline has announced that its H5N1 vaccine achieved a high immune response in a clinical trial in Belgium.

Investigators immunized 400 healthy adults with a vaccine that contained an inactivated H5N1 virus and a proprietary adjuvant. Subjects were vaccinated twice.

The lowest strength tested was 3.8 mcg of antigen, along with three higher doses. At 3.8 mcg, 80% of the patients demonstrated a seroprotective response.

The vaccine has not received marketing approval from any regulatory agency, although Jean-Pierre Garnier, GSK's chief executive officer, said the company will apply for approval in the coming months.

"This is the first time such a low dose of H5N1 antigen has been able to stimulate this level of strong immune response," Mr. Garnier said. "There is still a lot more work to be done with this program, but this validation of our approach provides us with the confidence to continue developing the vaccine, including assessment of its ability to offer cross-protection to variants of the H5N1 strain."

—Jonathan Gardner