

Two Avian Flu Vaccines for Birds Okayed in Europe

BY JONATHAN GARDNER
London Bureau

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 (EMA) gave a positive opinion to Nobilis Influenza H5N2 from Intervet Interna-

tional 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, EMA also requires enhanced safety monitoring by the two manufacturers.

London-based EMA 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 EMA 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.

"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



Assessing patient activity: An important clinical measure in COPD

The decline of lung function in patients with chronic obstructive pulmonary disease (COPD) is insidious. Its impact usually first becomes evident when patients perform daily activities.¹

► Compensating for COPD

Too often, patients simply compensate for COPD by gradually changing their behavior to reduce physical exertion.¹ For example, they may take an elevator rather than climb the stairs—without even noticing that there is a problem. This behavior is compounded by the fact that early COPD is not always initially obvious on physical examination.² As a result, patients with COPD are typically not diagnosed until they have reached a moderate level of severity.¹

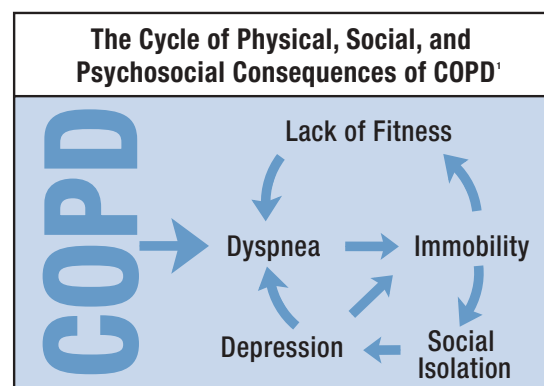
► Establishing baseline activity levels

Once COPD is diagnosed, the physician's ongoing assessment should include the impact of the disease on patients' activity.¹ Establishing a baseline activity level is helpful because, in addition to using spirometry, physicians may use changes in activity levels to determine COPD severity. For instance, patients with moderate COPD may only have dyspnea on exertion, while those with severe COPD may experience fatigue and shortness of breath when doing everyday activities.¹

► Breaking the cycle of COPD

The impaired ability to exercise negatively impacts patients' quality of life.¹ By improving patients' exercise tolerance—an important goal in COPD management—physicians can affect the cycle of COPD. Helping patients consider what

they can do physically, in addition to how they feel, can help lead to positive gains in other aspects of COPD and increase functional and social independence—another goal of COPD management.³



From the *Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease*, Global Initiative for Chronic Obstructive Lung Disease (GOLD): Updated 2005. Available from <http://www.goldcopd.org>.

► Conducting ongoing activity assessments

It is valuable to monitor the activity level of patients with COPD—both at the time of diagnosis and after diagnosis.^{1,2} Activity assessment is a key indicator that may help physicians evaluate the clinical efficacy of COPD treatments.

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