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D.O.No.50-171/05-LDT (AQ)

Dated the 3rd February 2006

**Subject: Avian Influenza – Vaccination for poultry – Requirements and Protocol for Access and Use**

An Action Plan for State Animal Husbandry Departments in respect of Bird Flu has been circulated by the Government of India. The Action Plan deals with strategic action to be taken in two situations viz., in case of suspicion of outbreak of Avian Influenza and in case outbreak of HPAI is confirmed. A series of actions are to be taken in case outbreak of HPAI is confirmed which have been dealt at Part II of the Action Plan (from pages 12-27). Vaccination is a recommended strategy in case of outbreak of HPAI especially in a densely populated poultry area. Para 2.24 and 2.25 of Part II of the Action Plan (pages 25-26) deal with vaccination. Ring vaccination may be carried out in the Intensive Surveillance Zone i.e., 3 to 10 km radius of the infected site. The State Governments are advised to contact the Department of Animal Husbandry, Dairying and Fisheries if it is desired to carry out ring vaccine in the Surveillance Zone stating reasons for vaccination, number of domestic avian species at risk, number of doses required etc. If convinced, DADF may arrange to procure and dispatch appropriate vaccines to the concerned District authorities.


A Central Strategic Reserve of H5 and H7 vaccines has now been developed and is being maintained by the Government of India at Kapashera, near Indira Gandhi International Airport. It is, therefore, considered necessary to lay down the procedure and process for accessing and using the vaccines from the Central Strategic Reserve of Government of India by the State Governments. Accordingly a 'Protocol For Access and Use of Vaccines for Avian Influenza' has been drawn up by this Department. Two copies of the Protocol are enclosed with this letter.

The technical specifications and other requirements concerning use of these vaccines are covered in this Protocol for further dissemination to the Veterinarians especially the Rapid Response Teams (RRTs) of vaccinators so that in case of outbreak valuable time is not lost in familiarizing the members of

the RRTs with such details in time of emergency. Presently the technical specifications/requirements of the H5 vaccines are being conveyed. The technical requirements of the H7 vaccine will be conveyed subsequently. It is requested that the concerned Veterinarians and especially the Rapid Response Teams of vaccinators are familiarized with the technical specifications of the vaccines.

The Procedure and the Process for accessing vaccines from the Government of India Reserve may please be perused and understood clearly for early activation in time of emergency.

Yours, sincerely,

  
(Upma Chawdhry)

To  
All Secretaries of State Animal Husbandry Deptt.  
(As per list enclosed)

**PROTOCOL FOR ACCESS AND USE OF VACCINES FOR 'AVIAN INFLUENZA'**

In developing country specific HPAI control strategies and programs, the broad principle of targeting the disease at source of infection is to be applied. This is universally acknowledged as the most effective strategy. The disease control options include risk-based surveillance, enhanced bio-security, control on movement of poultry, rapid humane culling of high risk poultry, strategic vaccination etc.

The global strategy supports the use of good quality vaccines. FAO and OIE have made recommendations for the use of OIE approved HPAI vaccines in accordance with the FAO/OIE guidelines (FAO Position Paper, September, 2004). Vaccination protects against clinical disease in chickens by reducing mortality and production losses. Vaccination of poultry also reduces the virus pool contaminating the environment and thereby the risk of infection to poultry and humans. It increases resistance to infection and protects from diverse field viruses within the same hemagglutinin subtype. According to current OIE recommendations, HPAI vaccinated poultry is not excluded from export trade although specific technical guidelines must be followed to ensure that the vaccine is being applied properly and monitored effectively.

It is important that vaccination alone is not considered the solution to the control of Notified Avian Influenza (NAI), both Highly Pathogenic Notifiable Avian Influenza (HPNAI) and Low Pathogenic Notifiable Avian Influenza (LPNAI) sub-types if eradication is the desired result. It must be undertaken in tandem with the application of monitoring systems, strict bio-security measures and de-population in the face of infection in case of an outbreak, etc. Whereas vaccination of commercial poultry farms can be carried out quite easily, vaccination of backyard, non-confined poultry poses significant logistical and technical problems. Several countries have adopted vaccination as a strategy in case of outbreak of HPAI. In countries practicing vaccination, the vaccination strategy was adopted mainly because the disease had spread widely throughout the smallholder poultry sector, particularly in production systems 2,3 and 4 (medium to low level of biosecurity) accompanied by high level of mortality. Given the large scale of infection and the limited capacity to mount large-scale surveillance, stamping out and bio-security measures, vaccination was considered as an

important part of the control strategies. There is good evidence to show that this approach has served to significantly reduce losses due to HPAI. (Source: FAO/OIE).

The Government of India has developed a Strategic Reserve of H5 and H7 vaccines being maintained at Kapashera, near Indira Gandhi International Airport, New Delhi. It is necessary to lay down the procedure and process for accessing/using the vaccines from the Central Strategic Reserve of Government of India by the State Governments as also share information on other issues concerning cold chain, technical requirements for vaccine etc. Accordingly the Protocol For Access and Use of vaccines for Avian Influenza has been drawn up by the Department. The Protocol has the following four parts:

- I. Technical specifications of vaccines available in the Central Strategic Reserve of GOI.
- II. Procedure to access vaccines
- III. Requirements to be met by the State Governments for receiving and utilizing vaccines
- IV. Related issues

#### PART I. Technical specifications of vaccines available in the Central Strategic Reserve of GOI.

H5 and H7 vaccines are available in the Central Strategic Reserve of Government of India.

##### I.1 Technical Specifications of H5 Vaccine

###### 1. Description:

It is an inactivated vaccine used to induce active immunity in chickens against Avian Influenza, type A, subtype H5. The virus is grown in embryonated eggs and is chemically inactivated. Subsequently the inactivated viral antigen is suspended in an aqueous phase and mixed with an oil phase to produce an emulsion to enhance immunity.

###### 2. Composition:

Active component is the inactivated Avian Influenza virus type A, subtype H5N2, strain A/ chicken/ Mexico/ 232/ 94/CPA.

###### 3. Indication:

Nobilis influenza H5 is meant to be used for active immunization of healthy poultry as an aid in the prevention of Avian Influenza type A, subtype H5.

#### 4. Recommended Vaccination Program

All flocks including backyard poultry within 3-10 kms. radius should be immediately vaccinated with the inactivated Avian Influenza vaccine @ 0.5 ml per bird . Birds less than three weeks should be vaccinated @ 0.25 ml per bird Subcutaneously in lower neck region. Booster vaccination will be carried out after 4-6 weeks.

#### 5. Dosage and Administration:

The vaccine is a liquid product ready to be used. Shake well before use. The vaccine is administered subcutaneously into the lower back part of the neck. Use a dose of 0.50 ml for vials with 1000 doses and a dose of 0.25 ml for vials containing 2000 doses. The present vaccine contains 1000 doses per 500-ml. bottles.

#### 6. Vaccination Reactions

In healthy birds no clinical reaction to vaccination will be observed. After vaccination a slight swelling may be felt at the site of vaccination. In the layers, drop in production may be seen due to the handling during this period.

#### 7. Withdrawal Period:

None

#### 8. Precautions And Warnings:

- Vaccinate healthy animals only.
- Shake well before using.
- Allow the vaccine to reach ambient temperature (18°-25° C before use).
- Use the content within 3 hours after opened.
- Do not mix with other veterinary medicinal products.

#### 9. Operator Warning:

If accidental self- administration (or bystander) occurs, a local reaction may be seen. It is recommended to seek physician's advice. Inform physician that vaccine is inactivated and is a water-in-oil emulsion.

#### 10. Storage Conditions

Store in refrigerator between 4° to 8° C. Protect from light. Do not freeze.

#### I.2 Technical Specifications of H7 Vaccine

The specifications of the H7 vaccine will be conveyed subsequently.

## PART II. Procedure to access vaccines

1. In case of suspicion of outbreak, the pathological samples are to be collected as detailed in Para 1.10 of the Action Plan. These samples are to be dispatched to HSADL, Bhopal immediately. In situation of suspicion of HPAI based on preliminary investigation the samples may be sent to HSADL, Bhopal directly and not to Regional Disease Diagnostic Laboratories (RDDL's). Information about dispatch of samples on suspicion of Avian Influenza must be given to Department of Animal Husbandry, Dairying, and Fisheries, Government of India immediately. The contact persons are Dr. S.K. Bandyopadhyay, Animal Husbandry Commissioner (Telefax No.: 2338 4146), Ms. Upma Chawdhry, Joint Secretary (Tel. No.2338 7804/Fax No.: 2338 6115) and Dr. A.B. Negi Joint Commissioner (Telefax No.: 2338 4190).

2. In case the situation warrants, arrangements to fly the samples to Bhopal can be considered by Government of India. In such a situation the States will have to provide logistical details of place/district/area from where samples have to be flown out; co-ordinates viz. longitude/latitude of possible landing location; nearest town/centre of importance etc. to enable landing of helicopter. The laboratory at Bhopal will take some time to confirm the result. The period available between dispatch of sample and confirmation one way or the other by Bhopal is to be utilised for certain actions including collection of data on poultry as already specified in Para 1.14 of the Action Plan. This data is to be collected both within the radius of 3 kms. and between 3-10 kms radius of the infected farm (which will be the infected zone and the surveillance zone respectively in case of confirmation). This data collection is important for three reasons as below:

- (i) Determine size of poultry to be culled within a radius of three kms of the farm premises to assess requirement of cullers.
- (ii) Verify claims and payment of compensation for culled poultry within a radius of 3kms of the infected farm.
- (iii) Quantify and assess requirement of vaccines and vaccinators in the 3-10 km zones.

3. If the sample is confirmed as positive by the Bhopal laboratory, the State Government is to take action as per the details contained in Part II of the Action Plan.

4. Vaccination is one action that can be considered to control and contain HPAI. The Action Plan for State Animal Husbandry Departments in respect of bird flu, which was prepared and circulated by the Government of India,

considers vaccination as an option under Para 2.24 and 2.25. The relevant Paras are reproduced below:

**"Vaccination**

2.24. Vaccinated birds may get protected against the disease but continue to spread the infection. OIE recommends that in case of an outbreak of HPAI in a densely populated poultry area, vaccination can be one of the options to be adopted as a control policy. Since there are various subtypes of influenza viruses, it is difficult to predict involvement of a particular sub-type and keep stocks ready. However, mass-vaccination with the most commonly used strain in an inactivated vaccine in the entire surveillance zone as ring vaccination could be adopted. If it is desired that ring vaccination be carried out in the intensive surveillance zone (ie, 3 to 10 kms radius of infected site), the Department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India may be contacted stating reasons for vaccination, no. of domestic avian species at risk, no. of doses required etc. If convinced, DADF may arrange to procure and dispatch appropriate vaccine to the concerned district authorities. Prior to receiving the vaccine, the district authorities should make all necessary arrangements for carrying out emergency vaccination including mobilisation of teams etc.

2.25. After a cooling off period of about three weeks, the poultry or products from the surveillance zone, which had undergone vaccination can be allowed to be traded outside the zone. It may be noted that vaccination is to be undertaken only during hours of crisis and not as a routine prophylaxis. It is emphasized that vaccination alone will not be sufficient to bring the outbreaks in poultry under control. It must be used in conjunction with comprehensive strategy, i.e., culling of affected birds, strict bio-security, quarantine and other measures to prevent further spread of the disease. If no vaccination is adopted, trading could be resumed four weeks after all birds within 3 kms are culled, provided no fresh case appeared in the surveillance zone between 3 to 10 kms. "

5. If the State Government is of the opinion that vaccination is to be carried out in the intensive surveillance zone i.e. 3 to 10 km. radius of infected site, it may contact the Department of Animal Husbandry Dairying and Fisheries, Government of India. The Government of India will require the following information:

- a. Poultry numbers in the surveillance zone
- b. Species- all poultry
- c. Doses required

d. Concentration of poultry

e. Type of poultry viz. organized/unorganized including backyard poultry etc.

f. Reasons for considering vaccination

6. Based on the request of the State Government and the information so received, the Government of India will decide and determine whether vaccination should be undertaken or not. Decision on vaccination will depend on the nature and severity of the outbreak; the density and type of poultry population etc. If convinced of the need to vaccinate poultry in the surveillance zone, the Government of India will dispatch the appropriate vaccine to the concerned State/district authorities. The vaccines will be carried by an officer of the Government of India and will be delivered by him at determined place to the designated officer of the State Government. The officer of the Government of India will also be in a position to brief the vaccinators on vaccine use, culling etc.

7. The Government of India will attempt to send the vaccines by air in case of emergency. Logistical details as already mentioned above will be required from the State Government in case vaccines are flown by air in emergency.

### PART III. Requirements to be met by the State Governments for receiving vaccines and utilizing vaccines

1. The Government of India will transport the vaccines in cold chain to the specified station. The vaccine will be packed in appropriate containers in ice-gel packs, which maintain the cold chain requirements for a certain period of time.

2. The cold chain has to be maintained thereafter till the vaccine is administered. The State Government will have to ensure this and make adequate arrangements for the same. The following equipment/materials will be required for the maintenance of the cold chain at the site of delivery:

a. Refrigerators (a 320 litres capacity refrigerator will accommodate 400 vials of 500 ml. containing 1000 doses per vial)

b. Power back up.

c. Vaccine carriers/Thermocol boxes.

d. Ice gel packs /ice for thermocol boxes/vaccine carriers.

#### 3. Vaccination Plan

i. The State Government should have a Plan for administering the vaccine so as to cover the area between 3-10 kms of the surveillance zone quickly and

comprehensively. Vaccine delivery systems and campaigns should be carefully organized and monitored.

ii. The Plan should be developed under overall control and supervision of the District Collector/ Sub-Divisional officer with technical assistance of veterinarians.

iii. The Plan should broadly consider the following points on the basis of the data, which is expected to be available with the District administration in terms of the exercise having been conducted as explained at Part II.1. above:

a. Manner of coverage of 7km. area

As per practice, ring vaccination is to be done i.e. vaccination is to start from periphery of surveillance zone, i.e. 10 Kms. of infected farm premises. It will move inward from 10 Kms. to 3 Kms. radius in stages.

b. No. of vaccination teams required

c. Availability of vaccination teams.

Sufficient number of teams of vaccinators should be available with required equipment. In case the need arises, the teams of vaccinators from neighboring areas/ districts should be rushed in immediately. Each team should have a designated coordinator.

d. Equipment/material required by the vaccination teams and its availability:

- PPE: As per letter No.50-172/2005-LDT (AQ) dated 25<sup>th</sup> November 2005 of Government of India, two sets of PPE have been suggested viz. for direct handlers and other than direct handlers.
- Vaccinators/syringes: Since the vial of H5 vaccine is of 500 ml., it is advisable to use vaccinator where the vial can be fitted directly to the vaccinator.
- Vaccine carrier with cold chain maintenance: It is suggested that the State Animal Husbandry Departments can also seek support if required of State Health Department, which also have considerable experience in maintenance of cold chain in the immunisation programme.

iv. A system of communicating with vaccination teams should be developed and put in place immediately. If required, special permission can be given to use mobile phones and the cost can be charged to the campaign. Alternate methods as per geographical location can be considered. Police networks can also be used. It is important to establish a communication with vaccination teams in case mid-course corrections are required and also for review/monitoring etc.

- v. Daily reporting and monitoring of vaccination through coordinator of the vaccination team is to be ensured.
- vi. System of Identification of vaccinated birds e.g. through colour marking is to be enforced to ensure that all birds are vaccinated.
- vii. Overall control and supervision, which should be vested in the District administration, not lower than at level of the Sub-Divisional officer/Collector with technical assistance of veterinarians is necessary.
- viii. The movement of the vaccinator teams should be clearly worked out assigning specific area to each team. The movement and operation of these teams should be closely monitored at the District/sub-divisional level under chairpersonship of the District Collector/Sub-Divisional officer.

#### PART IV. Related issues

1. Exit Strategy: The vaccines are to be used with a clearly defined objective linked to a time-phased exit strategy. Vaccination is not an end in itself and cannot be used indefinitely. Therefore, an exit strategy has to be identified. This will be done by the GOI in consultation with the State Government if vaccination is introduced in a particular area.
2. DIVA and Sentinel birds: A strategy that is capable of differentiating infected from vaccinated has been recommended. At the flock level, a simple method is to regularly monitor sentinel birds left unvaccinated in each vaccinated flock (e.g. 3 per hundred of vaccinated birds) though this approach has some management problems, particularly in identifying the sentinels in large flocks. For this purpose, it is suggested to use wing/leg bands in sentinel birds for identification. These sentinel birds need not be sold so that sampling can be done from other birds on a later date.
3. Data maintenance requirements in case of outbreak of Avian Influenza control vaccination are large and enormous. Data is to be gathered for no. of birds vaccinated. It is necessary to maintain data of vaccination, to differentiate between vaccinated and non-vaccinated birds (eg. sentinel birds), administration of second vaccination, post-vaccination surveillance to measure the efficacy of the dose etc. It would be appropriate to maintain data villagewise/farmwise. Data maintenance should proceed simultaneously with vaccination. Therefore, each vaccination team should have a person charged with data collection and maintenance.
4. Monitoring: The monitoring of vaccinated flock is very necessary. After the vaccination is carried out in the surveillance zone, following actions shall be taken:

- (a) Clinical surveillance of vaccinated flock shall be maintained to report any morbidity/ mortality, in which case sample will be sent to HSADL, Bhopal.
- (b) Clinical surveillance shall also be maintained over sentinel birds. In case of mortality/ morbidity in sentinel birds, samples shall be sent to HASDL, Bhopal.
- (c) Surveillance shall be carried out by vaccinations teams. Information will be coordinated at sub-division/district level through team coordinator. On a daily basis, Government of India will be kept informed.
- (d) Serum samples shall be collected after 21 days to determine the immunity level in the vaccination flocks. The sample should be drawn at least @ 1% of total poultry population in the surveillance zone. The sample should be randomly taken so as it is representative of the surveillance zone and sent to HSADL Bhopal.
- (e) The second vaccination will be administered as per the requirements after 4-6 weeks. Similar process will be following as explained above for first vaccination.
- (f) Thereafter, clinical surveillance will be maintained in the surveillance zone. If the area remains free from any further outbreak for a period of 6 months the samples shall be collected and sent for testing before the area is declared free from the disease.