Republic of the Philippines
Department of Agriculture
**BUREAU OF ANIMAL INDUSTRY**
***GaBAI sa Pag-unlad ng Paghahayupan***

25 September 2019

**MEMORANDUM CIRCULAR**
No. 30
Series of 2019

SUBJECT: **AMENDMENT OF THE GUIDELINES FOR THE CONDUCT OF LOCAL STUDIES/FIELD TRIALS ON VETERINARY BIOLOGICAL PRODUCTS**

In our desire to clearly define the requirements, guidelines and procedures in the conduct of local studies or field trials maybe permitted by this office.

1. The veterinary biological products shall undergo local studies or field trials for safety and efficacy for the following:
   1.1. Products of which vaccine strain are different from those registered in the country based on the evaluation of Veterinary Biologics Technical Evaluation Committee (VBTEC);
   1.2. Products with a new combination;
   1.3. Products that are derived from biotechnology and other advanced innovations; and
   1.4. Products that are locally produced.

2. The company shall develop a field trial protocol based on Field Trial Protocol Format for Safety and Efficacy of Veterinary Biological Products for Registration (Appendix A).

3. The protocol shall be submitted to the Animal Feeds, Veterinary Drugs and Biologics Control Division (AFVDBCD) for review, clearance and endorsement to the Director of the Bureau of Animal Industry (BAI) for approval.

4. Once the protocol is approved, Memorandum of Undertaking for the Conduct of Field Trial (Appendix B) between the company and BAI must be duly accomplished in two (2) copies and shall be forwarded to BAI for approval then back to the company for notarization. After notarization, the company will submit one (1) copy to AFVDBCD.

5. The Field Trial shall be conducted in at least three (3) farms at different geographical locations which **HAVE BEEN DIAGNOSED POSITIVE** by **Animal Disease Diagnosis and Reference Laboratory (ADDRL)** of the disease for which the product is intended for use.

6. The company shall have the option to choose the farm trial sites in accordance with approved guidelines.

7. The experimental animals to be used shall represent the ages and husbandry practices. (if applicable Good Animal Husbandry Practices (GAHP) compliant for which the product is indicated for)

8. The sample size shall be determined by the statistician provided by the respective companies.

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| 8.1. | Chicken | - minimum of 200 heads/farm (100 control, 100 experimental) |
| 8.2. | Swine | -minimum of 100 heads/farm (50 control, 50 experimental) |
| 8.3. | Ruminants | -minimum of 50 heads per farms (25control, 25 experimental) |
| 8.4. | Aquatic Animals | -will be coordinated with the Bureau of Fisheries And Aquatic Resources (BFAR) |

9. A representative from the Animal Feeds, Veterinary Drugs and Biologics Control division (AFVDBCD) and Veterinary Laboratories Division (VLD) shall monitor the conduct of field trial. Monitoring officer should be present during the presentation of the protocol. At least the officer should be present at the start and end of the trial and during the scheduled vaccination activities.

10. No change or modification in the approved field trial protocol shall be allowed for implementation without prior clearance from AFVDBCD and APPROVAL from BAI Director.

11. The approved protocol shall be conducted within one (1) year from the time of approval otherwise, the protocol shall be re-approved.

12. The company must submit the field trial report to the Veterinary Biologics Technical Evaluation Committee (VBTEC) for evaluation at least two (2) weeks before the presentation.

13. BAI will not extend any financial assistance for this undertaking. However, the company shall be given access to some of the needed laboratory services offered by the BAI with corresponding laboratory service fees.

14. BAI RESERVES the right to approve or reject the results as a requirement for the registration and/or issuance of Sanitary/Phytosanitary (SPS)-Import Clearance (IC).

15. Publication of results of the study or trial shall have prior clearance with BAI.

The BAI-Memorandum Circular shall take effect immediately.

**RONNIE D. DOMINGO, DVM, MSc**
Officer-In-Charge, Director

**APPENDIX A**

## FIELD TRIAL PROTOCOL FORMAT FOR SAFETY AND EFFICACY OF VETERINARY BIOLOGICAL PRODUCT FOR REGISTRATION

In order to properly comply with the requirements of the field trial for the initial registration of veterinary biological products, the hereto format must be followed:

**I. Introduction**

Information about the disease and vaccine

**II. Objectives of the Study/Trial**

**III. Methodology**

This section should contain details of the experiments:

A. Vaccine description

B. Farm profile – Name and location, type of operation, population and disease situation, animal health program particularly vaccination program of farms where study will be conducted

C. Experimental Design

- Treatments to be used and their schedules
- Number of replicates per farm
- Characteristics of the experimental units
- Safety parameters- evaluation of local and systemic reaction
- Efficacy parameters- production and reproduction performance, mortality and morbidity (gross pathology, histopathology and other available diagnostic procedures) will be done by ADDRL and UPLB or CLSU) and serology (if applicable) will be done by ADDRL

**IV. Statistical Analysis**

Indicate the statistical tools/methods to be used in the data analysis

**V. Evaluation Methods and Observations**

Comparative evaluation between the vaccinates from that of the control group based on the safety and efficacy parameters enumerated on item no. III.

**VI. Management of the Experiment**

Indicate personnel responsible in the implementation, monitoring, collection of data, and reporting of the field trial

**VII. Results and Discussions**

**VIII. Conclusion/Recommendation**

**APPENDIX B**

**MEMORANDUM OF UNDERSTANDING FOR THE CONDUCT OF FIELD TRIAL OF** _____

**MANUFACTURED BY** _____
**AND IMPORTED BY** _____

**WHEREAS,** Bureau of Animal Industry Memorandum Circular No.____, Series of 2019, promulgates guidelines in conducting local studies or field trials on veterinary biological products, a prerequisite for product registration and importation;

**WHEREAS,** in order to facilitate the conduct of local studies/field trials, there are conditions that must be satisfied before such undertaking is allowed;

**WHEREAS,** there is a need to define the areas of responsibility between the company and the Bureau of Animal Industry to identify respective accountabilities;

**NOW, THEREFORE, FOR AND CONSIDERATION OF THE ABOVE PREMISES,** _____ and the Bureau of Animal Industry hereby agree on the following terms and conditions:

1. It shall be the responsibility of _____ to undertake the following:

    a. Prepare and submit the field trial protocol to the Office of the Director;

    b. Provide the field trial sites together with the farm profile;

    c. Provide the required quantity in doses of veterinary biological product to be field-tested as well as other inputs that may be needed;

    d. Follow strictly the approved field trial protocol;

    e. Appoint a study leader in the supervision and monitoring of the field trial;

    f. Submit and present the field trial report to Veterinary Biologics Technical Evaluation Committee;

    g. Prepare and submit the final field trial report to the Office of the Director signed by the proponent, farm owner/ authorized representative and Veterinary Biologics Technical Evaluation Committee;
    h. Secure clearance from the BAI for the publication of the field trial report.

2. The Bureau of Animal Industry, on the other hand, shall undertake the following responsibilities:

   a. Evaluate and recommend for approval of the BAI Director the submitted field trial protocol of the company by the Veterinary Biologics Technical Evaluation Committee;

   b. Issue provisional permit for the importation of the required quantity in doses of veterinary biological products for the conduct of field trial;

   c. Assign/designate technical staff from the Animal Feeds, Veterinary Drugs and Biologics Control Division and/or Veterinary Laboratory Division to closely observe, monitor and report the compliance/non-compliance of the proponent based on the parameters set in the approved protocol;

   d. Evaluate the field trial report based on the merits of its results;

   e. Approval of the final field trial report by the BAI Director;

   f. Issue clearance to the company for the publication (if requested) of the approved field trial conducted; and

   g. Maintain confidentiality of all information related to the conduct of field trial.

Conforme:

| | |
|---|---|
| _____ | _____ |
| BAI Director | Company |

Witnesses

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|---|---|
| _____ | _____ |
| Chief, AFVDBCD | Company |