Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

August 25, 2005

ADMINISTRATIVE ORDER
No. 2005-0022

SUBJECT: Amendment to Administrative Order No. 164 s. 2002 (Subject: Revised Guidelines on Management of Animal Bite Patients) on the Immunization Proqram Policies

I. RATIONALE

Administrative Order No. 164, series of 2002 (Subject: Revised Guidelines on Management of Animal Bite Patients), was issued, among other things, to acknowledge and address rabies as public health problem in the Philippines and to prevent human deaths due to rabies infection by ensuring uniformity in the management of animal bite patients.

II. PURPOSE

The purpose of this Order is to amend certain provisions in the immunization Program Policies of Administrative Order No. 164, series of 2002 in line with the continuing review and evaluation of the government's anti—rabies management policy.

III. SCOPE AND COVERAGE

Item lV.B.1 of Administrative Order No. 164, s. 2002 provides:

“1. Active immunization

(a) Vaccine is administered to induce antibody and T—cell production in order to neutralize the rabies virus in the body. It induces an active immune response (in 7-40 days after vaccination) and may persist for one year or more.

(b) The type of anti-rabies vaccine available in the Philippines: a) Purified FreeCeil Rabies Vaccine (PVRV) —- 0.5 ml/vial; b) Purified Duck Embryo Vaccine (PDEV) — 1.0 ml/vial; and c) Purified Chick Embryo Cell Vaccine (PCECV) — 1.0 mi/vial.

(c) All vaccines are considered to be highly immunogenic and safe. For active immunization, any of the three vaccines may
be administered either intra—muscuiarly or intradermally."

The aforecited provisions are hereby amended to read as follows:

“1. Active Immunization

(a) Vaccine is administered to induce antibody and T-cell production in order to neutralize the rabies virus in the body. It induces an active immune response (in 7-10 days after vaccination) and may persist for one year or more.

(b) The type of anti-rabies vaccine available in the Philippines: a) Purified FreeCeii Rabies Vaccine (PVRV) - 0.5 mllvial; b) Purified Duck Embryo Vaccine (PDEV) — 1.0 mllvial; and c) Purified Chick Embryo Cell Vaccine (PCECV) — 1.0 mllvial.

(c) All vaccines are considered to be highly immunogenic and safe. For active immunization, any of the three vaccines may be administered either intra-muscularly or intradermally.

(d) Only rabies vaccines that have been evaluated and recognized by the World Health Organization (WHO); have gone through local clinical trials on safety, immunogenicity and efficacy (as evidenced by published clinical trials in peer-reviewed journals and local testing studies); evaluated by the DOH Rabies Technical Group; and registered with and approved by the Bureau of Food and Drugs (BFAD) can be used."

Item lV.B.2(b) of Administrative Order No. 164, s. 2002 provides:

“2. Passive immunization

XXX XXX XXX

(b) Only rabies vaccines and RIG that have been evaluated and recognized by WHO and approved by BFAD should be used. National health authorities should evaluate any new vaccine or RIG prior to use."

The aforecited provision is hereby amended to read as follows:

“2. Passive Immunization

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(b) All imported RIG introduced for the first time in the Philippines should undergo testing and evaluation by the WHO or WHO-recognized National Regulatory Authorities (NRA), or National Control Laboratory (NCL). The tests should include Rapid Fluorescent Focus Inhibition Test (RFFIT) or Mouse Neutralization Test (MNT), pre-clinical safety, pyrogenicity, and product purity. An animal survivorship study may be required. The results of the clinical trials conducted on the product should have been published in a peer-review journal. The local NRA/NCL should validate

the RFFIT or MNT and purity of the product and require local clinical trials on safety. The product should likewise be registered with and approved by BFAD before use.

Locally produced RIG should undergo the same evaluation and testing as mentioned above by the local NRAINCL and the product should be registered with and approved by BFAD before use."

IV. REPEALING CLAUSE

Items IV.B.1 and IV.B.2(b) of Administrative Order No. 164, s. 2002 are accordingly amended. All other administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

V. EFFECTIVITY

This Order shall take effect immediately.

FRANCISCO T. DUQUE III, M.D., M.Sc.
Secretary of Health