Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

18 January 2016

DEPARTMENT MEMORANDUM
No. 2016 - 0030

FOR: **ALL DIRECTORS OF REGIONAL OFFICES, SECRETARY OF HEALTH DOH-ARMM; MUNICIPAL HEALTH OFFICERS; AND OTHERS CONCERNED**

SUBJECT: **Revised prescribing information of RABIES VACCINE in the Philippine National Formulary Manual for Primary Healthcare 8th edition**

Please be guided on the following revisions in the prescribing information of **rabies vaccine** in the Philippine National Formulary Manual for Primary Healthcare 8th edition (pages 171-172):

RABIES VACCINE

Inj.: Lyophilized powder, 2.5 IU/dose + diluent **(1 mL) (IM, ID) purified chick embryo cell vaccine**
Lyophilized powder, 2.5 IU/dose + diluent **(0.5 mL) (IM, ID) purified Vero cell rabies vaccine**

Indications: Active immunization against rabies; **pre- and post-exposure prophylaxis.**
NOTE: WHO recommends pre-exposure immunization of individuals at increased risk of contracting rabies, including those at risk due to occupational exposure (such as health and laboratory workers, animal handlers, and veterinary surgeons), and people living or traveling to enzootic areas (in such areas, children aged 5-15 years are at particular risk of exposure).

Contraindications: **There are no absolute contraindications to rabies post-exposure prophylaxis (PEP).**

Dose:
NOTE: The treatment is dependent upon the individual's immune status and upon the level of risk of rabies. Doses may vary between products.

Pre-exposure prophylaxis against rabies, *by IM injection,* ADULT and CHILD, 3 doses on days 0, 7 and 28 (day 28 preferable, but administration may be advanced towards day 21 if time is limited); alternatively, *by ID injection,* 3 doses, each of 0.1 mL on days 0, 7, 28 (administration may be advanced towards day 21 if time is limited).
BOOSTER DOSES. Periodic booster doses are recommended only for individuals whose occupation puts them at continuous or frequent risk of rabies exposure. In such cases, a booster dose should be given at intervals dictated by regular testing for antibodies (a concentration of virus neutralizing antibodies of at least 0.5 IU/mL indicates protection). Where serological testing is unavailable, booster vaccination every 5 years may be an acceptable alternative.

Post-exposure **prophylaxis** against rabies in unimmunized individuals, *by IM injection,* ADULT and CHILD, 1 dose given on days 0, 3, 7, 14 and 28 (total of 5 doses); or, *alternatively* 2 doses on day 0 (one in each deltoid or thigh), followed by 1 dose on days 7 and 21 (total of 4 doses).

Post-exposure **prophylaxis** against rabies in unimmunized individuals, *by ID injection,* ADULT and CHILD **(2-site regimen), 1 dose of 0.1 mL at 2 sites on days 0, 3, 7, and 28 (total of 8 ID doses).**
****The 8-site regimen is no longer recommended by the DOH - National Rabies Prevention and Control Program (NRPCP).*

Post-exposure **prophylaxis** against rabies in **primary** immunized individuals, *by IM or ID injection,* ADULT and CHILD, **1 dose on days 0 and 3.**
NOTE: Check the antibody response to post-exposure immunization course in immunocompromised people as further doses may be needed.

Dose Adjustments: No information found.

Precautions:
Caution in individuals with history of systemic allergic reaction to any ingredient in the vaccine; acute febrile illness (postpone all vaccinations until patient is well); once initiated, rabies prophylaxis should not be interrupted nor discontinued because of development of local or mild systemic reactions (the risk of acquiring rabies should be weighed before deciding to discontinue vaccination).
NOTE: If schedule requires rabies vaccine and rabies immunoglobulin to be administered at the same time, they should be given using separate syringes and separate sites.

Adverse Drug Reactions:
Common: Abdominal pain, allergic reactions, diarrhea, dizziness, dyspnea, fainting, headache, lymphadenopathy, malaise, myalgia, nausea, rash, serum sickness-like reactions, transient fever, transient injection site reactions (pain, redness, itching, swelling or burning, small hard lump that may persist for some weeks), vomiting, weakness.
Less Common: Angioedema.
Rare: Neuroparalytic events.

Drug Interactions:
Monitor closely with:
Other vaccines and immunoglobulins - these can influence the ability of vaccines to induce an immune response (give a live vaccine on the same day or not < 4 weeks apart from another live vaccine).
*****DELETED: Drug interaction with anti-infectives and immunosuppressive agents and during radiation therapy.**

Administration: The bite wound must be thoroughly cleansed. When administered by *IM* injection, the vaccine should be given in the deltoid region in adults and children; the anterolateral thigh is the preferred site in children < 2 years of age.
NOTE: There may be a suboptimal response if a vaccine is injected incorrectly (route or area); local response may also be increased; *IM* injections must be given slowly to reduce pain.
NOTE: Vaccines should be stored within the safe temperature range of 2-8°C. Freezing is the most common cause of vaccine damage; do not use a defrosted vaccine unless freezing is the recommended storage condition.

Pregnancy Category: C

The above amendments were finalized in consultation with the DOH –NRPCP.

Kindly inform all concerned officials in your areas of responsibility to be appropriately guided by the said information. All are enjoined to ensure rational procurement, distribution and use of medicines in all government and private hospitals.

Your full cooperation in this endeavour is highly appreciated.

By Authority of the Secretary of Health:

KENNETH Y. HARTIGAN-GO, MD
Undersecretary of Health
Office for Health Regulations