



STATE OF NEW YORK DEPARTMENT OF HEALTH

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June 18, 2008

TO: Healthcare Providers, Hospitals, Pharmacies, Veterinarians, Animal Care Providers and Local Health Departments

FROM: NYSDOH Bureau of Communicable Disease Control, Zoonoses Program

HEALTH ADVISORY: UPDATE ON RABIES VACCINE SUPPLY AND USE

Please distribute immediately to the Emergency Department; Departments of Infectious Diseases, Internal Medicine, Family Practice, and Pediatrics; Director of Nursing, Medical Director, all patient care areas; Pharmacies; Veterinarians, Veterinary Technicians and all animal health support staff.

The purpose of this advisory is to provide an update on the current availability of rabies vaccine for postexposure (PEP) and pre-exposure (PreP) administration.

Rabies Vaccine for Postexposure Prophylaxis (PEP)

On Monday June 16, 2008, Novartis announced that, effective immediately, they are restricting the use of RabAvert (human rabies vaccine) only to emergency situations involving human rabies postexposure prophylaxis (PEP). RabAvert will only be available through consultation with state health departments and the Centers for Disease Control and Prevention (CDC), and only for situations such as severe allergic reaction to Imovax Rabies, the human rabies vaccine manufactured by Sanofi Pasteur. A letter from Novartis explaining this change was released to clinicians on June, 16, 2008 (see attachment). Novartis is taking this action because they have an extremely low supply of RabAvert available for use in the U.S. market.

The New York State Department of Health (NYSDOH) is advising all providers prescribing rabies PEP for patients to use only Imovax Rabies, made by Sanofi Pasteur. Providers requiring Imovax Rabies for a PEP situation should contact Sanofi Pasteur at 1-800-VACCINE (1-800-822-2463). If a situation requires the use of Novartis' RabAvert (e.g., an allergic reaction after Imovax Rabies administration), providers should contact the NYSDOH Zoonoses Program at 518-474-3186 to arrange for availability of the product.

New York State law also requires that providers consult with their local health department (LHD) prior to initiating rabies PEP to ensure appropriate use of these biologics.

It is unclear how long RabAvert will be in such limited supply, however the CDC remains in close contact with both vaccine manufacturers to continue monitoring the supply of rabies vaccines. As further information becomes available, the NYSDOH will provide additional updates through the Health Alert Network.

Rabies Vaccine for Pre-exposure Prophylaxis (PreP)

CDC has also notified us that they have temporarily suspended the program instituted last week for authorization of pre-exposure vaccination (PreP) through state health departments. **At this time, no PreP is available from either Sanofi Pasteur or Novartis.** Requests for PreP vaccine can still be faxed by providers to the Zoonoses Program at 518-473-6590 and these requests will be forwarded by NYSDOH to CDC, but it is unknown when the PreP vaccine requests will be filled.

Persons at increased risk for rabies exposure should take appropriate precautions to avoid rabies exposure (<http://www.cdc.gov/rabies/exposure/>). General rabies awareness and prevention messages should be promoted (<http://www.nyhealth.gov/diseases/communicable/zoonoses/rabies/>).

Additional Information

NYSDOH Rabies Website: www.nyhealth.gov/diseases/communicable/zoonoses/rabies/

NYSDOH Wadsworth Center Rabies Laboratory Website: www.wadsworth.org/rabies/

CDC Rabies Website: www.cdc.gov/rabies

Human Rabies Prevention, 2008 – Recommendations of the Advisory Committee on Immunization Practices (ACIP): <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5703a1.htm>

National Association of State Public Health Veterinarians (NASPHV) Compendium of Animal Rabies Control and Prevention: www.cdc.gov/mmwr/pdf/rr/rr5702.pdf

Please contact the NYSDOH Zoonoses Program at 518-474-3186 if you have any questions or concerns regarding this situation. We will provide additional updates as more information becomes available.



June 16, 2008

Dear Valued Customer:

This letter is intended to provide an update on the current supply situation of RabAvert® (Rabies Vaccine for Human Use). We are in consultation with public health officials at this time and have set aside an emergency supply of doses that will be released on a case by case basis only in conjunction with consultation of state health departments and the Centers for Disease Control and Prevention. It is strongly encouraged that you contact your Rabies Public Health Official if you need to order rabies vaccine for post-exposure prophylaxis. At this time, we will not be releasing any RabAvert that has not been confirmed through your state official. We are anticipating a RabAvert shipment in early July and additional material later in the fall which will help to alleviate some of the supply concerns.

At this time, Novartis Vaccines continues to remain in close contact with the CDC to ensure that appropriate usage of the vaccine for post-exposure prophylaxis is communicated to medical providers. Novartis Vaccines will continue to work closely with the CDC to manage supply in support of these critical public health efforts.

We seek your cooperation, in accordance with public health needs, until a more regular rabies vaccine capacity and inventory are re-established. Given the deadly nature of rabies, physicians should seek advice from knowledgeable state public health officials or the CDC for risk assessment and prophylaxis guidelines. Please refer to the CDC's website for more information:

http://www.cdc.gov/print.do?url=http%3A//www.cdc.gov/RABIES/news/2008-05-20_PreEVax.html

As your partner in the fight against this fatal disease, Novartis Vaccines wishes to emphasize its commitment to help provide a steady supply of RabAvert and will update you on any changes in availability.

Should you have any questions, please call 1-800-244-7668.

Regards,

Niranjana Kanesa-athan MD MTMH

Chief Medical Officer