Republic of the Philippines
DEPARTMENT OF THE INTERIOR AND LOCAL GOVERNMENT
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POLICIES AND GUIDELINES ON THE CAMPAIGN AGAINST THE SALE AND USE OF COUNTERFEIT VERORAB RABIES VACCINES

Memorandum Circular No. 2019-25

1.0 Background

1.1 A *Medical Product Alert* released by the World Health Organization (WHO), confirmed the circulation of falsified Verorab rabies vaccines in the country. The genuine Verorab vaccine, manufactured by Sanofi Pasteur, is used to protect those who are at risk of exposure to rabies (pre-exposure vaccination) and prevent the development of rabies after exposure to animal bite of an animal suspected to having rabies (post exposure prophylaxis).

1.2 The said alert provided product specification details of vaccines found to be falsified, which Sanofi Pasteur firmly denied manufacturing.

1.3 On December 27, 2018, the Department of Health-Food and Drug Administration (DOH-FDA), principally mandated to enforce Republic Act No. 8203 (*An Act Prohibiting Counterfeit Drugs, Providing Penalties for Violations and Appropriating Funds Therefore*), and its Implementing Rules and Regulations, issued Advisory No. 2018-334 dated December 27, 2018, warning the public on the purchase and use of said counterfeit vaccine product.

1.4 Section 16 of Republic Act (RA) No. 7160, otherwise known as the Local Government Code of 1991, provides that Local Government Units (LGUs) exercise the powers expressly granted to them for efficient and effective governance, and those which are essential to the promotion of the general welfare. Hence, Local Chief Executives shall ensure that these counterfeit vaccines are not allowed or sold in their respective areas of jurisdiction.

2. 0 Purpose

2.1 In support of the above-mentioned DOH-FDA Advisory and WHO Medical Product Alert, this Circular will enjoin all Local Government Units (LGUs) to intensify information, education and communication campaign on banning the sale and use of the counterfeit Verorab rabies vaccines.

3.0 Scope/Coverage

3.1 All Provincial Governors, City Mayors, Municipal Mayors, DILG Regional Directors, ARMM Regional Governor and All Others Concerned.

4.0 Policy Content and Guidelines

4.1 To ensure public awareness campaign against counterfeit vaccines, all LGUs are encouraged to undertake the following:

4.1.1 Develop and disseminate Information, Education, and Communication (IEC) materials such as, but not limited to, tarpaulins, leaflets, brochures, audio-visuals and similar materials;

4.1.2 Promote public awareness by highlighting the difference between genuine and falsified vaccines, as specified in DOH-FDA Advisory No. 2018-334, on streamers hanged in front of health facilities, Animal Bite Treatment Centers (ABTCs), Animal Bite Centers (ABCs). The use of local radio networks, Facebook and Twitter accounts may also be encouraged;

4.1.3 Ensure that Hospitals, Veterinary Clinics, Health Centers, Animal Bite Centers (ABTCs), Animal Bite Centers (ABCs), and Local Veterinarians administering rabies vaccination shall only use genuine vaccines;

4.1.4 Adopt stringent regulatory procedure and requirements in the issuance of business permits to manufacturing companies and distribution centers, medical agents, pharmaceuticals, and other related business establishments; and

4.1.5 Coordinate with DOH-FDA thru email address: info@fda.gov.ph and www.fda.gov.ph or Telephone No. (02) 809-5596, on suspected production, distribution and sale of counterfeit rabies vaccines in your locality, for proper investigation, filing and disposition of cases, as may be appropriate, pursuant to RA 8203 and other existing laws, rules and regulations.

4.2 All DILG Regional Directors and ARMM Regional Governor are hereby directed to cause the widest and immediate dissemination of this issuance to all local government units within their respective areas of jurisdiction.

5.0 Effectivity

5.1. This Memorandum Circular shall take effect immediately.

6. 0 References

6.1 Republic Act No. 8203 (enacted on August 27, 1996)

6.2 Republic Act No. 7160 (The Local Government Code of 1991)

6.3 DOH-FDA Advisory No. 2018-334 dated December 27, 2018

6.0 Approving Authority

EDUARDO M. AÑO
Secretary

DILG-OSEC 11052018-03746

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY

No. 2018-334

27 DEC 2018

TO: **ALL HEALTHCARE PROFESSIONALS, LOCAL HEALTH CENTERS, HEALTH INSTITUTIONS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product Verorab Rabies Vaccine**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Verorab rabies vaccine.

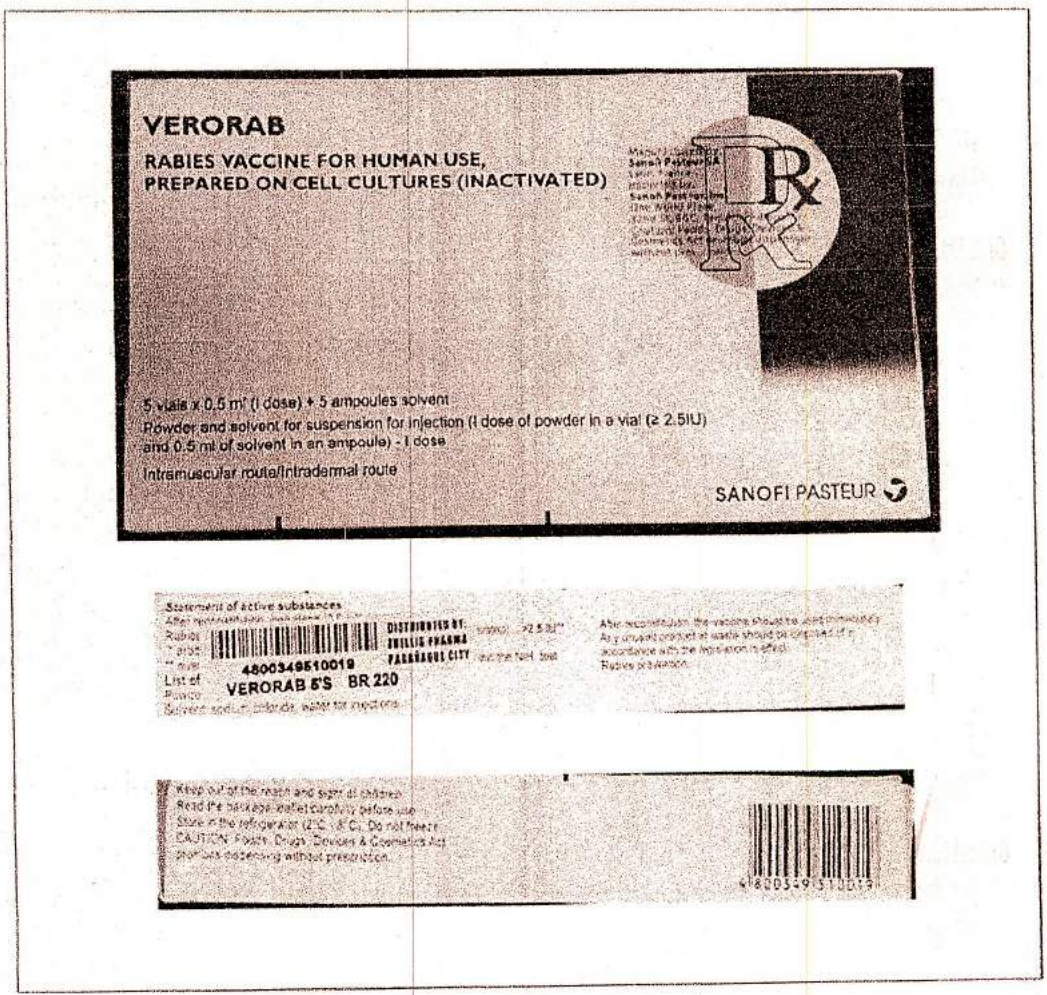


Figure 1. Box label of verified counterfeit Verorab Rabies Vaccine

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph

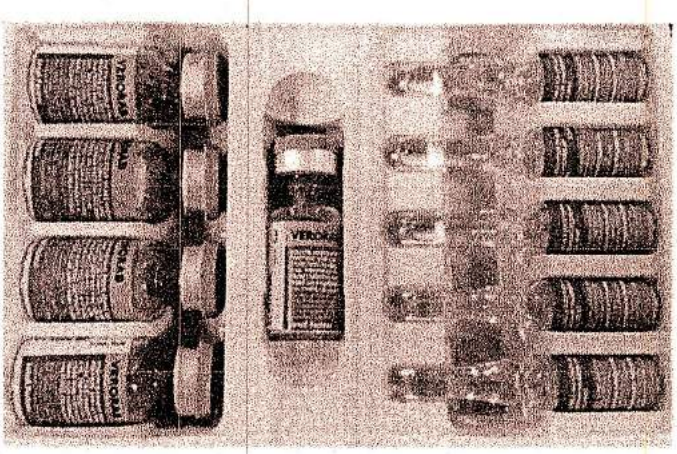


Figure 2. Verified counterfeit sample vials and ampoules of Verorab Rabies vaccine.

The FDA, together with the Marketing Authorization Holder (MAH), Sanofi Pausteur Inc., have verified that the above mentioned in Figure 1 and 2 sample drug product is counterfeit.

Figures 3 and 4 show the registered drug product Verorab Rabies Vaccine.

The principal display panel of the label of Verorab Rabies Vaccine for Human Use Prepared on Cell Culture (Inactivated) 2.5 IU/ 0.5 mL Powder for Suspension I.D./ I.M. Injection bears the following:

1. FDA-licensed Philippine importer and distributor
2. FDA registration number (BR-514)
3. Rx symbol
4. FDA caution statement on dispensing
5. Barcode

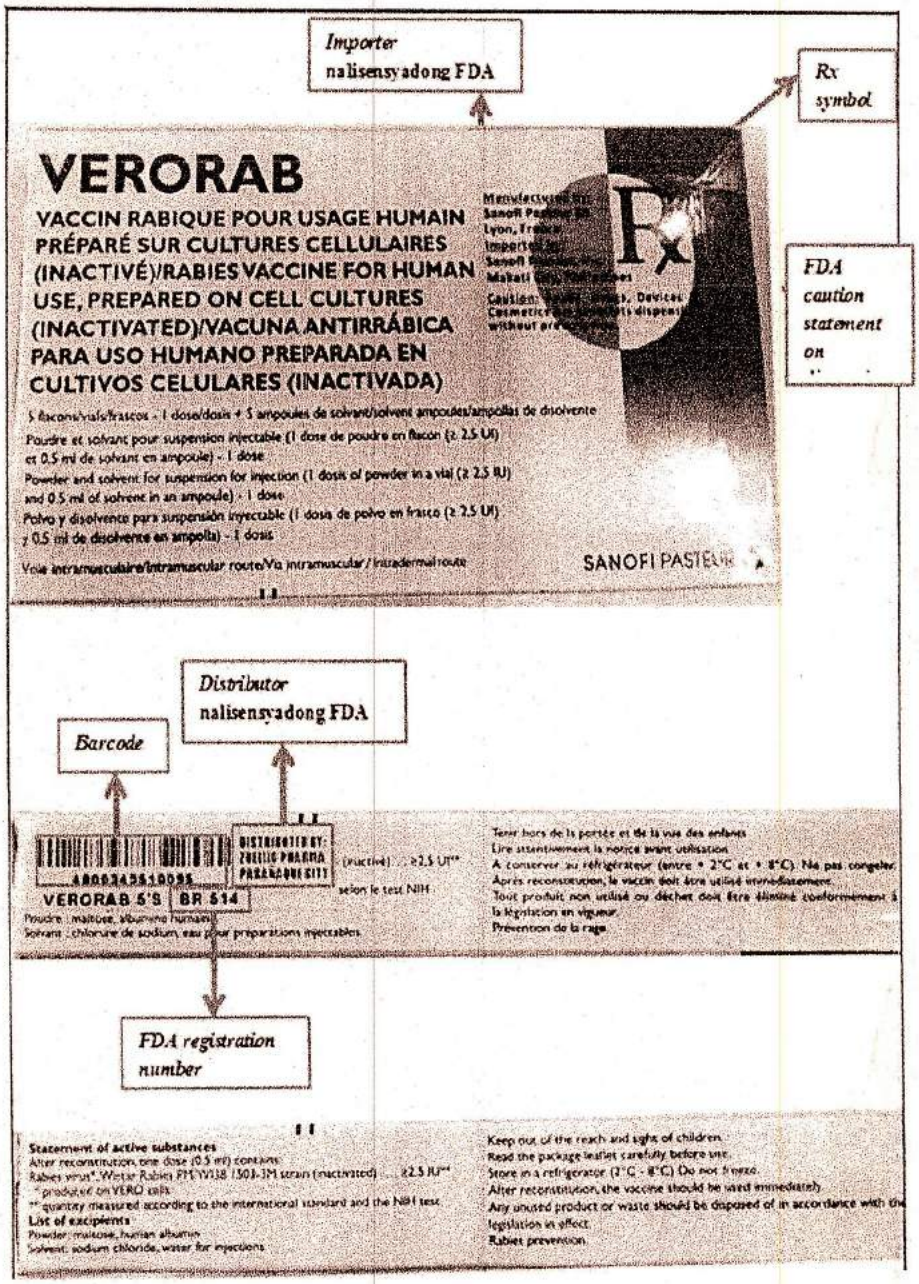


Figure 3. Box Label of Authentic Verorab Rabies Vaccine bearing the correct registration number (BR-514)

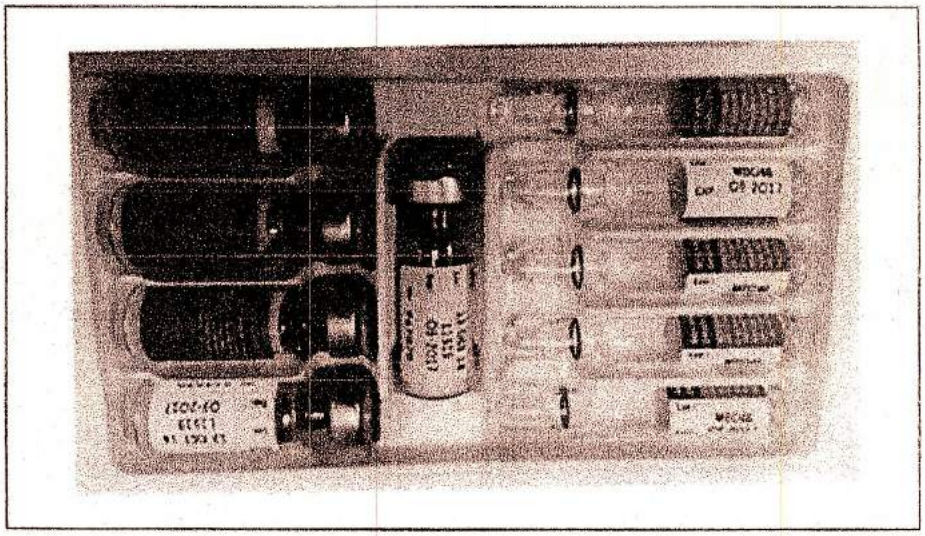


Figure 4. Registered Drug Product vials and ampoules of Verorab Rabies Vaccine

All healthcare professionals, local health centers, health institutions and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing this verified counterfeit drug product with the foregoing features. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711, or the Food and Drug Administration Act of 2009, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs, therefore a penalty shall be imposed.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02)809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **www.fda.gov.ph/adr-report-new** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

20181221143520

Consuelo Marquez **@CMarquezINQ**
INQUIRER.net / 06:13 PM January 31, 2019

MANILA, Philippines — The Food and Drug Administration (FDA) and the Department of Health (DOH) have given assurances that they will stop the distribution of counterfeit anti-rabies vaccine called the Verorab Vaccine.

"The FDA and DOH will make sure that the distribution of counterfeit vaccines is stopped," lawyer Michelle Lapuz, director of FDA's legal support service center, said in Filipino in an interview over DZMM.

Lapuz said they received the complaint about the vaccine from The Medical City in Pasig City, and they had investigated whether the samples were indeed counterfeit.

"Ang pinagmulan ng complaint from The Medical City. Inihain nila sa amin yung third party complaints. Nag-submit po sila ng samples ng produkto nito na pinaghihinalaan nila counterfeit (The source of the complaint is The Medical City. They filed third-party complaints. They submitted product samples that they suspected were counterfeit)," Lapuz said.

The FDA confirmed from Market Authorization Holder that the vaccine was not registered under their product line, Lapuz said.

"Nakipagsanggunì rin kami sa market authorization holder para i-verify kung counterfeit ang mga products na ito (We consulted with the market authorization holder to verify if these products are counterfeit), she said. "Nag-issue po ng (They issued) product verification that these are not legitimate and not registered product under their product line."

Lapuz added that FDA's Center for Drugs also found that the vaccine samples were fake and that source is the Philippines.

"Dito sa aming operation, ang source po talagang dito sa Philippines (Here in our operation, the source is really the Philippines)," she said.

Lapuz, however, said they could not offer "critical information" about their investigation as it is still ongoing, but the stocks of the anti-rabies vaccine have been pulled out from The Medical City.

Side effects

Lapuz also warned the public about the health risks and side effects of the fake anti-rabies vaccine.

Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Ref. EMP/SAV/Alert_n1.2019

30 January 2019

Medical Product Alert N°1/2019

Falsified Rabies Vaccines circulating in the Philippines

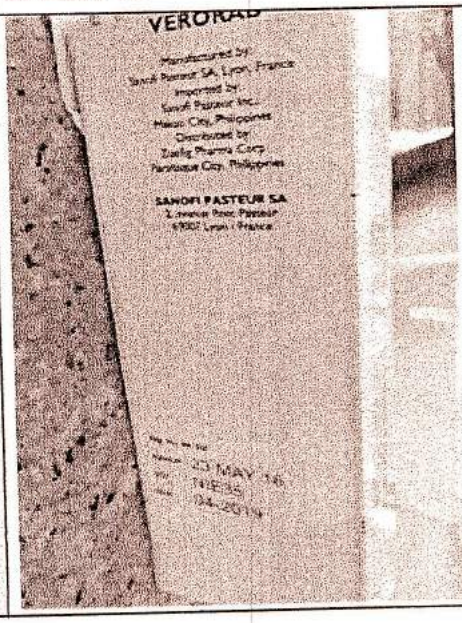
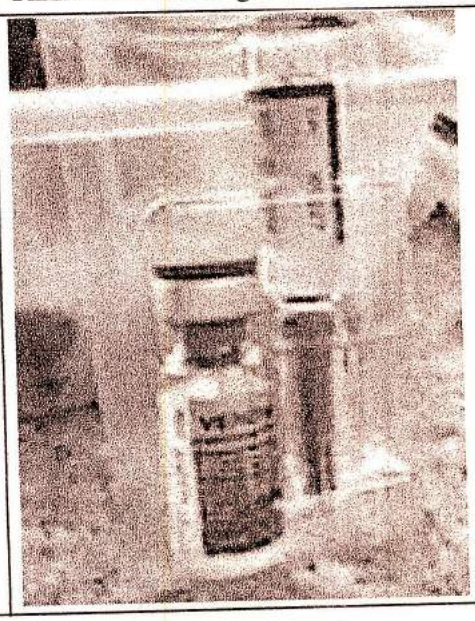
This Medical Product Alert relates to falsified Verorab® vaccines that have been identified in the Philippines and reported to WHO. This vaccine is used for the prevention of rabies in children and adults. It can be used to protect those who are at risk of exposure to rabies (pre-exposure vaccination) or to prevent the development of rabies after exposure has occurred, usually following the bite of an animal suspected of having rabies (post-exposure prophylaxis). Its genuine version is manufactured by Sanofi Pasteur.

Rabies is a vaccine-preventable viral disease that is almost always fatal following the onset of clinical symptoms. Rabies is present on all continents, with over 95% of human deaths occurring in the Asia and Africa regions.

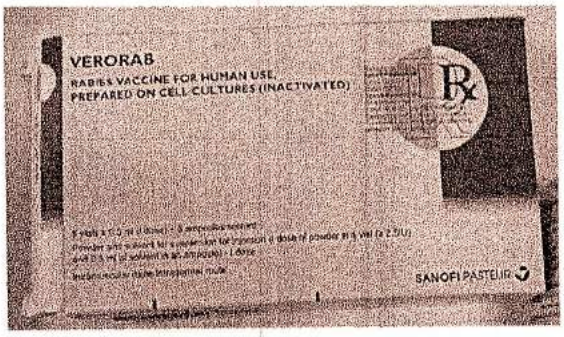
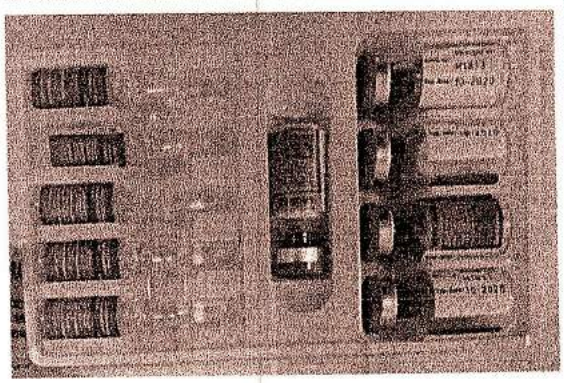
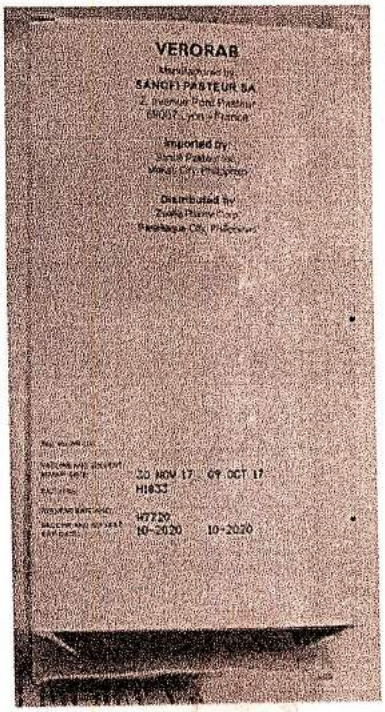
In December 2018, the Philippines Food and Drug Administration (FDA) issued a public health warning concerning falsified Verorab® vaccines circulating in the country. Since that date, a further batch of falsified Verorab® vaccines has been reported. Investigations are ongoing and laboratory analysis is underway to better assess the potential risk to public health.

Two falsified vaccines have so far been discovered and their details and available photographs are shown below.

1. *VERORAB, powder and solvent for suspension for injection*

Product Name	**VERORAB, RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED)**	
Stated Manufacturer	SANOFI PASTEUR	
Presentation	Secondary Packaging (Pack/Carton)	Primary Packaging (Powder in Vial and Solvent in Prefilled Syringe)
Batch Number	NIE35	Unknown at this stage
Expiry Date	04-2019	Unknown at this stage
Date of Manufacture	23 MAY 16	Unknown at this stage
Available Photographs		

2. ***VERORAB, powder and solvent for suspension for injection***

Product Name	**VERORAB, RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED)**	
Stated Manufacturer	SANOFI PASTEUR	
Presentation	Secondary Packaging (Pack/Carton) and Primary Packaging (Powder in Vial)	Primary Packaging (Solvent in Ampoule)
Batch Number	H1833	H7720
Expiry Date	10-2020	10-2020 or 10-2021
Date of Manufacture	30 NOV 17	09 OCT 17
Available Photographs	  	

It should be noted that:

- The stated manufacturer, Sanofi Pasteur, has confirmed they did not manufacture these falsified vaccines.
- Variable data shown in this alert do not correspond to the genuine manufacturer records.
- There have been no known adverse reactions reported to WHO at this stage.

WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified vaccines. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of vaccines.

If you are in possession of the above vaccines, please do not use. If you have used these falsified vaccines, or if you suffer an adverse event having used these vaccines, please seek immediate advice from a qualified healthcare professional, and ensure they report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

National health authorities are asked to immediately notify WHO if these falsified vaccines are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these vaccines, please contact rapidalert@who.int

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/
To sign up for WHO Medical Product Alerts, please visit: www.who.int/about/licensing/rss/en/