World Health Organization

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Medical Product Alert N°8/2019
Falsified Rabies Vaccines and Anti-Rabies Serum circulating in the Philippines

This Medical Product Alert relates to 3 different falsified rabies vaccines (Verorab, Speeda, and Rabipur) and 1 falsified anti-rabies serum (Equirab) circulating in the Philippines. It is linked to the WHO Medical Product Alert N°1/2019[1] issued on 30 January 2019 regarding falsified Verorab rabies vaccines circulating in the Philippines. Rabies is a vaccine-preventable viral disease that is almost always fatal following the onset of clinical symptoms. Rabies is present worldwide, with over 95% of human deaths occurring in the Asia and Africa regions. Genuine Verorab, Speeda and Rabipur vaccines are used for pre-exposure vaccination or post-exposure prophylaxis. Genuine Equirab anti-rabies serum provides passive immunization against rabies.

WHO recently received confirmation that falsified batches of Verorab, Speeda, Rabipur and Equirab were available at patient level in the Philippines. Investigations are ongoing, and laboratory analyses are being facilitated for available samples to determine their contents and better assess the risk to public health. At this stage, no adverse reactions attributed to the below mentioned falsified products have been reported to WHO. A rabies vaccine shortage is ongoing in the Philippines.

1. VERORAB, Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated)

Falsified versions of 4 different combinations of batch numbers have so far been discovered. Product details are listed in Table 1 below and are also contained in the Philippines Food and Drug Administration Advisory No. 2019-190[2]. Please refer to Annex 1 for available photographs.

Table 1: Details of falsified Verorab vaccine, subject of WHO Medical Product Alert N°8/2019

Secondary Packaging (Box/Carton)			**Primary Packaging (Powder in Vial)**			**Primary Packaging (Solvent in Ampoule, Vial or Pre-filled Syringe)**		
Batch No.	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***
N1E353M	23 MAY 16	04-2019	N1E35	23052016	04-2019	M0027 (syringe)	*Unknown*	04-2019
H 1742	30 NOV 16	10 - 2019	H1742	30112016	10-2019	H7720 (vial)	*Unknown*	10-2019
H1833	30 NOV 17	10-2021	H1833	30112017	10-2021	H7720 (vial)	*Unknown*	10-2021
N1J75V	28092017	12-2020	N1J75	28/09/2017	12/2020	P4AQ5 (ampoule)	*Unknown*	12/2020

Sanofi Pasteur, the genuine manufacturer and marketing authorization holder of Verorab, Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated) in the Philippines, stated:

- They did not manufacture the above listed products.
- The above listed products display labelling and packaging inconsistencies.
- The variable data do not correspond to the genuine manufacturing records.
- H1833, H1742, and N1J75V are falsified batch numbers.
- Batch number N1E353M is not a valid batch number for the Philippines market.

[1] Source: https://www.who.int/medicines/publications/drugalerts/drug_alert-1-2019/en/
[2] Source: https://www.fda.gov.ph/fda-advisory-no-2019-190-public-health-warning-against-the-purchase-and-use-of-five-other-versions-of-counterfeit-verorab-rabies-vaccine-for-human-use-prepared-on-cell-cultures-inactivated/

2. SPEEDA, Purified Rabies Vaccines (Vero Cell)

Falsified versions of 4 different combinations of batch numbers have so far been discovered. Product details are listed in Table 2 below and are also contained in the Philippines Food and Drug Administration Advisory No. 2019-153[3]. Please refer to Annex 2 for available photographs.

Table 2: Details of falsified Speeda vaccines, subject of WHO Medical Product Alert N°8/2019

Secondary Packaging (Box/Carton)			Primary Packaging (Powder in Vial)			Primary Packaging (Solvent in Ampoule)		
Batch No.	***Mfg Date.***	***Exp. Date***	***Batch No.***	***Mfg Date.***	***Exp. Date***	***Batch No.***	***Mfg Date.***	***Exp. Date***
201803067	03/15/2018	03/14/2021	201803067	03/15/2018	03/14/2021	201803067	*Unknown*	*Unknown*
201708295	08/31/2017	08/30/2020	201708295	08/31/2017	08/30/2020	20170520-1	08/28/2017	*Unknown*
201710356	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*
201803069	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*	*Unknown*

Liaoning Cheng Da Biotechnology Co., Ltd., the genuine manufacturer of Speeda, Purified Rabies Vaccines (Vero Cell), stated:

- They did not manufacture the above listed products.
- The above listed products display labelling and packaging inconsistencies.

3. RABIPUR, PCEC rabies vaccine for human use

Falsified versions of 2 different combinations of batch numbers have so far been discovered. Product details are listed in Table 3 below and are also contained in the Philippines Food and Drug Administration Advisory No. 2019-170[4]. Please refer to Annex 3 for available photographs.

Table 3: Details of falsified Rabipur vaccines, subject of WHO Medical Product Alert N°8/2019

Secondary Packaging (Box/Carton)			Primary Packaging (Powder in Vial)			Primary Packaging (Solvent in Ampoule)			Primary Packaging (Needle and Syringe)		
Batch No.	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***
3503	SEP 2016	AUG 2020	3503	09/2016	08/2020	S-196	06/2016	05/2021	17C2312 (needle only)	03/2017 (needle only)	02/2022 (needle only)
3479	JUL 2016	JUN 2020	3479	07/2016	06/XXXX *(year unknown)*	S-181	09/2015	08 2020 or 03/2020	17C2312 (needle only)	03/2017 (needle only)	02/2022 (needle only)

GlaxoSmithKline (GSK), the genuine marketing authorization holder of Rabipur, and Chiron Behring Vaccines Pvt. Ltd, the genuine manufacturer of Rabipur, stated:

- They did not manufacture the above listed products.
- The above listed products display labelling and packaging inconsistencies.
- Since July 2017, Chiron Behring Vaccines Pvt. Ltd has not exported this product nor has GSK imported this product into the Philippines.

[3] Source: https://www.fda.gov.ph/fda-advisory-no-2019-153-public-health-warning-against-the-purchase-and-use-of-the-verified-counterfeit-version-of-drug-speeda-rabies-vaccine/
[4] Source: https://www.fda.gov.ph/fda-advisory-no-2019-170-public-health-warning-against-the-purchase-and-use-of-the-counterfeit-versions-of-rabipur-pcec-rabies-vaccine-for-human-use/

4. EQUIRAB, Anti-Rabies Serum (Equine)

Falsified versions of 3 different combinations of batch numbers have so far been discovered. Product details are listed in Table 4 below and are also contained in the Philippines Food and Drug Administration Advisory No. 2019-152[5]. Please refer to Annex 4 for available photographs.

Table 4: Details of falsified Equirab anti-rabies serum, subject of WHO Medical Product Alert N°8/2019

Secondary Packaging (Box/Carton)			**Primary Packaging (Liquid in Vial)**		
Batch No.	***Mfg Date***	***Exp. Date***	***Batch No.***	***Mfg Date***	***Exp. Date***
A02717008	3/18	2/20	A02717008	3/18	2/20
A02718008	03/18	02/20	A02718008	03/18	02/20
A02718012	07/18	06/20	A02718012	07/18	06/20

Bharat Serums and Vaccines Limited, the genuine manufacturer of Equirab, stated:

- They did not manufacture the above listed products.
- The above listed products display labelling and packaging inconsistencies.

WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. 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 products, please do not use. If you have used these falsified products, or if you suffer an adverse event having used these products, 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 products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

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

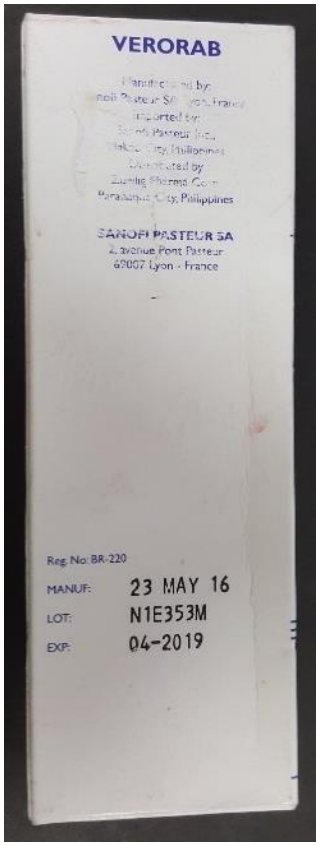
For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/

[5] Source: https://www.fda.gov.ph/fda-advisory-no-2019-152-public-health-warning-against-the-purchase-and-use-of-the-verified-counterfeit-version-of-anti-rabies-serum-equine-equirab-5ml-vial/

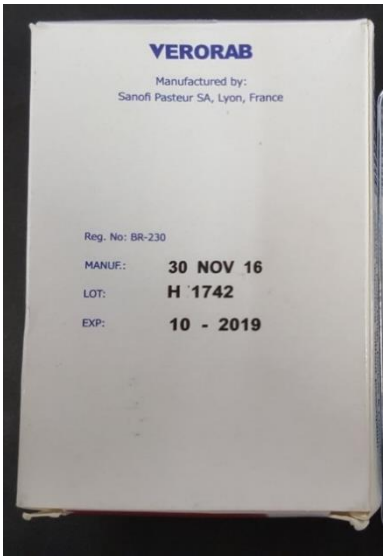
Annex 1: Available Photographs of Falsified Verorab, subject of WHO Medical Product Alert N°8/2019

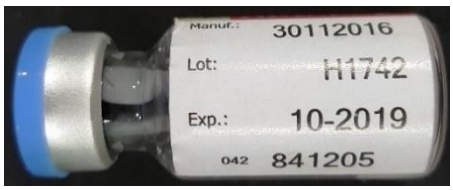
Please note that the photographs below are in the same order as Table 1.

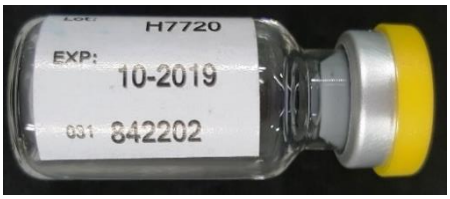
1. Photographs of falsified Verorab, batch number N1E353M



2. Photographs of falsified Verorab, batch number H 1742



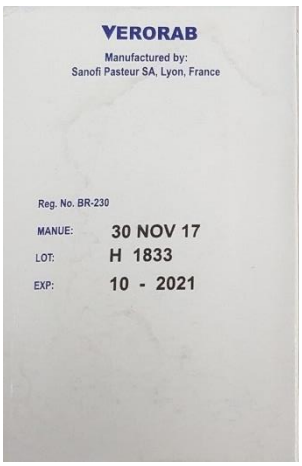




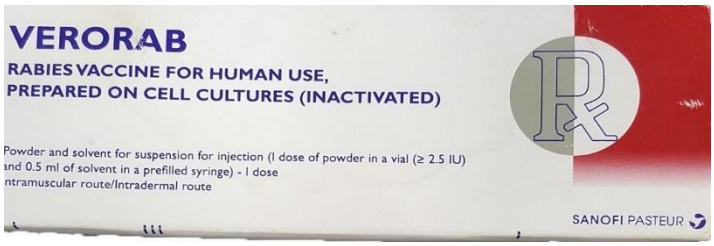
3. Photographs of falsified Verorab, batch number H1833

Note: Verorab with batch number H1833 (manufacturing date 30 NOV 17 and expiry date 10 – 2021) is available in two different packaging presentations.

Packaging Presentation 1:

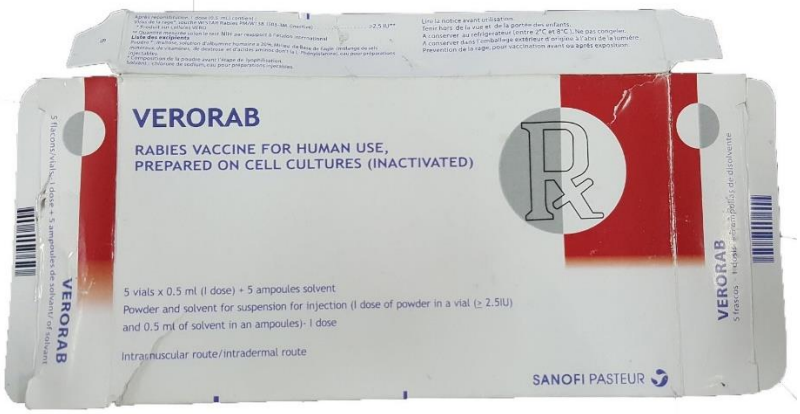


Packaging Presentation 2:



4. Photographs of falsified Verorab, batch number N1J75V

Note: No available photographs of powder in vial and solvent in ampoule.

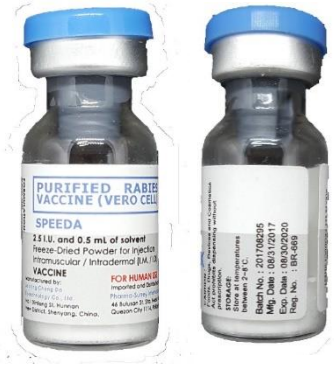


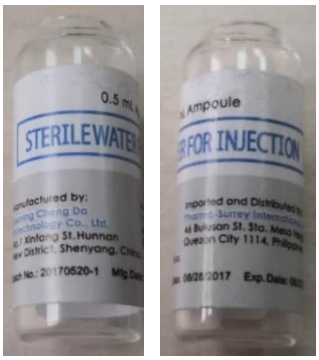
Annex 2: Available Photographs of Falsified Speeda, subject of WHO Medical Product Alert N°8/2019

Please note that the photographs below are in the same order as Table 2.

5. Photographs of falsified Speeda, batch number 201803067

6. Photographs of falsified Speeda, batch number 201708295





7. Photographs of falsified Speeda, batch number 201710356

No photos available.

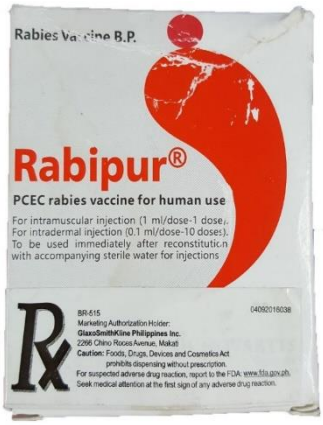
8. Photographs of falsified Speeda, batch number 201803069

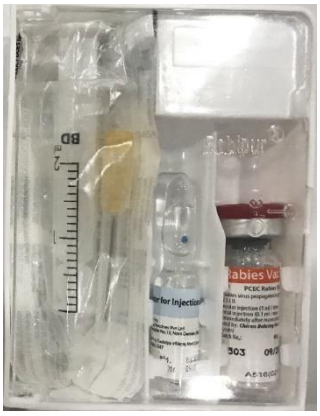
No photos available.

Annex 3: Available Photographs of Falsified Rabipur, subject of WHO Medical Product Alert N°8/2019

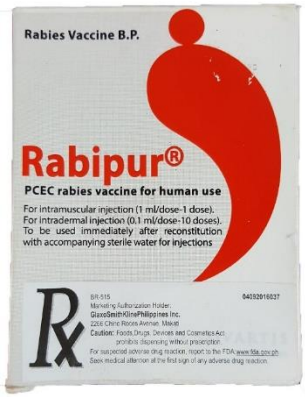
Please note that the photographs below are in the same order as Table 3.

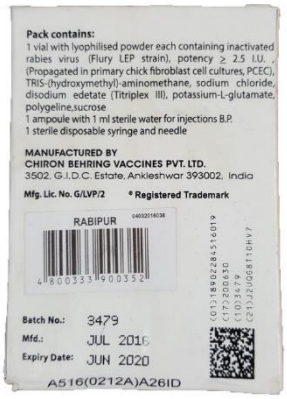
9. Photographs of Falsified Rabipur, batch number 3503

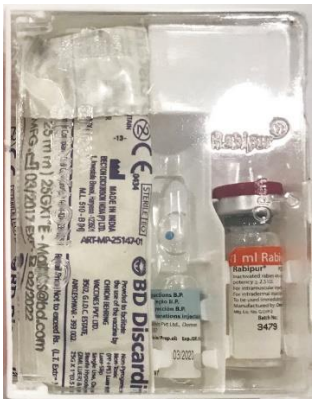


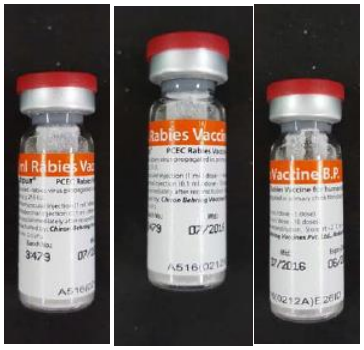


10. Photographs of Falsified Rabipur, batch number 3479





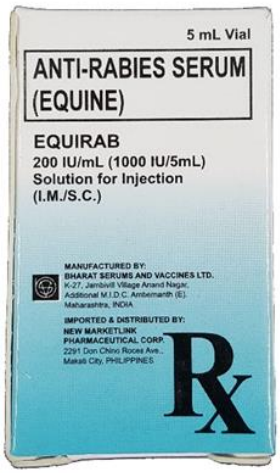




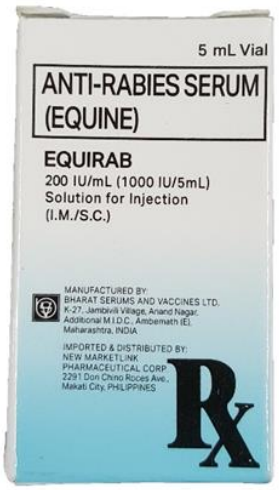
Annex 4: Available Photographs of Falsified Equirab, subject of WHO Medical Product Alert N°8/2019

Please note that the photographs below are in the same order as Table 4.

11. Photographs of falsified Equirab, batch number A02717008



12. Photographs of falsified Equirab, batch number A02718008



13. Photographs of falsified Equirab, batch number A02718012