গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
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নং-ডিজিডিএ/এলার্ট নোটিশ/এমসি-১৬/২০১৯/ ৭৪৫ তারিখঃ ২৫/০৭/২০১৯

বরাবর

1. DG,Directorate General of Health Services(Attn:Director,Hospital&Clinical Service)
2. Director, EPI.
3. Director, CMSD.
4. Secretary General, Bangladesh Medical Association (BMA), BMA Vaban, 15/2 Topkhana Road, Dhaka.
5. Secretary General, Bangladesh Society of Medicine, Dept. of Medicine, Dhaka Medical College, Dhaka.
6. Secretary General, Bangladesh Paediatric Association (BPA), Plot#7/3C, Barabag. sec#2, Mirpur, Dhaka-1216.
7. Secretary General, BAPI.
8. Secretary, Bangladesh Private Medical Practitioner's Association, 125/2, Darus Salam, Mirpur, Dhaka.
9. Chief Executive Officer, Apollo Hospital,Plot-81, Block-E,Bashundhara R/A, Dhaka
10. Chief Executive Officer, United Hospital,Plot-15, Road-71,Gulshan, Dhaka
11. President, Bangladesh Importers Association.

বিষয়ঃ বিশ্ব স্বাস্থ্য সংস্থা (WHO) মেডিক্যাল প্রোডাক্ট এলার্ট N° 8/2019 প্রসঙ্গে।

বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট N° 8/2019- এ এই মর্মে সতর্ক করেছে যে, Sanofi Pasteur কর্তৃক উৎপাদিত Verorab, Rabies Vaccine for Human Use এর ৪টি ব্যাচ (Batch No: N1E353M, H 1742, H1833, N1J75V); Liaoning Cheng Da Biotechnology Co., Ltd কর্তৃক উৎপাদিত Speeda Vaccines এর ৪টি ব্যাচ (Batch No: 201803067, 201708295, 201710356, 201803069), GSK কর্তৃক উৎপাদিত Rabipur Vaccine এর ২টি ব্যাচ (Batch No: 3503,3479), Bharat Serum and Vaccines Limited কর্তৃক উৎপাদিত Equirab, Anti Rabies Serum (Equine) এর ৩টি ব্যাচ (Batch No: A02717008, A02718008,A02718012) ফিলিপাইন এর বাজারে নকল (Falsified) হিসেবে পাওয়া গেছে। (সংযুক্ত কপিতে রঙ্গিন ছবি সহ টেব্যুলেটেড ফর্মে বিস্তারিত উল্লেখ করা আছে)।

Batch No	Manufacturing Date	Expiary Date
N1E353M	23 May, 2016	04-2019
H 1742	30 Nov, 2016	10-2019
H1833	30 Nov, 2017	10-2021
N1J75V	28.09.2017	12-2020
201803067	03.15.2018	03.14.2021
201708295	08.31.2017	08.30.2020
201710356	Unknown	Unknown
201803069	Unknown	Unknown
3503	Sep 2016	Aug 2020
3479	Jul 2016	Jun2020
A02717008	3/18	2/20
A02718008	03/18	02/20
A02718012	07/18	06/20

এমতাবস্থায়, উপরোল্লিখিত ১৩ (তের) টি ঔষধ ব্যবহার থেকে বিরত থাকার জন্য এবং এতদ্বসংক্রান্ত বিষয়ে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য অনুরোধ করা হল।

সংযুক্তিঃ ০৮ (আট) পাতা।

নায়ার সুলতানা 28/7/2019
পরিচালক (চঃদাঃ)
ঔষধ প্রশাসন অধিদপ্তর
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Ref. EMP/SAV/Alert_n8.2019

16 July 2019

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:

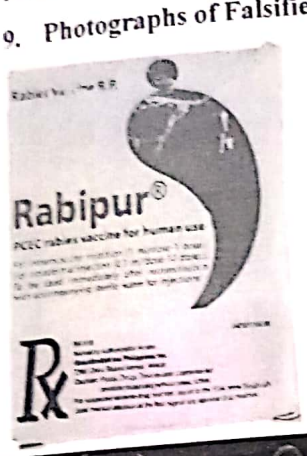
- They did not manufacture the above listed products.
- The above listed products display labelling and packaging inconsistencies.
- Since July 2017, Chiron Behring Vaccines Pvt. Ltd has not exported this product nor has GSK imported this product into the Philippines.

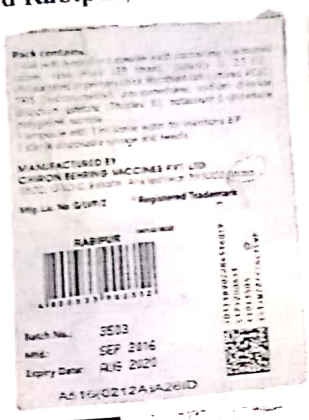
[3] Source: https://www.fda.gov.ph/fda-advisory-no-2019-153-public-health-warning-against-the-purchase-and-use-of-the-verified-counterfeit-version-of-drug-speeda-rabies-vaccine/
[4] Source: https://www.fda.gov.ph/fda-advisory-no-2019-170-public-health-warning-against-the-purchase-and-use-of-the-counterfeit-versions-of-rabipur-pcec-rabies-vaccine-for-human-use/

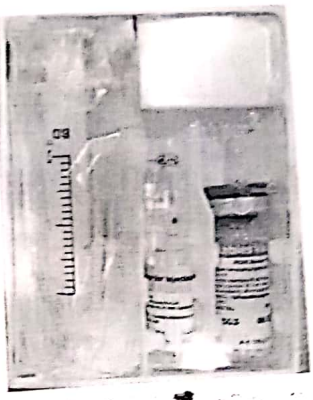
Annex 3: Available Photographs of Falsified Rabipur, subject of WHO Medical Product Alert N°8/2019

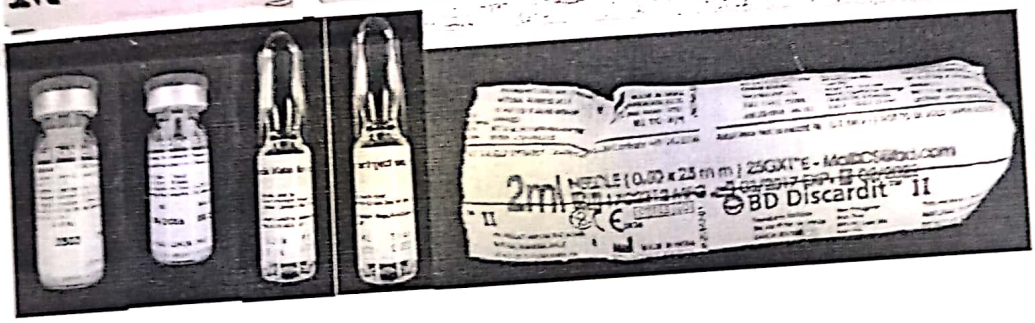
Please note that the photographs below are in the same order as Table 3.

9. **Photographs of Falsified Rabipur, batch number 3503**









10. **Photographs of Falsified Rabipur, batch number 3479**