



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**  
**No. 2018-138**

**11 APR 2018**

**TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT: Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product Purified Chick Embryo Cell Rabies Vaccine (Inactivated) (Rabipur) 2.5 I.U./mL Lyophilized Powder For Injection (ID/IM)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Purified Chick Embryo Cell Rabies Vaccine (Inactivated) (Rabipur) 2.5 I.U./mL Lyophilized Powder For Injection (ID/IM):

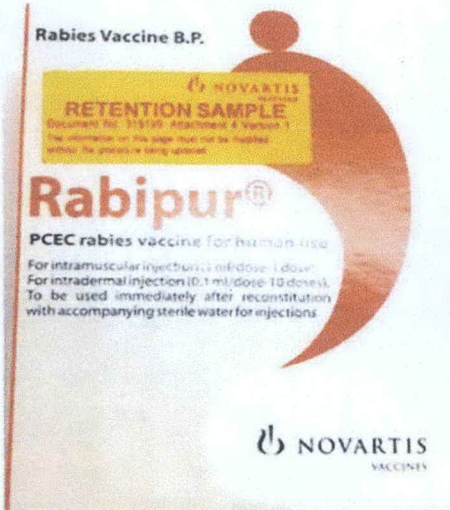
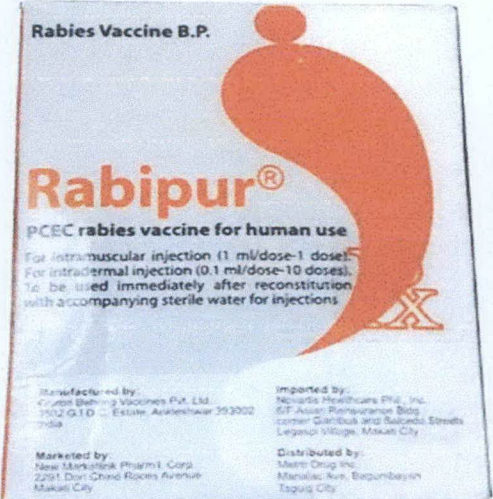


Figure 1. Verified counterfeit sample of Rabipur Vaccine





The FDA, together with the Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines, Inc., have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

AUTHENTIC	COUNTERFEIT
 <p>The authentic box features a yellow 'RETENTION SAMPLE' sticker at the top. The text on the box includes 'Rabies Vaccine B.P.', 'NOVARTIS', 'Rabipur®', 'PCEC rabies vaccine for human use', and 'NOVARTIS VACCINES' at the bottom.</p>	 <p>The counterfeit box lacks the yellow sticker and has different text for the manufacturer and distributor. It includes 'Rabies Vaccine B.P.', 'Rabipur®', 'PCEC rabies vaccine for human use', and lists 'Chiron Behring Vaccines Pvt. Ltd.' as the manufacturer and 'Novartis Healthcare Pte. Ltd.' as the importer.</p>

#### Secondary packaging: Box (Front)


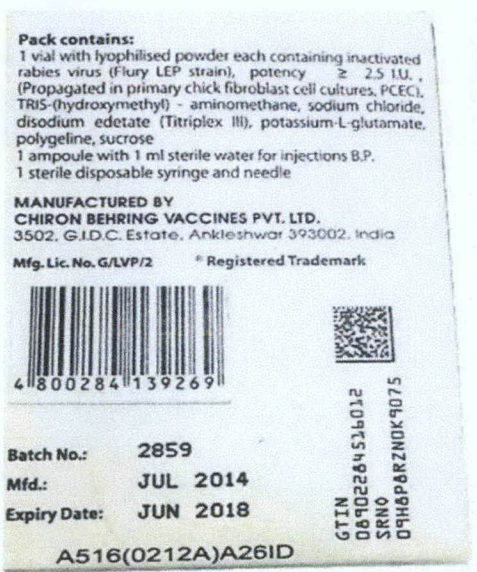
- Pre-printed text font size and colour of carton are different

*Note: (Authentic Rabipur) Two stickers were affixed on the front side of carton:*

(1) Rx sticker

(2) Brand owners details:

- "Manufactured by: Chiron Behring Vaccines Pte Ltd. – 3502 G. I.D. C. Industrial Estate, Ankleshwar 393 002, India"
- "Imported by: Novartis Healthcare Inc. – Asian Reinsurance Building, Salcedo corner Gamboa Streets, Legaspi Village, Makati"
- "New Marketlink Pharm'l. Corp. – 2291 Don Chino Roces Avenue, Makati City"
- "Distributed by: Metro Drug Inc. – Meralco Ave., Bagumbayan, Taguig City"

AUTHENTIC	COUNTERFEIT
 <p>The authentic secondary packaging includes detailed text about the pack contents, manufacturer (Chiron Behring Vaccines Pvt. Ltd.), and a QR code. It also lists the batch number (2859), manufacturing date (JUL 2014), and expiry date (JUN 2018).</p>	 <p>The counterfeit secondary packaging mimics the authentic one but contains different text for the manufacturer and distributor. It includes a barcode and the same batch number, manufacturing date, and expiry date as the authentic product.</p>



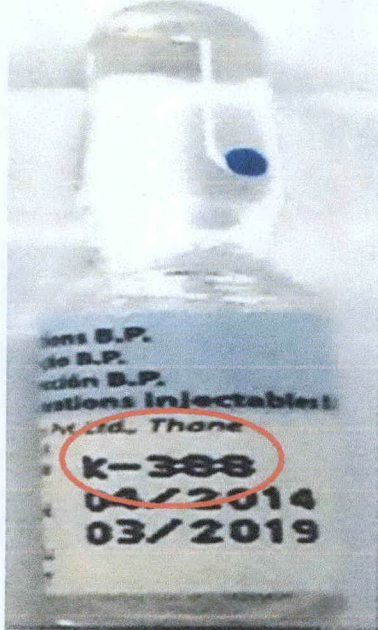
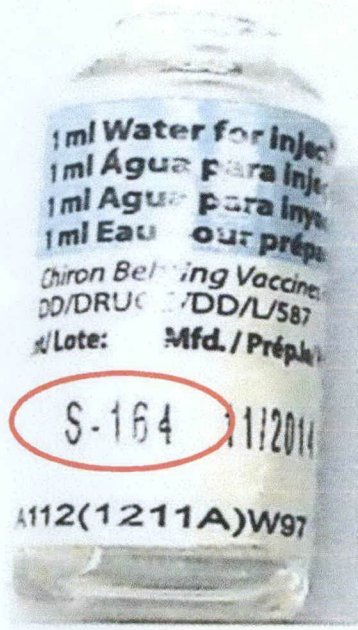
### Secondary packaging: Box (Back)

- Overprinted text matter font and its size are different
- 2D barcode printing pattern is different

AUTHENTIC	COUNTERFEIT
	

### Primary Packaging: Vial label

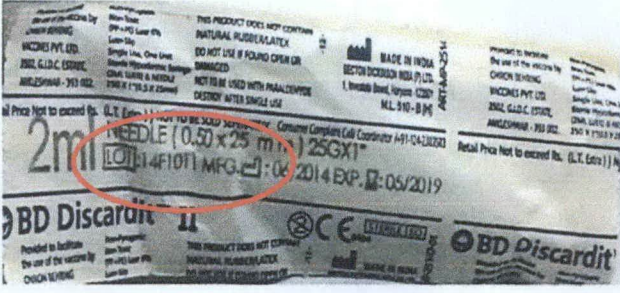
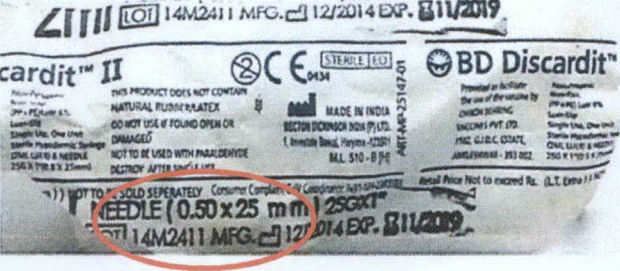
- Pre-printed text matter font size is different

AUTHENTIC	COUNTERFEIT
	

### Sterile Water for Injection (SWFI) Ampoule label

- Retention sample has SWFI Batch No. K-388, however the complaint sample of SWFI ampoule has Batch No. S-164



<p style="text-align: center;"><b>AUTHENTIC</b></p> 	<p><b>Syringe and Needle label:</b></p> <ul style="list-style-type: none"> <li>Batch No. is 14F1011</li> </ul>
<p style="text-align: center;"><b>COUNTERFEIT</b></p> 	<p><b>Syringe and Needle label:</b></p> <ul style="list-style-type: none"> <li>Batch No. is 14M2411</li> </ul>

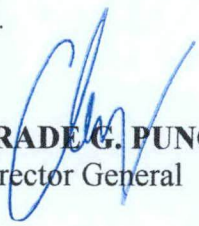
All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

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](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph), or through the online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://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](http://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

