

事務連絡
平成31年3月26日

各 都道府県
保健所設置市
特別区 衛生主管部（局）薬務主管課 御中

厚生労働省医薬・生活衛生局監視指導・麻薬対策課

経口コレラワクチン「Dukoral」の
 Bangladesh国内で確認された偽造品について（注意喚起）

今般、別紙のとおり、 Bangladesh国内で経口コレラワクチン「Dukoral」について、包装（箱）に正規品には存在しない表示がなされた偽造品が発見されたとWHOから報告がありました。

現時点では、当該偽造品の服用に起因すると考えられる健康被害の報告は確認されていません。また、日本国内への流入も確認されていませんが、このような偽造品を発見した場合には、決して、調剤、処方等をせず、流通させることがないように、貴管下の医療機関、薬局、医薬品の販売業者等に対する注意喚起をお願いいたします。



Ref. EMP/SAV/Alert N° 4.2019

21 March 2019

Medical Product Alert N° 4/2019

Falsified oral cholera vaccines circulating in Bangladesh

This Medical Product Alert relates to the circulation of confirmed falsified DUKORAL in the WHO region of South East Asia. Genuine Dukoral is a WHO pre-qualified oral cholera vaccine.

WHO was recently informed by the manufacturer Valneva that 8000 falsified packs of the oral cholera vaccine Dukoral were distributed in Bangladesh. WHO country office and health authorities in Bangladesh have quarantined the falsified vaccines identified to date.

Table 1: Specific details of falsified Dukoral, subject of WHO Alert N°4/2019

| | |
|----------------------------|--|
| <i>Product Name</i> | Dukoral Oral cholera vaccine / Vaccin oral contre le choléra |
| <i>Batch Number</i> | KV8262B1 |
| <i>Expiry Date</i> | 2020-04 |
| <i>Stated manufacturer</i> | Valneva Canada Inc. <i>Note that the logo of the manufacturer Crucell is also displayed</i> |

The packaging of this falsified Dukoral displays text in English and French language.

Samples are being sent for laboratory analysis to determine their contents and better assess the risk to public health. This medical product alert n°4/2019 will subsequently be updated and posted on the WHO website once laboratory results are known. No serious adverse reactions attributed to these falsified vaccines have been reported to WHO at this stage.

The manufacturer of genuine Dukoral is Valneva Sweden AB, formerly named Crucell Sweden AB.

The above product claims to be manufactured by Valneva Canada Inc. However, the manufacturer Valneva Sweden AB has stated that:

- the displayed batch number does not correspond to genuine manufacturing records of either Valneva Canada Inc, or Crucell; and
- the combination of the manufacturers Valneva Canada Inc and Crucell should not exist on any packaging in any market.

The next page shows photographs of the falsified Dukoral subject of this alert and provides advice for healthcare professionals and patients.



PHOTOGRAPHS OF FALSIFIED DUKORAL, BATCH NUMBER KV8262B1



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 or medical products.

If you are in possession of the above falsified vaccines, please do not use. If you have taken this falsified vaccine, or if you suffer an adverse event or an unexpected lack of efficacy, please seek immediate advice from a qualified healthcare professional, and ensure they report the incident to your local Ministry of Health or National Medicines Regulatory Authorities or 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 products, please contact rapidalert@who.int.

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

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

