DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION
PAKISTAN NATIONAL PHARMACOVIGILANCE CENTRE (PNPC)
Email: npc@dra.gov.pk; Website: www.dra.gov.pk; Twitter: @DRA_Pakistan
****

Islamabad, the 6th November, 2019.

ALERT OF FALSIFIED AMOXICILLIN + CLAVULANIC ACID PRODUCTS CIRCULATING IN HAITI.

On 16th October, 2019, World Health Organization (WHO) through its alert informed about two confirmed falsified version of amoxicillin + clavulanic acid products circulating in Haiti, presented under the names "Augmentin and Amoxicillin Clavulanate Potassium" and "Bactoclav". The details are as under:

Product Name No.1	Augmentin and Amoxicillin Clavulanate Potassium
Stated Manufacturer	Novopharm Limited and TEVA Pharmaceuticals USA
Batch Number	35405327A
Expiry Date	10/2020
Declared Active Ingredients	Augmentin and Amoxicillin Clavulanate Potassium for Oral Suspension, USP

Product Name No. 2	Bactoclav
Stated Manufacturer	MYLAN
Batch Number	BSTU0039
Manufacturing Date	06/2017
Expiry Date	05/2020
Declared Active Ingredients	Amoxicilline et Clavulnate de potasium pour suspension Orale USP

Both the manufacturers confirmed that neither did they manufactured these falsified versions of products nor have distributed these products anywhere in the world. WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified medical products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

Those patients, who are using any of above falsified product, should immediately stop it. If the patient has taken any of these falsified medical product, and has suffer an adverse event or an unexpected lack of efficacy, should immediately seek the advice from a qualified healthcare professional, and ensure that they report the incident to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan. All drugs must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked.

Other concern stakeholders are requested to take further necessary action on their part.

For further details see the enclosures.

World Health 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 N°11.2019 16 October 2019

Medical Product Alert N°11/2019

Falsified Amoxicillin + Clavulanic Acid products circulating in Haiti

This Medical Product Alert relates to two confirmed falsified versions of amoxicillin + clavulanic acid products circulating in Haiti, presented under the names "Augmentin and Amoxicillin Clavulanate Potassium" and "Bactoclav".

Genuine amoxicillin + clavulanic acid is used to treat a range of bacterial infections and is referenced on the WHO Essential Medicines List as an access group antibiotic.

WHO was informed by the Haiti Ministère de la Santé Publique et de la Population (MSPP) and Caribbean Public Health Agency's (CARPHA) VigiCarib network (which is a regional reporting system for pharmacovigilance and post market surveillance), that falsified "Augmentin and Amoxicillin Clavulanate Potassium" and "Bactoclav" were found in a pharmacy in Haiti. At this stage, laboratory testing of these products is being facilitated. Product details are listed in the tables below.

1. Augmentin and Amoxicillin Clavulanate Potassium

Table 1: Details of the falsified product Augmentin and Amoxicillin Clavulanate Potassium, subject of WHO medical product alert N°11/2019

Product Name	**Augmentin and Amoxicillin Clavulanate Potassium**
Stated Manufacturer	Novopharm Limited and TEVA Pharmaceuticals USA
Batch Number	35405327A
Expiry Date	10 2020
Declared Active Ingredients	Augmentin and Amoxicillin Clavulanate Potassium for Oral Suspension, USP

The above stated manufacturer has confirmed that:

- They did not manufacture this falsified version.
- The variable details on the product label do not correspond to the genuine manufacturing records.
- There are labelling and packaging inconsistencies.

It should also be noted that:

- At this stage, no adverse reactions have been reported to WHO.

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

2. Bactoclav

Table 2: Details of the falsified product Bactoclav, subject of WHO medical product alert N°11/2019

Product Name	Bactoclav
Stated Manufacturer	MYLAN
Batch Number	BSTU0039
Manufacturing Date	06/2017
Expiry Date	05/2020
Declared Active Ingredients	Amoxicilline et Clavulnate de potasium pour suspension Orale USP

It should be noted that:

- MYLAN does not manufacture, sub-contract the manufacture nor distribute these products anywhere in the world.
- The packaging is in French language but displays numerous inconsistencies, including spelling errors.
- At this stage, no adverse reactions have been reported to WHO.

Photographs are available on the following pages.

Falsified Amoxicillin + Clavulanic Acid products are regularly reported to the WHO Global Surveillance and Monitoring System. Therefore, WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified medical products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of the above specific products, please do not use. If you have taken these falsified medical products, 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/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 medical products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of this medical product please contact rapidalert@who.int .

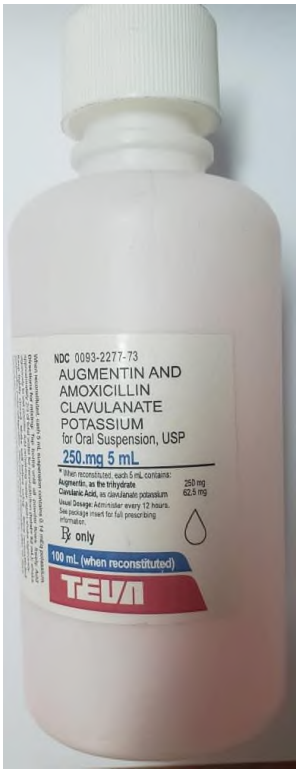
WHO Global Surveillance and Monitoring System
for Substandard and Falsified Medical Products

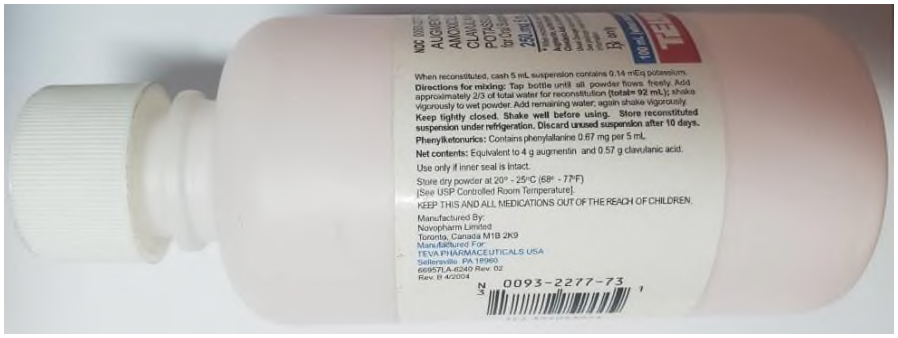
For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/

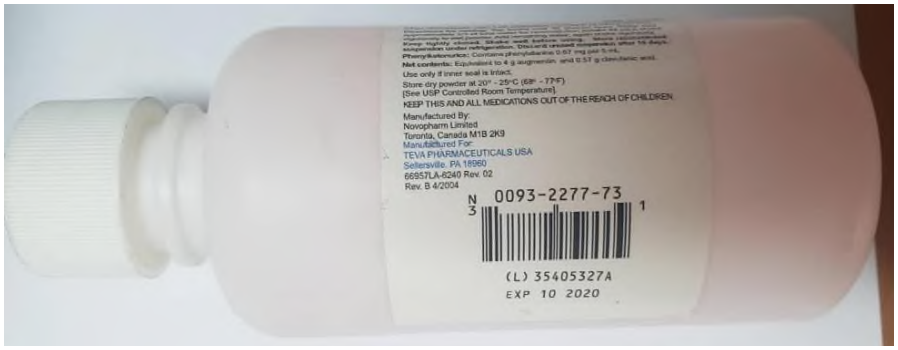
20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Photographs of Falsified Amoxicillin + Clavulanic Acid products, subject of WHO Medical Product Alert N°11/2019

1. Augmentin and Amoxicillin Clavulanate Potassium, batch number 35405327A







2. Bactoclav, batch number BSTU0039