Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2023-1569

30 JUN 2023

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

SUBJECT: **Voluntary Product Recall of the Specific Batches of Piperacillin (as sodium) + Tazobactam (as sodium) 2 g/250 mg Powder for Injection (IV Infusion) [Piptaz], Piperacillin (as sodium) + Tazobactam (as sodium) 4 g/500 mg Powder for Injection (IV Infusion) [Piptaz], Co-Amoxiclav 600 mg Powder for Injection [Amoclav] and Co-Amoxiclav 1.2 g Powder for Injection (I.V.) [Amoclav]**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holder (MAH) on the affected batches of the subject product from the market. The details of the products are as follows:

DRUG PRODUCTS	**Piperacillin (as sodium) + Tazobactam (as sodium) [Piptaz]**		**Co-Amoxiclav [Amoclav]**	
DOSAGE STRENGTH	**2 g/250 mg Powder for Injection (IV Infusion)**	**4 g/500 mg Powder for Injection (IV Infusion)**	**600 mg Powder for Injection (I.V.)**	**1.2 g Powder for Injection (I.V.)**
REGISTRATION NO.	**DR-XY32669**	**DR-XY32668**	**DR-XY23656**	**DR-XY23657**
PACKAGING	**20 mL Clear Transparent USP Type I Glass Vial (Box of 1's)**	**30 mL Clear Transparent USP Type I glass vial (Box of 1's)**	**Clear colorless, Type I glass vial with rubber stopper and aluminum seal (Box of 1's)**	**1.2 g in 20 mL USP Type I Glass Vial (Box of 1's)**
BATCH NO./ EXP. DATE	**SEE ATTACHED LIST**			
MANUFACTURER	**Astral Steritech Pvt. Ltd.- India**			
IMPORTER/DISTRIBUTOR	**United Laboratories, Inc. - 66 United St., Mandaluyong City**			
FOR	**UNILAB, Inc.- 66 United St., Mandaluyong City**			

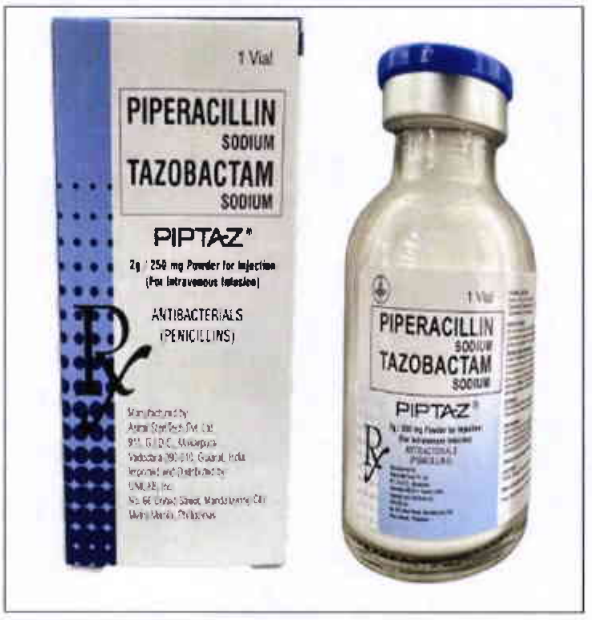

Figure 1. Piperacillin (as sodium) + Tazobactam (as sodium) 2 g/250 mg Powder for Injection (IV Infusion) [Piptaz]

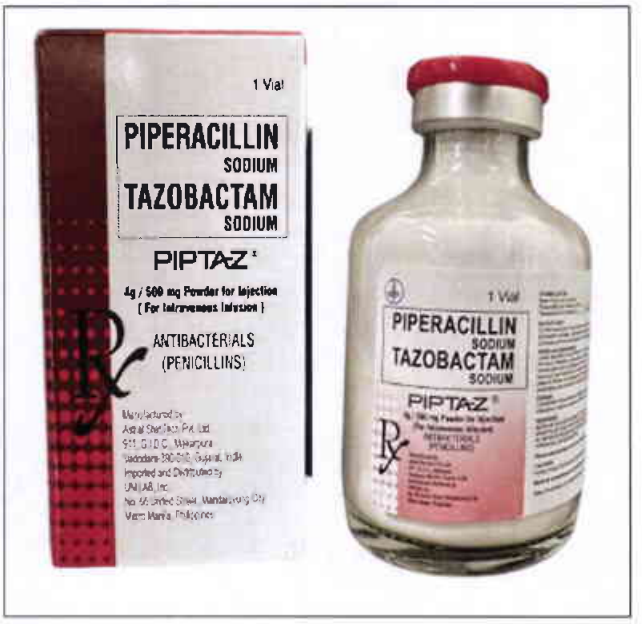

Figure 2. Piperacillin (as sodium) + Tazobactam (as sodium) 4 g/500 mg Powder for Injection (IV Infusion) [Piptaz]

Figure 3. Co-Amoxiclav 600 mg Powder for Injection (I.V.) [Amoclav]

Figure 4. Co-Amoxiclav 1.2 g Powder for Injection (I.V.) [Amoclav]

Piperacillin/Tazobactam is a combination of a bactericidal antibiotic with a beta-lactamase inhibitor. It is used for the treatment of moderate to severe infections caused by piperacillin-resistant, piperacillin/tazobactam-susceptible, and beta-lactamase producing strains of microorganisms.

Co-amoxiclav is an antibiotic used for the treatment of infections in the upper and lower respiratory, genito-urinary tract and abdominal, skin and skin structure, bone and joint, dental, and other infections. It contains amoxicillin (an antibiotic from the penicillin group of medicines) mixed with clavulanic acid.

The MAH pursued the voluntary recall of the abovementioned drug products due to an Out-of-Specification (OOS) data observed during a routine environmental monitoring at the manufacturer's facility located in Vadodara, Gujarat, India. Due to the Good Manufacturing Practice (GMP) issues on the manufacturer's sterile facilities, the integrity of the specific batches produced can no longer be assured and could relatively cause health risks to the patients. Thus, the stated batches present quality and safety concerns.

Distributors, hospitals, retailers, pharmacies, or clinics that have the affected lot of the drug product are therefore instructed to discontinue further distribution, sale, and use. All healthcare professionals and consumers are likewise advised not to purchase or use the affected product batches and may contact UNILAB, Inc through info@unilab.com.ph for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batches are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

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List of Affected Batches (Piptaz and Amoclav)

Piperacillin (as sodium) + Tazobactam (as sodium) 2g/250mg Powder for Injection (IV Infusion) [Piptaz]

BATCH NUMBER	MFG DATE	EXP DATE
AUPM-001	01 May 2020	30 April 2023
AUPM-002	04 May 2020	30 April 2023
AUPM-003	30 July 2020	30 June 2023
AUPM-004	17 October 2020	30 September 2023
AUPM-005	17 October 2020	30 September 2023
AUPM-101	21 January 2021	31 December 2023
AUPM-102	22 January 2021	31 December 2023
AUPM-103	04 March 2021	29 February 2024
AUPM-104	04 May 2021	30 April 2024
AUPM-105	15 June 2021	31 May 2024
AUPM-106	15 June 2021	31 May 2024
AUPM-107	16 June 2021	31 May 2024
AUPM-108	17 September 2021	31 August 2024
AUPM-109	17 November 2021	31 October 2024
AUPM-201	19 January 2022	31 December 2024
AUPM-202	06 April 2022	31 March 2025
AUPM-203	27 April 2022	31 March 2025
AUPM-204	10 May 2022	30 April 2025
AUPM-205	15 December 2022	30 November 2025

Piperacillin (as sodium) + Tazobactam (as sodium) 4g/500mg Powder for Injection (IV Infusion) [Piptaz]

BATCH NUMBER	MFG DATE	EXP DATE
AUPI-004	02 May 2020	30 April 2023
AUPI-005	02 May 2020	30 April 2023
AUPI-006	02 May 2020	30 April 2023
AUPI-007	02 May 2020	30 April 2023
AUPI-008	09 May 2020	30 April 2023
AUPI-009	09 May 2020	30 April 2023
AUPI-010	29 July 2020	30 June 2023
AUPI-011	29 July 2020	30 June 2023
AUPI-012	15 October 2020	30 September 2023

AUPI-013	15 October 2020	30 September 2023
AUPI-014	15 October 2020	30 September 2023
AUPI-101	23 January 2021	31 December 2023
AUPI-102	25 January 2021	31 December 2023
AUPI-103	30 January 2021	31 December 2023
AUPI-104	13 February 2021	31 January 2024
AUPI-105	15 February 2021	31 January 2024
AUPI-106	02 March 2021	29 February 2024
AUPI-107	03 March 2021	29 February 2024
AUPI-108	01 June 2021	31 May 2024
AUPI-109	02 June 2021	31 May 2024
AUPI-110	03 June 2021	31 May 2024
AUPI-111	03 June 2021	31 May 2024
AUPI-112	25 June 2021	31 May 2024
AUPI-113	26 June 2021	31 May 2024
AUPI-114	01 July 2021	30 June 2024
AUPI-115	01 July 2021	30 June 2024
AUPI-116	02 July 2021	30 June 2024
AUPI-117	02 July 2021	30 June 2024
AUPI-118	03 July 2021	30 June 2024
AUPI-119	03 July 2021	30 June 2024
AUPI-120	18 September 2021	31 August 2024
AUPI-121	18 September 2021	31 August 2024
AUPI-122	08 October 2021	30 September 2024
AUPI-123	15 November 2021	31 October 2024
AUPI-124	18 November 2021	31 October 2024
AUPI-125	22 November 2021	31 October 2024
AUPI-126	15 December 2021	30 November 2024
AUPI-127	15 December 2021	30 November 2024
AUPI-128	20 December 2021	30 November 2024
AUPI-129	21 December 2021	30 November 2024
AUPI-130	22 December 2021	30 November 2024
AUPI-201	20 January 2022	31 December 2024
AUPI-202	20 January 2022	31 December 2024
AUPI-203	04 April 2022	31 March 2025
AUPI-204	05 April 2022	31 March 2025
AUPI-205	07 April 2022	31 March 2025
AUPI-206	07 April 2022	31 March 2025
AUPI-207	09 May 2022	30 April 2025

AUPI-208	15 June 2022	31 May 2025
AUPI-209	16 June 2022	31 May 2025
AUPI-210	14 December 2022	30 November 2025

Co-Amoxiclav 600 mg Powder for Injection [Amoclav]

BATCH NUMBER	MFG DATE	EXP DATE
AUAM-101	12 November 2021	31 October 2023
AUAM-201	21 May 2022	30 April 2024
AUAM-202	09 July 2022	30 June 2024
AUAM-203	06 September 2022	31 August 2024
AUAM-204	01 November 2022	31 October 2024
AUAM-301	11 February 2023	31 January 2025

Co-Amoxiclav 1.2g Powder for Injection (I.V.) [Amoclav]

BATCH NUMBER	MFG DATE	EXP DATE
AUAI-101	12 November 2021	31 October 2023
AUAI-201	21 May 2022	30 April 2024
AUAI-202	09 July 2022	30 June 2024
AUAI-203	05 September 2022	31 August 2024
AUAI-204	01 November 2022	31 October 2024
AUAI-301	11 February 2023	31 January 2025