FOOD AND DRUG ADMINISTRATION

DRUG SAFETY NEWSLETTER

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Pharmacovigilance Corner

The Food and Drug Administration (FDA) monitors the safety of medicines through different PV activities such as Adverse Drug Reaction (ADR) reporting, signal detection, and timely communication.

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems (WHO, 2002).

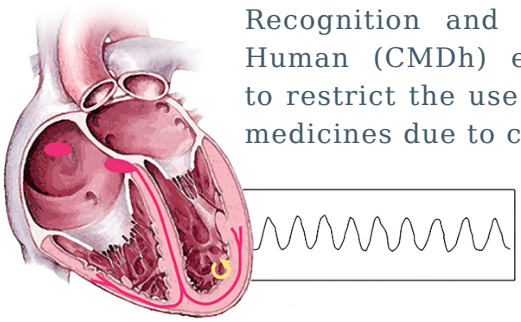
Safety Assessment

To ensure the safety of our medicines, the PV Team assessed the safety of Domperidone and Topical Corticosteroids following triggers from stakeholders.

On 22 May 2023, a meeting with stakeholders was held to discuss the findings of the PV Team on the safety assessment of Domperidone and Topical Corticosteroids.

Domperidone and increased risk of cardiac adverse reaction

Domperidone is a dopamine antagonist with prokinetic and antiemetic properties indicated for dyspeptic symptom complex and nausea and vomiting.



Picture from https://www.hopkinsmedicine.org/health/conditions-and-diseases/ventricular-tachycardia

In 2014, EU's Co-ordination Group for Mutual Recognition and Decentralized Procedures-Human (CMDh) endorsed recommendations to restrict the use of domperidone-containing medicines due to cardiac adverse effects such as QT interval prolongation and arrythmias. Although these reactions were included in

In this issue:

the product information, continued reports prompted re-evaluation of its benefit-risk.

Following assessment and evaluation of the current data available in the Philippines, the following are recommended:

For patients and consumers:

- Patients who have heart problems or are taking cardiac medicines should consult a doctor or pharmacist prior to taking domperidone.
- Domperidone should only be used for short periods of time.
- Seek medical attention immediately if you experience heart-related symptoms such as irregular heartbeat.

For healthcare professionals (HCPs):

- Doctors should prescribe domperidone in the lowest effective dose for the shortest possible duration, taking caution in older patients and those with history of cardiac disease.
- Pharmacists are advised to dispense domperidone considering the contraindications, special warnings, and precautions on its use particularly on cardiovascular effects.
- Advise the patient to take the lowest dose for shortest time up to a maximum daily dose of 3 tablets (30 mg/day).

Topical Corticosteroids and its risk for abuse/misuse

Topical corticosteroids are applied externally to the skin or scalp and used to treat dermatologic conditions.

The risk for its abuse/misuse that could lead to local and systemic adverse reactions triggered this safety assessment.

Prescription sharing from friends and relatives are rampant especially on treating similar looking skin problems. Some are doing self medication and purchase medicines that are available over-the-counter. Thus, benefits of rational and ethical use and the harm of overuse and misuse for nonmedical, especially for cosmetic purposes, should be clearly conveyed.

The following are the recommendations after assessment and evaluation:

Safety Information for the General Public:

- Avoid prescription sharing from friends and relatives. Not all skin problems have the same management.
- Avoid searching through the internet to address skin problems. Consult with your physician or nearest pharmacist for proper recommendations.

Safety Information for HCPs:

- Healthcare professionals should inform their patients on the risk of topical steroids withdrawal, provide instruction on the correct, safe, and effective use, and should advise them to regularly check their skin for new marks or growths and any changes to existing marks.
- Pharmacists should advise the patients correctly about the safety of topical corticosteroids and not to dispense the product without a written prescription from dermatologists or treating physicians. Upon presentation of prescription, patients should undergo counseling on the proper use of the product to avoid serious health risks and worsening of their conditions.

All are encourage to report any adverse reaction experienced directly to the FDA or to your HCPs.

Setting up pharmacovigilance in the industry

The aim of PV is essentially the same with the industry and regulatory agencies which is to ensure the safety of medicines. Aside from ensuring that the public has access to the medicines they produce and supply, it is important that it does not cause unnecessary harm to the patient.

To fulfill such obligations, it is essential to establish a system that monitors the safety of their respective medicines that were given authorizations.

Basic steps in setting up PV for the Market Authorization Holders (MAHs)

1. As part of the FDA requirements, designate a PV officer or qualified person for pharmacovigilance (QPPV).

a. Create the unit by assigning or recruiting a staff in charge of setting up PV within the company. In some companies, PV is under the Medical Affairs while others prefer it to be under the Regulatory Affairs. It may also be an independent unit within the company.

b. Define the PV Unit's qualification requirements and the job description/roles and responsibilities of the staff in the PV unit – documents to reflect adequate level of education and understanding of the role and responsibilities of PV employees.

c. Train pharmacovigilance staff on:

i. Local/global regulations and guidelines on pharmacovigilance.

ii. Standard Operation Procedures and standards for relevant processes including but not limited to:

- Data collection and verification
- Interpreting and coding adverse reactions (e.g. MedDRA terminologies)
- Coding of drugs (e.g. WHODrug Global)
- Case causality assessment
- Signal detection and management
- Risk management
- Aggregate reporting
- Training requirements and training management for PV unit staff
- Information security/document management - including archiving process & facilities, access rights management
- PV regulatory intelligence and impact assessment
- Management of audits and inspections
- Business continuity

iii. Platforms and systems related training (as applicable)

- Database for adverse events and regulatory submissions
- Platform for signal management
- Contracts management

2. Design reporting systems and processes to capture the reports from healthcare professionals, patients, and consumers.

a. Reporting mechanisms to receive/contact the PV Unit during office hours and after office hours or Business Continuity Plan situation. Recommended reporting mechanism include:

- Paper-based reporting
- Phone or mobile call
- Online reporting system

b. Review councils to review marketing and sales programs that may be able to generate/solicit adverse event (AE) reports (examples: market research, patient support programs, social media projects, etc.).

c. Design a process for training requirements for AE reporting of the MAH employees (who needs to receive training, who is responsible for assigning and monitoring completion of training of relevant staff, what training method and material is required/acceptable, when training should be received (initial and refresher)).

The sales department may capture the ADR reports from various sources. It is also important to train the sales department in collecting the necessary information relative to the ADR reports as they may be approached by health professionals or clients.

Such reporting information may be added in the product labels and other externally published platforms to facilitate reporting. Promote the importance of reporting by providing education to contractual partners with regards to pharmacovigilance.

3. Establish a database for the storage and retrieval of ADR data, including life cycle documentation.

Use of spreadsheet may be useful for the start but soon may require information system for ease of analysis and retrieval of data including observance of the regulatory reporting timeframes.

References:
Ebeling, L. & Bordel, R. (2007). Designing efficient pharmacovigilance system. *Pharmind*. *69*(12), 1390-1395. https://www.diapharm.com/en/news/designing-efficient-pharmacovigilance-systems/

FDA Circular No. 2020-003 Guidelines for Pharmaceutical Industry on Pharmacovigilance https://www.fda.gov.ph/wp-content/uploads/2020/02/FDA-Circular-No.2020-003.pdf

Hematologic adverse events reported after COVID-19 vaccination in the Philippines: A national database study

In partnership with the Philippine College of Hematology, the study aimed to analyze hematologic adverse events after COVID-19 vaccination and their outcomes and to provide information on its benefit-risk to address vaccine hesitancy and provide recommendations on the management of hematologic AEs.

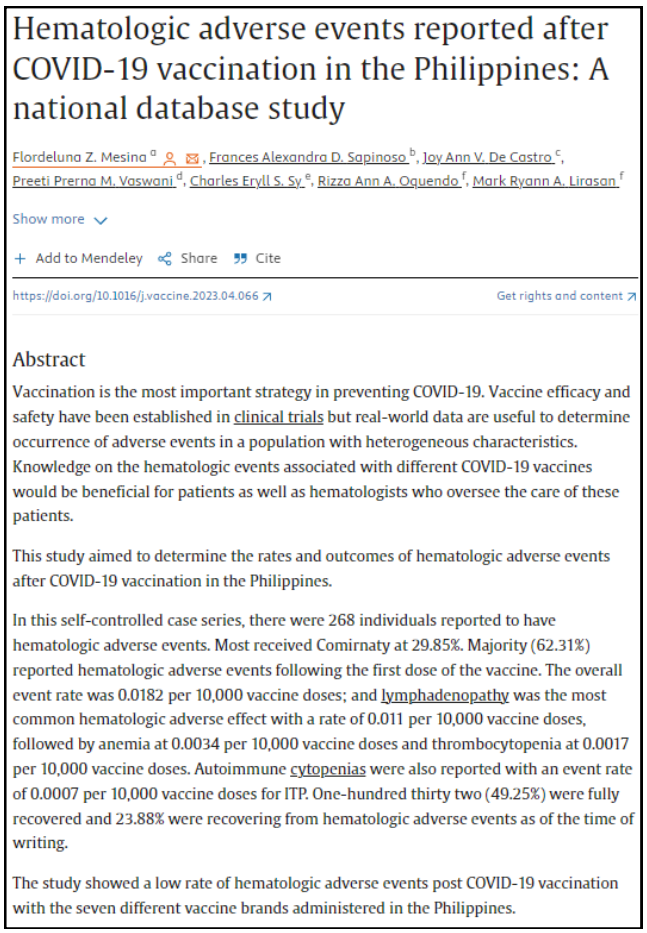
Abstract
Vaccination is the most important strategy in preventing COVID-19. Vaccine efficacy and safety have been established in clinical trials but real-world data are useful to determine occurrence of adverse events in a population with heterogeneous characteristics. Knowledge on the hematologic events associated with different COVID-19 vaccines would be beneficial for patients as well as hematologists who oversee the care of these patients.

This study aimed to determine the rates and outcomes of hematologic adverse events after COVID-19 vaccination in the Philippines.

In this self-controlled case series, there were 268 individuals reported to have hematologic adverse events. Most received Comirnaty at 29.85%. Majority (62.31%) reported hematologic adverse events following the first dose of the vaccine. The overall event rate was 0.0182 per 10,000 vaccine doses; and lymphadenopathy was the most common hematologic adverse effect with a rate of 0.011 per 10,000 vaccine doses, followed by anemia at 0.0034 per 10,000 vaccine doses and thrombocytopenia at 0.0017 per 10,000 vaccine doses. Autoimmune cytopenias were also reported with an event rate of 0.0007 per 10,000 vaccine doses for ITP. One-hundred thirty two (49.25%) were fully recovered and 64 (23.88%) were recovering from hematologic adverse events as of the time of writing.

The study showed a low rate of hematologic adverse events post COVID-19 vaccination with the seven different vaccine brands administered in the Philippines.

https://doi.org/10.1016/j.vaccine.2023.04.066



Hematologic adverse events reported after COVID-19 vaccination in the Philippines: A national database study

Flordeluna Z. Mesina [a], Frances Alexandra D. Sapinoso [b], Joy Ann V. De Castro [c], Preeti Prerna M. Vaswani [d], Charles Eryll S. Sy [e], Rizza Ann A. Oquendo [f], Mark Ryann A. Lirasan [f]

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Abstract

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Newly Approved Medicines Corner

This section includes New Chemical Entities (NCEs) - these are the newly approved medicines with an active substance that has not been previously registered for any pharmaceutical use in the country.

Below is a list of the newly approved medicines in 2023:

PRODUCT NAME	REGISTRATION NUMBER	INDICATION
Casirivimab + Imdevimab (Ronapreve) 120 mg/mL Concentrate for Solution for Injection (SC)/Infusion (IV)	BR-1437	Antiviral Monoclonal Antibodies As treatment: For confirmed COVID-19 in patients aged 12 years and older and weighing at least 40 kg that do not require supplemental oxygen for COVID-19 and who are at high risk of progressing to severe COVID-19. As prevention: For individuals aged 12 years and older and weighing at least 40 kg who meet one or more of the following criteria: • have been exposed or are at high risk of exposure to SARS-CoV-2 • have a medical condition making them unlikely to respond to or be protected by vaccination It is not intended to be used as a substitute for COVID-19 vaccination.
Tremelimumab (Imjudo) 25 mg/1.25 mL (20 mg/mL) Concentrate for Solution for Infusion (IV)	BR-1459	Monoclonal Antibody Tremelimumab in combination with durvalumab is indicated for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC). Tremelimumab in combination with durvalumab and platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic non-small cell lung cancer (NSCLC) with no sensitising EGFR mutations or ALK positive mutations.
Tremelimumab (Imjudo) 300 mg/15 mL (20 mg/mL) Concentrate for Solution for Infusion (IV)	BR-1458	

The safety of NCE products are closely monitored by the PV Section.

Everyone is encouraged to report any suspected ADRs especially on newly approved medicines in order to improve their safety profile.

Product Recall Corner

The FDA ensures that registered drug products that pose health risk and considered not safe are removed from the market.

Recall is the method of withdrawing or correcting unsafe or hazardous health products from the distribution chain that may present a health hazard to the consumer or user.

Below is the list of all recalled medicines in 2023:

PRODUCT NAME	DOSAGE STRENGTH	BATCH/LOT NUMBER	REASON OF RECALL	STATUS OF RECALL
Betamethasone (as diproprionate)/ Betamethasone (as sodium phosphate) (Diprospan) Suspension For Injection DRP-6247	5 mg/2 mg	U038437 W005751 W025758 W036602	Detection of Impurities	Ongoing
Erdosteine (Ectrin) Capsule DR-XY29596	300 mg	E031185	Out of Specification Result	Completed
Cloxacillin (as sodium) (Cloxasaph-125) Powder for Oral Suspension DRP-8295	125 mg/5 mL	NPCSDS125-08	Out of Specification Result	Ongoing
Inactivated Newcastle Disease (ND) + Infectious Bronchitis (IB) + Egg Drop Syndrome (EDS) + Avian Rhinotracheitis Virus Vaccine (Gallimune 407 ND + IB + EDS + ART) Emulsion for Injection (IM/SC) VR-4398 (Vet.)	-	D35883	Detection of Impurities	Ongoing
Paracetamol + Thiamine Mononitrate (Vitamin B1) + Pyridoxine Hydrochloride (Vitamin B6) + Cyanocobalamin (Vitamin B12) (Dolo-Neurobion) Tablet DR-XY32133	500 mg/ 50 mg/100 mg/ 100 mcg	E0217875 E0218876 E0247877 E0248878 E0249879 E0250880 E0355886 E0356887 E0357888 E0358889 E0390890 E0391891 E0392892 E0446893 E0447894 E0448895 E0449896 E0470897 E0471898	Detection of Impurities	Ongoing
Isopropyl Alcohol (Sampaguita) Solution DRHR-264	70 mL/ 100 mL (70% v/v)	E220118	Out of Specification Result	Ongoing

PRODUCT NAME	DOSAGE STRENGTH	BATCH/LOT NUMBER	REASON OF RECALL	STATUS OF RECALL
Panitumumab (Vectibix) Concentrate for Solution for Infusion (IV) BR-896	100 mg/5 mL (20 mg/mL)	1153398	Packaging Defect	Ongoing
Cefepime (as hydrochloride) Powder for Injection (IM/IV) DR-XY35933	1 g	AUXM-201	Out of Specification Result	Ongoing
Cefepime (as hydrochloride) Powder for Injection (IM/IV) DR-XY35932	2 g	AUXI-101 AUXI-201	Out of Specification Result	Ongoing
Piperacillin (as sodium) + Tazobactam (as sodium) (Piptaz) Powder for Injection (IV Infusion) DR-XY32669	2 g/250 mg	AUPM-001 AUPM-002 AUPM-003 AUPM-004 AUPM-005 AUPM-101 AUPM-102 AUPM-103 AUPM-104 AUPM-105 AUPM-106 AUPM-107 AUPM-108 AUPM-109 AUPM-201 AUPM-202 AUPM-203 AUPM-204 AUPM-205	Out of Specification Result	Ongoing
Piperacillin (as sodium) + Tazobactam (as sodium) (Piptaz) Powder for Injection (IV Infusion) DR-XY32668	4 g/500 mg	AUPI-004 AUPI-005 AUPI-006 AUPI-007 AUPI-008 AUPI-009 AUPI-010 AUPI-011 AUPI-012 AUPI-013 AUPI-014 AUPI-101 AUPI-102 AUPI-103 AUPI-104 AUPI-105 AUPI-106 AUPI-107 AUPI-108 AUPI-109	Out of Specification Result	Ongoing

PRODUCT NAME	DOSAGE STRENGTH	BATCH/LOT NUMBER	REASON OF RECALL	STATUS OF RECALL
Piperacillin (as sodium) + Tazobactam (as sodium) (Piptaz) Powder for Injection (IV Infusion) DR-XY32668	4 g/500 mg	AUPI-110 AUPI-111 AUPI-112 AUPI-113 AUPI-114 AUPI-115 AUPI-116 AUPI-117 AUPI-118 AUPI-119 AUPI-120 AUPI-121 AUPI-122 AUPI-123 AUPI-124 AUPI-125 AUPI-126 AUPI-127 AUPI-128 AUPI-129 AUPI-130 AUPI-201 AUPI-202 AUPI-203 AUPI-204 AUPI-205 AUPI-206 AUPI-207 AUPI-208 AUPI-209 AUPI-210	Out of Specification Result	Ongoing
Co-Amoxiclav (Amoclav) Powder for Injection (IV) DR-XY23656	600 mg	AUAM-101 AUAM-201 AUAM-202 AUAM-203 AUAM-204 AUAM-301	Out of Specification Result	Ongoing
Co-Amoxiclav (Amoclav) Powder for Injection DR-XY23657	1.2 g	AUAI-101 AUAI-201 AUAI-202 AUAI-203 AUAI-204 AUAI-301	Out of Specification Result	Ongoing
Clozapine (Ziproc-25) Tablet DRP-3291	25 mg	B345J001	Out of Specification Result	Ongoing
Clozapine (Ziproc-100) Tablet DRP-3289	100 mg	B344J001	Out of Specification Result	Ongoing

PRODUCT NAME	DOSAGE STRENGTH	BATCH/LOT NUMBER	REASON OF RECALL	STATUS OF RECALL
Cefuroxime axetil (Zinnat) Suspension DRP-11854	125 mg/5 mL	PK4Y	Packaging Defect	Ongoing
Ethyl Alcohol (Michael) Solution DRHR-1084	70%	MEA22006	Out of Specification Result	Ongoing
Paracetamol Solution for Intravenous Infusion	10 mg/mL	23105402	Detection of Impurities	Ongoing
Phenylephrine hydrochloride + Paracetamol (Noflu Non-Drowsy) Tablet DRP-7441	10 mg/500 mg	00K04BA22	Out of Specification Result	Ongoing
Multivitamins + Minerals (Multimin) Capsule Dr-XY46211	-	00A05LA22	Out of Specification Result	Ongoing
Multivitamins + Lysine + Iron (VitaLyfe) Capsule DR-XY46210	-	00B02HA22 00B03LA22	Out of Specification Result	Ongoing

If the medicine you are taking is being recalled, don't panic! Do the following:

(1) Stop taking the medicine immediately

(2) Contact your HCP for possible alternatives or replacement of your medicine

(3) Observe for possible ADRs and report.

For more information, visit the FDA website for the issued FDA Advisories on product recall.

Counterfeit Medicines Corner

The FDA safeguards the public by evaluating suspected counterfeit medicines through product verification.

Counterfeit medicines refer to medicinal products with the following characteristics: (1) correct ingredients but not in the correct amount, (2) wrong ingredients, (3) without active ingredients, (4) with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products (R.A. No. 8203).

The WHO simplified this definition as those medicines that are substandard, falsified, and unregistered. Substandard or Out-of-Specification (OOS) products are those that fail to meet their quality standards/specification. Falsified medicines are those that are deliberately or fraudulently misrepresent their identity, composition, or source. While Unregistered products are those that have not gone evaluation and approval of the FDA (WHO, 2018).

Counterfeit or fake medicines continue to pose a threat to the public, as all types of medicines, including branded, generic, prescription, and OTC medicines, can be counterfeited.

In 2023, 151 products were evaluated and verified to be counterfeit. Out of these, 116 are OTC products, 31 are prescription medicines, and four (4) are home remedy (HR) products. The top counterfeited medicines were the following:

- Biogesic
- Decolgen Forte
- Bioflu
- Alaxan FR
- Diatabs
- Neozep Forte
- Medicol Advance
- Solmux
- Equirab
- Dolfenal

In case you suspect you bought a counterfeit medicine, do the following:

(1) Do not take the product.

(2) Report to the FDA through telephone (02) 8857 1900 or email at ereport@fda.gov.ph. You may also contact the legitimate product owner (pharmaceutical company).

(3) If you took the medicine, observe any possible ADRs and report.

For more information on the issued drug advisories on counterfeit medicines, visit the FDA website.

National Consciousness Week Against Counterfeit Medicines (NCWACM) 2023

The FDA through the Center for Drug Regulation and Research (CDRR) hosted the NCWACM 2023 last 20-24 November 2023, with the theme *"Strengthening Communication and Unity through Collaboration in Combating Counterfeit Medicines"* and a tagline *"Pekeng Medisina, Banta sa Kalusugan. Sama-sama sa Paglaban!"*. The 5-day event aimed to strengthen the collaboration with all stakeholders and raise awareness on the dangers of counterfeit medicines.

The Opening Ceremony was held during the flag raising of the Philippine National Police (PNP) at Camp Crame, Quezon City, where Director General Samuel A. Zacate served as guest of honor and speaker. In his speech, he emphasized the role that strengthened communication and unity through collaboration play in our relentless battle against counterfeit medicines.

The week-long celebration consisted of a series of lectures in the different regions of the country. Topics discussed include product registration process, an overview of counterfeit medicines and its regulations, how FDA detects counterfeit medicines through its product verification process and laboratory testing, and the aspects of FDA inspection and regulatory enforcement when dealing with counterfeit medicines.

The lectures were attended by various stakeholders who are partners in this fight. The audience included uniformed and non-uniformed personnel of the Philippine National Police, pharmacy and criminology students, and various consumer groups.

The Culminating Activity was held on the last day, 24 November 2023, at Vivere Hotel in Alabang. The FDA was joined by members of the House of Representatives, government agencies, non-government agencies, academe, professional organizations, consumer groups, and international and local speakers.

The flow of the event revolved around the theme of the celebration. Cong. Ron Salo emphasized in his special message of support that "In a world where counterfeiting has reached alarming proportions, the battle against counterfeit medicines is not merely a regulatory endeavor but a collective responsibility. It is a call of action that transcends political boundaries, affiliations, and interests." Speakers presented the statistics and impacts of these counterfeit medicines and provided suggestions on possible countermeasures.

The celebration came to an end but the fight against counterfeit medicines continues. In DG Zacate's speech during the Opening Ceremony, he highlighted that "the theme underscores the urgency of working together in unison. Collaboration is the linchpin that holds our efforts together. Whether it's forging partnerships between governments, international organizations, pharmaceutical companies, healthcare professionals, or the public, it is only through a shared commitment that we can effectively combat this global issue."

Let us be united in this fight. Our small steps now will make an impact in this battle of eradicating counterfeit medicines in the future.

You may check the recap of the week-long celebration in the FDA Facebook page.

Figure 1. Ceremonial activity with PNP

Figure 2. NCWACM at Region III

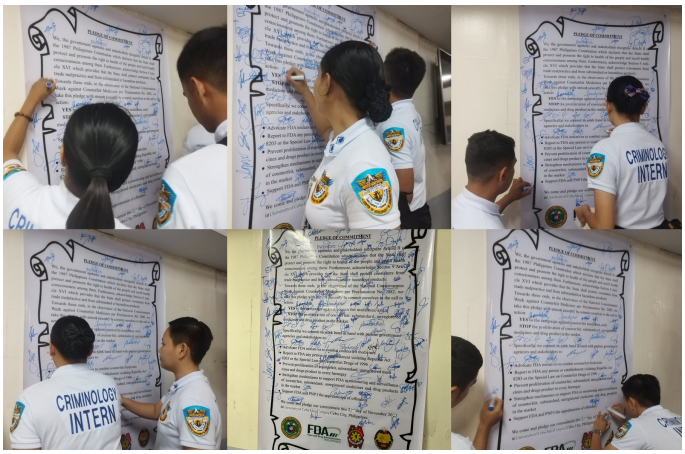

Figure 3. Ceremonial activity with Criminology students at University of Cebu at Region VII


Figure 4. Awarding of winner for poster making contest at Region XI

Figure 5. NCWACM at Region XII

Policy Corner

As mandated by the Republic Act No. 9711 or the FDA Act of 2009, the FDA, as a policy-making institution, is responsible for developing internal and external policies to serve as a basis for decisions and actions and achieve rational public health outcomes. Administrative issuances formulated and issued by the agency are intended for internal and external stakeholders for compliance.

The Policy and Standards Development Sections ensures that the policies are updated and at par with international standards.

Below is the list of released issuances for 2023:

FDA Circular No. 2023 004 Guidelines on Regulatory Reliance on the Conduct of Clinical Trials

17 February 2023

This Circular provides guidelines on reliance for approval of clinical trial applications and to promote a more efficient and effective approach to the regulations in the oversight of the conduct of clinical trials in the Philippines.

FDA Advisory 2023-0771 Adoption of the World Health Organization Updated Guidelines on the Evaluation of Similar Biotherapeutics Products (SBPs) in Compliance with Administrative Order No. 2014-0016

05 May 2023

The Advisory provides updated globally acceptable principles for the licensing of biological products that are similar to biological products of assured quality, safety and efficacy, the WHO Expert Committee on Biological Standardization on its seventy-fifth meeting on 4-8 April 2022 adopted the new guidelines on evaluation of biosimilars as replacement to the Annex 2 of WHO Technical Report Series No. 977.

FDA Circular No. 2023-008 Guidelines on the Publishing of Package Insert and Patient Information Leaflet of Registered Drug Products in the Food and Drug Administration (FDA) Verification Portal System

18 August 2023

This Circular shall provide guidelines to all Marketing Authorization Holders (MAHs) of drug products on the publishing of the package insert and patient information leaflet of registered drug products.

Contact Us

Product Research and Standards Development Division
Center for Drug Regulation and Research
Food and Drug Administration

(02) 8809 5596

pharmacovigilance@fda.gov.ph
cdrr_postmarketsurveillance@fda.gov.ph
cdrr.productverification@fda.gov.ph

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Civic Drive, Filinvest City, Alabang, 1781 Muntinlupa City, Philippines