



SWAMY VIVEKANANDHA COLLEGE OF PHARMACY

(Affiliated to the The Tamil Nadu Dr.MGR. Medical University, Chennai,
Approved by PCI, Accredited by NBA, New Delhi)
Elayampalayam, Tiruchengode-637 205, Namakkal (Dt), Tamil Nadu.



Department of Pharmacy Practice

Presents

ADR PULSE RADAR

(SPOT IT, STOP IT)

VMCH ADR ALERT: APRIL 2026

'Pharmacovigilance - Passive Surveillance'

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SWAMY VIVEKANANDHA COLLEGE OF PHARMACY

Tiruchengode, Namakkal (Dt). Tamil Nadu

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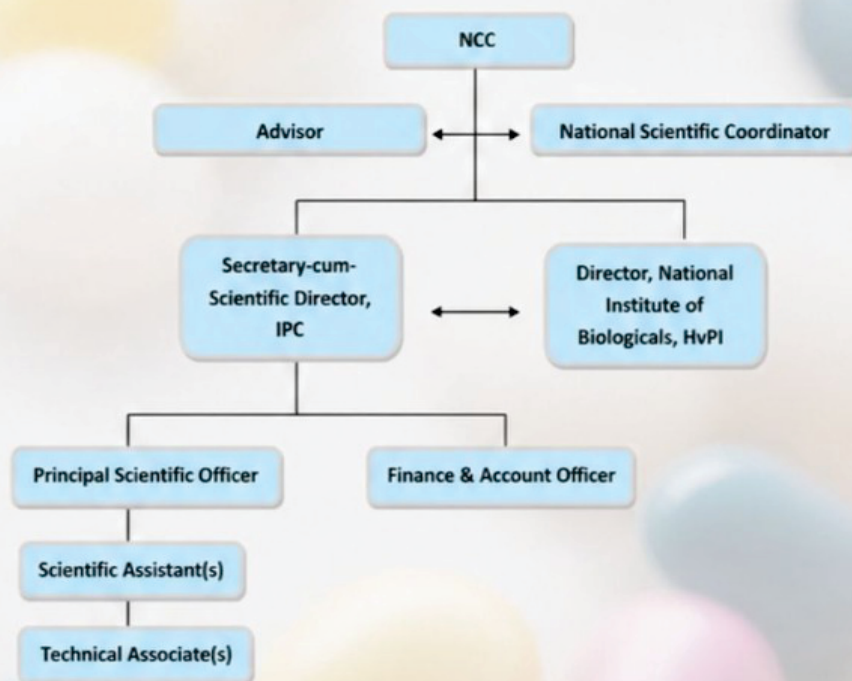
VMCH ADR MONITORING CENTER: Vol.1, Issue 4

NATIONAL COORDINATION CENTRE

- **Indian Pharmacopoeia Commission (IPC)** is an autonomous institution of the Ministry of Health and Family Welfare, Government of India and functioning as **National Coordination Centre** for Pharmacovigilance Programme of India.
- The main responsibility of NCC is to **monitor all the adverse reactions of medicines** being observed in Indian population.
- NCC is operating under the supervision of **Steering Committee** and **Working Group** which recommends procedures and guidelines for regulatory interventions.
- With a view to establish a centre of excellence for pharmacovigilance in India, NCC is participating in the WHO International Drug Monitoring Programme and collaborating with the **WHO-Uppsala Monitoring Centre, Sweden**.
- IPC also sets standards for drugs that are manufactured, sold and consumed in India.

- It further publishes Indian Pharmacopoeia and National Formulary of India to improve quality of medicine and promotes rational use of generic medicine.

ORGANOGRAM OF NCC



REFERENCE

1. <https://who-umc.org/media/1075/india.pdf>.

FDA DRUG INFORMATION

FDA Approves First-Ever Gene Therapy for Treatment of Genetic Hearing Loss Under National Priority Voucher Program [APRIL 23, 2026]

- The U.S. Food and Drug Administration approved **Otarmeni** (lunsotogene parvecwcha), the first-ever dual adeno-associated virus (AAV) vector-based gene therapy.
- Otarmeni is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound **sensorineural hearing loss** (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the **OTOF gene**.^[1]



IF ANY ADR, SCAN AND REPORT HERE



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FDA DRUG INFORMATION

FDA Approves First Non-Antipsychotic Drug to Treat Agitation Associated with Dementia [APRIL 30, 2026]

- Auvelity was found to be efficacious for treating **agitation** in Alzheimer's disease in two randomized trials.
- The most common side effects include **dizziness, upset stomach, headache, diarrhea, drowsiness, dry mouth, sexual dysfunction, and uncontrolled sweating**.
- Auvelity has a Boxed Warning about increased risk of **suicidal thoughts and behaviors** in adolescents and young adults taking antidepressants.^[2]

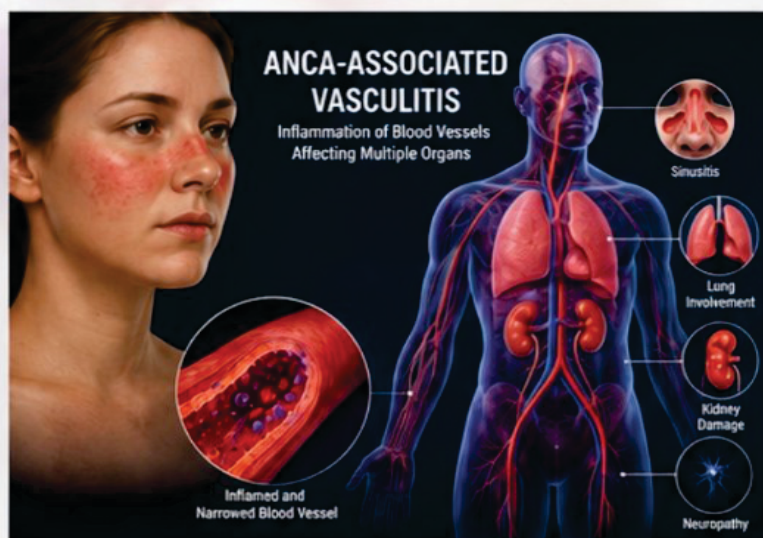


REFERENCES

1. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-ever-gene-therapy-treatment-genetic-hearing-loss-under-national-priority-voucher>
2. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-non-antipsychotic-drug-treat-agitation-associated-dementia>

FDA DRUG INFORMATION

TAVNEOS (Avacopan)



Tavneos works by **blocking the complement C5a receptor to reduce inflammation and immune-mediated vessel injury**. Although effective in controlling vasculitis symptoms, continuous monitoring is necessary due to the risk of hepatotoxicity.

The FDA recommends regular liver function monitoring during treatment. Healthcare professionals should discontinue the drug if patients develop signs of liver injury such as **yellowing of the skin, dark urine, abdominal pain, or persistent nausea**. This safety update highlights the importance of pharmacovigilance and adverse drug reaction (ADR) monitoring in identifying rare but serious adverse effects after drug approval and marketing.

The U.S. Food and Drug Administration issued a safety warning for Tavneos (avacopan), a drug used in the treatment of **severe active ANCA-associated vasculitis**, a rare autoimmune disease that causes **inflammation of blood vessels**. FDA identified cases of **serious liver injury** associated with Tavneos during post-marketing safety surveillance. Reported adverse reactions included **elevated liver enzymes, jaundice, drug-induced liver injury (DILI)**, and rare cases of **vanishing bile duct syndrome**, which may lead to severe liver damage.

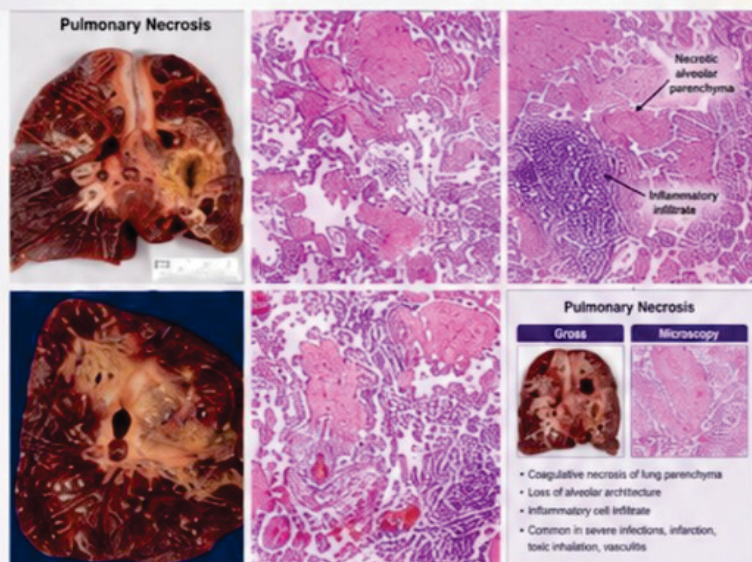


REFERENCES

1. <https://www.fda.gov/drugs/drug-safety-communications/fda-identifies-cases-serious-liver-injury-patients-taking-tavneos-avacopan-severe-active>.

SHORT COMMUNICATION

Pulmonary nocardiosis is a rare lung infection caused by *Nocardia* species, mainly affecting immunocompromised patients. Its symptoms and radiological findings often resemble tuberculosis or fungal infections, causing delayed diagnosis. Early microbiological confirmation and appropriate antimicrobial therapy are essential for better outcomes.

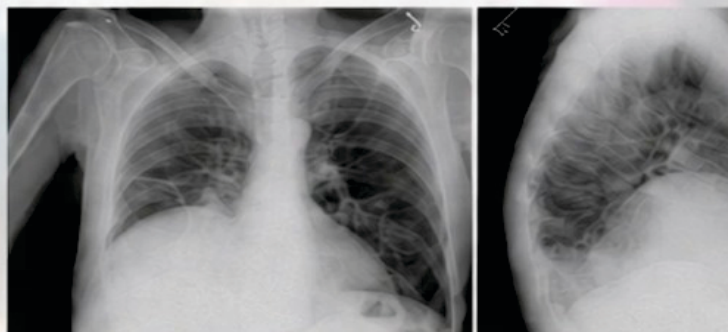


SUMMARY

This case highlights the importance of early diagnosis, appropriate antimicrobial therapy, supportive care, and clinical pharmacist involvement in improving outcomes in pulmonary nocardiosis.

CASE REPORT

A 72-year-old female, a known case of pulmonary nocardiosis with type 1 respiratory failure on tracheostomy treatment for the past month, had a history of LRTI for 15 years and meningioma. Chest imaging revealed multiple nodular infiltrates with cavitory lesions suggestive of pulmonary infection. Sputum culture and microbiological examination confirmed Pulmonary Nocardiosis caused by *Nocardia asteroides*. She was treated with TMP-SMX and supportive oxygen therapy. During hospitalization, electrolyte imbalance and mild renal impairment were monitored and corrected. Clinical pharmacist interventions included medication review, ADR monitoring, drug interaction assessment, dose optimization, and patient counseling. The patient showed gradual symptomatic improvement with continued therapy.





ADR CASE



BIPHASIC ISOPHANE INSULIN INDUCED HYPOGLYCEMIA



PATIENT DETAILS



Age & Sex : 83 / Male



Date of Admission (DOA) : 24/04/26



Drug Name : Inj. Biphasic
Isophane Insulin



Dose : 25 U



Route : Subcutaneous



Frequency : 1-0-1



Diagnosis : Type 2 Diabetes
Mellitus



CAUSALITY

WHO-UMC
(Probable/Likely)



OUTCOME

Recovered



MANAGEMENT

The drug was
withdrawn and
Inj. Dextrose 5%
was administered.





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"Vidhya Rathna"

Prof. Dr. M. KARUNANITHI, B.Pharm., M.S., Ph.D., D.Litt.,
Chairman & Secretary

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- ★ VIVEKANANDHA DENTAL COLLEGE FOR WOMEN
- ★ SWAMY VIVEKANANDHA COLLEGE OF PHARMACY
- ★ VIVEKANANDHA COLLEGE OF NURSING
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