SUSPECT ADVERSE REACTION REPORT

2025-060950(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
Unknown	DOMINICAN Cont..	Unknown	Unknown	Unknown	Unknown	Unknow Cont..	Unknown	Unknown	Unknown	

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

MedDRA Version : v.27.1

1) PANCYTOPENIA (Pancytopenia (10033661), Pancytopenia (10033661))
Unknown

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☑ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) REVLIMID (LENALIDOMIDE) (Suspect) (Capsule)(Unknown)
Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)

(25 milligram(s))

16. ROUTE(S) OF ADMINISTRATION

1) Unknown

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☐ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Multiple myeloma [10028228 - Multiple myeloma]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
Unknown	Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

MedDRA Version : v.27.1
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : BMS
UNITED STATES OF AMERICA
aepbusinessprocess@bms.com

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-060950(0)
24c. DATE RECEIVED BY MANUFACTURER: 23/Apr/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 29/Apr/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

3. SEX

Unknown

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

This case was received via {BP} Adium Pharma S.A. (formerly Tecnofarma)(Reference number: DO-ADIUM-DO- 0023-20250423).

This spontaneous case was received on April 23, 2025, via email from the SALES FORCE, to whom a PHYSICIAN referred information about a patient of unknown sex and age who had begun treatment with Revlimid 25 mg capsules at a dose of 25 mg for multiple myeloma (therapy start date unknown).

The physician reports grade 5 pancytopenia.

The source document does not include the batch and expiration date.

Reporter category: Physician.

The causality analysis is performed by Asofarma Central America and the Caribbean Pharmacovigilance Department using the data received from the source document.

The reporter does not provide a causal relationship between the adverse event(s) and the drug(s).

The reporter agrees to be contacted for future follow-up.

Company Remarks (Sender's Comments) :

This patient had pancytopenia after initiation of therapy with lenalidomide for multiple myeloma. Considering the underlying malignancy as a significant risk factor and the limited information pertaining to the therapy onset date to assess latency and relevant laboratory reports to compare baseline and current blood counts; it cannot be ascertained with reasonable possibility that lenalidomide therapy caused the reported pancytopenia.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	: REVLIMID
Active Substance	: LENALIDOMIDE
Drug Characterization	: Suspect
Form of Admin	: Capsule
Lot Number	: Unknown
Daily Dose	: (25 milligram(s))
Route of Admin	: Unknown
Indications	: Multiple myeloma [10028228 - Multiple myeloma]
Action(s) Taken With Drug	: Unknown

Causality

1) PANCYTOPENIA (Pancytopenia - 10033661, Pancytopenia - 10033661)

Causality as per reporter	: No Information
Causality as per Mfr	: Not Related
DeChallenge	: Unknown

Labeling :

1) PANCYTOPENIA

CORE	Labeled

Primary Reporter:

Physician

DOMINICAN REPUBLIC