The Arab Republic of Egypt
Egyptian Drug Authority
Central Administration for Pharmaceutical Care
General Administration for Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة لليقظة الصيدلية

PVGA final assessment report

Serial: 30547/2025
Code: 23380/2025
Out letter ID:

Dear / Local Safety Responsible (LSR)

Janssen scientific office – Egypt {Janssen- Cilag Egypt}

Thank you for submitting the requested data regarding distribution the new SmPC approved by pharmacology for your product:

Product Name	Opsumit
Active substances	Macitentan
Pharmaceutical form & Strength	10 mg FCT

General administration for pharmaceutical vigilance (PVGA) approves the following:

1) The distribution of submitted new SmPC (3-5-2025).
2) The proposed distribution list (102 physician).
3) The proposed distribution timeframe (1 month).
4) The proposed dissemination mechanism (E-mail).

MAH is expected to start distribution of the materials from the release date of this letter.

A progress report should be submitted to PVGA (through **Follow-up compliance reception**) within **40 calendar days** from the release date of this letter which ends on (**Deadline:16/12/2025**) (Affirming the complete distribution of the materials to all HCPs included in the list)

Knowing that the above-mentioned activities are obligatory to be implemented by MAH. Any changes regarding implementation of such activities should be informed to PVGA proactively.

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