

Erratum to CPMG Briefing Document

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and Psychopharmacologic Drugs Advisory Committee Meeting, November 19, 2024

The erroneous text is followed by the correction in **bold**.

1. The 4th paragraph on page 9, date “15 September 2016” should be corrected to “15 September **2015**”.
2. p.46, Table 32: the middle column should be corrected from 1,084,430 and 110,651 to 1,089,386 and 110,730, respectively.

Table 1: Number of PSFs Submitted

Description	Previous Reporting Period (29 Jul 2021 – 30 Nov 2022)	Most Recent Reporting Period (01 Dec 2022 – 29 May 2024)
PSFs submitted	1,089,386	1,732,050
Count of unique patients	110,730	120,943

PSF = Patient Status Form.

3. p. 78, Table 79: the number of treatment rationales submitted from 29 Jul 2021 – 30 Nov 2022 should be corrected from 285 to **619**.

Table 79: Use of Treatment Rationale

Reporting Period	Treatment Rationales Submitted	Number of Patients With Neutropenia (ANC <999 cells/ μ L)
Legacy REMS		
16 Jul 2016 – 15 Jul 2017	150	751
16 Jul 2017 – 15 Jul 2018	191	545
16 Jul 2018 – 31 Dec 2019		
16 Jul 2018 – 27 Feb 2019	119	360
28 Feb 2019 – 31 Dec 2019	177	580
01 Jan 2020 – 31 Dec 2020	188	796
01 Jan 2021 – 15 Nov 2021	221	623
Modified REMS		
29 Jul 2021 – 30 Nov 2022	619	7,384
01 Dec 2022 – 29 May 2024	282	2,560

ANC = absolute neutrophil count; REMS = Risk Evaluation and Mitigation Strategy.

4. p.70, Table 70: the mean score of linked questions for the reporting period 01 Jan 2020 – 31 Dec 2020 should be corrected from 84.0% to 91.0%.

Table 70: Key Risk Message 1 – Understand the Risk of Severe Neutropenia Associated With Clozapine: Prescriber Survey

Reporting Period	Mean Score of Linked Questions	Lowest-Scoring Questions
Legacy REMS		
16 Jul 2016 – 15 Jul 2017	86.0%	True/False: Clozapine treatment should be interrupted as a precautionary measure in any patient who develops a fever of 38.5°C (101.3°F) or greater, and an ANC should be obtained (56% answered correctly)
16 Jul 2018 – 31 Dec 2019	92.0%	No low-scoring question
01 Jan 2020 – 31 Dec 2020	91.0%	No low-scoring question
Modified REMS		
01 Dec 2022 – 29 May 2024	93.0%	No low-scoring question

ANC = absolute neutrophil count; REMS = Risk Evaluation and Mitigation Strategy.