Life Science Solutions

Pisa, 12/09/2025

CHMP Chairman: Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherland

Subject: Withdrawal of Tuzodi, midazolam hydrochloride, 2.5 mg/spray, nasal spray, solution-
Procedure Number: EMEA/H/C/005658/0000

Dear Dr. Sepodes,

We would like to inform you that, at this point of time, Regulatory Pharma Net s.r.l has taken the decision to withdraw the application for Marketing Authorisation of Tuzodi 2.5 mg/spray, nasal spray, solution, which was intended to be used for the treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and toddlers (from 2 years of age).

Following the receipt of the D120 List of Questions (LoQ) dated 19th June 2025, we carefully assessed the requested data and the associated activities required to provide comprehensive responses. A detailed plan and timelines were subsequently prepared and discussed during the clarification meeting with EMA CHMP Team (29th July 2025). Based on this assessment, on 29th August 2025, we submitted a formal request for a clock-stop extension to allow sufficient time for the generation and compilation of the required data. However, as communicated to us on 09th September 2025, this request was found unacceptable by the CHMP and, therefore, we are not in the position to provide the responses within the timeframe established by the ongoing procedure.
Based on the above described situation, we decided to withdraw the above mentioned Marketing Authorization Application.

I agree for this letter to be published on the EMA website.

Yours sincerely,

[redacted]

[redacted]