

EMA Accepts Teva and Medincell's MAA for Monthly Olanzapine Long-Acting Injectable

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The investigational subcutaneous formulation could address adherence challenges in schizophrenia by offering a once-every-four-weeks olanzapine option.



The European Medicines Agency has accepted Teva's Marketing Authorisation Application for olanzapine long-acting injectable, a once-monthly investigational treatment for adults with schizophrenia developed with Medincell.

The filing addresses a persistent gap in schizophrenia management: treatment adherence. While oral olanzapine is widely used in Europe, daily medication can be difficult to sustain in real-world settings, contributing to relapse, hospitalisation and long-term disease burden.

The investigational product, TEV-'749, is designed to deliver olanzapine in a subcutaneous formulation once every four weeks. It uses Medincell's proprietary SteadyTeq copolymer technology to provide controlled and prolonged release of olanzapine.

The EMA acceptance is supported by an extensive clinical development programme, including the Phase 3 SOLARIS study. Across development, TEV-'749 demonstrated efficacy, systemic safety profile and exposure consistent with oral olanzapine. The product is not currently approved by any regulatory authority worldwide.

Schizophrenia affects an estimated 0.3 to 1.5 percent of the European population, with affected individuals often facing social isolation, unstable employment and reduced life expectancy. A practical long-acting olanzapine option could therefore have relevance for both clinical outcomes and health system resource use.

The EMA acceptance highlights interest in long-acting injectable formulations that improve adherence in chronic disease. For CNS care, drug delivery innovation may become increasingly important where treatment continuity is closely linked to relapse prevention and long-term functional outcomes.