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Questions and answers on Seroquel XR and associated names (50, 150, 200, 300 and 400 mg prolonged-release tablets containing quetiapine)

Outcome of a procedure under Article 6(13) of Regulation (EC) 1084/2003 as amended

The European Medicines Agency has completed an arbitration procedure for Seroquel XR and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that Seroquel XR can be used as add-on to ongoing treatment for major depressive episodes in patients with major depressive disorder who have had sub-optimal response to treatment with other antidepressants.

What is Seroquel XR?

Seroquel XR is an antipsychotic medicine that contains the active substance quetiapine. It is used in patients with schizophrenia, a mental illness with a number of symptoms, including disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (false beliefs). It is also used for the prevention and treatment of bipolar disorder, a mental illness in which patients have manic episodes (periods of abnormally high mood), alternating with periods of normal mood, as well as episodes of depression.

The exact mechanism of action of quetiapine is unknown, but it attaches to several receptors on the surface of nerve cells in the brain, including the receptors for the neurotransmitters dopamine and serotonin. As neurotransmitters are chemicals that allow nerve cells to communicate with each other, this disrupts signals transmitted between brain cells. Since these neurotransmitters are involved in schizophrenia and bipolar disorder, quetiapine helps to normalise the activity of the brain, reducing the symptoms of these diseases.

Seroquel XR is available as prolonged-release tablets. Prolonged-release means that the active substance is released slowly from the tablet over a few hours. Seroquel XR is also marketed under other trade names: Seroquel Depot, Seroquel Prolong, and Seroquel SR. The company that markets these medicines is Astra Zeneca.



Why was Seroquel XR reviewed?

Seroquel XR is authorised in Austria, Belgium, Cyprus, Germany, Denmark, Greece, Spain, Finland, Ireland, Iceland, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, and Sweden under a mutual recognition procedure on the basis of the initial authorisation granted by the 'reference Member State', the Netherlands, in August 2007.

On 15 May 2009, the Netherlands and all the other concerned Member States rejected a change (variation) to the marketing authorisation to add as a new indication the treatment of recurrent depressive episodes in patients with major depressive disorder (MDD). The indication excluded the use of Seroquel XR as initial treatment, and restricted its use only to patients who cannot be appropriately managed on alternative antidepressant treatment.

The variation to the marketing authorisation was rejected because the Member States concluded that the benefit-risk balance of the medicine was unfavourable. Not enough data had been submitted to support the restriction to patients not responsive to standard antidepressants. In addition, evidence in support of the proposed dose was insufficient.

However, Astra Zeneca was not in agreement with the grounds for refusal and, on 22 May 2009, it referred the matter to the CHMP for arbitration.

What are the conclusions of the CHMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that a new indication for Seroquel XR can be granted. The Committee recommended that the medicine be used as add-on to ongoing treatment for major depressive episodes in MDD patients who have had sub-optimal response to monotherapy with another antidepressant.

The European Commission issued a decision on 26 August 2010.

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