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Questions and answers on Seroquel, Seroquel XR and associated names (quetiapine)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 22 May 2014, the European Medicines Agency completed a review of Seroquel and Seroquel XR. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for these medicines in the European Union (EU).

What are Seroquel and Seroquel XR?

Seroquel and Seroquel XR are antipsychotic medicines that contain the active substance quetiapine. They are 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). They are 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. Seroquel XR can also be used as add-on treatment in major 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 affects signals transmitted between brain cells. Since these neurotransmitters are involved in schizophrenia, bipolar disorder and major depression, quetiapine helps to normalise the activity of the brain, reducing the symptoms of these diseases.

Seroquel is available as tablets (25, 100, 150, 200 and 300 mg) while Seroquel XR is available as prolonged-release tablets (50, 150, 200, 300 and 400 mg). Prolonged-release means that the active substance is released slowly from the tablet over a few hours. Seroquel and Seroquel XR are also marketed under other trade names. The company that markets these medicines is Astra Zeneca.

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Why were Seroquel and Seroquel XR reviewed?

Seroquel and Seroquel XR are authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicines can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicines are marketed.

Seroquel and Seroquel XR were identified by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) as needing harmonisation.

On 12 June 2013, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Seroquel and Seroquel XR in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the use of the medicines, the CHMP agreed that Seroquel and Seroquel XR can continue to be used for the treatment of schizophrenia and treatment and prevention of bipolar disorder, but recommended harmonised wordings for these indications as follows:

- treatment of schizophrenia;
- treatment of moderate to severe manic episodes in bipolar disorder and major depressive episodes in bipolar disorder;
- prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to quetiapine treatment.

Seroquel XR can also continue to 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.

4.2 Posology and method of administration

The CHMP also harmonised the dosing recommendations, particularly how to increase the dose and the recommended daily dose.

4.6 Fertility, pregnancy and lactation

Having reviewed the data available on the use of quetiapine during pregnancy, the CHMP concluded that no definite conclusion can be drawn on the risk of malformations in the unborn child when the medicine is used during early pregnancy (first trimester). Therefore, quetiapine should only be used during pregnancy if the benefits justify the potential risks. Additionally, the data available show that newborns who were exposed to antipsychotics (including quetiapine) during late pregnancy (third trimester) are at risk of side effects including agitation, somnolence, breathing and feeding problems. Consequently, newborns should be monitored carefully.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.4 (special warnings and precautions for use) and 4.8 (undesirable effects).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 6 August 2014.