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Review of Tysabri started

The European Medicines Agency (EMA) has started a review of the multiple sclerosis medicine Tysabri (natalizumab). The aim of the review is to assess whether the advice given to healthcare professionals and patients on how to manage the known risk of progressive multifocal leukoencephalopathy (PML) with this medicine should be revised in the light of new scientific evidence.

PML is a rare brain infection caused by John Cunningham virus (JCV), which has symptoms that may be similar to those of a multiple sclerosis attack, and may result in severe disability or death. It is already known that the risk of PML increases the longer a patient has been receiving Tysabri, especially in patients treated for more than two years. The risk of PML is also higher if the patient used immunosuppressant medicines (medicines that reduce the activity of the immune system) before starting Tysabri, or if the patient has tested positive for antibodies against the virus that causes PML (a sign that the virus may be present in the body).

Scientific evidence on PML is rapidly growing. New data seem to indicate that the methods used to calculate the risk of PML may need to be revised and that testing for PML in patients with no symptoms may need to be performed more frequently than currently recommended. New diagnostic tests have recently been developed and there is a need to assess whether this has an impact on the current prescribing advice.

EMA will now evaluate the available data on the risk of PML with Tysabri with the aim of better defining the risk of PML and identifying further measures to minimise it, and will issue an opinion on whether changes to the marketing authorisation are needed.

More about the medicine

Tysabri is a medicine used to treat adults with highly active multiple sclerosis (MS), a disease of the nerves in which inflammation destroys the protective sheath surrounding the nerve cells. Tysabri is used in the type of MS known as 'relapsing-remitting' MS, when the patient has attacks (relapses) in between periods with no symptoms (remissions). It is used when the disease has failed to respond to treatment with a beta-interferon or glatiramer acetate (other types of medicines used in MS), or is severe and getting worse rapidly.

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The active substance in Tysabri, natalizumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific part of a protein called 'α4β1 integrin'. This is found on the surface of most leucocytes (the white cells in the blood that are involved in the inflammation process). By blocking the integrin, natalizumab stops the leucocytes from going from the blood into the brain. This reduces the inflammation and nerve damage caused by MS.

Tysabri was authorised in the European Union in June 2006.

More about the procedure

The review of Tysabri has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendation will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.