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Review of Symbioflor 2 started

The European Medicines Agency (EMA) has started a review of the medicine Symbioflor 2 (*Escherichia coli* bacteria), which is authorised in some Member States of the European Union (EU) for treating diseases affecting the stomach and gut including irritable bowel syndrome.

The review of Symbioflor 2 has been requested by the German medicines agency (BfArM) following concerns that the effectiveness of the medicine has not been adequately demonstrated. BfArM was concerned that the use of an ineffective treatment would leave patients exposed to the long-term symptoms of the disease and reduce their quality of life.

EMA will now review the available information on Symbioflor 2 and recommend whether the marketing authorisations for this medicine should be maintained, varied or suspended across the EU.

More about the medicine

Symbioflor 2 is a medicine used to treat functional gastrointestinal diseases. These are diseases that affect the normal function of the stomach and gut, without the organs showing any signs of structural abnormalities. They include irritable bowel syndrome, which is a long-term disorder of the gut characterised by pain or discomfort in the abdomen and bloating together with altered bowel habits.

Symbioflor 2 contains *Escherichia coli* bacteria. It has been authorised in the following EU Member States through national procedures: Austria, Germany and Hungary. It is also available under other trade names.

More about the procedure

The review of Symbioflor 2 has been initiated at the request of the German medicines agency (BfArM), under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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