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SCIENCE MEDICINES HEALTH

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Refusal of the marketing authorisation for Dexxience (betrixaban)

Outcome of re-examination

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Dexxience, intended for the prevention of venous thromboembolism. The company that applied for authorisation is Portola Pharma UK Limited.

The company requested a re-examination of the initial opinion. After considering the grounds for this request, the CHMP re-examined the opinion and confirmed the refusal of the marketing authorisation on 26 July 2018.

What is Dexxience?

Dexxience is a medicine that contains the active substance betrixaban. It was to be available as capsules.

What was Dexxience expected to be used for?

Dexxience was expected to be used to prevent venous thromboembolism (formation of blood clots in veins). It was to be used in adults admitted to hospital for the treatment of a recent medical illness. These patients may be at high risk of blood clots because of reduced mobility during their hospital treatment as well as other underlying conditions that increase the risk.

How does Dexxience work?

Blood clots that start off in the veins can move to another part of the body such as the lungs and the brain where they can cause severe problems with breathing or stroke.

The active substance in Dexxience, betrixaban, is a 'factor Xa inhibitor'. This means that it blocks factor Xa, a protein which is involved in the production of thrombin. Thrombin is needed for blood to clot. By blocking factor Xa, the medicine reduces the levels of thrombin in the blood and this reduces the risk of blood clots forming in blood vessels.



What did the company present to support its application?

The company presented the results of one main study involving over 7,500 adults who had been admitted to hospital for a recent medical illness. The patients were at high risk of venous thromboembolism because of their age, presence of a protein indicating a blood clot, previous blood clots, cancer and lack of mobility during hospital treatment. Treatment with Dextience was compared with enoxaparin, another medicine for preventing blood clots. The main measure of effectiveness was the occurrence of deep vein thrombosis (blood clot in a deep vein, usually in the leg), or of pulmonary embolism (blood clot in the lung), or death from a blood clot.

What were the CHMP's main concerns that led to the refusal?

The CHMP considered that the main study did not satisfactorily show Dextience's effectiveness when used for preventing blood clots in patients admitted to hospital for recent medical illness. Also, patients treated with Dextience had more episodes of bleeding than those treated with the comparator medicine. This was considered an important concern given that the medicine was expected to be used in patients with serious underlying conditions for whom any episode of bleeding could have serious consequences, and Dextience's long persistence in the body could complicate management of bleeding.

Therefore, at that point in time, the CHMP was of the opinion that the benefits of Dextience did not outweigh its risks and recommended that it be refused marketing authorisation. The CHMP refusal was confirmed after re-examination.

What consequences does this refusal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials with Dextience.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is treating you in the clinical trial.