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# Refusal of the marketing authorisation for Xervyteg (allogeneic faecal microbiota, pooled)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Xervyteg, a medicine intended for the treatment of acute graft-versus-host disease (aGvHD), when donor cells attack the body shortly after a transplant.

The Agency issued its opinion on 25 June 2026. The company that applied for authorisation, MaaT Pharma, may ask for re-examination of the opinion within 15 days of receiving the opinion.

## What is Xervyteg and what was it intended to be used for?

Xervyteg was developed as a medicine for treating acute GvHD. It was to be used in adults with aGvHD affecting the gut for whom corticosteroids and ruxolitinib (other treatments for aGvHD) have not worked well enough.

The medicine contains the active substance human allogeneic faecal microbiota, pooled, and was to be available as a rectal suspension (to be given into the rectum, the lowest part of the gut that stores faeces).

Xervyteg was designated an 'orphan medicine' (a medicine used in rare diseases) on 25 February 2019 for the treatment of graft-versus-host disease. Further information on the orphan designation can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-18-2083

## How does Xervyteg work?

The active substance in Xervyteg, human allogeneic faecal microbiota, pooled, is prepared from the stools of several healthy donors and contains bacteria and other microorganisms (the "microbiota").

In people with aGvHD, the gut microbiota can become disturbed, which can lead to inflammation resulting in symptoms such as diarrhoea. Giving microbiota from healthy donors to patients with aGvHD affecting the gut was expected to help restore the balance, thereby reducing inflammation and improving symptoms such as diarrhoea.

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## What did the company present to support its application?

The company submitted the results of a study involving 67 adults with acute GvHD following an allogeneic stem cell transplant (using stem cells from a donor) and with symptoms affecting their gut. Treatment with ruxolitinib or corticosteroids for aGvHD had not worked in these patients. The study looked at the proportion of patients who had either reduced symptoms (partial response) or no signs of symptoms (complete response) after three or four doses given over 28 days. The study did not compare Xervyteg with another medicine or placebo (a dummy treatment).

## What were the main reasons for refusing the marketing authorisation?

The Agency considered that the main study could not reliably show that the medicine was safe and effective, or how much benefit it provides to patients.

This was related to the design of the main study. As the study did not include a comparison group (for example, patients receiving standard treatment or a placebo), it was difficult to determine whether the observed effects were due to the medicine or to other factors. In addition, the study was an open-label study (a type of study in which both the healthcare providers and patients are aware of the treatment being given). Patients also received other treatments at the same time, making it difficult to separate the effects of Xervyteg from those of other therapies or from the natural course of the disease.

In addition, the data did not clearly show how the medicine works in relation to the observed effects, and it was not possible to distinguish treatment-related infections from those caused by the disease.

Therefore, the Agency's opinion was that the balance of benefits and risks of Xervyteg in the treatment of aGvHD could not be established. Hence, the Agency recommended refusing marketing authorisation.

## Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no consequences for patients in clinical trials or compassionate use programmes with Xervyteg. If you are in a clinical trial or compassionate use programme and need more information about your treatment, speak with your doctor who is giving it to you.