18 September 2026
EMA/210795/2026
EMEA/H/C/006678

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

Re-examination confirms refusal

After re-examining its initial opinion, the European Medicines Agency has confirmed its recommendation to refuse marketing authorisation for the medicine Xervyteg. The medicine was 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 after a re-examination on 17 September 2026. The Agency had issued its initial opinion on 25 June 2026. The company that applied for authorisation of Xervyteg is MaaT Pharma.

What is Xervyteg and what was it intended 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 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 get disrupted, which can lead to inflammation of the gut resulting in symptoms such as diarrhoea. Giving microbiota from healthy donors to patients with

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aGvHD affecting the gut was expected to help restore the balance, thereby reducing inflammation and improving symptoms such as diarrhoea.

What did the company present to support its application?

The main study the company presented to support the application involved 67 adults with acute GvHD following an allogeneic stem cell transplant (using stem cells from a donor) and with symptoms affecting the gut. The enrolled patients had received other treatments like corticosteroids or ruxolitinib for aGvHD but these treatments had not worked well enough.

The study looked at the proportion of patients who had either reduced symptoms (a very good partial response or partial response) or no signs of symptoms (a complete response) with three (or sometimes four) doses of Xervyteg 28 days after starting treatment. The study did not compare Xervyteg with another medicine or placebo (a dummy treatment).

What were the main reasons for refusing the marketing authorisation?

At the end of initial evaluation, 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.

It was difficult to determine whether the observed effects were due to the medicine or to other factors, as the study did not include a comparison group (for example, patients receiving standard treatment or a placebo). 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.

After re-examining its initial opinion, the Agency concluded that it was still not possible to show the medicine was safe and effective or to determine how much benefit it provides to patients. Therefore, the Agency's opinion was that the benefits of Xervyteg did not outweigh its risks, and the initial refusal was confirmed.

During the re-examination, the Agency consulted a group of experts in the treatment of aGvHD and considered the opinions of health professionals who contacted the Agency.

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

The company informed the Agency that there will be no consequences for patients currently enrolled or actively receiving treatment in clinical trials or compassionate use programmes with Xervyteg.

If you are enrolled in a clinical trial or compassionate use programme with Xervyteg and need more information about your treatment, speak with the doctor who is giving it to you.