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Withdrawal of application for the marketing authorisation of Azacitidine Adienne (azacitidine)

Adienne S.r.l. withdrew its application for a marketing authorisation of Azacitidine Adienne for the treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML).

The company withdrew the application on 13 July 2026.

What is Azacitidine Adienne and what was it intended to be used for?

Azacitidine Adienne was developed as a medicine for the treatment of adults with certain disorders and cancers of the blood and bone marrow when they cannot have haematopoietic stem cell transplantation (when the patient receives stem cells to restore the bone marrow's ability to produce healthy blood cells):

- myelodysplastic syndromes, a group of conditions where too few blood cells are produced by the bone marrow. In some cases, myelodysplastic syndromes can lead to acute myeloid leukaemia (AML, a cancer affecting white blood cells called myeloid cells). Azacitidine Adienne was to be used in patients with an intermediate to high risk of progressing to AML or death;
- chronic myelomonocytic leukaemia (CMML, a cancer affecting white blood cells called monocytes). Azacitidine Adienne was to be used when the bone marrow consists of 10 to 29% abnormal cells and the bone marrow is not producing large numbers of white blood cells;
- AML that has developed from a myelodysplastic syndrome and the bone marrow consists of 20 to 30% abnormal cells;
- AML, when the bone marrow has more than 30% abnormal cells.

Azacitidine Adienne contains the active substance azacitidine and was to be available as a powder for suspension for injection under the skin.

Azacitidine Adienne was developed as a generic medicine. This means that Azacitidine Adienne contained the same active substance as an authorised reference medicine, Vidaza, and was intended to work in the same way.

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How does Azacitidine Adienne work?

The active substance in Azacitidine Adienne and Vidaza, azacitidine, belongs to a group of medicines called antimetabolites. Azacitidine is an analogue of cytidine, which means that it is incorporated into the genetic material of cells (RNA and DNA). It is thought to work by altering the way the cell turns genes on and off and also by interfering with the production of new RNA and DNA. These actions are thought to restore the maturation and growth of young blood cells in the bone marrow that cause myelodysplastic disorders, and to kill cancer cells in leukaemia.

What did the company present to support its application?

As for every medicine, the company provided studies on the quality and characteristics of Azacitidine Adienne. The applicant provided data intended to show that the chemical characteristics of Azacitidine Adienne were the same as those of the reference medicine. With this approach the applicant argued that when given by injection under the skin, the azacitidine in both products was expected to be absorbed in the same way and that there was therefore no need for 'bioequivalence' studies to investigate whether Azacitidine Adienne is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's responses to the Agency's questions, at the time of the withdrawal, the Agency had some concerns that the data provided did not show that the chemical characteristics of Azacitidine Adienne were the same as those of its reference medicine. In addition, the Agency had concerns about the levels of impurities in the medicine and its provisional opinion was therefore that Azacitidine Adienne could not have been authorised for the proposed indications.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it had decided to withdraw the application for Azacitidine Adienne because additional data needed to be collected to address quality issues raised by EMA's scientific committee, the CHMP.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no clinical trials with Azacitidine Adienne.