08 August 2021
EMA/305416/2021
EMEA/H/C/005300

Public statement

Azacitidine Celgene

Withdrawal of the marketing authorisation in the European Union

On 19 May 2021, the European Commission withdrew the marketing authorisation for Azacitidine Celgene (SRD) (azacitidine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Celgene Europe BV, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Azacitidine Celgene was granted marketing authorisation in the EU on 2 August 2019 for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with:

- intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS),
- chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder,
- acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification,
- AML with >30% marrow blasts according to the WHO classification.

The marketing authorisation was initially valid for a 5-year period.

Azacitidine Celgene is identical to Vidaza, which is authorised in the EU for the same indications as Azacitidine Celgene. The marketing authorisation holder will maintain the marketing authorisation for Vidaza.

The European Public Assessment Report (EPAR) for Azacitidine Celgene will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union