



Dr. Eric Abadie  
Chairman - CHMP  
European Medicines Agency  
7 Westferry Circus  
Canary Wharf, London  
E14 4HB  
United Kingdom

Celgene Europe Limited  
Morgan House • Maiden Way  
Windsor • Berkshire SL4 1EP  
United Kingdom  
Tel: +44 (0)1753 498600  
Fax: +44 (0)1753 861484  
[www.celgene.com](http://www.celgene.com)

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**Subject:** Withdrawal of Marketing Authorisation Application for Lenalidomide –  
Celgene Europe (lenalidomide), 5 mg & 10 mg, hard capsules, EMEA/H/C/000688

Dear Dr. Abadie,

***For the withdrawal of initial marketing authorisation application***

I would like to inform you that, at this time, Celgene Europe Limited ("the Applicant") has taken the decision to withdraw the application for Marketing Authorisation of Lenalidomide – Celgene Europe (lenalidomide), 5 mg & 10 mg, hard capsules, which was intended to be used for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

This withdrawal is based on the following reason:

- The CHMP considers that the currently available data, obtained from a single-arm Phase II study, do not allow it to conclude on a positive benefit-risk balance.

The Applicant is continuing its clinical development program with lenalidomide in this and other indications and reserves the right to make further submissions at a future date in this or other indications.

The Applicant agrees for this letter to be published on the EMEA website.

Yours sincerely,

Celgene Europe Limited