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

June 20, 2012

Subject: Withdrawal of the Type II variation for new indication and the Type 1B pack size variations within the grouped variation application for Lenalidomide – EMA/H/C/717/X/46G

Dear Dr. Salmonson,

I would like to inform you that, at this time, Celgene Europe Limited ("the MAH") has taken the decision to withdraw the new indication variation and the pack size variations within the above mentioned grouped variation. The MAH would like to continue with the 2.5 mg and 7.5mg line extension applications which are included in this grouped variation.

This withdrawal is based on the following reason:

- The CHMP considers that the data provided to date requires additional follow-up with more mature data to allow it to reach a clear benefit/risk conclusion

The MAH reserves the right to make further submissions at a future date in this or other therapeutic indications.

The MAH agrees for this letter to be published on the EMA website.

Yours sincerely,