Celgene | Bristol Myers Squibb™ Company

Date: 21st October 2020

Direct Healthcare Professional Communication

Notification of typographical error in the Revlimid® (Lenalidomide) Hard Capsules Patient Information Leaflet (PIL)

Dear Healthcare Professional,

Biologix FZCo and Celgene, a wholly owned company of Bristol Myers Squibb Company in agreement with Saudi Food and Drug Authority (SFDA) would like to provide you with important safety information regarding the use of Revlimid® (*lenalidomide*) Hard Capsules.

Summary:

We have discovered typographical errors in the Arabic translation of the Revlimid 25mg patient information leaflet (PIL) in section 3 (version dated April 2018) where the issue is with incorrect numerical digits (15 mg instead of 25 mg) as detailed in the below table:

PIL ID number and version	Status of the version	Description of the issue	Arabic Text	English Text
LENX550ABPL0021V03	Obsolete	Inverted numerical digits (15 instead of 25)	الجرعة المعتادة من ريفليميد هي 15 ملغ مرة واحدة يومياً. تناول ريفليميد لمدة 21 يوماً متتالية، ثم أوقف العلاج لمدة 7 أيام بعدها.	The usual dose of Revlimid is 25 mg once a day. Take Revlimid for 21 consecutive days then stop the treatment for the next 7 days

The PIL error referred to is in the section relevant to Revlimid 25mg dose only. The corresponding English version of the PIL is accurate and aligns with the reference summary of product's

characteristics (SmPC). The composition of the 25 mg capsule remains unaffected by the typographical error. This error is not on the outer carton nor blister of the 25 mg pack.

Celgene/BMS safety and medical departments have reviewed and assessed this typo error and determined that it is unlikely to have a safety impact considering the patients are required to follow the instructions provided by the healthcare professionals. It is also unlikely to have an impact on efficacy as the patient's prescription are filled with the correct dosing for the individual.

Recommendations to Health Care professional:

- Healthcare professionals should prescribe a patient's dosage in accordance with the SmPC, which is accurate and inform the patient to follow instructions of use as prescribed (and not the Arabic version of the leaflet).

- Pharmacists should alert patients about the leaflet error in Arabic translation and advise them to refer to their physicians' prescription and recommendation for the treatment, and to speak with their treating healthcare professional should they have any questions or confusion about their dosage or treatment.

Call for reporting:

In case of any adverse event occurrence with the use of Revlimid®, we kindly ask you to report it as soon as possible to :

Biologix FZCo:

- E-mail: Pharmacovigilance-KSA@blgx.net

National Pharmacovigilance and Drug Safety Center:

- At: https://ade.sfda.gov.sa/Home/Report
- E-mail: npc.drug@sfda.gov.sa
- Toll free no.:19999

Company Contact Point:

- For any additional inquiries you may contact Biologix FZCo on the following email address: medinfo@blgx.net

Sincerely yours,

Dr Rachida Merad Boudia
Head of Medical Affairs
Local Representatives markets
Bristol Myers Squibb