1 April 2016
EMA/CHMP/206166/2016
Committee for Medicinal Products for Human Use (CHMP)

Overview of comments on 'lenalidomide hard gelatine capsules 2.5, 5, 7.5, 10, 15 and 25mg product-specific bioequivalence guidance' (EMA/CHMP/PKWP/152216/2015)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
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1. General comments

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	Food significantly affects oral absorption of the reference lenalidomide product, reducing Cmax by 50% and AUC by 20%. A larger effect of food for a generic product would lead to underdosing and affect the efficacy of lenalidomide. Thus, it is in the best interest of patients to test the in vivo bioequivalence under two separate conditions (fast and fed) for generic products. This dual measure would assure that generic products are expected to achieve safety/efficacy outcomes equivalent to the reference product. Based on the rationale above, we recommend adding a bioequivalence study under fed condition.	The comment has been acknowledged. For products where the SmPC recommends intake of the reference medicinal product irrespective of food intake, the bioequivalence study should be conducted under fasting conditions because fasting conditions are considered to be the most sensitive condition to detect a potential difference between formulations (Guideline on the investigation of bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **).” In order to consider the need for studies in the fed and fasted state, the innovator will need to submit data demonstrating that the food effect is depending on the (immediate release) formulation as justification.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome