15 December 2022
EMA/CHMP/839131/2022
Committee for Medicinal Products for Human Use (CHMP)

Overview of comments received on 'Lanreotide acetate, prolonged-release solution for injection in prefilled syringe 60, 90 and 120 mg product-specific bioequivalence guidance' (EMA/CHMP/559891/2021)

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

Stakeholder no.	Name of organisation or individual
1	Ipsen

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1. General comments – overview

Stakeholder no.	General comment	Outcome (if applicable)
1	Ipsen welcomes the opportunity to comment of the draft bioequivalence guidance for prolonged release lanreotide. Related to the section called 'waiver of bioequivalence study', the bioequivalence should be required (similar to octreotide) due to the prolonged release properties. This is justified by: - The physico-chemical characterization and supramolecular properties of the supersaturated solution allow to demonstrate similarity of the drug product when it is coming out of the syringe, but its predictivity to the in vivo extended release of the product, which is dependent on a transformation of the product that occurs only after deep subcutaneous injection, was never demonstrated. So, the BE should not be waived. - Delivery device design and performance can affect rate and extent of in-vivo release, and therefore it should be demonstrated that the product behave similarly in vivo when a different device is being used.	**Not accepted.** It is still considered that a waiver of bioequivalence studies can be granted if the test product has the same quantitative composition as the reference product and demonstrates equivalent properties as the reference product in different tests as listed in the proposed product specific guidance. It is agreed that it is important that the injectability is part of the sameness comparison; however, this is already covered by the product specific guidance.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
No comments received			