1 April 2015
EMA/CHMP/116544/2014
Committee for Medicinal Products for Human Use (CHMP)

Overview of comments received on 'Draft oseltamivir product-specific bioequivalence guidance' (CHMP/PKWP/EMA/CHMP/116544/2014)

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 – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	1. Some APIs are stated as BCS Class I or III (e.g. sunitinib, Emtricitabine/tenofovir disoproxil, etc.), and also requirements for BE study are stated. It is unclear if the meaning is this API is not qualify for BCS-biowaiver. 2. Maybe add one row of “remarks for biowaiver”? information for additional strengths, BCS-biowaiver, and solution with sorbitol (e.g. Oseltamivir) can put here. 3. Background is written differently for the same statement in BCS and strength. 4. With regards to API with unknown BCS, should we give recommendations for biowaiver? We have seen “The available data on solubility does not allow the BCS classification of oseltamivir. If the Applicant generates the solubility data and classifies the drug according to the BCS criteria as highly soluble, a BCS biowaiver could be applicable.” This recommendation never appears with other APIs under the same conditions.	1. Accepted. 2. The comment has been acknowledged; however, this is addressed in the guideline, therefore no further action is needed. 3. Accepted. 4. Accepted.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
BCS Classification		**Comment:** The solution may be waived if the same amount of sorbitol is used as in the originator. **Proposed change (if any):**	Accepted.