MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

Commission Delegated Act on Principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

Comments from the Spanish Agency of Medicines and Medical Devices (AEMPS)

Nº	Num.	ACTUAL TEXT	PROPOSED TEXT	REASON FOR THE PROPOSED CHANGE
1	Several places in the text	manufacturer	manufacturer**/importer**	No reference to the importers is made. Article 63 of Regulation (EU) 536/2014 refers to Manufacturing **and import.** The text must be reviewed to include the importers.

Spain, 23 November 2015

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