ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION G.INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD)

1.3. **IMPD in cases of placebo**

54. If the investigational medicinal product is a placebo, the information requirements shall be limited to quality data. No additional documentation is required if the placebo has the same composition as the tested investigational medicinal product (with the exception of the active substance), is manufactured by the same manufacturer, and is not sterile.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Division 54..