ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION
H.AUXILIARY MEDICINAL PRODUCT DOSSIER

55. Without prejudice to Article 65, the documentation requirements set out in sections F and G shall also apply to auxiliary medicinal products. However, where the auxiliary medicinal product is authorised in the Member State concerned, no additional information is required.

Status:
Point in time view as at 31/01/2020.

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 H..