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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 23.. (See end of Document for details)

ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION D.PROTOCOL

23. The protocol shall be accompanied by the Charter of the Data Safety Monitoring Committee, if applicable.

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 23..