ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION

A.INTRODUCTION AND GENERAL PRINCIPLES

1. The sponsor shall, where appropriate, refer to any previous applications. If these applications have been submitted by another sponsor, the written agreement from that sponsor shall be submitted.

2. Where a clinical trial has more than one sponsor, detailed information of the responsibilities of each of the sponsors shall be submitted in the application dossier.

3. The application shall be signed by the sponsor or a representative of the sponsor. This signature confirms that the sponsor is satisfied that:

(a) the information provided is complete;

(b) the attached documents contain an accurate account of the information available;

(c) the clinical trial is to be conducted in accordance with the protocol; and

(d) the clinical trial is to be conducted in accordance with this Regulation.

4. The application dossier for an application limited to Part I of the assessment report referred to in Article 11 shall be limited to sections B to J and Q of this Annex.

5. Without prejudice to Article 26, the application dossier for an application limited to Part II of the assessment report referred to in Article 11 and the application dossier for an application referred to in Article 14 shall be limited to sections K to R of this Annex.

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 A..