ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION

L.SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE (INFORMATION PER MEMBER STATE CONCERNED)

61. All information given to the subjects (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation shall be submitted together with the form for written informed consent, or other alternative means according to Article 29(1) for recording informed consent.

62. A description of procedures relating to informed consent for all subjects, and in particular:

(a) in clinical trials with minors or incapacitated subjects, the procedures to obtain informed consent from the legally designated representatives, and the involvement of the minor or incapacitated subject shall be described;

(b) if a procedure with consent witnessed by an impartial witness is to be used, relevant information on the reason for using an impartial witness, on the selection of the impartial witness and on the procedure for obtaining informed consent shall be provided;

(c) in the case of clinical trials in emergency situations as referred to in Article 35, the procedure for obtaining the informed consent of the subject or the legally designated representative to continue the clinical trial shall be described;

(d) in the case of clinical trials in emergency situations as referred to in Article 35, the description of the procedures followed to identify the urgency of the situation and to document it;

(e) in the case of clinical trials where their methodology requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products, as referred to in Article 30, and where, as a consequence, simplified means for obtaining informed consent will be used, the simplified means shall be described.

63. In the cases set out in paragraph 62, the information given to the subject and to his or her legally designated representative shall be submitted.

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 L..