Section J. (*Formerly Section K*) CHECK LIST OF INFORMATION

(Information that the concerned Member State's Competent Authority and Ethics Committees (CA & EC[1]) require according to the table in Attachment 1)

CA	EC		INFORMATION PROVIDED
		1	**General**
☐	☐	**1.1**	Receipt of confirmation of EudraCT number
☐	☐	**1.2**	Covering letter
☐	☐	**1.3**	Application form
☐	☐	**1.4**	List of Competent Authorities within the Community to which the application has been submitted and details of decisions
☐	☐	**1.5**	Copy of ethics committee opinion in the MS concerned when available
☐	☐	**1.6**	Copy/summary of any scientific advice
☐	☐	**1.7**	If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor
		2	**Subject related**
☐	☐	**2.1**	Informed consent form
☐	☐	**2.2**	Subject information leaflet
☐	☐	**2.3**	Arrangements for recruitment of subjects
		3	**Protocol related**
☐	☐	**3.1**	Clinical trial protocol with all current amendments
☐	☐	**3.2**	Summary of the protocol in the national language
☐	☐	**3.3**	Peer review of trial when available
☐	☐	**3.4**	Ethical assessment made by the principal/coordinating investigator, if not given in the application form or protocol
		4	**IMP related**
☐	☐	**4.1**	Investigator's brochure
☐	☐	**4.2**	Investigational Medicinal Product Dossier (IMPD)
☐	☐	**4.3**	Simplified IMPD for known products (see table 1)
☐	☐	**4.4**	Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)
☐	☐	**4.5**	Outline of all active trials with the same IMP
		4.6	If IMP manufactured in E.U. and if no marketing authorisation in EU:
☐	☐	**4.6.1**	Copy of the manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		4.7	If IMP not manufactured in E.U. and if no marketing authorisation in EU:
☐	☐	**4.7.1**	Certification of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP, or that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality
☐	☐	**4.7.2**	Certification of GMP status of active biological substance
☐	☐	**4.7.3**	Copy of the importers manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		4.8	Certificate of analysis for test product in exceptional cases :
☐	☐	**4.8.1**	Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected
☐	☐	**4.9**	Viral safety studies when applicable.
☐	☐	**4.10**	Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals

[1] Tick all boxes to show information provided to the ethics committee concerned (EC) and the competent authority (CA).

CA	EC		INFORMATION PROVIDED
☐	☐	**4.11**	TSE Certificate when applicable
☐	☐	**4.12**	Examples of the label in the national language
		5	**Facilities & staff related**
☐	☐	**5.1**	Facilities for the trial
☐	☐	**5.2**	CV of the coordinating investigator in the MS concerned (for multicentre trials)
☐	☐	**5.3**	CV of each investigator responsible for the conduct of a trial in a site in the MS concerned (principal investigator)
☐	☐	**5.4**	Information about supporting staff
		6	**Finance related**
☐	☐	**6.1**	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial
☐	☐	**6.2**	Any insurance or indemnity to cover the liability of the sponsor or investigator
☐	☐	**6.3**	Compensation to investigators
☐	☐	**6.4**	Compensation to subjects
☐	☐	**6.5**	Agreement between the sponsor and the trial site
☐	☐	**6.6**	Agreement between the investigators and the trial sites
☐	☐	**6.7**	Certificate of agreement between sponsor and investigator when not in the protocol