



Checklist

IMP **without** a marketing authorisation within EEA

	Enclosed	Not enclosed	Comments
Cover letter			
Copy of the allocation of the EudraCT number			
Print-out of the application from the EudraCT system signed by the applicant			
EES/EudraCT application on xml format (CD – one copy is adequate)			
Signature form (one form for each site in Iceland)			
Copy of the National Bioethics Committee application			
Trial protocol, including amendments			
Investigator's brochure			
Investigational medicinal product dossier (IMPD), if available electronically please send also CD-Rom/DVD			
Description of all other clinical trials using the investigational medicinal product (IMP)			
Letter of authorisation, if the sponsor is not the applicant			
Statement allowing conduct of the clinical trial and permission to access medical records			
Information for subjects			
Subject informed consent			
Mock-up of labelling in Icelandic			
List of the competent authorities to whom the application has been submitted and the status of the application			
If the IMP is manufactured within the EEA or a batch release takes place within the EEA provide a copy of the manufacturing licence			

	Enclosed	Not enclosed	Comments
If the IMP is manufactured outside the EEA a declaration of the Qualified Person (QP) from the importer of the IMP to the EEA stating that the manufacturing site operates according to GMP standard at least equal to the GMP standard required within the EEA			
Copy of the GMP certificate for the manufacturer			
Declaration that the manufacturing of biological substances is performed according to GMP standards			
Verification of testing of the investigational agent as a part of data for the IMP can be submitted, if impurities have not been reported in the specification for the agent or when unexpected impurities are identified that are not mentioned in the specification			
Copy of approval to use an agent with specific qualities, i.e. genetically modified organisms (GMOs) and radioactive agents			
Copy of TSE certificates			
Copy of the insurance certificate with terms and conditions of the insurance			
Copy of scientific advice			
CV for the principal investigator of each site and the coordinating investigator/ supervisor of the trial if the trial is multisite			
Import licence application for IMP			
If the applicant has requested to be exempted from storing the investigational medicinal product in the custody and under supervision of a pharmacy or hospital pharmacy, standard operating procedures (SOPs) regarding reception, handling, delivery, storage and disposal should be included in the application			