



Checklist IMP with a marketing authorisation within EEA

	Enclosed	Not enclosed	Comments
All documents supporting the CTA should be provided electronically (CD Rom or USB flash drive)			
Cover letter (see further information on IMAs web page)			
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 Rom – one copy is adequate)			
Signature form (see further information on IMAs web page)			
Trial protocol, including amendments (see further information on IMAs web page)			
Investigator's brochure (see further information on IMAs web page)			
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 (including questionnaires, advertisement, diary)			
Subject informed consent			
Summary of Product Characteristics (SmPC) if the IMP/comparator has a marketing authorisation within the EEA			
Mock-up of labelling in Icelandic (for IMP/comparator/placebo)			
List of the competent authorities to whom the application has been submitted and the status of the application			
Copy of the insurance certificate with terms and conditions of the insurance			
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/comparator/placebo			
A copy of the contract with the pharmacy in question, when storing the investigational medicinal product in the custody and under supervision of a pharmacy or hospital pharmacy			

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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			
Copy of Scientific advice			