



## Checklist IMP with 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			
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			
Summary of Product Characteristics (SPC)			
Mock-up of labelling in Icelandic			
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			
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			