Checklist
IMP without a marketing authorisation within EEA

	Enclosed	Not enclosed	Not applicable
All documents supporting the CTA should be provided electronically (CD Rom/USB flash drive or via CESP)			
Cover letter (see further information on IMAs web page)			
Copy of the allocation of the EudraCT number			
The EudraCT application signed by the applicant. If item E.8.7 of the EudraCT form is ticked, please submit information of the committee members.			
EudraCT application on xml format			
Signature form (one form for each site in Iceland) (see further information on IMAs web page)			
Commitment of sending annual report (DSUR)/final report (see further information on IMAs web page)			
Commitment of posting clinical trial summary results in EudraCT (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)			
Investigational medicinal product dossier (IMPD) (see further information on IMAs web page)			
Description of all other clinical trials using the investigational medicinal product (IMP), if applicable			
Certificates of Analysis signed by the QP for released batches of IMP			
Summary of Product Characteristics (SmPC) if the comparator has a marketing authorisation within the EEA			
Letter of authorisation, if the sponsor is not the applicant			
Statement allowing conduct of the clinical trial and permission to access medical records			
Subject information and informed consent form			
Questionnaires, advertisement, diary etc., if applicable			
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, if applicable			
If the IMP is manufactured within the EEA or a batch release takes place within the EEA provide a copy of the manufacturing licence (see further information on IMAs web page)			
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 (see further information on IMAs web page)			
Copy of the GMP certificate for the manufacturer (see further information on IMAs web page), if applicable			
Declaration that the manufacturing of biological substances is performed according to GMP standards, if applicable			

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, if applicable			
Copy of TSE certificates, if applicable			
Copy of the insurance certificate with terms and conditions of the insurance			
Copy of scientific advice, if applicable			
Copy of Paediatric Investigation Plan (PIP), including the Paediatric Committee's assessment and the EMA's decision, if applicable			
CV for the principal investigator of each site and the coordinating investigator/ supervisor of the trial if the trial is multisite (signed and dated)			
Import licence application for IMP/comparator/placebo			
Agreement with the pharmacy in question, when storing the investigational medicinal product in the custody and under supervision of a pharmacy or hospital pharmacy (see further information on IMAs web page)			
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			

This checklist is to support applicants to submit the required documents for a valid application to IMA. Please fill the checklist out and send along with the application.

Regulatory advice is available, if needed, prior to submission of an application to discuss specific issues related to the application. Information about the fees are here, https://www.ima.is/licences/clinical_trials/fees/

Regulatory advice is not available for ongoing clinical trial application/submitted application.