Checklist
VHP Procedure – national application

	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). Confirmation that documents submitted are the same as approved in VHP procedure			
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			
EES/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 result in EudraCT (see further information on IMAs web page)			
Invoice details			
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)			
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 (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			