Checklist
VHP Procedure – national application

	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). Confirmation that documents submitted are the same as approved in VHP procedure			
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)			
Copy of completed application form for the National Bioethics Committee (form on NBC website)			
Signature form (see further information on IMAs web page)			
Commitment of sending annual report (DSUR)/final report (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			
Information for subjects (including questionnaires, advertisement, diary)			
Subject informed consent			
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			
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			
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			