Application to the Bulgarian Drug Agency Bulgaria as Reference Member State in the mutual recognition (MRP)/decentralised (DCP)

Proposed name of the medicinal product in Bulgaria	
Strength/s	
Pharmaceutical form/s	
Active substance(s):	
ATC Code	
Legal basis of application ☐ Art. 8 (3) ☐ Art. 10 (1) ☐ Art. 10 (3) ☐ Art. 10 (4) ☐ Art. 10a ☐ Art. 10b ☐ Art. 10c ☐ Art. 16a ☐ Extension	
This is a duplicate of an ongoing or finalised procedure ☐ Indicate the procedure number of original dossier. Indicate the number of duplicates:	
The new product will be marketed in the proposed RMS ☐Yes ☐ No	
Reference product which is or has been authorised in Bulgaria, if applicable (product name, strength, pharm. form)	
Specification – Has the reference medicinal product been authorised for not less than 6/10 years in the EEA and what type of authorisation procedure has been used? Product name, strength, pharmaceutical form:	
MAH of the reference medicinal product:	
The reference medicinal product was first authorised (dd-mm-yyyy) in the European Economic Area on:	
Medicinal product intended for MRP first granted a MA on (dd-mm-yyyy):	
Member State(s) in which the medicinal product intended for MRP has/have been authorised:	
The MAH intends to submit the application for marketing authorisation on (dd-mm-yyyy):	
Intended number of CMSs (if known):	
Applicant: name, address, telephone number, fax number, e-mail address	
Applicant: Authorised contact person: Name, address, telephone and fax number, e-mail address	
Other information : - Specification of site of the bioequivalence study or other studies; compliance with GCP - Specification of manufacturing sites of the medicinal product in third countries not inspected by an authority in the European Economic Area - comparative outline of information under 4.1 in the SPC related to: medicinal product proposed for authorisation through MRP/DCP, reference medicinal product in Bulgaria and/or reference medicinal product in each future CMS included in the MRP/DC procedure having Bulgaria as RMS.	
Date (dd-mm-yyyy):	Signature of the Applicant