

APPENDIX 11 VARIATION APPLICATION FILING AND SUBMISSION ENQUIRY FORM**VARIATION APPLICATION FILING AND SUBMISSION ENQUIRY FORM**

Please ensure all sections in this form are filled up to facilitate the process.

Email the completed form to HSA_CTT_Enquiry@hsa.gov.sg.

APPLICANT PARTICULARS

Date:	
Name of Applicant:	
Designation:	
Company Name:	
Email:	
Tel. No.:	

PRODUCT DETAILS

Product Licence Number:	
Product Name <i>(including dosage form & strength):</i>	

VARIATION DETAILS

Proposed Variation(s):	
Proposed supporting dossier/ document for submission:	
Enquiry Details:	

Variation Status in Other Countries: <i>Regulatory agency/ country, date of submission or date of approval/ withdrawl/ rejection</i>	
Below For Official Use Only	
Enquiry reference number:	
Enquiry response officer:	
Recommendation for applicant:	
Submit as a MAV-1	
Submit as a MIV-1	
Submit as a MIV-2	
Submit the proposed dossier sections/ documents	
Include this inquiry form in the variation application	
Submit the following supporting documents/ sections	
HSA reserves the right to re-route the application type, split unrelated changes or request for additional information during the course of the screening/ evaluation.	

REVISION HISTORY

Guidance Version (Publish Date)
ATPB-GN-011-000 (March 2021)