1.0	**DETAILS OF PRODUCT**
1.1	Proprietary name:
1.2	Registration number:
1.3	International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API):
1.4	Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
1.5	Pharmacotherapeutic classification (Anatomic-Therapeutic Classification system):
1.6	Distribution category:
1.7	Dosage form:
1.8	Route(s) of administration (use current list of standard terms):
1.9	Packing/pack size:
1.10	Visual description:
1.11	Name and address (physical and postal) of FPP manufacturing facility: Name: Address: Country: Telephone: Telefax: E-Mail:

2.0	**DETAILS OF REGISTRANT**
2.1	Name and address (physical and postal) of Applicant: (Company):Name: Address: Country: Telephone: Telefax: E-Mail:
2.2	Name and address (physical and postal) of Local Technical Representative (Local Agent): Name: Address: Country: Telephone: Telefax: E-Mail:
3.0	**DETAILS OF CHANGE**
3.1	List of change(s) requested *(Please state all changes included in this application)* 1. 2. 3.
3.2	Scope *(Please specify scope of the change(s) in a concise way)*

3.3	Type of change(s) *(State which type of Variation):* Minor: Major:
3.4	Other Application(s) *(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s))*
3.5	Background for change & Justification for Consequential change(s) (If applicable) *Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s)*

3.6 Present *(Please specify precise present wordingor specification)*	Proposed *(Please specify precise proposed wording or specification)*

In the case of changes to the Summary of Product Characteristics and/or package leaflet, applicants should always enclose a working model clearly showing the differences (new text and deleted text) between the proposed new version and the current text, previous version or

reference text.

Declaration of the Applicant:

I hereby submit an application for the above Marketing Authorization to be varied in accordancewith the proposals given above.
I declare that (Please tick the appropriate declarations):

☐ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');

☐ Where applicable, Variation fees have been paid;

☐ Change will be implemented from: Next production run/next printing

Name:

Qualification:

Position in the company:

Signature:

Date: Official stamp: