# PART B: MODULE 1

Module 1 should contain all administrative documents (e.g. application forms and certifications), labelling, general correspondence and annexes as needed. Documents should be organised in the order listed below. Generally, all of the documents in Module 1, other than the annexes, can be provided in a single volume. The annexes to the module should be submitted in separate volumes.

## Module 1.0 Letter of Application

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| Documentation | | |
| 1. | 1.0 | Letter of Application |

Applicants should include a *Letter of Application* with all applications. A copy of the letter should be placed at the beginning of Module 1.

At least the following should be addressed in the letter of application:

* If the application is being submitted simultaneously with one or more additional applications for the identical product this should be stated and also confirmed that the submissions are identical except for the proprietary name
* If the dossier has been licensed in from a third party and the third party’s name or logo is included in documents in the dossier, an explanation should be provided in the cover letter to clarify the relationship between the third party and the applicant
* Clarification if the proprietary name in the original dossier (e.g. where a product has been licensed in) differs from the proposed proprietary name included in the application for registration
* If relevant, justification for empty sections in Module 1 is to be provided in the cover letter.

For further submissions during the registration process or post-registration amendments the covering letter should be included here.