**1.1 Comprehensive Table of Contents**

***Example for generic with no biostudy – up to section 1.4 completed as example***

***N/A under MRF1 means not requirement of the MRF1; N/A under CTD means not yet requirement***

***Replace MRF1 with MBR1 where update is from MBR1***

**Module 1: Administrative information**

| **Section / document number** | **Section Title** | **MRF1 Part** | **MRF1 Page** | **CTD Module** | **CTD Volume** |
| --- | --- | --- | --- | --- | --- |
| **1.0** | **Letter of application** | N/A | N/A | 1 | 1 |
| **1.1** | **Comprehensive table of contents** | See CTD | See CTD | 1 | 1 |
| **1.2** | **Application** |  |  |  |  |
| 1.2.1 | Application form |  |  |  |  |
| *1.2.1.1* | *Application form: Dummy 1* | See CTD | See CTD | 1 | 1 |
| *1.2.1.2* | *Application form: Dummy 2* | See CTD | See CTD | 1 | 1 |
| **1.2.2** | **Annexes** |  |  |  |  |
| 1.2.2.1 | Proof of payment | N/A | N/A | N/A | N/A |
| 1.2.2.2 | Letter of authorisation for communication on behalf of the applicant/PHCR | See CTD | See CTD | 1 | 1 |
| 1.2.2.3 | Dossier product batch information | 3H | 3H.1 | See MRF1 | See MRF1 |
| 1.2.2.4 | Electronic copy declaration | N/A | N/A | 1 | 1 |
| 1.2.2.5 | Curriculum vitae of the person responsible for pharmacovigilance | N/A | N/A | 1 | 1 |
| 1.2.2.6 | API change control | N/A | N/A | N/A | N/A |
| 1.2.2.7 | EMA certificate for a Vaccine Antigen Master File (VAMF) | N/A | N/A | N/A | N/A |
| 1.2.2.8 | EMA certificate for a Plasma Master File (PMF) | N/A | N/A | N/A | N/A |
| **1.3** | **South African labelling and packaging** |  |  |  |  |
| 1.3.1 | South African Package Insert |  |  |  |  |
| 1.3.1.1 | Package Insert | See CTD | See CTD | 1 | 1 |
| 1.3.1.2 | Standard References | See CTD | See CTD | 1 | 1 |
| 1.3.2 | Patient Information Leaflet | See CTD | See CTD | 1 | 1 |
| 1.3.3 | Labels | See CTD | See CTD | 1 | 1 |
| 1.3.4 | Braille | N/A | N/A | N/A | N/A |
| **1.4** | **Information about the experts** |  |  |  |  |
| 1.4.1 | Quality | 2C | 2C.50 | See MRF1 | See MRF1 |
| 1.4.2 | Non-clinical | N/A | N/A | N/A | N/A |
| 1.4.3 | Clinical | N/A | N/A | N/A | N/A |
| **1.5** | **Specific requirements for different types of applications** |  |  |  |  |
| 1.5.1 | Literature based submissions |  |  |  |  |
| 1.5.2 | Amendments/Variations |  |  |  |  |
| 1.5.2.1 | Tabulated schedule of amendments |  |  |  |  |
| 1.5.2.2 | Medicines Register Details |  |  |  |  |
| 1.5.2.3 | Affidavit by Responsible Pharmacist |  |  |  |  |
| 1.5.3 | Proprietary name applications and changes |  |  |  |  |
| 1.5.4 | Genetically modified organisms |  |  |  |  |
| 1.5.5 | Clinical Package Insert and Patient Information Leaflet amendments/updates |  |  |  |  |
| **1.6** | **Environmental risk assessment** |  |  |  |  |
| 1.6.1 | Non-GMO (genetically modified organisms) |  |  |  |  |
| 1.6.2 | GMO |  |  |  |  |
| **1.7** | **Good manufacturing practice** |  |  |  |  |

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