***New Dossier Submission Checklist –Application for full assessment***

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| DOSSIER/PRODUCT INFORMATION | |
| ***Proprietary / Product Name.*** |
| ***INN, strength, dosage form.*** |
| ***Applicant***. |
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| CHECKLIST DETAILS | |

* Please Tick ✔ or X or write as applicable
* The dossier should have named folders of the CTD e.g., 5 folders of Module 1-5. Each folder should have sub-folders e.g., for Module 3 there should be 3 sub-folders of 3.2.S – Drug Substance, 3.2.P – Drug Product and 3.2.R – Regional Information.
* Sub-folders of 3.2.S should have 7 labeled sub sub-folders e.g., 3.2.S.2.4 Controls of Critical Steps and Intermediates.
* Files should be in named folders e.g., GMP certificate should be in sub-folder of 1.7 Good Manufacturing practice.

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|  | Applicant | MRA use |
| 1. Duly signed and dated Application Form |  |  |
| 1. (a) SmPC / SPC / Package insert   (b) Patient Information leaflet |  |  |
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| 1. GMP Certificates for 2. API manufacturing site(s) 3. FPP manufacturing site(s) |  |  |
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| 1. Valid Manufacturing Licence(s) of the FPP manufacturing site (s) |  |  |
| 1. Certificate of Pharmaceutical Product (CPP or COPP) |  |  |
| 1. Registration certificates from: 2. Stringent Regulatory Authority(ies) 3. Other Regulatory Authority |  |  |
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| 1. API information presented as 2. WHO CPQ 3. CEP 4. Full details used to present API data |  |  |
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| 1. QOS completed in Word format |  |  |
| 1. (a) Bioequivalence study is required, the BTIF is in Word format 2. Bioequivalence study is not required, the Biowaiver-BCS Application Form is in Word format 3. For additional strengths, Biowaiver-Additional strengths Application Form is in word format. 4. Clinical studies information – Innovator products |  |  |
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| 1. Comparator/Reference used for the BE/BW studies is acceptable as per Botswana Guideline for Bioavailability and Bioequivalence, page 15 & 16. |  |  |
| 1. (a) Stability data for the FPP is at least 6 months at the accelerated condition and 12 months at the long-term condition for at least 2 batches 2. Stability data for the API is at least 6 months at the accelerated condition and 12 months at the long-term condition for at least 2 batches |  |  |
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| 1. Validation or verification of analytical procedures for: 2. API (if in the open part) 3. FPP |  |  |
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| 1. Validation of manufacturing process of the FPP |  |  |
| 1. (a) Copy of executed biobatch manufacturing records 2. Copy of blank master production record(s) for commercial production batch(es) |  |  |
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| 1. Signed and dated 2. API Specifications from the FPP manufacturer 3. FPP Specifications |  |  |
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