***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
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| 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)
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| 1. Certificate of Pharmaceutical Product (CPP or COPP)
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| 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
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| 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.
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| 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
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| 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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