|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S/N** | **PATHWAY** | **CATEGORY** | **ELIGIBILITY** | **REQUIREMENTS** |
| 1. | **RISK CATEGORIZATION** | **LOW** | 1. Already registered generic 2. Local Contract Manufacture for product that has existed in the Nigeria market for at least five (5) years 3. Products from Toll Manufacturing facility (Local applicant) approved by NAFDAC on the same line as an already registered product by the Agency that has been on the market for two(2) years. 4. Products from SRA, WHO-ML3 countries (with at least 6 months’ post approval reference) 5. Products accepted under WAHO joint assessment, WHO-PQ NRA & WHO-SRA NRA products 6. Products approved through the SwissMedic MAGHP | **Eligibility 1 , 2 and 3**   1. Notarized letter of confirmation from the FPP manufacturer that the formulation, equipment and processes are the same as an already registered NAFDAC product 2. A copy of NAFDAC registration certificate for the product 3. A dossier in CTD format   **Eligibility 4, 5 and 6**   1. Reliance pathway will be applied ( Assessment report, NAFDAC-SRA- QIS and Product dossier ) |
|  | **MEDIUM** | 1. Existing manufacturer introducing a new product different active ingredient of same dosage form as an already registered product. 2. Products made in Nigeria from New manufacturer 3. Products from Toll Manufacturing facility (imported products) approved by an NRA on the same line as an already registered product that has been in the Nigeria market for Ten (10) years. | 1. Dossier submission in CTD format. |
|  | **HIGH** | 1. Products from New Manufacturer from non-SRA region. 2. Known manufacturer introducing a new dosage form. 3. New Molecules 4. All other products that do not meet the criteria for low and medium products. | 1. Pre-submission meeting 2. Dossier Screening 3. Full Dossier |