## **SCHEDULE 5**

**PRODUCT INFORMATION AND DOCUMENTS REQUIRED FOR UNREGISTERED DRUG**

Tenderer is required to complete the following form for every item offered.

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| **DETAILS OF ITEM OFFERED**  *\* Please list the item no. and item description as listed in Section 2 Specifications and Requirements* | |
| **Item No.\*** |  |
| **Item Description\*** |  |
| **Product / Brand Name :** |  |
| **Name & Address of Manufacturer :** |  |
| **Name & Address of Product License / Marketing Authorization Holder :** |  |

| **DESCRIPTIONS** | | **Please tick Yes or No**  **If No, please elaborate** | | **FOR OFFICIAL USE ONLY** |
| --- | --- | --- | --- | --- |
| **YES** | **NO** |
| **Labelling: The labels state -Unit Carton** | 1. Product Name |  |  |  |
| 2. Dosage Form |  |  |  |
| 3. Name of Active Ingredient(s) |  |  |  |
| 4. Strength of Active Ingredient(s) |  |  |  |
| 5. Batch Number |  |  |  |
| 6. Manufacturing Date |  |  |  |
| 7. Expiration Date |  |  |  |
| 8. Route of Administration |  |  |  |
| 9. Storage Condition |  |  |  |
| 10. Product Registration Number |  |  |  |
| 11. Name and Address of Marketing Authorisation Holder |  |  |  |
| 12. Name and Address of Manufacturer |  |  |  |
| 13. Special Labelling (if applicable) eg. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, porcine) |  |  |  |
| 14. Recommended Daily Allowance (For Vitamins and Minerals) |  |  |  |
|  | 15. Warning (if applicable) |  |  |  |
| 16. Pack sizes (Unit/Volume) |  |  |  |
| **Labelling: The labels state -Inner Label**  \* exempted for small ampoule and vial | 1. Product Name |  |  |  |
| 2. Dosage Form\* |  |  |  |
| 3. Name of Active Ingredient(s) |  |  |  |
| 4. Strength of Active Ingredient(s) |  |  |  |
| 5. Batch Number |  |  |  |
| 6. Manufacturing Date\* |  |  |  |
| 7. Expiration Date |  |  |  |
| 8. Route of Administration |  |  |  |
| 9. Storage Condition\* |  |  |  |
| 10. Product Registration Number\* |  |  |  |
| 11. Name and Address of Marketing Authorisation Holder\* |  |  |  |
| 12. Name and Address of Manufacturer\* |  |  |  |
| 13. Special Labelling (if applicable) eg. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, porcine)\* |  |  |  |
| 14. Recommended Daily Allowance (For Vitamins and Minerals)\* |  |  |  |
| 15. Warning (if applicable)\* |  |  |  |
| 16. Pack sizes (Unit/Volume) |  |  |  |

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| **Labelling: The labels state -Blister / Strip**  # exempted for multi-ingredients product with more than 3 ingredients. | 1. Product Name |  |  |  |
| 2. Name of Active Ingredient(s)# |  |  |  |
| 3. Strength of Active Ingredient(s)# |  |  |  |
| 4. Batch Number |  |  |  |
| 5. Expiration Date |  |  |  |
| 6. Name/Logo of Manufacturer/Product Owner/Marketing Authorisation Holder (country specific) |  |  |  |
| 7. Product Registration Number (country specific) |  |  |  |
| **Documents**  A certified copy of the following documents is required to be submitted together with the tender offer:  1. Certificate of Analysis  2. Certificate of Pharmaceutical Product  3. Stability Data Report  4. Bioequivalence Study / Clinical studies (upon request, if applicable)  5. Batch Release Certificate (Blood Products) | |  |  |  |
| **Package Insert**  - Package Insert/ Patient Information Leaflet | |  |  |  |
| **Product Registration Reference Number**  **[in recognised reference countries], Please list:** | |  | | |