**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220) 4380632, [www.mca.gm](http://www.mca.gm)

\*Write N/A if an item is not applicable

|  |  |
| --- | --- |
| **Section 1: Study identification** | |
| Study title |  |
| Observation Plan, date, and version**1** |  |
| Study identification, where applicable |  |
| Purpose of the study |  |

1 Any translation of the observation plan should be assigned the same date and version as those in the original document

|  |  |
| --- | --- |
| **Section 2: Identification of the Responsible Person** | |
| Name of the responsible person |  |
| Name of the organisation, if applicable |  |
| Address |  |
| Telephone number |  |
| E-mail |  |
| Website (if applicable) |  |
| Qualification (Medical doctor, other) |  |
| Status | Commercial  Non-commercial |
| ***Persons the responsible person has delegated functions to2*** | |
| Name of the organisation |  |
| Name of the person |  |
| Function |  |
| Professional Address |  |
| Telephone number |  |
| E-mail |  |
| Website (if applicable) |  |

2 Repeat as necessary

|  |  |
| --- | --- |
| **Section 3: Details of location3** | |
| Name of location |  |
| Physical address |  |
| Contact person including telephone and email |  |
| Name(s) of the medical doctor (s) |  |
| MDCG Registration number(s) |  |

3 Repeat as necessary

|  |  |
| --- | --- |
| **Section 4: Information on the Products under observation4** | |
| Name of the product |  |
| Marketing Authorisation Holder |  |
| Manufacturer |  |
| Marketing Authorisation Number |  |
| ATC code(s) of medicine |  |
| Pharmaceutical form of medicine |  |
| Strength |  |
| Dosage Regimen |  |
| Route of administration/application |  | |
| Name of each active substance of medicine (INN) |  | |
| Is the medicine (if applicable)?   * Immunological product (vaccine, allergen, immune serum) * Plasma derived product * Recombinant product * Radiopharmaceutical product * Herbal medicinal product * Other, specify |  | |
| Is the related product (if applicable)?   * Medical device * Cosmetic * Homeopathic medicine   Other, specify |  | |
| Date of publication of the product information |  | |

4 Present this information for each product to be under observation

|  |  |
| --- | --- |
| **Section 5: Information on the patients** | |
| Medical condition or disease5 the product is prescribed for |  |
| Number of patients |  |

5 Present this information for each product to be under observation

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| --- | --- |
| **Section 6: Study duration** | |
| Total duration of the study |  |
| Start date |  |
| End date |  |

**DECLARATION BY THE APPLICANT**

I, the undersigned have submitted all requested and required documentation, and have disclosed all information that may influence the approval of this application.

I, hereby declare that all information contained therein, or referenced by, this application is complete and accurate and is not false or misleading.

Signature of the Responsible Person

Name Signature Date

**OFFICIAL USE**

|  |  |
| --- | --- |
| Date received: | Application fee: |
| Comments | |