

**Supplementary information for Licence to import Medicine/ Medical Device/Borderline product as samples for Clinical Trial purpose**

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| 1. **Information on the Investigational Medicinal Product (IMP) /Non - investigational product** | | |
| 1.1 | Category of product  Medicine Medical Device Borderline product | |
| 1.2 | Type of the product  **Investigational Non – investigational** | |
| 1.3 | Name of the medicine /medical device(s) |  |
| 1.4 | Brand name (if any) |  |
| 1.5 | Name and country of the manufacturer |  |
| 1.6 | Name of the supplier |  |
| 1.7 | Quantity |  |
| 1.8 | Storage condition |  |
| 1. **Information on the Clinical Trial** | | |
| 2.1 | Name of the trial to be used |  |
| 2.2 | Approved protocol number (latest) by NMRA |  |
| 2.3 | Total quantity of the product planned to be imported during the conduct of trial as per the approved protocol |  |
| 1. **Information on handling of IMP in the trial site** | | |
| 3.1 | Name and address of the trial center that the product is being use |  |
| 3.2 | Name of the investigator of the trial site |  |
| 3.3 | Name of the responsible pharmacist/officer handling the IMP in the trial site |  |

***Declaration of the applicant***

I /We ……………………………………………………………………………….hereby declare that the information provided with this application is true and correct and certify that all relevant documents submitted with the application which are marked herewith are accurate and most recent as per to date.

1. Letter of Authorization issued by NMRA for the trial
2. Performa Invoice of the imported product/s
3. Sample labels
4. List of devices used in the trial certified by the Principle Investigator

(Applicable only for devices)

I agree to provide further information and documents required by National Medicines Regulatory Authority (NMRA), which is required for processing of this application.

I further declare that I take full responsibility of all consequences which might arise from false or erroneous information submitted in the application and that I will cooperate with any official of the NMRA for any such investigations relevant to the application.

…………………………………

Signature of the applicant

Name : ……………………………………………………

Designation : ……………………………………………..

***For official use only:***

Above sample licence can be approved / cannot be approved.

Total allowable quantity as per the approved protocol : ………………..

Quantity approved : …………………

Remaining quantity : ………………..

Signature of the responsible pharmacist : ……………………….

Date : ……………………….

P Code : ………………………………………