**PETITION FORM FOR CONSENT IN PROCESS OF THE DEVELOPMENT DOSSIER MEDICATION CLINIC (DDCM)**

**National Health Surveillance Agency**
**Petition Form for consent in the process of the Dossier of Clinical Drug Development (DDCM)**

| Document Identification |
|---|
| (For use by the receiving agency) |

**Company Data**

| | | | |
|---|---|---|---|
| 1 | **Requester:**<br>**CNPJ:** | 2 | **City/State/Country** |

**Product Data**

| | |
|---|---|
| 3 | **( ) Synthetic or Semi-synthetic**<br>**( ) Phytotherapy**<br>**( ) Biological**<br>**( ) Radiopharmaceutical**<br>**( ) Other: Specify** |
| | **4* Product codes under development, if applicable: 5* Active** |
| | **Pharmaceutical Ingredient or active substance, if applicable: 6* Commercial** |
| | **name in Brazil, if applicable: 7* Commercial name** |
| | **abroad, if applicable: 8 Manufacturer's name: 9 Class** |
| | **Therapeutic (Anatomical, Country:** |
| | **Therapeutical and Chemical Code) / category: 10 Medicine approved in Brazil: ÿYes ÿ No** |
| | **Registration nº._____ 11 Medicine approved in the World: ÿYes ÿ No 12 Countries** |
| | **where the medicine is approved:_____ 13 The** |
| | **process fits in the exceptions described in §3 of Art.36: ( ) Yes - ( ) No If** |
| | **yes, in which option(s): ( ) National Development ( ) Biological In the case of "non-new" biological** |
| 13-1 | **medicines, the same intends to be**<br>**developed through comparability? ( ) Yes No ( ) Clinical Development Phase I or II** |
| 14 | |
| | **15 List of countries in which the clinical development of the investigational drug is intended:** |
| 16 | **Is there consent(s) in clinical trial(s) process(ies) already filed with Anvisa to be linked to this clinical drug development dossier (DDCM)? If so, inform the case number.** |

*** At least one field for items 4, 5, 6 and 7 must be filled in.**

**Statement of responsibility**

**We assume full civil and criminal responsibility for the information provided here, as well as for the quality of the experimental drug to be used in the clinical development presented, including, where appropriate, its sterility and/or apyrogenicity.**

**Legal representative**
**(Signature and Stamp)**

**Pharmacist responsible**
**(Signature and Stamp)**