Announcement About the Application for Approval to Import the Investigational Medicinal Product used in Clinical Studies and The Inspection of Bioavailability/Bioequivalence Centers

Previous announcements related to **the application for approval to import the investigational medicinal product (IMP) used in clinical studies** and the inspection of bioavailability/bioequivalence (BA/BE) centers have been changed **as follows**:

- The data and documents in Appendix-1 **shall be submitted** to receive official approval to import the medicine used in clinical studies.

- **The BA/BE centers certified by** FDA, WHO, and/or EU member countries and Japan **will not be inspected.** The BA/BE centers in other countries and the BA/BE centers in Turkey shall submit the data and documents in Appendix-2 for the inspection.

APPENDIX-1

The following data and documents shall be submitted to receive the official approval to import the medicine used in clinical drug studies:

1. Applicant:

Any corporate or contract research organisition or other than the sponsor applies to import the medicine shall submit the original document or notary certified photocopy of authorization released by the sponsor.

2. Initial Approval Given by the General Directorate of Pharmaceuticals and Pharmacies:

- **Initial approval letter issued by the General Directorate of Pharmaceuticals and Pharmacies.**
- If a conditional approval has been given by the General Directorate of Pharmaceuticals and Pharmacies, the satisfactory completion of the condition is required.

3. Proforma invoice fee of imported IMP:

- The original and copy of the statement of account which will be received in return of depositing 130 YTL to the account number 350-101-521 of **"Center Director of Accounting of Turkish Republic Health Ministry, Central Bank/Ankara"** and to the account number 49531312-5001 at **"Ziraat Bank/Bulvar"**.
- Each statement of account has to be deposited in bank for each proforma invoice and added to dossier.

4. Proforma invoice of imported IMP:

- Serial numbers of the IMP imported in proforma invoice, and the lots of these IMPshave to be declared.
- Two proforma invoices registered and signed by corporate have to be added to the dossier including page numbers on it.

5. Analysis certificate of each imported IMP lot:

The analysis certificate has to be put into dossier.

6. Label samples:

- Name and/or code of study product,
- Assigned number for the volunteer,
- Production date, serial number and expire date,
- Storage conditions,
- The motto of **"Only For Clinical medicine Study"**,
- (If applicable) randomization code,
- The motto of **"Keep out of the reach of children"** (only for outpatients).

7. Table of drugs and the locations of centers:

- Name of studied centers,
- Name and surname of person in those centers to whom the IMP be delivered,
- Number of volunteers,
- The dose of IMP be given per volunteer,

- The distrubition of total amount of IMP be used by outpatients in centers,
- Total quantity of IMP be used,

Ps: The data mentioned above will be demonstrated in tables.

8. Information related to the package:

- Number of boxes,
- Number of unit package in each box,
- Quantity of IMP in each unit package.

9. Other important issues:

The aplication data and documents for the approval of import:

- Be kept in plastic dossier,
- Each section will be given a number,
- Each section will be separated with file separator,
- Only the certificates belong to analysis be in the dossier, not the others.
- If the medicine be used in the study is subject to control (narcotic and/or psychotrophic substances), a permission shall be taken from General Narcotic and Psychotrophic Substances Studies Branch Directorate.
- If the products obtained from blood be used in clinical study, regarding the disease of Creutzfeld Jacob (CJ), the corporate has to give an “appostill authentication” declaring that the donors neither have CJ, nor any doubt of the excistence of JC among the donors.

APPENDIX-2

Required data and documents for the application dossier related to inspection of bioavailability/bioequivalance centers:

- General information,
- Location of the center.
- Center's organization chart,
- Study flowchart,
- CV of key persons (quality control director, principal investigator etc.),
- Standard operating procedures (SOP),
- The centers located in other countries should submit the copy of certification of the center given by local authorities.
- The lists or certificates of previous inspections for the centers located in other countries.
- Bank receipt and photocopy of application fee deposited in **Center Director of Accounting of Ministry of Health Republic of Turkey.**

Dossiers for clinical and analytical centers for BA/BE studies have to prepared separately; data and documents should be separated from others.