Non-compliances Observed During Review of Applications for Registration and Import Licences of Medical Devices

Categories of Non-compliances

1. Covering Letter
2. Legal Documents
3. Regulatory Documents
4. Technical Documents

Non-compliances - Covering Letter

- Does not specify objective of Application
- Not Indexed, Numbered, Marked
- Authority Letter not submitted for authorizing signatory
- Mentions that data will be submitted subsequently

Non-compliances – Legal Documents

- Form 40
- TR6 Challan
- Power of Attorney
- Schedule D (I) & D (II)
- Form 8
- Form 9

FORM -40

- Does not indicate the name & designation of the authorized signatory
- Name (s) of the device (s) differs from those mentioned in the regulatory certificates
- Names and Addresses of actual & legal manufacturer not mentioned
- More than one devices clubbed as a single device
- Not as per the Performa prescribed in the Drugs and Cosmetics Act & Rules
- Not stamped

TR6 Challan

- Amount less than prescribed fee
- Does not indicate USD equivalence, no additional bank verification in terms of USD equivalence submitted
- Not submitted in Bank of Baroda & in proper Head of Account
- Challan submitted for only few products
- Does not have a clearance stamp
- Not Submitted

Power of Attorney

- Not co-jointly signed by Manufacturer as well as the Indian Agent
- Not Apostilled/Attested by the Indian Embassy in the country of origin
- Does not list the names of the devices proposed to be registered
- List of products enclosed, not part of attestation
- Does not indicate the name & designation of the authorized signatory
- Details such as Name & addresses of Indian Agent/Manufacturer, product names cannot be correlated with Form 40
- Not as per Drugs & Cosmetics Act & Rules
- Photocopy submitted

Schedule D (I) & D (II)

- D (I) Undertaking not submitted
- Usually the Performa indicates that the information is annexed, however no annexure are attached for the same
- Not signed & Stamped by the manufacturer; signed by Indian Agent
- Does not indicate the name & designation of the authorized signatory of the manufacturer
- Not Submitted
- Incomplete Performa submitted

Form 8

- Not as per the Performa prescribed in the Drugs & Cosmetics Act & Rules
- Details such as name & addresses cannot be correlated with registration certificate issued
- Not signed & stamped by the authorized signatory
- Not stamped
- Does not indicate the name & designation of the authorized signatory
- Does not list the names of the products
- List of proposed products not signed & stamped by authorized signatory
- List of proposed products does not correlate with that of Form 9 and/ Free Sale Certificate

Form 9

- Not as per the Performa prescribed in the Drugs & Cosmetics Act & Rules
- Details such as name & addresses cannot be correlated with registration certificate issued
- Not signed & stamped by the authorized signatory
- Not stamped
- Does not indicate the name & designation of the authorized signatory
- Does not list the names of the products
- Does not list all the proposed products/ Product list cannot be correlated with that of Form 8
- Not notarized (in case signed by the manufacturer)
- Not signed and stamped by the principal Indian agent/ Manufacturer (in case the importer is not the principal Indian Agent)

Regulatory Documents

- Free Sale Certificate
- ISO 13485 Certificate
- CE Full Quality Assurance Certificate
- CE Design Certificate
- Drugs Sale License in Form 20B & 21B

Non-compliances - Regulatory Documents

- Not Submitted
- Not submitted in respect of the proposed products
- Not Valid
- Manufacturing site does not correlate with the manufacturing site proposed to be registered
- Not notarized; Not Notarized from the country of origin; Photocopies or scanned copies of notarized certificate submitted
- Free Sale Certificate Not issued by the National Regulatory Authority of the country of origin/ Self-issued Free Sale Certificates submitted
- Free Sale Certificate not submitted in English/no translation submitted
- Design Certificate not submitted in respect of the proposed products

Technical Documents

- Plant Master File
- Device Master File

Non-compliances - Technical Documents

- Not Submitted
- Details as per Drugs & Cosmetics Act & Rules not submitted
- Not Notarized; Not notarized from the country of origin
- Not in English
- Detailed Biocompatibility, Stability, Sterilization Validation reports not submitted
- Only Protocol for PMS submitted, no actual data submitted
- Details of vendors/sub-vendors/contract manufacturer (s) not submitted

Contd…

Non-compliances - Technical Documents

- Package Inserts not submitted
- Labels not submitted
- Certificate of Analysis not submitted
- Performance Evaluation Reports not submitted in case of Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis & Cancer marker detection kits

Miscellaneous Non-Compliances

- Time of submission of Endorsement Application
- Time of submission of Re-registration Application
- Incomplete Registration details provided at time of Re-registration
- Changes in manufacturing site, devices etc. not notified at right time