GUIDELINES FOR IMPORT AND MANUFACTURE OF MEDICAL DEVICES

The Ministry of Health and F.W. under Gazette notification S.O. 1468 (E) dated 6/10/2005 declared the following sterile devices to be considered as drugs under Section 3 (b) (iv) of the Act.

1. Cardiac Stents.
2. Drug Eluting Stents.
3. Catheters.
4. Intra Ocular Lenses.
5. I.V. Cannulae.
6. Bone Cements.
7. Heart Valves.
8. Scalp Vein Set.
9. Orthopedic Implants.
10. Internal Prosthetic replacements.

It was also notified vide GSR 627 (E) dated 7/10/2005 that control over manufacture of these devices would be exercised by CLAA i.e. DCG(I) under the said Rules.

The Ministry of Health and Family Welfare have now approved the following procedures to be adopted in respect of licensing of import as well as manufacture of these Medical Devices in the country.

These guidelines shall be effective from 1st March 2006.

IMPORT OF MEDICAL DEVICES

For the purpose of import of Devices specified above, the procedure for registration and import licence as prescribed under the Drugs and Cosmetics Rules shall be followed.

1. A period of 60 days would be provided for the importers to make application for import and registration from the date of publication of these guidelines.
2. In case of devices which have not been imported in the country before the date of notification no import would be permitted without the approval of the competent authority.

3. For the time being and for a period upto six months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use will be permitted to be sold. In case of stents or drug eluting stents the import will not be permitted if the applicant has sold less than One thousand stents of the particular specification prior to the date of issue of these guidelines.
4. Separate committees consisting of subject experts and representative of DCG(I) office would be setup for their expert advice for evaluation of specific categories of devices. The expert committees would formulate their own benchmarks and procedures for evaluations and the standards to which such devices should conform.

REGISTRATION OF MEDICAL DEVICES FOR IMPORT

1. Application for Registration Certificate in respect of the premises and the devices manufactured by the manufacturer and meant for import into India is required to be made by the manufacturer or importer or his agent in India, in Form 40 and in form and manner as under Rule 24A of the Drugs and Cosmetics Rules. The application addressed to the Drugs Controller General (India) shall be deposited at the CDSCO, FDA Bhawan, Kotla Road, Near Mata Sundari College, ITO, New Delhi-110002.
2. A fee of US$ 1500 or its equivalent shall be paid alongwith the application as registration fee for the premises where the devices, intended to be imported are being manufactured by the manufacturer.
3. A fee of US$ 1000 or its equivalent shall be paid for registration of single Medical Device (which may include variation in sizes or shape without any change in the material or method of use) and an additional fee US$1000 for each additional device shall be paid.
4. The fee shall be paid through a challan in the Bank of Baroda as prescribed under the said Rules.
5. The informations and undertakings required to be furnished under Schedule DI and DII may be modified to suit the requirements of devices in place of normal pharmacological products. The information shall include the following details:-

(A) Applicant Details

1. Applicant's company name, address and contact number.
2. Name and address of foreign manufacturer (Manufacturing premises).
3. Copy of the Plant Master File.

4. Name and address of the local authorized representative.
5. Name and address of the importer.
6. Local manufacturer, if any processing is being done in the country.

(B) Product Information

1. Proprietary/Brand name.
2. Brief description of the device.
3. Category of device.
4. Intended use and method of use.
5. Medicals specialty in which the device is used.
6. Qualitative and quantitative particulars of the constituents.
7. Brief description of the method of the manufacture and specification of the materials used.
8. Contraindications, warnings, precautions potential adverse events and alternate therapy, wherever applicable.
9. List of accessories and other devices or equipment to be used in combination with the device. Other descriptive information, including accessories packaged with the product.
10. Variations in shape, style or size of the device, if applicable.
11. Labeling details conforming to Drugs and Cosmetics Rules, 1945.
12. Physician manual and promotional literature (Literature insert) in English.
13. Packaging description including pack sizes.
14. Recommended storage conditions.
15. Summary indications of any reported problems.
16. Details of standards to which the device conform alongwith the copy of the standard.

(C) Regulatory Status

1. Approval of the product from any other regulatory agency (Separate evidence for the approval from the each agency)

    (i) US FDA clearance/approval.
    (ii) EU medical device directive (CE Certificate).
    (iii) Australia/Canada/Japan approval.
    (iv) Approval in any other country.

1. Copy of ISO/EN Certification if any for the manufacturing facility.
2. List of countries where the device is being sold.

3. List of countries where device is withdrawn from sale with reasons, if any.

(D) Master File (Details of Good Manufacturing Practices employed by the manufacturer to ensure quality of the device)

1. Component/Material used.
2. Device Master File.
3. Manufacturing process/Flow Chart.
4. Quality Assurance procedures/process controls.
5. Final product testing or design inputs/outputs verification, if applicable.
6. Functionality Test protocol and report, if applicable.
7. Risk Assessment as per ISO 14971.
8. Sterilization process and validation/verification.
9. Stability data or statement of established stability of material used as applicable.
10. Shelf life of the device.
11. Biocompatibility and Toxicological data, wherever applicable.
12. Device GMP Certificate.

(E) Devices containing medicinal product

1. If device incorporates a medicinal product, which is liable to act upon the body with action ancillary to that of the device, data on the safety, quality and usefulness of the medicinal substance used.
2. Data on compatibility with medicinal products, if device intended to deliver medicinal products.
3. Clinical data and published articles, if any.
4. Batch Release Certificate for products incorporating any medicinal substance or substances of animal origin.
5. For devices not approve for marketing in the country of origin, the applicant shall submit reports of clinical trials, details of sales, certificates of satisfactory use from the medical specialists about the use of the device and details of product complaints, if any.

(Medical Devices with prior approval from any of the recognized regulatory authorities will be subjected to an abridged evaluation and only a summary of all the studies and information described above is to be submitted)

(F) Post Market Surveillance

1. Procedures for distribution of records.
2. Complaint handling.
3. Adverse incident reporting.
4. Procedure for product recall.

(G) Undertaking of conformity with respect to product standards, safety and effectiveness requirements and quality systems in the country of origin.

5. The Registration Certificate shall be issued in Form 41 of the said Rules.
6. The application for import licence shall be made in Form 8 alongwith a fee of Rs. 1000/- in the Form and manner prescribed under the Drugs and Cosmetics Rules.

MANUFACTURE OF MEDICAL DEVICES IN THE COUNTRY

1. Application for the grant of licence for manufacture of these notified sterile Devices in the country shall be made in Form 27 to the State Licensing Authority, accompanied by the requisite fee in the Form and manner as prescribed in the said Rules alongwith a copy to the office of DCG(I).
2. A period of 60 days would be provided for making the application for manufacture from the date of publication of these guidelines.
3. In case of devices belonging to above said categories which have not been manufactured in the country before the date of notification, no manufacture would be permitted hence forth without the approval of the competent authority as per norms prescribed.
4. The applicant shall provide the following information alongwith the application for consideration of the licensing authority.

Manufacturing Details:-

(a) Complete details about the names, addresses of the directors of the company and addresses of the manufacturing premises and registered offices of the manufacturer.
(b) A brief project highlight indicating the plans of the company, devices to be manufacture, their viability and other relevant profiles.
(c) Copy of the Site Master File.

(d) A brief description of the manufacturing process of the devices to be manufactured.
(e) Details of the standards followed by the company for Good Manufacturing Practices and product evaluation.
(f) Name, qualification and experience of technical staff under whose supervision the devices will be manufactured.
(g) Copies of ISO or any other certifications, if any, obtained by the firm for its manufacturing facility.

Product Details:-

A. Proprietary/Brand name.
B. Brief description of the device.
C. Category of device.
D. Intended use and method of use.
E. Medical specialty in which the device is used.
F. Qualitative and quantitative particulars of the constituents.
G. Specifications of the materials used.
H. Testing facilities available in the manufacturing premises for testing.
I. Standards and procedures for testing the device.
J. Contraindications, warnings, precautions potential adverse events and alternate therapy, wherever applicable.
K. List of accessories and other devices or equipment to be used in combination with the device. Other descriptive information, including accessories packaged with the product.
L. Information on stability of the product.
M. Details of clinical trials, (wherever applicable) carried out on the product.
N. Variations in shape, style or size of the device, if applicable.
O. Labeling details conforming to Drugs and Cosmetics Rules, 1945.
P. Physician manual and promotional literature (Literature insert) in English.(if any)
Q. Packaging description including pack sizes.
R. Recommended storage conditions.
S. Summary indications of any reported problems.

5. For the purpose of evaluation of Medical Devices which are new or do not have any benchmark certification, Expert Committees shall be setup

to examine in detail the information provided by the applicant for the assessment of the device.

6. The committee after completing their assessment forward the opinion regarding suitability of the device to the competent authority for the purpose of grant of permission for placing the device in the market.
7. The State Licensing Authority after Joint Inspection and verification would forward the licence to CLAA for approval.
8. The licence shall be issued in Form 28 of the said Rules after due approval of CLAA.

SALE OF MEDICAL DEVICES IN THE COUNTRY

The importers, stokists and retail sellers of Medical Devices shall obtain appropriate sale licences from the State Licensing Authorities for these Medical Devices within a period of 3 months form the issue of these guidelines.