ADDITIONAL CLARIFICATION TO GUIDELINES FOR IMPORT REGISTRATION AND MANUFACTURE OF MEDICAL DEVICES (5/9/2007).

1. Free Sale Certificate in country of origin issued by the Ministry of Health/National Regulatory Authority is a pre-requisite for the registration of medical device under the provisions of the Drugs and Cosmetics Rules.

2. Clarification with regard to Requirement of regulatory status of a medical device to be registered in India is as follows:

   (i) In case of medical devices manufactured in USA, USFDA approval for manufacture and free sale in USA in respect of the device is to be submitted.
   (ii) As regards medical devices manufactured in Australia, Japan and Canada, approval for manufacture and free sale in the respective country of origin is to be submitted.
   (iii) In case of medical devices manufactured in European Countries CE certification alongwith approval for manufacture and Free Sale Certificate from respective country of origin is to be submitted.
   (iv) In respect of medical devices manufactured in countries other than those specified above approval for manufacture and free sale in the respective country of origin alongwith approval from any one of the following viz. USFDA/TGA Australia/Health Canada/ Ministry of Health, Labour and Welfare Japan or CE Certification is to be submitted.

3. It is clarified that "All Peripheral Stents" are covered under the provisions of the Drugs and Cosmetics Rules and hence need to be registered for import and licenses approved by Central License Approving Authority (CLAA) for indigenous manufacture.

4. As per the advise of the Expert Committee on Cardio Vascular System, all "Cardiac Patches" and "Occluders" used in interventional cardiology/closing holes in the cardio vascular system is to be considered as an "Internal Prosthetic Replacement" (Medical Devices) and require to be registered under the provisions of the Drugs and Cosmetics Rules. Import of any cardiac patches and occluders would require a valid Registration Certificate and a Form 10 Licence with immediate effect.

5. The O/o the DCG(I) has identified Sree Chitra Thirunal Institute for Medical Sciences & Technology, Trivandrum to test the quality of Drug Eluting Stent (DES) marketed in the country. In this regard instructions have been issued to all the Port Offices to draw one

sample (comprising of 3 stents) of each manufacturer from among the imported consignments of Drug Eluting Stents for test and analysis.

6. In case of import registration of Drug Eluting Stent it is clarified that atleast 1000 Stents (DES) to be registered should have been sold in India prior to 1/3/2006.

7. In case of manufacturers whose stents are already in use abroad and they wish to introduce the same in India a six months clinical trial has to be done on 100 patients.

8. In case of stent which are new in nature and not used anywhere a 12 months clinical trials has to be done on 100 patients.

9. A discussion was also carried out on Global clinical trials. Whenever a firm applies only for Global Clinical Trial to be carried out in the country, this can be permitted as per the present norms been followed in case of drugs. However, if the same company wishes to also market the product in India, it has to comply with the norms mentioned above.

10. Any change in the Design and/or change in Material and/or change in Composition of an already approved Medical Devices require prior approval of Drugs Controller General (India).

11. EC Design Certificate under Annex II Section 4 of the MDD 93/42/EEC is a pre-requisite for Registration of Class III Medical Devices (except medical devices manufactured in USA, Canada, Japan and Australia in which cases CE Certificates are not mandatory).

12. The notified Medical Devices being drugs copies of Whole Sale Drug Licence on Form 20-B and 21-B issued by the respective State Licensing Authority (SLA) should be submitted alongwith the application for the purpose of import registration.