MINISTRY OF HEALTH & FAMILY WELFARE

OFFICE OF THE DRUGS CONTROLLER GENERAL (INDIA)

FDA BHAWAN, KOTLA ROAD, NEW DELHI - 110002

PUBLIC NOTICE

The Government of India in the Ministry of Health & Family Welfare had issued a notification S.O.No.1468(E) dated 6th October, 2005 declaring the following Medical Devices as drugs under the provisions of the Drugs & Cosmetics Act, 1940.

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

The Notification GSR 627(E) dated 7.10.2005, further declared that these devices are required to be licensed for manufacture for sale or distribution by the Central Licence Approving Authority (viz. Drugs Controller General India) appointed by the Central Government under the Drugs & Cosmetics Rules, 1945.

The manufacture, import, sale and distribution of the above said categories of Medical Devices (including accessories which are implanted with the devices e.g. screws, etc.) is prohibited under the Act without a requisite licence for import or manufacture for sale of these devices issued under the said Rules. The applicant is required to make application for the grant of the licence to the State Licensing Authority (State Drugs Control authorities) appointed by the State Government of the respective State under whose jurisdiction the manufacturer is located. The licence in turn would be approved by the Central Licence Approving Authority i.e. the Drugs Controller General (India).

It is understood that certain manufacturers are still continuing to manufacture devices belonging to the said categories without obtaining the requisite manufacturing licences from the designated authorities. This activity is considered unlawful and would attract penalty under the Drugs & Cosmetics Act.

In view of the above, it is requested that the manufacturers of the said devices, who are still carrying out the manufacturing activity without licence may obtain the requisite licences under the Drugs & Cosmetics Act. Manufacturers may contact the undersigned for the purpose of registration / guidance for obtaining the requisite licences.

Details of the procedure for obtaining a licence is available on the CDSCO website : www.cdsco.nic.in. email :ddci@nb.nic.in.

Dr. Surinder Singh
Drugs Controller General (India)