THE HINDU BUSINESS LINE
WEDNESDAY, FEBRUARY 12, 2020

Medical devices will now be treated as drugs

OUR BUREAU

New Delhi, February 11

The Ministry of Health and Family Welfare (MoHFW) has brought medical devices within the regulatory ambit, treating them as a category of 'drugs' for the purpose of regulating them under the Drugs and Cosmetics Act (DCA).

A gazetted notification to this effect was issued on Tuesday, which will come into effect from April 1.

Regulatory oversight

The move implies that any product used to treat a patient — be it an implant like a cardiac stent or a knee implant, or devices like CT scan, MRIs, dialysis machines, or even the thermometer — will come under the ambit of the DCA. Simply put, the government will now have oversight on the medical devices industry and its activities in the country.

A list of 37 devices has been drawn up and it includes syringes, needles, stents, catheters, intraocular lenses, intravenous cannulae, prosthetic replacements, ligatures, sutures, staplers, condoms, blood bags, nebulisers, blood pressure monitoring machines and digital thermometers.

The manufacturer or importer will have to upload the generic name, model number, intended use, class of medical device, material of construction, dimensions, shelf life and brand name on the online portal of the Central Drugs Standard Control Organisation, the notification says. Once the device is registered, the manufacturer or the importer will have to mention the registration number on the device.

The MoHFW has specified that all such devices including instruments, apparatus, appliances, implants or other articles, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specifically on human beings or animals, will be considered for this purpose.