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'Labelling mandatory for medical devices'

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The Union health ministry has revised rule 109A of the Drugs and Cosmetics Rules (D&C) to make labelling of medical devices mandatory in the country.

The ministry said in a notification that the particulars will be printed in indelible ink on the label or sticker on the shelf pack of the medical device.

According to the ministry, the label should carry a proper name of the medical device; the details necessary for the user to identify the device and its use; the name of the manufacturer and address of the manufacturing premises where the device has been manufactured; the correct statement of the net quantity in terms of weight, measure, volume, number of units, and the number of the devices contained in the package shall be expressed in the metric system; and the date of manufacture and date of expiry; alternately the label shall bear the shelf life of the product.

Also, it should provide, wherever required, an indication that the device contains medicinal or biological substance; any special storage or handling conditions applicable to the device.

It should label the device, if the device is intended for single use; to overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation; and to overprint on the label of the device, the words "Physician's Sample--Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample.

The label of a medical device should provide, except for imported devices, the manufacturing licence number.

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