INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

March 18, 2015

Shri Ajoy Mehta,
Chairman,(Incharge)
Maharashtra Pollution Control Board
Kalpataru Point, 3rd & 4th Floor,
Opp. Cine Planet, Sion Circle,
Road No. 8, Jay Bharat Mata Nagar,
Air Force Quarters, Sion,
Mumbai, Maharashtra 400022

Dear Sir,

We have received the following query from a Member based in Maharashtra State enquiring whether separate Authorization under Bio-Medical Waste (Management and Handling) Rules, 1998 needs to be adopted for disposal of media used for testing microbial load on drugs and APIs.

"As per the regulatory norms pertaining to Drugs & Cosmetic Act, we have to establish Quality Control Laboratory at manufacturing sites which is part of our manufacturing set-up and meets the criteria specified by National / International standards, as applicable. All these laboratories are periodically audited and certified by various regulatory bodies.

As part of our laboratory set-up, we do have one section dealing with microbial activities in which we are testing the drugs / APIs for microbial load. At the end of the process we are deactivating the media, in a dedicated Autoclave within the same area / section, by way of autoclaving so as to ensure absence of microbial media at the end of the cycle. Said procedure is based on the national / international protocols and is validated system.

Recently during our internal review, thought has been given about applicability of Bio-Medical Waste (Management and Handling) Rules, 1998 to our laboratory and necessity of requirement of adopting Authorization there under.

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As a manufacturing set-up, we have taken necessary Authorization for disposing of waste under Rule 5 of the Hazardous Wastes (Management, handling and Trans boundary Movement) Rules 2008 and we are not very clear whether we need to adopt separate Authorization under Bio-Medical Waste (Management and Handling) Rules, 1998.

We need to have guidance on considering all above facts as well as industrial practices to guide us further whether we need to adopt a separate Authorization under Bio-Medical Waste (Management and Handling) Rules, 1998 for our laboratories."

Kindly guide us on the requirements as requested above so that the same can be communicated to all our Members as a Standard Operating Practice.

Thanking you in anticipation of your positive response.

Yours sincerely,

Daara B. Patel
Secretary-General