केन्द्रीय प्रदूषण नियंत्रण बोर्ड
CENTRAL POLLUTION CONTROL BOARD
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय भारत सरकार
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE GOVT. OF INDIA

By Speed Post

October 07, 2021

F.No.B-31011/BMW (53)/2021/WM-I 7630

To,

Member Secretary
Maharashtra Pollution Control Board
Kalptaru Point, 2nd - 4thfloor,
Opp. Cine Planet, Sion Circle, Sion (E),
Mumbai – 400 022

Sub.: Representation regarding effective management of liquid biomedical waste - reg.
Ref.: CPCB letter no. F.No.-B-31011/BMW (53)/2020/WM-I/1399-1433 dated 15.09.2020

Sir,

This has reference to above referred CPCB letter dated 15.09.2020 regarding utilisation of liquid biomedical waste for production of drugs, reagents, chemicals etc. by pharmaceutical vendors/firms. It has come to our notice vide representation from one of the pharmaceutical company that the authorization to such companies is not granted by the State Pollution Control Boards and healthcare facilities are directed to handover entire biomedical waste including liquid biomedical waste to Common Biomedical Waste Treatment Facilities for final treatment & disposal.

CPCB guidelines for "Management of Healthcare Waste by Healthcare Facilities as per Biomedical Waste Management Rules, 2016" and "Handling of biomedical waste for Utilisation" stipulates that if any hospital desires to dispose biomedical waste such as pleural fluids, ascetic fluid etc. to any company involved in utilization of such waste for production of drugs, reagents, chemicals etc. the hospitals may have agreement with such venders with prior approval from State Pollution Control Boards.

In view of above, it is requested that vendors/firms may be encouraged for utilization of biomedical waste in line with BMW Rules and guidelines of CPCB.

Yours Faithfully,

(V. P. Yadav)
Additional Director &
Divisional Head, WM-I Division

GUIDELINES FOR HANDLING OF BIOMEDICAL WASTE FOR UTILIZATION

CENTRAL POLLUTION CONTROL BOARD
(Ministry of Environment, Forest and Climate Change)
Parivesh Bhawan, East Arjun Nagar
DELHI-110 032
website: www.cpcb.nic.in
February 2019

1. Introduction

Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016) notified by Ministry of Environment Forest & Climate Change in March, 2016, stipulates that every Healthcare Facility shall take all necessary steps to ensure that biomedical waste is handled without any adverse effect to human health and the environment. Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc are also generated by the Healthcare Facilities (HCFs) which are being utilized by pharmaceutical industry for production of drugs, reagent chemicals, markers, etc.

These guidelines provide guidance to Healthcare Facilities as well as the industry/vendors involved in utilization of biomedical wastes in collection, sending, transportation, utilization and disposal by ensuring adequate safeguards from risk of spread of infection during such handling. Following guidelines would be applicable for such utilization of bio-medical waste;

2. Applicability of Authorization

a) The industries/vendors involved in collection and transportation of biomedical waste for the purpose of utilization shall obtain authorization from the concerned Pollution Control Board/Pollution Control Committee of the State/UT where they are engaged in collection and transportation of biomedical waste. They shall also obtain authorization for collection, use and disposal of biomedical waste from State / Union Territory where their facility exists.

b) The Health Care Facility involved in providing biomedical waste to an industry or vendor for the purpose of their utilization shall inform concerned SPCB and they shall provide such details while seeking renewal of authorization.

c) The industry/vendor engaged in utilization of biomedical waste shall be liable for any environmental and health risk that may arise during transport and handling of biomedical waste from the point of collection till utilization and disposal as per the provisions laid down under E(P) Act, 1986, including payment of environmental compensation charges as may be applicable.

3. Responsibilities of the Healthcare Facilities

a) Inform the prescribed authority about the type of biomedical waste which is handed over to the vendor and accordingly shall amend the authorisation while applying afresh or seeking renewal of the same.

b) Hospitals shall provide bio-medical waste only to those industries / vendors who are authorised by concerned SPCB/PCC under BMWM Rules, 2016 for collection and transportation of biomedical waste.

c) Bio-medical waste intended for utilization shall be collected by the nursing staff directly into the leak proof, puncture proof, tamper proof containers/bottles provided by the authorised vendor/industry.

d) The containers / bottles containing bio-medical waste shall be stored in temporary bio-medical waste storage area.

e) Records should be maintained indicating the type of biomedical waste, quantity, date & time of generation and date of collection by the vendor/industry.

4. Responsibilities of Vendor/Industry

a) Shall obtain authorization from concerned SPCB/PCC where they are engaged in collection and transportation of BMW for utilization.

b) Ensure use of appropriate bottles/containers and safe packaging as specified in section 5 of this document.

c) The containers/bottles used for collection of bio-medical waste shall be labelled with bio-hazard symbol in accordance with BMWM Rules, 2016.

d) The containers/bottles used for collection of bio-medical waste shall be labelled with the following information with indelible ink:

Name of the Sender (Healthcare Facility): Address & Contact Number: Name of the ward : Type of biomedical waste : Date of collection : Name of the receiver (Industry/vendor): Address & Contact number:

e) Shall ensure safe transportation of biomedical waste either by own vehicles or by any transport agency.

f) Industry or vendor shall be liable for any leakages and environmental consequences thereof.

g) Ensure disposal of used or residual BMW as well as the containers used in collection and transportation of BMW through an authorised CBWTF located close to the facility where the BMW is intended to be utilized.

h) Ensure disposal of un-used or spent biomedical waste, as per BMWM Rules, 2016.

i) Shall maintain records / log book for the waste being collected by industry/vendor.

j) The industry / vendor shall possess valid consent and authorisation from the State, where their unit is installed.

5. Procedure for packaging:

The substances in bio-medical waste intended for utilization might contain viable microorganism such as bacterium, virus, parasite or fungus that may cause disease in humans or animals. Therefore, packaging of such bio-medical waste shall be done in triple packaging system comprising of three layers of packaging as specified below:

- Primary receptacle: Bottle/container for bio-medical waste shall be leak proof, puncture proof and tamper proof. Each bottle containing biomedical waste shall be sealed in self sealing plastic bags provided with absorbent so as to absorb the liquid in case of any leakages. In case of liquid bio-medical waste, size of each bottle shall not exceed 500ml.

- Secondary receptacle: This is a second layer of packing which will be water tight, leak proof receptacle such as big plastic bag to enclose and to protect primary receptacle. Several primary receptacles wrapped along with absorbent may be placed in one secondary receptacle.

- Third receptacle: After secondary layer packaging, the secondary receptacle shall be placed in hard / rigid box for protection. This box shall also contain absorbent material such as foam cushioning to absorb the leakages, if any.

- The packaging material should be labelled with symbol of biohazard along with warning text as below;

"Sealed Bio-Medical Waste – Handle with Care"

As per Authorization: .....
dated ..... issued by .....
Date of collection: _____

6. Transportation of Biomedical Waste:

Following guidelines shall be applicable for transportation of bottles/containers containing BMW packaged for utilisation purpose as per the procedure given under section 5;

a) Can be transported by road or by railways, and by ensuring compliance to relevant provisions under Motor Vehicles Act and Indian Railways Act.
b) For transportation by air, WHO guidelines vide WHO/HSE/GCR/2015.2 entitled "Guidance on regulations for the transport of infectious substance 2015-2016" shall be followed.

c) Industry/vendor may make own arrangement for transportation of BMW or may engage professional transportation agency.

d) A spill kit containing absorbent material, a disinfectant, a leak proof waste disposal container and heavy duty reusable glove should be kept in the transport vehicle.

e) All the vehicles used for collection of bio-medical waste from the health care facilities should have symbol of BMW.

f) The industry/vendor utilizing biomedical waste shall be responsible for transportation and the risks and liabilities associated with transportation.

g) Only covered vehicles should be used for transportation of bio-medical waste

7. Management of plastic containers:

a) After emptying the plastic containers (used for the collection of biomedical fluids), packaging material (zip lock bag, plastic jumbo bag, gloves, masks etc.) should also be disposed as per the provisions under BMWM Rules, 2016.

b) The plastic containers used for collection of biomedical fluids should be emptied and Pre-treated by autoclaving or by non-chlorinated chemicals. The pre-treated containers should be collected in red colour coded bags/containers and handed over to Common Biomedical Waste Treatment Facility (CBMWTF) authorized by the State Pollution Control Board/Pollution Control Committee for further treatment and disposal.

c) Residual/discarded biomedical fluids shall be collected separately and pre-treated for disinfection (by non-chemical methods) prior to mixing with other effluent in industry for further treatment. Treatment Methods specified for Yellow (f) category waste as specified in CPCB guidelines for management of Healthcare waste asper BMW Rules, 2016.

d) Red coloured bags/containers should be provided with bio hazard symbol and should be labeled as per Schedule IV of the BMWM Rules, 2016.

e) Separate temporary storage area shall be provided inside the premises of industry for temporary storage of colour coded biomedical waste bags/containers.

f) Daily records should be maintained with respect to waste generation in yellow and red coloured bag/container.

g) In case plastic crates in which the bottles are placed are to be re-used , then the same shall be disinfect with sodium hypochlorite and shall be washed with detergent prior to re-use the same.

h) Other solid waste like gloves, mask, cotton, gauze piece, syringe, gels, plastic columns, etc. used or generated during the process of utilization shall be stored in yellow colour plastic bag/container and handover the same to CBWTF operator.

8. Management of liquid waste from utilization process

a) Industry shall provide Effluent Treatment plant (ETP) for the treatment of effluent generated during the process of utilization, washing of containers, floors etc.

b) Effluent generated from the process of utilization shall be disinfected followed by further treatment in ETP.

c) Treated effluent should comply with the liquid discharge standards stipulated under the BMWM Rules, 2016 and other standards as may be stipulated by SPCBs/PCCs.

d) ETP sludge shall be analyzed to check the hazardous constituents and in case the hazardous constituents are present beyond the prescribed limit as given in Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016 then the ETP sludge should be disposed through Hazardous Waste Treatment, storage and Disposal Facility.

e) Records should be maintained w.r.to the waste water generation, its treatment and disposal.

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MAHARASHTRA POLLUTION CONTROL BOARD

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No. BO/CAC-Cell/ B-2 Date: 19/01/2021

Circular

Sub: Guidelines for "Handling of BMW for Utilization"- Reg...

Ref:
1. Guidelines published by the CPCB on Feb-2019.
2. CPCB letter dated 15/9/2020
3. Decision of CAC meeting dated 06.11.2020.

Health Care Establishments (HCE) were made mandatory to obtain Authorization under Bio Medical Waste (M & H) Rule 1998 and amendment thereof. Subsequently, as per the CPCB direction dated 04.06.2012 and 07.03.2016, HCE were included in consent management regime and was made mandatory to obtain consent to Establish/operate under the provision of the Water (P & CP) Act, 1974 and the Air (P& CP) Act, 1981 & Authorization under BMW Rule.

Biomedical Waste Management Rules, 2016 (BMW Rules, 2016) Notified by Ministry of Environment Forest & Climate Change in March, 2016, stipulates that, every Healthcare Facility shall take all necessary steps to ensure that, biomedical waste is handled without any adverse effect to human health and the environment

Recently, the CPCB has issued guidelines for handling of BMW vide dated 11.03.2019, further CPCB has issued guidelines vide letter dated 25.03.2019 for handing over BMW such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc to various Pharmaceutical industries. **They have also mentioned that PCC/SPCB's shall facilitate the firms engaged in utilization of BMW for above purposes vide letter dated 15.09.2020.**

The Consent Appraisal Committee (CAC) in its meeting dated 06.11.2020 deliberated on above issue in details and was decided to implement the above direction of the CPCB by amending consent by imposing following conditions:

1. HCEs shall **preferably** handover Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc. to the Pharmaceutical industry / Biotechnology firms for production of drugs, reagent chemicals, markers, etc, if any such Pharmaceutical industry / Biotechnology firms approaches them for the same. If there are any difficulties in the matter, the same may be communicated to such firm and copied to the Board also.
2. HCEs shall strictly follow the procedure for packaging & transportation of Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc. to the Pharmaceutical industry / Biotechnology firms as per the guidelines of CPCB published in Feb- 2019 for "Handling of BMW for utilization".
3. HCEs shall submit the report to the Board office about type, quantity and frequency of handling over such BMW on yearly basis.
4. Industry to enter into legal agreement with HCE's and inform the MPC Board and competent authority of State Public Health Department about such collection of BMW along with quantity and type of waste collected.

...2/-

5. In case of any technical difficulty towards handing over the required BMW then, you shall inform to the Board accordingly.
6. HCEs shall properly dispose and handover the waste to authorised user / facilities having valid consent to operate from MPCB.

In view of above, and as per the decision of Consent Appraisal Committee, all the CCA granting authorities shall amend the combined Consent and BMW Authorization of all the HCEs of the state within 30 days by incorporating above conditions.

(Ashok Shingare, IAS)
Member Secretary

Copy submitted for information to:
The Hon'ble Chairman, MPCB Sion, Mumbai.

Copy to:
The AS(T)/PSO/JD(WPC)/JD(APC)/RO(HQ)/LO/CAO

Copy for implementation to:
The Regional Officer- Mumbai, Navi Mumbai, Raigad, Thane, Kalyan, Pune, Kolhapur, Nashik, Aurangabad, Amravati, Nagpur & Chandrapur.