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IMMEDIATE

S-12016/43/2019-NACO(NBTC)
Government of India
Ministry of Health and Family Welfare
(National Blood Transfusion Council

***

9th Floor, Chandralok Building,
36, Janpath, New Delhi-110001
Dated 1st January, 2020

OFFICE MEMORANDUM

Subject : Draft norms for sending TTI reactive blood bags by licensed Blood Banks - reg.

The undersigned is directed to refer to deliberations of 29th Meeting of Governing Body of National Body Transfusion Council (NBTC) held on 23.10.2019 and to enclose draft NBTC norms for sending TTI reactive blood bags by licensed Banks.

2. In this regard, all the stakeholders are requested to give their inputs/comments/ suggestions for finalization these norms to Dr. Srinivas C. Murthy, DD (NBTC) on his email ID srinivasc.murthy41@cghs.nic.in ***latest by 31st January, 2020.***

(DR. SHOBINI RAJAN)
Director, NBTC
Tel No. 011-23731810

1. All Members of Governing Body of NBTC
2. All Members of BTS TRG
3. All Directors State Blood Transfusion Council
4. NIC - for uploading this OM of website the Ministry
5. IEC/ IT - for uploading OM on the website of NACO / NBTC

NBTC Norms for sending TTI reactive blood bags by licensed Blood Banks

Technical Resource Group for Blood Transfusion Services under NACP reiterated that all licensed blood banks are responsible for proper disposal of such blood bags in accordance to the Biomedical Waste Management Rules.

In light of frequent requests received by licensed blood banks to send TTI reactive blood bags for purposes of research/ diagnostic kit manufacture/ quality control etc. the norms for handling such requests were circulated vide Notification number S-12016/01/2019-NACO(NBTC) dated 27th February 2019.

Further, based on the representations from Association of Diagnostic Manufacturers of India (ADMI) against point (b) of Annexure II in the, where in it is stated that "***TTI sero reactive blood bags may not be sent to any commercial private entity like kit manufacturers, diagnostic laboratories etc***" in light of Medical Device Rules, 2017 and considering the issue of non availability and access to the critical raw material to indigenous manufactures being in contravention to the "Make in India" initiative of the Government of India, the norms are reviewed and revised in supersession of previous communication as under.

General Norms:

1. Licensed Blood Banks shall be permitted to send TTI sero-reactive blood bags to identified Reference Laboratories and PT providers in the Public and Charitable sectors for the purposes of preparation of sero-conversion panels and QC panels.
2. TTI sero-reactive blood bags shall not be sent to any commercial private entity except indigenous manufacturers in accordance to norms thereof.
3. NOC for the same shall be issued by the respective State Blood Transfusion Councils after receipt of application from the concerned organization identifying blood banks who would supply the blood bags.
4. The blood bags shall be issued free of cost without levy of any processing charges thereof except in the case of indigenous manufacturers.
5. The organization receiving such blood bags shall undertake in writing to ensure disposal of the remainder infective material in accordance to the extant rules obviating the issuing blood bank of any such responsibility.
6. Records of such a transaction shall be maintained at licensed blood banks as per format prescribed by NBTC/SBTC.
7. Use of TTI reactive blood bags for the purpose of research shall be governed under the directions given by ICMR following approval of Institutional Ethics Committee.
8. All licensed blood banks would take the informed consent of the blood donors at the time of blood donation that their blood/ blood components/ products may be used for the purposes of preparation of panels, scientific research and indigenous manufacture to address all ethical concerns.

Norms specific to Indigenous manufacturers of kits and medical devices:

1) TTI sero reactive blood bags shall only be issued to indigenous manufacturers with a valid manufacturing licence from State Licensing Authority and Central License Approving Authority.
2) When the manufacturers apply for a manufacturing license, auditors from CDSCO, shall check
   - Risk management protocols
   - Records for usage, handling and disposal of infectious materialsin use, at the manufacturing facility.
   - To ensure employee health safety and environment protection.
3) That each such firm shall submit an affidavit to the licensed blood bank and copy to respective State Licensing Authority and Central License Approving Authority stating that the firm shall utilize the collected TTI sero reactive blood as a raw material for preparing IVD reagents and shall not divert the material for purposes other than IVD usage.
4) The applicants (Manufacturer/Test License holder) shall be required to submit an undertaking to the concerned blood bank, stating that they would adhere to the **Biomedical Waste Management Rules, 2016** laid down for bio hazardous materials, while collecting, transporting, storing, using and discarding such sera.
5) Blood banks shall be permitted to invoice the unused sero-reactive units to a manufacturer to compensate for some expense incurred on the unit.
6) Blood Bank shall maintain the record of the number of the blood bags given to the manufacturers and the similar records shall be kept by the manufacturers for traceability from the collection point till the manufacture of the Kits
7) The manufacturer shall hand over a receipt at the time of collection of the blood bag/s to the firm which shall clearly mention:
   a. -TTI reactive blood bag number
   b. - Number of units
   c. -Date of collection
   d. -Complete address and contact details of both parties
   e. -The same shall be signed and stamped by both parties and copies retained.
8) The manufacturer shall maintain the following records
   a. Reconciliation record of the blood collected and its usage at all times.
   b. Quantity of the antigen used for the manufacture of the kits to avoid the misuse of the TTI reactive blood bag.
9) An MoU shall be signed between the Blood Bank and the manufacturers for the above purpose.