No. 4-21/2020-I&E
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drugs Regulatory Authority of Pakistan
TF Complex, Sector G-9/4, Islamabad
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"SAY NO TO CORRUPTION"

Islamabad, the 23rd June, 2020.

Additional Director, DRAP, Lahore.	Additional Director, DRAP, Peshawar.
Officer In-charge, DRAP, Quetta.	Additional Director, DRAP, Karachi.

SUBJECT: CHECK LIST FOR NO OBJECTION CERTIFICATE FOR IMPORT OF UN-REGISTERED/NOT AVAILABLE MEDICAL DEVICE(S) UNDER MEDICAL DEVICES RULES, 2017.

Refer to subject cited above, following is the checklist required for grant of NOC:

A. Formal application for the NOC clearly stating the name and quantity of the medical device, the name of manufacturer, name of exporter (if different from manufacturer).
B. Purchase order from procurement agency including NDMA, hospital (public or private) /institution/charitable trust (registration of NGO, if applicable) clearly mentioning the name and quantity of the medical devices.
C. Proof of free sale in country of export shall be accompanied with free sale certificate or Emergency Use Authorization (EUA) (from the country of export or reference countries) or any other document which authorized officer shall deem to fulfill the purpose.
D. An undertaking on stamp paper duly notarized and signed and stamped by Proprietor or Chief Executive or Managing Director or an authorized officer (authority letter from owner of establishment) containing following conditions: -
    (i) the medical device shall not be sold or distributed in the market;
    (ii) the medical device shall be on free sale in the country of origin;
    (iii) the medical device shall be used in the hospital or institution only and not for the purpose of clinical trial, examination, test or analysis;
    (iv) clearance certificate must be obtained from assistant director, or officer authorized, of the Authority, at the time of arrival of shipment, before customs clearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified technical staff as specified in these rules; and
    (v) the medical device is not enlisted or registered or available in Pakistan.
    (vi) Certified that the documents and the information provided herein are genuine and correct and if found at any stage to be misinterpreting or incorrect it shall lead to

legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made thereunder.

E. Each page of the dossier shall be signed and stamped.

02. This issues with approval of CEO DRAP.

-sd/-
Ishtaiq Shafiq
Assistant Director, QA & LT

Copy to: -

1. PS to CEO, DRAP, Islamabad.
2. Additional Director, MIS, with request to upload on the website.
3. Additional Director, MDMC,DRAP, Islamabad.
4. Office Copy

23-06-2020
Assistant Director, QA & LT