Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
T.F. Complex, Sector G-9/4, Islamabad
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Islamabad, dated the 29th July, 2021

NOTIFICATION

F. No. 16-4/2019-MD. In supersession of earlier notification of Authority of even number dated 26th May, 2021 and in exercise of the powers conferred by the clause (c) of section 7 of the Drug Regulatory Authority of Pakistan (DRAP) Act, 2012 (XXI of 2012), the DRAP is pleased to issue the following guidelines for manufacturing of Medical Devices, by the Drug Manufacturing License (DML) Holders;

a) The manufacturers (DML holders) already manufacturing:

i. the products mentioned under Schedule-E notified vide S.R.O.526(I)/2021 dated 30th April, 2021 and dialysis solutions will be allowed to continue manufacturing in the same locations.

ii. rest of the medical devices will be given one year relaxation time line not later than 30th June, 2022, to comply with the guideline.

b) The Pharmaceutical drugs/medicines and medical devices (except the products included in Schedule E and Dialysis solution) can be manufactured in the same plot but in a separate building after the requisite regulatory approvals. In the said scenario, the same quality control laboratory can be used for both drugs and medical devices, if required.

c) All those Drug Manufacturing License (DML) holders under the Drugs (Licensing, Registering & Advertising) Rules, 1976, who are only manufacturing medical devices shall be converted to the Establishment License to Manufacture Medical Devices (ELM) under Medical Devices Rules, 2017 and MDB will grant ELM for remaining period of validity of DML issued by the Central Licensing Board and subsequently, the Central Licensing Board will cancel these licenses under intimation to Medical Devices Board (MDB).

(DR. GHAZANFAR ALI KHAN)
Additional Director
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29/7/2021