

DRUG REGULATORY AUTHORITY OF PAKISTAN

TF Complex Mauve Area G-9/4, Islamabad
www.dra.gov.pk



PRESS RELEASE

Medical Devices & Medicated Cosmetics Division

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1. After promulgation of DRAP Act, 2012, Medical Devices Rules were initially promulgated in 2015 to regulate the medical devices for first time in Pakistan. The said Rules were revisited in 2017 after consultation with stakeholders and resultantly, new rules were promulgated in 2018. Under these rules exemption period (timelines) to different classes of medical devices was provided for seamless transition to avoid any possible shortage of medical devices due to instantaneous restriction on import of medical devices with immediate implementation of said Rules. Thereafter, several importers approached Courts and got restraining orders against these Rules. Subsequently, after active follow up of DRAP, the Lahore High Court (LHC) dismissed all these petitions. Meanwhile, DRAP continued granting enlistment/registrations to a large number of applicants of medical devices.
2. However, as there are numerous medical Devices in the market, therefore it is apprehended that even after the disposal of all submitted requests for enlistments/registration with DRAP, a possible shortage may occur and lead to hampering of surgical interventions/operations, which can adversely affect health system in this crucial time of pandemic. Therefore, considering the sensitivity as well as urgency of the situation, process for amendments in the Medical Devices Rules, 2017 has been initiated and DRAP has recommended the extension in the exemption period of various classes of medical devices. Recommendations of DRAP after due process has been submitted and are expected to be placed in next Cabinet meeting for final disposal.

