

No.F.16-3/2021-MD Government of Pakistan Ministry of National Health Services, Regulations & Coordination Drug Regulatory Authority of Pakistan

Islamabad the 26th August, 2021.

Subject: ONLINE SUBMISSION OF LICENCE APPLICATIONS OF MEDICAL DEVICES

I am directed to refer to the subject cited above and to state that in line with the Government of Pakistan's initiative for ease of doing business, DRAP has developed an online system for processing of applications of establishment license to import or manufacture medical devices. The web portal is available on the home page of DRAP website (www.dra.gov.pk) under the heading of DRAP MIS System, titled MDMC Online System For Establishment of License (https://e.dra.gov.pk/login). The user guide is also available on the home page of the website.

- 2. The above mentioned portal is for new applicants as well as for renewal applications of establishment license to import or manufacture medical devices. Moreover, the firm already possessing license to import or manufacture medical devices (ELI or ELM respectively) shall also enter their particulars in the said system so that their applications for post licensing variations, enlistment/registration of their medical devices and subsequently renewal may be processed in the future.
- 3. You are, therefore, advised to direct your member companies/relevant stakeholders to compulsorily register on the above mentioned portal and submit their applications on line.

(Dr. Ghazanfar Ali Khan) Additional Director (NIDMG

Distribution:

- Chairman, Healthcare Devices Association of Pakistan.
- Chairman, Pakistan Pharmaceutical Manufacturers Association.
- 3. Executive Director, Pharma Bureau.
- President, Pakistan Medical Disposable Manufacturer Association.
- 5. Secretary, Health Department, Punjab/Sindh, KPK, Balochistan, AJK, GB.
- 6. Chief Commissioner, ICT, Islamabad.
- Additional Director, DRAP, Lahore/Karachi/Peshawar.
- Additional Director (QA<), DRAP, Islamabad.
- Officer Incharge, DRAP, Quetta.

Copy to:-

- 1. P.S to CEO, DRAP, Islamabad.
- Section Officer (Admn-II), M/o National Health Services, Regulations & Coordination, 3rd Floor, Kohsar Block, Pak Secretariat, Islamabad.
- Deputy Director (PRMI), Prime Minister's Office, Board of Investment, 6th Floor, Kohsar Block, Pak Secretariat, Islamabad.