F. No.6-2/2025-MD
Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
Division of MD&MC
*****

Islamabad, the 18th July, 2025

CIRCULAR

ATTENTION: ALL MANUFACTURERS AND IMPORTERS OF MEDICAL DEVICES

Subject: - **DISPOSAL OF SUBMITTED APPLICATIONS OF MEDICAL DEVICES.**

It is in continuation to this officer letter of even no dated 27th February 2025, and to inform that MDMC Division, DRAP has addressed the medical device applications submitted till 30th April 2025. The decisions of the applications have been uploaded on the official website of DRAP (*dra.gov.pk)>Publications>Minutes of meeting>Medical Device Board*.

2. In line with DRAP's vision to promote transparency, ease of doing business, and advancing regulatory reforms through digital transformation, DRAP is set to launch the MDMC **Licensing & Product Registration Portal** with effect from 21st July 2025. It has been informed by Health Care Devices Association of Pakistan (HDAP) that despite DRAP's comprehensive efforts to clear the backlog of these manual submissions a limited number of applications are still pending. Therefore, to ensure complete resolution of these pending cases not considered in Medical Device Board submitted till 30th April 2025, stakeholders and applicants are hereby once again directed to submit (within 30 days of issuance of this letter) data/soft dossier on E-App portal of DRAP (***https://eapp.dra.gov.pk/***) accompanied by authentic and verifiable proof of original submission (DRAP's R&I) as per procedure given in Annex-I (procedure) and Annex-II (format for class A, B, C & D products) for quick disposal of the applications.

3. Your cooperation in this matter is crucial for the efficient conclusion of this transitional phase.

4. This is issued with the approval of the CEO, DRAP.

18/07/2025

(Mr. Asif Jalil)
Additional Director (MD&MC)

Distribution:

1. Healthcare Devices Association of Pakistan (HDAP).
2. Pakistan Electro-Medical Equipment Manufacture and Distribution Association

Copy for information to: -

1. PS to CEO, DRAP, Islamabad.
2. Director (MD&MC), DRAP, Islamabad.
3. Director MIS (with the request to upload on the official website of DRAP).
4. Office Copy

Annex-I

Procedure to submit data for already submitted applications of Medical Devices

Step 1. Login to e-application portal of DRAP

Step.2 Go to Case Management (Query Form)

Step.3 Select the Medical Devices from the Division drop down options.

Step. 4 Read the instructions in the pop up massage box before further processing.

Step. 5 Select class A/B/C/D documents in functions drop down option

Step.6 write the subject matter and place the filled table in the cover note portion

Step.7 Upload the documents using the drop box options

Sgep.8 Enter the data of the product as per Format given in Annex-II.

Annex-II

AGENDA FORMAT FOR CLASS A MEDICAL DEVICES

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Brief Description	Remarks
1.	M/s ---------- ELI-00000 R&I Details dd/mm/yyyy Fee Challan No..... dated	Legal Manufacture: (Name & Address) Manufacturing Site(s): (Name & Address) FSC Validity: dd/mm/yy LOA Validity: dd/mm/yy	Brand Name (Generic Name) Class A Shelf life: Codes/Sizes (if any)		

AGENDA FORMAT FOR CLASS B,C&D MEDICAL DEVICES

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Brief Description	Remarks
2.	M/s ---------- ELI-00000 R&I Details dd/mm/yyyy Fee Challan No.....dated....	**Legal Manufacture** (Name & Address) **Manufacturing Site (s)**: (Name & Address) **LOA**: Validity: 00-00-20-- **FSC**: Country of Origin Validity: 00-00-20— **FSC**: FSC of **Reference** Country (as mentioned in rule, 67) Validity: 00-00-20— OR **EC Certificate**: Validity: 00-00-20— OR **WHO PQ** (verifiable from the official WHO site) **ISO 13485**: Validity: 00-00-20--	Brand Name (Generic Name) Class B Shelf life: 00 Years Codes/Sizes (if any) Provide complete details in case of cluster		