



Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
(P E & R Division)

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"SAY NO TO CORRUPTION"

No.F.76-DRAP/2020 (PE&R)

Islamabad, the 04th June, 2020

CIRCULAR

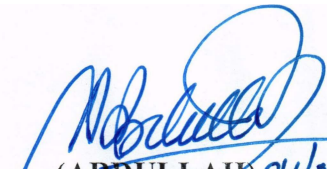
Subject: **PRIORITY APPROVAL / REGISTRATION OF DRUGS DURING THE COVID-19 PANDEMIC.**

In continuation of this Authority's Circulars of even number dated 06th April, 30th April & 5th May, 2020 respectively on the subject captioned above and to inform that Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 has discussed priority registration/emergency use authorization of Remdesivir and Tocilizumab for use in Covid-19 patients and decided for registration of **Remdesivir and Tocilizumab** in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

- The applicants can submit their applications till 31-07-2020 and these applications will be considered out of queue.
- Registration Board shall consider grant of registration under proviso of Rules 29(6) (8) of the Drug (Licensing, Registration & Advertising) Rules, 1976 and shall follow precautions/terms & conditions as adopted by the Reference Regulatory Authorities.
- The registration holders including those granted registration under Form 5-D as a new drug will submit data of product development and 6 months real time stability studies data within one year along-with other data as may be required by Registration Board. The data will be considered by Registration Board for further decision.

2. The Authority further extended the time lines till **31-07-2020** for submission of registration applications on Form 5/Form 5-A/ Form 5-D for molecules already approved by the Authority for the management of Covid-19.

3. Accordingly, above decision of DRAP is hereby circulated for information of all pharmaceutical manufacturers/importers.


(ABDULLAH) 04/06/20
Additional Director (PE&R)

Distribution:

- Chairman, Pakistan Pharmaceutical Manufacturers Association. Islamabad.
- Executive Director, Pharma Bureau, Karachi.
- Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
- ✓ iv. Additional Director, MIS Division, for uploading on DRAP's website.

Copy for information to:

- PS to Chief Executive Officer, DRAP.
- APS to Director, PE&R, DRAP.