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 06th July, 2020

CIRCULAR

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

In continuation of this Authority's earlier Circulars of even number dated 6th April, 30th April, 5th May & 4th June, 2020 respectively on the subject captioned above and to inform you that Drug Regulatory Authority of Pakistan in its 85th meeting held on 09th June, 2020 discussed **Favipiravir** use in COVID-19 management by countries like China, Russia & Saudi Arabia and further its approval in Japan as antiviral against influenza viruses. Keeping in view the current outbreak of COVlD-19, the Authority allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form SF for registration of **Favipiravir** with following additional conditions:

a. The applicants can submit their applications till 31-07-2020 and these applications will be considered out of queue.
b. 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.
c. 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.

6-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.

7-Accordingly, above decision of DRAP 1s hereby circulated for information of all pharmaceutical manufacturers/importers.

(ABDULLAH)
Additional Director (PE&R)

Distribution: -

i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.

Copy for information to:

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