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 COVID-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 is hereby circulated for information of all pharmaceutical manufacturers/importers.

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.