



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 06<sup>th</sup> July, 2020

**CIRCULAR**

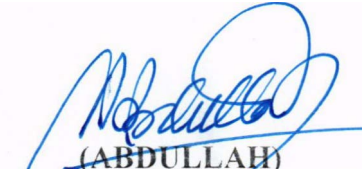
Subject: **PRIORITY APPROVAL / REGISTRATION OF DRUGS DURING THE COVID-19 PANDEMIC.**

In continuation of this Authority's earlier Circulars of even number dated 6<sup>th</sup> April, 30<sup>th</sup> April, 5<sup>th</sup> May & 4<sup>th</sup> June, 2020 respectively on the subject captioned above and to inform you that Drug Regulatory Authority of Pakistan in its 85<sup>th</sup> meeting held on 09<sup>th</sup> 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.

  
(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.