

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

“SAY NO TO CORRUPTION”

No.F.1-21/2019-Add:Dir.(PE&R)

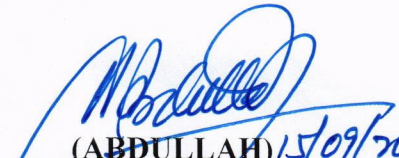
Islamabad, the 15th September, 2020

CIRCULAR

Subject: **FAST TRACK REGISTRATION OF FLUDROCORTISONE.**

Drug Regulatory Authority of Pakistan (DRAP) in its 91st meeting held on 4th September, 2020 discussed the issue of unavailability of Fludrocortisone Tablets (for Congenital Adrenal Hyperplasia) in Pakistan as highlighted by Pakistan Citizen's Portal and others. Accordingly, the Authority exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018 allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5-F, for registration of Fludrocortisone tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions;

- i. The applicants can submit their applications **till 30-09-2020** and these applications will be considered out of queue.
 - ii. Registration Board may consider grant of registration and submission of data of product development and 6 months accelerated & 6 months real time stability studies data before sale of product along with other data as may be required.
2. Accordingly, above decision of DRAP is hereby circulated for information of all pharmaceutical manufacturers/importers.


(ABDULLAH) 15/09/2020
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.
- ✓ iv. Director, MIS Division, with the request to upload on DRAP's website.

Copy for information to: -

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