

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan
(Division of Biological Evaluation & Research)

◇◇◇◇
"SAY NO TO CORRUPTION"

No.F.1-28/2020-AD(BD)

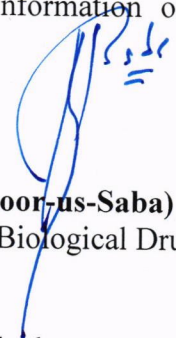
Islamabad, the ^{25th} January, 2021

CIRCULAR

Subject: **EMERGENCY USE AUTHORIZATION FOR COVID-19 VACCINES**

Please refer to the subject cited above; Drug Regulatory Authority of Pakistan in its 101st meeting held on 06-01-2021 has discussed emergency use authorization of COVID-19 vaccines and decided for registration of **COVID-19 Vaccines** in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

- i. The applicants can submit application till 06-06-2021 and these applications of COVID-19 vaccines will be considered out of queue.
 - ii. Registration Board shall consider grant of Emergency Use Authorization 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.
 - iii. The authorization holders including those granted authorization 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 granted the permission till **06-06-2021** for submission of registration applications on Form 5/Form 5-A/ Form 5-D instead of Form 5-F for COVID-19 Vaccines.
3. Accordingly, above decision of DRAP is hereby circulated for information of all manufacturers/importers.


(Dr. Noor-us-Saba)
Director, Biological Drugs

Distribution: -

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

Copy for information to: -

- ✓ 1. PS to Chief Executive Officer, DRAP Islamabad.
2. Chairman Registration Board, DRAP Islamabad.