Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan

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"SAY NO TO CORRUPTION"

No.F.1-11/2019- AD (BD) Islamabad, the 25th January, 2021

OFFICE MEMORANDUM

Subject: - **INTIMATION OF DRUG REGULATORY AUTHORITY'S DECISION ON STEM CELLS**

It is clarified that as per Schedule-I(1)(d) of DRAP Act 2012, the stem cells are biological therapeutic goods. This clarification is issued in light of 73rd meeting of DRAP Authority held on 6th November, 2019 wherein following decision was made;

i. *The division process the case for clarification that stem cells are biological therapeutic drugs as per Schedule-I(1)(d) of DRAP Act 2012 and*
ii. *Finished product containing stem cells will follow same pathway of approval/ registration as for other biological products.*

2. Therefore, the applications for registration of stem cells should be submitted in BE&R division of DRAP.

3. This issues with the approval of Competent Authority i.e. CEO DRAP.

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Dr. Noor-us-Saba
Director, Biological Drugs

1. Chairman, Pakistan Pharmaceutical Manufacturer Association (PPMA), PPMA House, House No.474, Street No.34, Sector I-8/2, Islamabad.
2. Executive Director, Pharma Bureau, Chamber of Commerce & Industries Building, Talpur Road, Karachi.
3. Executive Director, Pakistan Chemist & Druggists Association (PCDA), 504, 4th Floor Mashriq Centre, Near Civic Centre, Gulsha-e-Iqbal, Block-14, Karachi.

Copy to:

1. P.S to CEO, DRAP.
2. Chairman Registration Board, Islamabad.
3. Director QA & LT DRAP, Islamabad for onward communication to DRAP sub offices to inform all importers and manufacturers of biological products in their area of jurisdiction.
4. Director MIS for uploading of the above decision of the Authority on official website of DRAP.
5. Office/ Master folder.

Director, Biological Drugs