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भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
महानिदेशालय, के० स० स्वा० यो०
निर्माण भवन, मौलाना आज़ाद रोड, नई दिल्ली
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Dated: 08-02-2023

कार्यालय ज्ञापन/ OFFICE MEMORANDUM

Subject: Policy on Bio-similar medicines in CGHS for purpose of procurement and issue to CGHS Beneficiaries

The Central Drug Standard Control Organization's (CDSCO) Biological Division is the regulatory authority for approval of drugs in India, and issues guidelines of bio-similar medicine/drugs. The guidelines define biosimilar as "*a similar biologic product which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability*".

Therefore, it has been decided that, for the purpose of procurement & issue to CGHS beneficiaries, the bio-similar medicine shall be at par with the reference authorized biologic/original biologic molecule/formulation of biologic medicine on the lines of guideline issued by CDSCO in this regard.

Signed by Anjana Rajkumar

Date: 08-02-2023 14:40:01

Reason: Approved

(डॉ. अंजना राजकुमार)

Director CGHS

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Copy of information to:

1. PPS to Hon'ble HFM
2. PPS to SS & DG CGHS
3. PS to JS CGHS
4. Director Policy, 9th Floor, Chanderlok Building, Janpath, New Delhi
5. ADDG, Nirman Bhawan
6. The Additional Director (HQ), CGHS Bhawan, R.K.Puram Sector 13, Delhi
7. The Additional Director All cities (as per standard list)
8. The Additional Director (MSD), Udyan Marg, New Delhi
9. The Additional Director Zones, Delhi (North, South, East, Central)
10. The Additional Director (R&H), CGHS Bhawan, R.K.Puram Sector 13, Delhi
11. Nodal Officer, MCTC, CGHS with the request to upload the document on the CGHS Website

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