

No. 31011/ 3 /2017-Policy
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
(Policy Section)

Shastri Bhawan, New Delhi,
Dated, the 31st March, 2017

OFFICE MEMORANDUM

Subject:-Committee for ensuring enhanced accessibility of Drugs to the poor-regarding.

Medicines constitute a major portion of the high out of pocket expense of a patient. Due to soaring prices of medicines, the Drugs (Display of Prices) Order 1962 and the Drugs (Control of Prices) Order 1963 were promulgated under the Defence of India Act to bring the prices of drugs under statutory control for the first time by Government of India in the wake of the Chinese aggression and the declaration of emergency in 1962. These orders had the effect of freezing the prices of drugs as on 1st April 1963. Thereafter, from 1970 onwards, price control orders have been issued under the Essential Commodities Act, 1955 from time to time (in 1979, 1987 and 1995)

2. In 2012, Government notified the National Pharmaceutical Pricing Policy, 2012 with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of Pharma Industry, thereby meeting the goals of employment and shared economic well-being for all. Subsequently, the Drugs (Prices Control) Order, 2013 was notified by the government on 15.05.2013. The DPCO-2013 inter-alia provides that ceiling price(s) for the medicine(s) added in the First Schedule (of DPCO-2013) shall be fixed in accordance with the DPCO-2013. NPPA has fixed the ceiling prices of 835 Drugs (upto 24.03.2017) under these provisions.

3. The Department has received various requests/representations including from the National Pharmaceutical Pricing Authority (NPPA), the Pharma Industry Associations and other stake holders suggesting improvements in the provisions of DPCO-2013 based on the experience gained during its implementation.

4. In the light of these representations and to further improve the availability, affordability and accessibility of drugs for the domestic patients, the Government in the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers has decided to constitute a group consisting of the following members:-

- (i) Joint Secretary (Policy), D/o Pharmaceuticals
- (ii) Joint Secretary (NIPER & PSU), D/o Pharmaceuticals
- (iii) Joint Secretary, Ministry of Health & Family Welfare
- (iv) Joint Secretary & Member Secretary, National Pharmaceutical Pricing Authority(NPPA)
- (v) Drugs Controller General of India (DCGI)
- (vi) Executive Director, National Health System Resource Centre (NHSRC)

to recommend to the Government further steps in this regard.

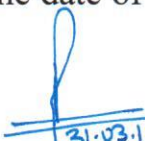
Director (Policy), D/o Pharmaceuticals shall be the Convener of the group.

5. The Group will submit its recommendations on:-

- i. Measures to be taken for making pricing policy more in favour of poor patient's affordable Medicare and Health Security;
- ii. Review the scope of the Drugs (Price Control) Order, 2013 (DPCO, 2013), and to suggest ways for strengthening the regulatory provisions of the order;
- iii. Suggest ways for making the existing mechanisms for collection of market-based data on prices of medicines more robust and streamlined and for strengthening the existing pharmaceutical database management system.

- iv. Procedural improvements and process re-engineering in NPPA to ensure better and quicker implementation of Government Policy (Drug Price Control Order) and bring greater transparency so as to reduce litigations and review petitions. Draft detailed Standard Operating Protocol (SOPs) may be recommended for identified regulatory functions such as pricing of medicines, monitoring and enforcement activities, action against pharmaceutical companies in overpricing cases etc.;
- v. Suggest ways to make DPCO, 2013 more comprehensive in light of past experience of implementing DPCO.
- vi. The Group may also consult other Government agencies, officials or representatives of industry or civil society in the interest of a more effective DPCO.

6. The Group will submit its report within six weeks from the date of its constitution.


(Raj Kumar)

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To,

Joint Secretary (SP), DoP
Joint Secretary (RT), DoP
Joint Secretary & Member Secretary (NPPA)
Joint Secretary, Ministry of Health & Family Welfare
Drugs Controller General of India (DCGI)
Executive Director (National Health System resource Centre)
Director (Policy), DoP

Copy to Director (NIC) DoP with the request to upload the same on the DoP's website

Copy for information:

PS to M (C&F)/PS to MoS (C&F)/PS to Secretary (Pharma)/PS to Secretary(H&FW)/PS to Chairman (NPPA)