

F.No.31015/14/2017-Pricing
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
(Pricing Section)

Room No. 340B, A-Wing, Shastri Bhawan,
New Delhi, dated the 30.11.2017

Order

Sub:- Constitution of a Committee of Experts - regarding

In view of the experience gained from implementation of Drugs (Prices Control) Order, 2013 (DPCO, 2013), it has been decided to constitute a single multi-disciplinary "Committee of Experts" by the Government as envisaged by two different nomenclature i.e. Standing Committee of Experts under para 5(2) (i) & para 15(1) and the Committee of Experts under para 11(4) to discharge the functions under DPCO, 2013 for consultation on all technical issues related to pricing, launch of new drugs along with other ancillary provisions where more clarity may be required, and opine on matters referred to it by the National Pharmaceutical Pricing Authority (NPPA) in discharge of its functions.

2. The Committee of Experts shall comprise of the following members:-

- (i) Member Secretary, National Pharmaceutical Pricing Authority (NPPA)- **Convener**;
- (ii) Representative (Scientist/Expert) from Central Drugs Standard Control Organization (CDSCO) (Subject matter expert) not below the rank of Dy. DCGI - **Member**;
- (iii) Representative (Scientist/Expert) from the Department of Health Research (DHR)/Indian Council of Medical Research (ICMR) (Subject matter expert) not below the rank of Deputy Secretary or equivalent – **Member**;
- (iv) Representative (Pharmacoeconomics expert) from NIPER (to be nominated by DoP). – **Member**;

3. The above said Committee would be empowered to invite or co-opt any other specialist (like Medical Devices) depending on exigencies of the circumstances requiring resolution of any specific matter arising out of implementation of various provisions of DPCO, 2013, as and when it may be required.

4. The Terms of Reference (TOR) of the Committee shall be as under:-

- (a) To deliberate and recommend its opinion on the claims of pharma companies about additional therapeutic features associated with any formulation including in terms of Para 11 (3) of DPCO, 2013 and recommending separate ceiling price of scheduled formulations or retail price of a new drug with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation;
- (b) To deliberate, interpret and recommend its opinion on the claims of pharma companies about additional Pharmacoeconomics features associated with any formulation/API including in terms of Para 15 (1) of DPCO, 2013;

(c) To deliberate, interpret and recommend its opinion on the technical related issues whether the drug is scheduled or non-scheduled on the basis of ingredients used in the formulation;

(d) To deliberate, interpret and recommend its opinion on the claims of pharma companies about novelty associated with indigenous R&D content passed through the development process of relevant API/formulation; and recommend exemption from the application of provisions of para 32 of DPCO, 2013 for a period of five years.

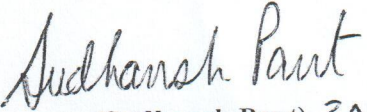
(e) To discuss any other issue referred to the Committee of Experts concerning technical matters involved in disposing of any issue raised by any stakeholder.

5. NPPA shall decide and refer the relevant issues within 4 weeks of receiving the applications, to the Committee for its opinion.

6. The Committee shall submit its report with its findings and opinion in each case within a period of 4 weeks.

7. The recommendations of this committee shall be considered by the NPPA which shall pass a reasoned order within 4 weeks from receiving the recommendations of the Committee, deciding the issue(s) in hand finally.

8. This issues with the approval of Hon'ble Minister (C&F).


(Sudhansh Pant) 30/11/2017
Joint Secretary
Department of Pharmaceuticals

Copy to:-

1. Secretary, Department of Health Research/DG, ICMR, Nirman Bhawan, New Delhi - with the request to nominate an expert to represent your Department.

2. Chairman, NPPA, 3rd/5th Floor, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi.

3. Dr. G.N. Singh, Drugs Controller General (India), Ministry of Health & Family Welfare, FDA Bhawan, ITO, Kotla Road, New Delhi - with the request to nominate an expert to represent your organisation.

4. Joint Secretary (NIPER) - with the request to nominate a Pharmacoeconomics expert as representative of DoP from NIPER.

Copy for information to:-

(i) PS to Minister (Chemicals & Fertilizers)

(ii) PS to Minister of State (Chemicals & Fertilizers)

(iii) Secretary, Department of Pharmaceuticals.