National Pharmaceutical Pricing Authority

Sub: Internal Guidelines on fixation/revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO, 2013.

(Approved by the Authority in its 147th Meeting held on 16.05.2014)

In exercise of the powers conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394 (E) dated the 30th May, 2013, NPPA is empowered to fix/revise the ceiling or retail prices of both scheduled and non-scheduled formulations under certain circumstances, in public interest. Accordingly, ceiling prices / retail prices of formulations shall have to be fixed / revised by the NPPA in pursuance of paragraph 19 of DPCO, 2013. In this connection, NPPA could also cause enquiry, call for information as the case may be and fix / revise the prices of scheduled formulations, non-scheduled formulations and 'new drugs' if considered necessary so to do in public interest.

2. In order to have an uniform policy for price fixation / revision under para 19 of DPCO, 2013, the Authority in its meeting held on 16.05.2014 has decided that the following guidelines will be followed in this regard:-

(a) NPPA will monitor 'inter-brand price differences' of non-scheduled formulations on the basis of monthly MRP based data provided by the IMS-Health. To begin with, this exercise of monitoring of 'inter-brand price difference' will be carried out in respect of single ingredient formulations/medicines used for anti-cancer, HIV medicines, anti-tuberculosis, anti-malaria, cardiovascular, anti-diabetics, anti-asthmatic; Immunologicals (sera/vaccines) etc. From the data obtained from IMS-Health, NPPA would identify the cases where the MRP of the price of brand(s) exceeds 25% of the simple average price of the medicines in that group. Monitoring Division after verification of the data / MRP reported by the IMS-Health will initiate the case for price fixation under paragraph 19 of DPCO, 2013.

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(The Authority also decided that the guidelines for therapeutic groups indicated above may be extended to other therapeutic groups also if required and in this regard Drugs Controller General (India) and State Drugs Controllers will also be requested to identify any other therapeutic groups / diseases to be covered under the guidelines).

(b) As there is no control on the launch price of non-scheduled formulations under DPCO, 2013, for the therapeutic groups specified in para (a) above, Monitoring Division of the NPPA will monitor the prices of these single ingredient formulations launched by the manufacturers for the first time on the basis of monthly MRP based data of IMS-Health. Wherever prices of such formulation packs are found to be more than the price of highest price brand, Monitoring Division will initiate price fixation of those packs to reduce to the level of existing highest price brand under para 19 of DPCO, 2013.

(c) The cases of shortages of scheduled and non-scheduled formulations reported by the SDCs / Governments may be examined, on case to case basis, for price fixation / revision under para 19 of DPCO, 2013.

(d) In respect of cases lying sub-judice in various courts, appropriate action will be considered by NPPA depending upon the directions / order / judgment passed by the Hon'ble courts in such cases.

3. The above guideline shall be put in place prospectively and all the cases under examination shall be processed as per these revised guidelines.

(Jagdish Kumar)
Director (M&E)
29.05.2014