



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Regulatory Affairs Division (RAD), IPA



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Editorial

Recent controversy regarding fixing of price of medicines not included in the National Essential Medicines List 2011 (NLEM 2011) is a whistleblower to the policy makers. NPPA exerted its power as per the provision of Paragraph 19 of DPCO 2013, which authorizes the NPPA "in extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it deems fit". Recent withdrawal of the internal guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014 vide notification dated 22.09.2014 by NPPA has created apprehension that price of medicines will be out of control and emergency medicines especially antiretroviral, anticancer, antidiabetic, cardiovascular, anti TB etc. will be out of reach of the patients.

This situation cropped up due to the several reasons-

Firstly the EML which was prepared in the year of 2011 is not updated, as a result some other strength or dosage form of the existing medicines left out. Some more drugs showed more efficacy over the existing medicines and being prescribed by the doctors frequently are not included in the existing EML.

Secondly it is a tendency of a sector of manufacturers to manufacture and promote medicines in the strength & dosage form not been included in the existing EML to avoid price control. This situation can be avoided by regular updating the NLEM like WHO, who updated the list every two years and strict enforcement of EML. Judicious approval of new strength and dosage form of the medicines already included in the existing EML and restricting aggressive marketing of medicines having no or least therapeutic advantage could be an effective measure.

The recent decision of withdrawal of the internal guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014 vide notification dated 22.09.2014 by NPPA has created strong reaction amongst the health care providers, who are apprehending uncontrolled price hike of the emergency medicines.

*Dr. Subhash C. Mandal
Editor*

Internal Guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014

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.

(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

Withdrawal of the Internal Guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014 vide notification dated 22.09.2014

F. No.23(01)/2014/Div-III(M&E)/NPPA

National Pharmaceutical Pricing Authority

Dated 22nd September, 2014

Sub: Internal Guidelines on fixation / revision of prices of scheduled and non-scheduled formulations under paragraph 19 of DPCO, 2013 dated 29.05.2014....reg.

In compliance with the directions received from the Government in the Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers vide letter no.31026/53/2014-PI-II dated 19.09.2014, the aforesaid internal guidelines issued by the NPPA on 29.05.2014 under paragraph 19 of the DPCO, 2013 are hereby withdrawn with immediate effect.


(Jagdish Kumar)
Director (M&E)
22.09.2014

NPPA develops IPDMS to create mechanism of obtaining market-based data related to drugs

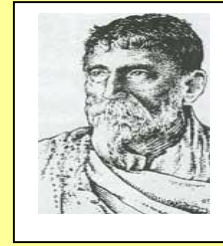
With the objective of creating an appropriate mechanism of obtaining market-based data related to drugs, the NPPA in collaboration with the National Informatics Centre (NIC) has developed the Ingredient Pharmaceutical Database Management System (IPDMS), which is aimed at facilitating on-line submission of mandatory returns/reports under the DPCO, 2013 by manufacturers as defined under 2(1) (n) of the DPCO, 2013.

The NPPA has now asked all the pharma companies in the country to register themselves under IPDMS for online filing of returns in Form II, III and V under DPCO 2013. "The above mentioned reporting obligation on the manufacturers is a legal obligation, which they are required to carry out with full and correct disclosure of information in a timely manner at prescribed intervals. Any default in reporting would be deemed to be an act of contravention of the DPCO 2013 and therefore, attract penalties under the Essential Commodities Act, 1955", an NPPA order said.

For details: Pharmabiz.com

Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2014 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3rd week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.



IPA, Bengal Branch Executive Committee select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy.

Any member of IPA can recommend name of the person with their detailed Bio-data and Two Page summary of the Bio data for 2014 award, which may be sent by 15th October 2014 to:

The Hony. Secretary,
Indian Pharmaceutical Association, Bengal Branch,
22 B Panchanontola Road,
Kolkata – 700029
e-mail: ipabengalbranchn@gmail.com

N.B.: Biodata should include the following points-

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
 - a. Whether member of IPA? If yes, how many years?
 - b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
 - a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
 - b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.