What's New **24.11.2017**

Guidelines for examination of cases of launch of 'New Drugs' by Pharma companies without obtaining prior price approval as required under the DPCO 2013

NPPA has decided to follow a standard and uniform procedure as discussed in the paragraphs given hereunder, in respect of cases of launch of new drugs without prior price approval(WPA).

Earlier NPPA had issued Office memorandum dated 17.05.2017 and 26.05.2017 to communicate identification of formulation (new drug) launched by Pharma companies on the basis of market data (Pharmatrac) without following the provisions contained in the Drugs (Price Control) Order, 2013.

NPPA has issued Show Cause notices to Pharma companies to submit reply with requisite documents even for such Formulations which were launched by them well before implementation of DPCO 2013 as well as for the formulations which are launched by pharma companies after retail price approval of 'new drug'.

During the course of examination of replies submitted by various companies, NPPA has observed that the pharma companies have not submitted the requisite document(s) to support their contention.

WPA cases will be dropped in the following cases and the company will be duly informed:

(a) The company produces evidence (license issued by State Drug Controller (SDC) / Drug Controller General (India) (DCG(I)) and invoices and samples prior to 15th May 2013, certified by Chartered Accountant (CA)/ Cost Accountant(CMA) in support of the claim that the formulation was launched before the DPCO 2013 came into force;

(b) If AIOCD-Pharmatrac data confirm that the formulation was launched prior to 15th May 2013.

(c) If the company claims and produces sufficient evidence to support the claim that the formulation does not come under the definition of a "new drug" under paragraph 2 (u) of the DPCO 2013, i.e.

(i) either the Company is not an "existing manufacturer" of the Scheduled formulation: or
(ii) none of the components of the formulation is under Schedule I of the DPCO 2013 as amended from time to time.

(d) The Company claims are duly supported with sufficient evidence i.e. samples and invoices the the formulation is a scheduled formulation and the ceiling price is complied therewith and followed in accordance with provisions of the DPCO 2013.

(e) The Company's claim that the formulation was never manufactured/ marketed by it is confirmed by AIOCD -Pharmatrac.

(f) The Company has changed only the pack size and launched the new pack size (i) at a price equal or less than the pro rata price of the previous pack size, or (ii) the increase in pro rata price if any taken by the company is in conformity with the provisions of paragraph 20(1) of DPCO 2013.

The Company will be required to submit evidence (licence issued by SDC/ DCG(I) , Invoice and sample, duly certified by CA/CMAregarding the previous and the existing pack size of concerned formulation manufactured / marketed by it.

(g) The Company has launched the new brand having same composition as in earlier brand with a different brand name (i) at the price equal to or less than that of the earlier brand, or (ii) the increase in price taken by the company is in conformity with the provisions of paragraph 20(1) of DPCO 2013.

The Company will be required to submit evidence (licence issued by SDC/ DCG(I), and invoice and sample, duly certified by CA/CMA regarding the previous and the existing brand of concerned formulation manufactured / marketed by it.

(h) In cases where the brand has been procured / re- launched under a different name by another Company post - DPCO 2013, keeping the same composition of the formulation concerned as in the earlier brand (i) at the price equal to or less than that of the earlier brand, or (ii) the increase in price taken by the company is in conformity with the provisions of paragraph 20(1) of DPCO 2013.

The Company will be required to submit evidence (licence issued by SDC/ DCG(I), and invoice and sample, duly certified by CA/CMA regarding the previous and the existing brand manufactured / marketed by it.

Any WPA case not coming under any of the above categories will be referred for price fixation and after fixing the price concerned companies shall be liable to deposit overcharged amount alogwith interest from the date of overcharge, in addition to penalty, as per provisions of paragraph 15 of the DPCO 2013.

NPPA has instructed Companies to submit the complete and requisite documents as stipulated above. Companies are advised to check 'new drug', if any, has been launched by them and obtain requisite price approval after complying with IPDMS requirements by submitting Form I prescribed in Schedule II of DPCO 2013, along with the documents as required by NPPA vide O.M.No. 19(78)/2014/Div.II/NPPA dated 07.02.2017 and O.M.No. 19(78)/2014/DP/NPPA/Div II dated 01.05.2017, if not done earlier.

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