



# Drug Information Bulletin

*Drug Information Centre (DIC)*

Indian Pharmaceutical Association

Bengal Branch

Tele fax: 033 24612776, E-mail: [ipabengal.dic@gmail.com](mailto:ipabengal.dic@gmail.com)

Web Site: <http://www.ipabengal.org>

Contact: 09830136291

&

**Regulatory Affairs Division (RAD), IPA**

**Volume: 13**

**Number: 07**

**30<sup>th</sup> June 2019**

## Content

- **Editorial**
- **Indian Govt. is going to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to specify the medicines to be supplied by RMP to their patients as decided in the last DCC meeting**
- **The Department of Health & Human Services (HHS) of US proposal to lower drug prices**
- **NPPA fixes retail prices of 17 formulations under DPCO 2013**
- **Finance ministry opines that additional discount given by a company to a dealer will attract GST**
- **CDSCO, Govt. of India issued an advisory on active participation of Pharmaceutical and Bio-Pharmaceutical manufacturing units in the Recognition of Prior Learning with Best-in-Class Employers (RPL-BICE) under Pradhan Mantri Kaushal Yojana (PMKVY) 2016-20 on 25<sup>th</sup> June**
- **Forthcoming Event**

## Editorial

*The long pending demand of pharmacy professionals for inclusion of Pharmacy subjects in the Indian Administrative Examination (IAS) has been ignored by the concerned authority, creating dissension amongst the pharmacy community.*

*In India most of the students pursuing professional courses like Medical, Engineering courses are getting an advantage in the examination to be qualified for IAS. Pharmacy students are not getting this advantage as Pharmacy subjects are not included in the said examination. Resolutions have been taken in this respect on several occasions by the IPCA in the past but result is yet to be positive. Similar situation is prevailing in case of examination for selecting Patent Examiners in which Pharmacy subject is not included though thirteen subjects like -Chemistry, Chemical Engineering, Electric Engineering have been included. It may be noted that patent application on Pharmaceuticals have a major share on the total number of patent application in India. This issue has been raised by a certain quarter before the concerned authority but no positive results are yet visible. In India most of the decisions are taken and executed by the bureaucrats, where the opinions of the technocrats are mostly ignored, absence of bureaucrats with pharmaceutical background is a disadvantage in taking decision in the matter of Pharmaceuticals.*

*These are two issues amongst several such that are deterrent to the development of the profession in our country. Policy makers require think over proper utilization of the huge manpower in pharmaceutical profession in India.*

*IPA is trying its best by submitting memorandum to the concerned authorities and trying to pursue the matter continuously, but expected result is yet to be achieved.*

*Therefore, it is high time for taking up these issues by all of the pharmaceutical professional organizations jointly.*



**Dr. Subhash C. Mandal**  
Editor

E mail: [subhash.mandaldr@gmail.com](mailto:subhash.mandaldr@gmail.com)

Mob. 9830136291

## **Indian Govt. is going to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to specify the medicines to be supplied by RMP to their patients as decided in the last DCC meeting**

DCC was apprised that Registered Medical Practitioners (RMP) can supply different categories of medicines including vaccines to their patients as per the exemption provided with certain conditions under Schedule K of the Drugs and Cosmetics Rules, 1945. Currently, there is no specific category which can be supplied by RMP to their patients. It is proposed that, the following additional conditions may be incorporated under the conditions of exemption to prevent the misuse of the exemption:

1. The Registered Medical Practitioner shall supply generic medicines only.
  2. The Registered Medical Practitioners shall supply the 'Physicians Samples' at free of cost.
- DCC deliberated the proposal and agreed to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to specify the medicines to be supplied by RMP to their patients.

## **The Department of Health and Human Services (HHS) of US send proposal to lower drug prices**

The Department of Health and Human Services (HHS) of US sent to the White House for review a proposal to lower certain drug prices in Medicare by linking them to the lower prices paid in other countries, an idea called the international pricing index. Trump unveiled the original proposal in October, but it was in the early stages then, with several more steps in the regulatory process. There has been some speculation that the administration would never actually finalize the rule, and was simply using it as a bargaining chip to push for other drug pricing changes.

But the move to send the proposal to the White House for review, along with supportive comments from HHS Secretary Alex Azar on Friday, indicate the idea is at least moving forward.

It is unclear how long the process of White House review will take, and whether the White House will seek to make significant changes to the proposal. The idea, which is a sharp departure from traditional free-market GOP thinking on

drug prices, has drawn opposition from some congressional Republicans.

The pharmaceutical industry, a powerful force in Washington, is also fiercely opposed to the idea.

Source: The Hill

## **NPPA fixes retail prices of 17 formulations under DPCO 2013**

The national drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices of 17 formulations under Drugs Prices Control Order (DPCO)- 2013 in related notification dated June 26, 2019.

Name of the formulations are tacrolimus ointment (Mylimus 0.1% 10gm), tacrolimus ointment (Mylimus 0.1% 20gm), amoxicillin +potassium clavulanate suspension, atorvastatin +clopidogrel capsule, atorvastatin +vitamin d3 tablet, olmesartan medoxomil +amlodipine +chlorthalidone tablet, rosuvastatin + aspirin + clopidogrel capsule, paracetamol + mefenamic acid suspension, clopidogrel +aspirin tablet, tetanus toxoid, ibuprofen, etc.

All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services taxes applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price as specified plus goods and services taxes applicable, if any.

All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price as specified plus goods and services taxes applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013. The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price specified.

The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of notification as per paragraph 24 of

the DPCO, 2013 to NPPA through IPDMS and submit a copy to state drug controller and dealers.

As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same. The manufacturers not complying with the ceiling price and notes specified herein above shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities (EC) Act, 1955.

Consequent to the issue of ceiling prices of such formulations as specified in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the said date of notification, stand(s) superseded, the NPPA in its notification said.

Source: Pharmabiz

### **Finance ministry opines that additional discount given by a company to a dealer will attract GST**

The Finance Ministry on Friday said the additional discount given by a company to a dealer in certain cases will be liable to Goods & Services Tax (GST). The GST Policy Wing of the Central Board of Indirect Taxes & Customs (CBIC) under the Finance Ministry issued a clarification on various doubts related to treatment of secondary or post-sale discounts for applicability of indirect tax. It said where the discount is linked to specific activities to be done by the dealer such as advertisement, exhibition, etc, it would qualify as a supply by the dealer to the company and the dealer would have to pay GST.

Similarly, additional discount given for special reduced price to augment the sales will be liable to GST. According to the circular, where any reduction in prices are allowed by supplier to dealers with the condition of the same being passed on by the dealers to the end customer, it would be added to the value of supply of dealer to consumer for payment of GST.

Customers, if registered, will be eligible to claim ITC (Input Tax Credit) of the tax charged by the

dealer only to the extent of the tax paid by the said customer to the dealer.

Abhishek Jain, Tax Partner at EY, said the clarification on input tax credit being eligible for the full GST charged even where adjustments in value are made through financial/commercial credit notes is a welcome one for businesses. However, on other clarifications like “taxability of discounts linked with performance incentives, applicability of GST on discounts offered by manufacturers to dealers with condition of these being passed on, would obligate businesses to relook at their current tax positions and legally re-evaluate the GST positions.”

The circular further said that there will be no reduction in ITC in case of financial / commercial credit notes. The dealer will not be required to reverse ITC attributable to the tax already paid on such post-sale discount received by him through issuance of financial / commercial credit notes.

According to chartered accountant Pritam Mahure, it has already been a matter of debate whether the additional discount provided post-supply to a dealer / distributor is a discount or incentive/ commission. The circular will open a Pandora's Box for various FMCG, textile, pharma companies etc as “they will have to determine whether each discount is against certain activity or generic discount (eligible for deduction).”

Source: File No. CBEC-20/16/04/2018-GST dated 28.06.2019.

### **CDSO, Govt. of India issued an advisory on active participation of Pharmaceutical and Biopharmaceutical manufacturing units in the Recognition of Prior Learning with Best-in-Class Employers (RPL-BICE) under Pradhan Mantri Kaushal Vikas Yojana (PMKVY) 2016-20 on 25<sup>th</sup> June 2019**

Recognition of Prior Learning (RPL) under Pradhan Mantri Kaushal Vikas Yojana (PMKVY) 2016-20 was initiated by Ministry of Skill Development and Entrepreneurship (MSDE), Government of India with the aim to recognize the existing skill sets & prior experience of the beneficiaries and provide certification after assessment through-R PL Camps, Employer Premises and Centres. Subsequently, the idea of RPL with Best in Class

Employers (RPL- BICE) was launched considering the immense potential of this mode of RPL. RPL will enable advancement of formalized skilling in the industry which will serve as a benchmark for internal improvements and comparison amongst the various players in the industry. The RPL-BICE certificate and formalization will lead to an increase in skilled manpower, improved safety and productivity. The Government of India had entrusted the work relating to development of qualification packs (National Occupational Standards) to the Life Sciences Sector Skill Development Council (LSSSDC) with the objective of upgrading the skills of persons employed in the Life Sciences sector in the country. RPL was launched in September 2016 at LSSSDC under mandate of Ministry of Skill Development and Entrepreneurship. Considering the importance of RPL, MSDE has requested Ministry of Health and Family Welfare to issue an advisory for active participation in the Recognition of Prior Learning

with Best-in-Class Employers (RPL-BICE) under Pradhan Mantri Kaushal Vikas Yojana (PMKVY) 2016-20.

In view of above, all Pharmaceutical Associations are advised to request their members having the Pharmaceutical and Bio-pharmaceutical manufacturing units to actively participate in the Recognition of Prior Learning with Best-in-Class Employers (RPL-BICE) under Pradhan Mantri Kaushal Vikas Yojana (PMKVY) 2016-20

In case of any assistance, the following officers of LSSSDC may be contacted: (1) Shri Ranjit Madan, CEO, Life Sciences Sector Skill Development Council Tel. 011 -41042407/08/09/10 Email: ranjit.madan@lsssdc.in and (2) Shri Anshul Saxena, Director-Standards & Training Advisory Life Sciences Sector Skill Development Council Tel.011-41042407/08/09/10; Mob.9650433002 Email: anshul.saxena@lsssdc.in

Source: CDSCO



**IPA President Dr. T.V.Narayana and other IPA office bearers in the inaugural programme of PHARMAC SOUTH**

### **Forthcoming Event**

## **71<sup>st</sup> Indian Pharmaceutical Congress**

20-22 December 2019

**Venue:** Sri Ramchandra Institute of Higher Education and Research, Chennai

**Organized by:** Indian Pharmaceutical Congress Association (IPCA)

**Hosted by:** All India Drugs Control Officer's Confederation (AIDCOC)

### **DISCLAIMER:**

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.