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# IDMA BULLETIN

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## Indian APIs & Formulations for Global Healthcare

### ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT (APPQM)

**A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021**

*(Details on Page Nos. 4 & 5)*

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS

*A Publication of*
**Indian Drug Manufacturers' Association**
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# IDMA BULLETIN

**Vol. No. 51 Issue No. 42 08 to 14 November 2020**

MBA-STYLE INTERNATIONAL EDUCATIONAL PROGRAM FOR POTENTIAL LEADERS


Empowerment
Through Education
Living A Dream,
Building A Future

# ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

## A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021

**For further information / queries, please open the below links on our website www.idma-assn.org:**

Circular / Covering Note | NSF Presentation | WHY APPQM? By Mr S M Mudda | APPQM 5 Modules | APPQM Series 1 FEEDBACK | REGISTRATION FORM

*APPQM FOR DEVELOPING CHANGE AGENTS FOR QUALITY EXCELLENCE*

### APPQM - Program Modules

1. **Pharmaceutical Quality Management Systems – Best Industry Practices**
   *(How to ensure your QMS drives business improvements)*
2. **Managing Change: Change Control and Deviations**
   *(Advanced problem solving, deviation management, report writing and change management)*
3. **Human Factors – Getting people to follow the rules**
   *(How to improve performance, reduce human error, embed a quality mind-set & keep your people)*
4. **Transforming Data into Information – the Practical Application of Statistics to Transform your Business**
   *(The practical application of statistics to transform your business)*
5. **Quality by Design, Process Validation and Technology Transfer**
   (Building a foundation for Product Quality and Knowledge Management)

### Advantages of NSF's Virtual Training

- NSF's virtual training combines live instructor-led virtual classrooms and self-paced learning online (easy to navigate e-learning) to provide participants with an interactive and engaging learning experience.
- Enhanced Virtual Interactivity – such as polls, etc.
- Virtually managed Break-out rooms - These are as good as physical break out groups
- Use of Team works – specially smaller group sizes
- Use of Tasks and Case Studies
- Courses managed Brilliantly by NSF - Each course is managed on NSF Learning Management System (LMS), with electronic course material
- Time for self-study each day.
- Guest Speakers (including MHRA, US FDA ex-regulators) enhance the modules and motivate the delegates

### Additional Benefits:

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees **(from £8000 to £3300)**
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

**Why APPQM in INDIA?***

When launching the first series of the APPQM, we at IDMA along with NSF, UK reflected on the perceived trust deficit with international regulators despite being regarded as a 'Pharmacy of the World' and offered a global education program APPQM, in collaboration with NSF Health Sciences, UK, as a collective proactive response from the industry. We boldly stated APPQM would be Unique, World-Class and transform the operation efficiency of companies attending. Well, did series one live up to expectations?

Over 40 delegates attended series one.

This is what they thought:

"Transformative", "world-class", "best business investment we've ever made", "life changing", "worth every penny and more", "my company will be sending more delegates to series two", "has helped transform our quality culture" are just some examples of the feedback we've received from APPQM delegates.

Nearly 30 'work placement projects' have been completed by APPQM delegates.These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

*Please visit IDMA website for details of benefits

### Current Challenges & APPQM

In this challenging times, the pharmaceutical industry will become competitive only if the 3 factors - **Legacy & Reputation** (License to Operate), **Profit & Efficiency** (Cost Control) and **Customer service** are balanced and managed well.

The COVID-19 pandemic has created unique challenges as well as opportunities for the industry. In the absence of any regulatory inspections happening until quarter III of 2021 and reduced physical oversight by the corporate QA functions, the external interventions on the site will be reduced. There is an urgent need to use this time for building a strong leadership at the site for quality and compliance.

We recommend the virtual APPQM for the site teams for keeping themselves updated with the changing regulatory expectations in the post COVID-19 phase, once the physical inspections start.

**The need of the hour is to focus on long term preventive measures aimed at achieving continual improvements rather than short term Compliance-Oriented approach.**

Please don't get left behind and register for the second series of APPQM to have a competitive edge in the global market and to be future ready.

**REGISTRATION FEE FOR SERIES TWO**

The Registration Fee for **APPQM SERIES 2** is restructured at

**Rs.3,15,000/- (Rupees Three Lakh Fifteen Thousand Only) Plus 18% GST Per Participant.**

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

### Registration Procedure :

Please fill the Registration Form and send it to

| | |
|---|---|
| **Melvin Rodrigues**<br>actadm@idmaindia.com<br>9821868758 | **Batul**<br>technical@idmaindia.com<br>9920045226 |

**For further information / queries :**

You may also contact **Mr. S. M. Mudda**, @ **mudda.someshwar@gmail.com** / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

| | | | |
|---|---|---|---|
| **S M MUDDA**<br>Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM | **MAHESH H DOSHI**<br>National President, IDMA | **DR. GEORGE A PATANI**<br>Hon. General Secretary & Vice Chairman, Industry Institution Interaction Committee, IDMA | **DAARA B PATEL**<br>Secretary – General, IDMA |

# IDMA supports India's Joint Proposal in WTO to overcome COVID-19 pandemic

The Indian Drug Manufacturers' Association (IDMA) wholeheartedly welcomes the joint proposal of India, South Africa, Kenya and Eswatini to waive obligations regarding the protection and enforcement of Copyrights, Industrial Designs, Patents, and Trade secrets under the TRIPS Agreement, in the context of current COVID-19 pandemic.

An effective response to COVID-19 requires the availability of and access to a range of Pharmaceutical products especially diagnostics, medicines, vaccines, and antibodies at an affordable price. The Indian Pharmaceutical industry continues to play a major role in making available critical medicines at the National and Global levels even during the COVID-19 pandemic. The industry is technologically equipped to produce any medicines, vaccines or antibodies for COVID-19, complying with quality, safety, and efficacy standards.

However, various Intellectual Property (IP) protections can create legal barriers and prevent the production of IP protected medical products for prevention of COVID-19 related diseases.

Though Compulsory Licenses can be used to acquire freedom of operation it is procedurally cumbersome and has to be issued product-by-product. So while it is a useful tool in the normal circumstances, the COVID-19 pandemic demands a swift response to overcome the IP barrier. The suspension of protection and enforcement of Patents, Trade secrets, Copyrights, and Industrial Designs clearly brings legal clarity and provide the freedom of operation to the pharmaceutical industry to scale up the production of diagnostic kits, medicines, vaccines, or antibodies required for the prevention and treatment of COVID-19.

IDMA fully supports Government of India's proactive role in this regard and requests the Government to pursue the waiver proposal to its logical end with the like-minded countries. It also calls on other countries, especially those opposing the proposal, to respond to this much needed initiative and ensure that people across the world can get access to COVID-19 related medical products.

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# Cabinet approves PLI Scheme to 10 key Sectors for Enhancing India's Manufacturing Capabilities and Enhancing Exports – Atmanirbhar Bharat *(Excerpts)*

## *Government approves further PLI Scheme of Rs.15,000 Crores for Pharma Industry*

The Union Cabinet chaired by the Prime Minister, Shri Narendra Modi has given its approval to introduce the Production-Linked Incentive (PLI) Scheme in the following 10 key sectors for Enhancing India's Manufacturing Capabilities and Enhancing Exports – *Atmanirbhar Bharat*.

| Priority | Sectors | Implementing Ministry/Department | Approved financial outlay over a five-year period Rs.crore |
|---|---|---|---|
| 1. | Advance Chemistry Cell (ACC) Battery | NITI Aayog and Department of Heavy Industries | 18100 |
| 2. | Electronic/Technology Products | Ministry of Electronics and Information Technology | 5000 |
| 3. | Automobiles & Auto Components | Department of Heavy Industries | 57042 |
| 4. | Pharmaceuticals drugs | Department of Pharmaceuticals | 15000 |
| 5. | Telecom & Networking Products | Department of Telecom | 12195 |
| 6. | Textile Products: MMF segment and technical textiles | Ministry of Textiles | 10683 |
| 7. | Food Products | Ministry of Food Processing Industries | 10900 |
| 8. | High Efficiency Solar PV Modules | Ministry of New and Renewable Energy | 4500 |
| 9. | White Goods (ACs & LED) | Department for Promotion of Industry and Internal Trade | 6238 |
| 10. | Speciality Steel | Ministry of Steel | 6322 |
| **Total** | | | **145980** |

The PLI scheme will be implemented by the concerned Ministries/Departments and will be within the overall financial limits prescribed. The final proposals of PLI for individual sectors will be appraised by the Expenditure Finance Committee (EFC) and approved by the Cabinet. Savings, if any, from one PLI scheme of an approved sector can be utilized to fund that of another approved sector by the Empowered Group of Secretaries. Any new sector for PLI will require fresh approval of the Cabinet.

The PLI scheme across these 10 key specific sectors will make Indian Manufacturers Globally competitive, attract investment in the areas of core competency and cutting-edge technology; ensure efficiencies; create economies of scale; enhance exports and make India an integral part of the Global Supply Chain.

- The Indian pharmaceutical industry is the third largest in the world by volume and 14$^{th}$ largest in terms of value. It contributes 3.5% of the total drugs and medicines exported globally. India possesses the complete ecosystem for development and manufacturing of Pharmaceuticals and a robust ecosystem of allied industries. The PLI scheme will incentivize the Global and domestic players to engage in high value production.

**The above will be in addition to the already notified PLI scheme:**

| Sectors | Implementing Ministry/ Department | Financial outlays Rs. Crore |
|---|---|---|
| Critical Key Starting Materials/Drug Intermediaries and Active Pharmaceutical Ingredients | Department of Pharmaceuticals | 6940 |

The Prime Minister's clarion call for an *'Aatma Nirbhar Bharat'* envisages policies for the promotion of an efficient, equitable and resilient manufacturing sector in the country. Growth in production and exports of industrial goods will greatly expose the Indian industry to foreign competition and ideas, which will help in improving its capabilities to innovate further. Promotion of the manufacturing sector and creation of a conducive manufacturing ecosystem will not only enable integration with global supply chains but also establish backward linkages with the MSME sector in the country. It will lead to overall growth in the economy and create huge employment opportunities.

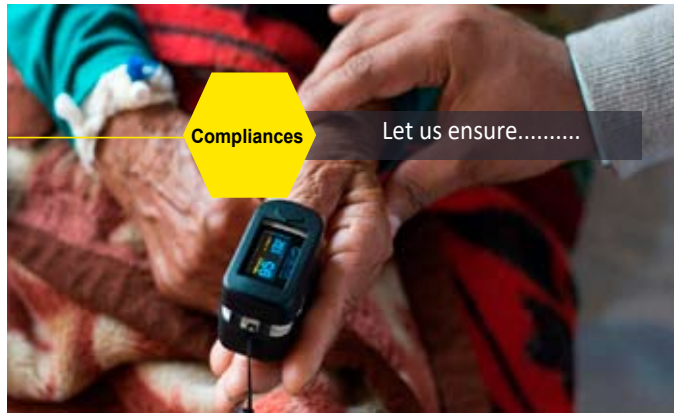
**Sector wise Product Lines:**

| Sector | Product Lines |
|---|---|
| Pharmaceuticals | **Category 1:**<br>i. Biopharmaceuticals;<br>ii. Complex Generic Drugs;<br>iii. Patented Drugs or Drugs nearing patent expiry;<br>iv. Cell based or gene therapy Products;<br>v. Orphan Drugs;<br>vi. Special empty Capsules;<br>vii. Complex Excipients.<br>**Category 2:**<br>i. Active Pharma Ingredients (APIs) /Key Starting Materials (KSMs) and /Drug Intermediaries (DIs).<br>**Category 3:**<br>i. Repurposed Drugs;<br>ii. Auto-immune drugs, Anti-cancer drugs, Anti diabetic drugs, Anti Infective drugs, Cardiovascular drugs, Psychotropic drugs and Anti-Retroviral drugs;<br>*iii.* *In vitro* Diagnostic Devices (IVDs);<br>iv. Phytopharmaceuticals;<br>v. Other drugs not manufactured in India;<br>vi. Other drugs as approved; |

*Source: PIB, Union Cabinet Press Release, 11.11.2020*

# GST Updates

*Courtesy:* ***B G Barve,*** *Chairman-Excise & Taxation Committee, IDMA*


**E Invoice System**

**One time relaxation in implementation of E Invoice system for the month of October 2020.**

********

**30 Days to obtain IRN**

73/2020-Central Tax dated 01.10.2020

CBIC has notified a special procedure for the registered persons required to prepare the tax invoice by obtaining an Invoice Reference Number (IRN) for such invoice by uploading specified particulars in FORM GST INV-01 on the Common Goods and Services Tax Electronic Portal but who could not prepare tax invoice in the said manner.

**Such class of persons shall, during the period from the 1st day of October, 2020 to the 31st day of October, 2020, follow the special procedure.**

**Such persons shall obtain an Invoice Reference Number (IRN) for such invoice by uploading specified particulars in FORM GST INV-01 on the Common Goods and Services Tax Electronic Portal, within thirty days from the date of such invoice, failing which the same shall not be treated as an invoice.**

**GSTR 9 AND GSTR 9C - Last date for submission- 31.12.2020.**

Notification No. 80/2020 –Central Tax dated 28th October, 2020

**Last date for submission of GSTR 9 and GSTR 9C is now 31.12.2020.**

**IDMA also requested to authorities for extension of due dates till 31st December 2020.**

Taxpayers are required to report only the values pertaining to Financial Year 2018-19 and the values pertaining to Financial Year 2017-18 which may have already been reported or adjusted are to be ignored.

No adverse view would be taken in cases where there are variations in returns for taxpayers who have already filed their GSTR-9 of Financial Year 2018-19 by including the details of supplies and ITC pertaining to Financial Year 2017-18 in the Annual return for FY 2018-19.

**Proposals for Union Budget 2021-22**

**Ministry of Finance seeks inputs for Budget 2021-22**

Ministry of Finance has called for inputs / suggestions for Budget 2021-22 to be submitted by 13th November 2020.

We request all members to give their inputs / suggestions /Concerns related to GST / Excise / Customs by 5th November 2020.

We shall forward IDMA proposals to Ministry of Finance like every year.

Key issues to be focused will be -

1. Deduction for Research and Development expenses
2. GST Rates on Hand Sanitizers
3. Revision of Returns
4. Utilisation of accumulated ITC at different locations under same PAN
5. Decriminalisation of offences under GST

Notification No. 79/2020-CT, dated October 15, 2020

**Central Goods and Services Tax (Twelveth Amendment) Rules, 2020.**

1. Empowers the Board to specify a class of registered person or supply of goods or services, require mentioning HSN code
2. CGST Rules w.r.t. filing of nil GSTR 1 or GSTR 3B or CMP 08 through SMS amended.
3. Taxpayers having aggregate turnover of up to 5 crores, not required to furnish GSTR 9C for F.Y. 2019-20.
4. No generation of Part A of e way bill will be allowed w.e.f. 16th October 2020 if Two consecutive returns are not filed for the tax period up to August 2020.
5. CGST Rules amended to make it optional for the proper officer to communicate the liability before issuing SCN under section 73/74 of the CGST Act 2017.

Notification No. 78/2020-CT, dated October 15, 2020

**Number of digits of HSN code required in tax invoice**

**CBIC notifies the number of HSN digits required on tax invoice w.e.f. 01st day of April, 2021.**

**Provided that a registered person having aggregate turnover up to five crores rupees in the previous financial year may not mention the number of digits of HSN Code, as specified in the corresponding entry in column (3) of the said Table in a tax invoice issued by him under the said rules in respect of supplies made to unregistered persons.**

| Sl. No. | Aggregate Turnover in the preceding Financial Year | Number of Digits of Harmonised System of Nomenclature Code (HSN Code) |
|---|---|---|
| 1 | Up to rupees five crores | 4 |
| 2 | more than rupees five crores | 6 |

Notification No. 77/2020-CT, dated October 15, 2020

**Filing of annual return for 2019-20 optional for taxpayers having aggregate turnover less than Rs 2cr.**

**CBIC notifies to make filing of annual return GSTR 9 under section 44 (1) of CGST Act for F.Y. 2019-20 optional for small taxpayers.....**

Registered Taxpayers whose aggregate turnover is less than Rs 2 crores and who have not filed the said return before the due date will be covered and benefitted.

Notification No. 76/2020-CT, dated October 15, 2020

**Due dates of Form GSTR 3B for the months of October 2020 to March 2021**

CBIC has notified that the return in FORM GSTR-3B of the said rules for each of the months from October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the **twentieth day of the month succeeding such month**.

*For **taxpayers having an aggregate turnover of up to five crore rupees** in the previous financial year, whose principal place of business is in the States of Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana, Andhra Pradesh, the Union territories of Daman and Diu and Dadra and Nagar Haveli, Puducherry, Andaman and Nicobar Islands or Lakshadweep, the return in FORM GSTR-3B of the said rules for the months of October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the **twenty-second day of the month succeeding such month.***

*For **taxpayers having an aggregate turnover of up to five crore rupees** in the previous financial year, whose principal place of business is in the States of Himachal Pradesh, Punjab, Uttarakhand, Haryana, Rajasthan, Uttar Pradesh, Bihar, Sikkim, Arunachal Pradesh, Nagaland, Manipur, Mizoram, Tripura, Meghalaya, Assam, West Bengal, Jharkhand or Odisha, the Union territories of Jammu and Kashmir, Ladakh, Chandigarh or Delhi, the return in FORM GSTR-3B of the said rules for the months of October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the **twenty-fourth day of the month succeeding such month.***

Notification No. 75/2020-CT, dated October 15, 2020

**Time limit to furnish GSTR 1 for registered persons having aggregate turnover of more than INR 1.5 cr. extended**

CBIC notifies to extend the time limit for furnishing the details of outward supplies in FORM GSTR-1 of the Central Goods and Services Tax Rules, 2017, by such class of registered persons having aggregate turnover of more than 1.5 crore rupees in the preceding financial year or the current financial year, for each of the months from October, 2020 to March, 2021 till the **eleventh day of the month succeeding such month.**

The time limit for furnishing the details or return, as the case may be, under sub-section (2) of section 38 of the said Act, for the months of October, 2020 to March, 2021 shall be subsequently notified in the Official Gazette.

Notification No. 74/2020-CT, dated October 15, 2020

**Time limit to furnish GSTR 1 for registered persons having aggregate turnover of up to INR 1.5 cr.**

CBIC notifies the registered persons having aggregate turnover of up to 1.5 crore rupees in the preceding financial year or the current financial year, as the class of registered persons who shall follow the special procedure as mentioned below for furnishing the details of outward supply of goods or services or both in GSTR 1.

| Sl. No. | Quarter for which details in FORM GSTR-1 are furnished | Time period for furnishing details in FORM GSTR-1 |
|---|---|---|
| 1 | October, 2020 to December, 2020 | 13th January, 2021 |
| 2 | January, 2021 to March, 2021 | 13th April, 2021 |

**Notification No. 71/2020-CT, dated October 15, 2020**

**Dynamic QR Code for B2C supplies deferred till December 01, 2020**

CBIC amends Notification No. 14/2020 – CT, dated 21st March, 2020 which notifies that an invoice issued by a registered person, whose aggregate turnover in a financial year exceeds 500 crore rupees, other than those referred to in sub-rules (2), (3), (4) and (4A) of rule 54 of said rules, and registered person referred to in section 14 of the Integrated Goods and Services Tax Act, 2017, **to an unregistered person**, shall have **Dynamic Quick Response (QR) code** from the **1st day of October, 2020.**

*Now, an invoice issued by a registered person, whose aggregate turnover in a financial year exceeds five hundred crore rupees, other than those referred to in sub-rules (2), (3), (4) and (4A) of rule 54 of said rules, and registered person referred to in section 14 of the Integrated Goods and Services Tax Act, 2017, **to an unregistered person , shall have Dynamic Quick Response (QR) code from the 1st day of December, 2020**.*

**Notification No. 70/2020-CT, dated September 30,2020**

**E Invoicing Notification amended.**

CBIC amends Notification No. 13/2020 – Central Tax, dated the 21st March, 2020 which notifies registered person whose aggregate turnover in **a financial year** exceeds Five hundred crore rupees, as a class of registered person who shall prepare invoice and other prescribed documents, in terms of sub-rule (4) of rule 48 of the said rule in respect of supply of goods or services or both to a registered person.

*Now, a registered person whose aggregate turnover in any preceding financial year **from 2017-18 onwards exceeds Five hundred crore rupees** as a class of registered person who shall prepare invoice and other prescribed documents, in terms of sub-rule (4) of rule 48 of the said rules in respect of supply of goods or services or both to a registered person or **for exports**.*


**Writ Appeal No. 53/ 2020 dated October 16, 2020**

**Division Bench of Madras HC disallowed Cess transition into GST**

**Issue:**

**Whether the Respondent is entitled to carry forward the accumulated unutilized amount of EC, SHEC and KKC to be utilized against the output GST tax liability?**

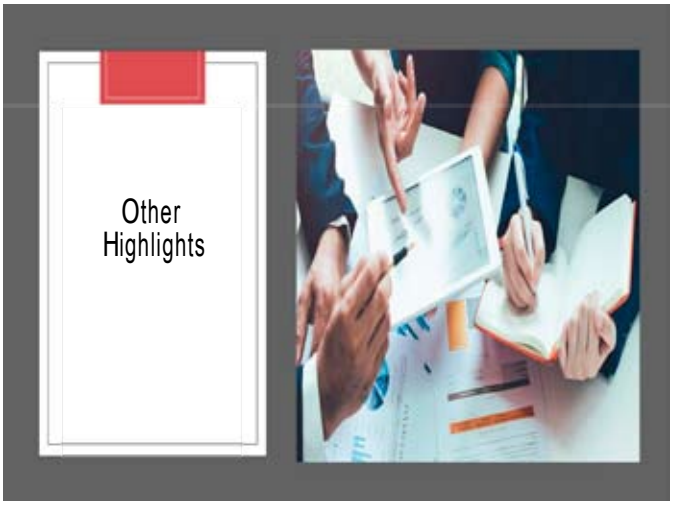
**Held:**

**The Petitioner is not entitled to carry forward and set off of unutilised EC, SHEC and KKC against the GST Output Liability with reference to Section 140 of the CGST Act.**

*GST Law subsumed 17 indirect taxes which were applicable prior to July 1, 2017. The transition of unutilised ITC could be allowed only in respect of taxes and duties which were subsumed in the new GST Law.*

*Admittedly, the three types of Cess, namely Education Cess (EC), Secondary and Higher Education Cess (SHEC) and Krishi Kalyan Cess (KKC) were not subsumed in the new GST Laws, either by the Parliament or by the States. Credit of such EC and SHEC which could not be utilised against the output EC and SHEC liability, while the said impost was in force prior to Finance Act, 2015, became a dead claim in the year 2015 itself and therefore, there was no question of allowing a carry forward and set off after a gap of two years against the output GST Liability w.e.f. July 1, 2017.*

*Accordingly, We should not avail Credit of such EC and SHEC and KKC.....*




| | |
|---|---|
| Export ban on of alcohol based hand sanitizer lifted | **DGFT Notification No.40/ 2015-2020 dated 15th October 2020**<br>**The export of alcohol based hand sanitizers in container with dispenser pumps is free for export with effect from 15th October 2020.** |
| GST on hand sanitizers to continue at 18% | **42nd GST Council meeting on 5th October 2020.....**<br>**GST Council has rejected the proposal to reduce rates on Ayurvedic hand sanitizers from 18% to 12%.**<br>**Also affirms to continue 18% GST on alcohol based hand sanitizer.** |
| Jammu and Kashmir Government extends last date for filing of claims under Budgetory Support Scheme | Jammu and Kashmir Government vide Notification SO- 325 to 328 all dated October 23, 2020 notified to allow industrial units to file their claims under Budgetary Support Scheme (Scheme) before the concerned jurisdictional officer by or before December 31,2020. |

# Income Tax Updates

*Courtesy:* ***B G Barve,*** *Chairman-Excise & Taxation Committee, IDMA*

- No requirement of scrip wise reporting for day trading and short-term sale or purchase of listed shares in the return of income for AY 2020-21.
  - The scrip wise details in the return of income for AY 2020-21 is required to be filled up only for the reporting of the long-term capital gains for the listed shares/units which are eligible for the benefit of grandfathering.

*(Press release dated 26/09/2020)*

- Income tax has issued Clarification on doubts arising on account of new TCS provisions.

*(Press release dated 30/09/2020)*

- Rule 5 of Income tax Rules,1962 is amended to include 115BA, 115BAA, section 115BAB, section 115BAC and section 115BAD, thereby a person opting for a lower tax regime cannot claim depreciation allowance more than @40% for any block of assets

*(Notification No. 82/2020 dated 01/10/2020)*

- CBDT has issued Form 3CD Schema Change document V1.21 dated 22nd October,2020
- CBDT releases instructions (guidelines) for ITR forms for AY 2020-21 dated 23rd October,2020

*(Changes in ITR 6 from already updated through Income Tax Notification Updates August,2020)*

- Extension of due date of furnishing of Income Tax Returns and Audit Reportsas follows:

*(Press release dated 24/10/2020 and Notification No. 85/2020 dated 27/10/2020)*

| Particulars | OriginalDue Date | Last Extended Date | Further Extended |
|---|---|---|---|
| Filing of original or revised income tax returns for F.Y. 2018-19 | 31st March, 2020 | 30th September, 2020 | 30th November, 2020 |
| Income Tax Return filing for F.Y. 2019-20* | | | |
| - Company assesse | 31st October, 2020 | 30th November, 2020 | 31st January, 2021 |
| - Audit is mandatory | 31st October, 2020 | 30th November, 2020 | 31st January, 2021 |
| - A partner in a firm whose audit is mandatory | 31st October, 2020 | 30th November, 2020 | 31st January, 2021 |
| - Transfer Pricing Audit | 30th November, 2020 | 30th November, 2020 | 31st January, 2021 |
| - Any other case | 31st July, 2020 | 30th November, 2020 | 31st December, 2020 |
| Tax Audit Report filing for F.Y. 2019-20 | 30th September, 2020 | 31st October, 2020 | 31st December, 2020 |
| Payment of tax without additional amount under Vivad se Viswas Scheme | 31st March, 2020 | 31st December, 2020 | 31st March, 2021 |

**If Self-Assessment Tax exceeds Rs.1 lakh, taxpayer is liable to pay Interest u/s 234A of the income Tax Act from the expiry of original due dates.*

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# Maleic Anhydride (Quality Control) Order, 2020 notified - reg.

**Chemicals & Fertilizers Notification No.S.O.4000(E), dated 4th November, 2020**

*(Published in the Gazette of India on 5th November, 2020)*

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), (hereinafter referred to as the said Act), the Central Government, being of the opinion that it is necessary or expedient so to do in the public interest after consultation with the Bureau of Indian Standards, hereby makes the following Order, namely:-

**1. Short title, commencement and application:**

(1) This order may be called the **Maleic Anhydride (Quality Control) Order, 2020.**

(2) It shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such goods or articles meant for export.

**2. Conformity to standards and compulsory use of Standard Mark -** Goods or articles specified in column (1) of the Table below shall conform to the corresponding Indian Standard given in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standards as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

**3. Certification and enforcement authority –** The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified in column (1) of the Table.

**4. Penalty for contravention -** Any person who contravenes the provisions of this Order shall he punishable under the provisions of the said Act.

**TABLE**

| Goods or article | Indian Standard | Title for Indian Standard |
|---|---|---|
| (1) | (2) | (3) |
| Maleic Anhydride, Technical | IS 5149:2020 | Specification for Maleic Anhydride, Technical |

**F.No.PC-II- 46016/6/2020-Tech.CPC**

*Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.*

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# Methyl Acrylate, Ethyl Acrylate, n-Butyl Acrylate (Quality Control) Order, 2020 notified - reg.

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*(Published in the Gazette of India on 5th November, 2020)*

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), (hereinafter referred to as the said Act), the Central Government, being of the opinion that it is necessary or expedient so to do in the public interest after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

**1. Short title, commencement and application:**

(1) This order may be called the **Methyl Acrylate, Ethyl Acrylate, n-Butyl Acrylate (Quality Control) Order, 2020.**

(2) It shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (2) of the Table below, but shall not apply to such goods or articles meant for export.

2. **Conformity to standards and compulsory use of Standard Mark -** Goods or articles specified in column (2) of the Table below shall conform to the corresponding Indian Standard given in column (3) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standards as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

3. **Certification and enforcement authority -** The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified in column (2) of the Table.

4. **Penalty for contravention -** Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

**TABLE**

| Sr. No. | Goods or article | Indian Standard | Title for Indian Standard |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 1 | Methyl Acrylate | IS 14707: 1999 | Methyl Acrylate - Specification |
| 2 | Ethyl Acrylate | IS 14708: 1999 | Ethyl Acrylate - Specification |
| 3 | n-Butyl Acrylate | IS 14709: 1999 | n-Butyl Acrylate - Specification |

**F.No.PC-II-46016/6/2020-Tech.CPC**

*Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.*

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IPR MATTERS

# Delhi High Court declines injunction on Dapagliflozin citing "Public Interest" - Big boost to Patients and Generics

On 2nd November, 2020 Hon'ble Mr Justice Rajiv Shakdher of the Delhi High Court passed a remarkable order in Dapagliflozin infringement suit giving big boon to patients and big boost to generics. Just like in the case of Erlotinib wherein Hon'ble Mr Justice Ravindra Bhat took into consideration "Public Interest", Hon'ble Mr Justice Rajiv Shakdher also endorsed "Public Interest" while noting the difference in prices of drugs ranges between 250% to 350%. Hence, Defendants were allowed to manufacture and market generics which would be far cheaper. The Court also noted the admission by the Plaintiff in several paragraphs of the Plaint including the Prayer that Dapagliflozin was covered by the claims of genus patent IN'147. Hence, the entire principal claim of IN'625 is vulnerable to revocation.

While refusing to grant interim injunction against Intas Pharmaceuticals Limited and Alkem Laboratories Limited, the Defendants were directed to place on Court's record every quarter the details, quantum, and value of drug manufactured and sold as also indirect and direct taxes paid in that behalf.

**Source: http://delhihighcourt.nic.in/index.asp**

*Courtesy: CIPROM NEWSLETTER, Volume No.4 Issue No.11, November 2020*

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# Patent Amendment Rules 2020 notified for fees to be paid by start-up or small entity – reg.

**Gazette Notification No.G.S.R.689(E), dated 4th November, 2020**

Whereas, the draft of certain rules, further to amend the Patents Rules, 2003 were published as required under sub-section (3) of section 159 of the Patents Act, 1970 (39 of 1970), vide notification of the Government of India in the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade) number G.S.R.799(E) dated the 18th October, 2019 in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of thirty days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 18th day of October, 2019;

And whereas, the objections and suggestions received from the public in respect of the said draft rules have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 159 of the Patents Act, 1970 (39 of 1970), the Central Government hereby makes the following rules further to amend the Patents Rules, 2003, namely:-

**1. Short title and commencement:**

(1) These rules may be called the **Patents (2nd Amendment) Rules, 2020.**

(2) They shall come into force on the date of their publication in the Official Gazette.

**2.** In the Patents Rules, 2003 (hereinafter referred to as the principal rules), in rule 7, -

(i) for sub-rule (3), the following sub-rule shall be substituted, namely:-

"(3) In case an application processed by a natural person or startup or small entity is fully or partly transferred to a person other than a natural person, startup or small entity, the difference, if any, in the scale of fees between the fees charged from the natural person, startup or small entity and the fees chargeable from the person other than a natural person, startup or small entity in the same matter, shall be paid by the new applicant with the request for transfer.";

(ii) sub-rule (3A) shall be omitted;

(iii) sub-rule (3B) shall be omitted;

(iv) after sub-rule (3), the following explanation shall be inserted, namely:—

"Explanation— Where a startup or small entity, having filed an application for a patent, ceases to be a startup or small entity due to the lapse of the period during which it is recognized by the competent authority, or its turnover subsequently crosses the financial threshold limit as notified by the competent authority, no such difference in the scale of fees shall be payable.";

(v) explanation to sub-rule (3B) shall be omitted.

**3.** In the principal rules, for Table I of the FIRST SCHEDULE, the following table shall be substituted, namely:—

| Number of Entry | On what payable | Number of the relevant Form | For e-filing | | For physical filing | |
|---|---|---|---|---|---|---|
| | | | Natural person(s) or Startup(s) or Small entit(y)/(ies) | Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies) | Natural person(s) or Startup(s) or Small entit(y)/(ies) | Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies) |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | | | Rupees | Rupees | Rupees | Rupees |
| 1. | On application for a patent under sections 7, 54 or 135 and rule 20(1) accompanied by provisional or complete specification—<br>(i) for each sheet of specification in addition to 30, excluding sequence listing of nucleotides and/ or amino acid sequences under sub-rule (3) of rule (9);<br>(ii) for each claim in addition to 10;<br>(iii) for each page of sequence listing of nucleotides and/ or amino acid sequences under sub-rule (3) of rule (9). | 1 | 1600<br>Multiple of 1600 in case of every multiple priority.<br>(i) 160<br>(ii) 320<br>(iii) 160 subject to a maximum of 24000 | 8000<br>Multiple of 8000 in case of every multiple priority.<br>(i) 800<br>(ii) 1600<br>(iii) 800 subject to a maximum of 120000 | 1750<br>Multiple of 1750 in case of every multiple priority.<br>(i) 180<br>(ii) 350<br>Not allowed | 8800<br>Multiple of 8800 in case of every multiple priority.<br>(i) 880<br>(ii) 1750<br>Not allowed |
| 2. | On filing complete specification after provisional up to 30 pages having up to 10 claims –<br>(i) for each sheet of specification in addition to 30, excluding sequence listing of nucleotides and/ or amino acid sequences under sub-rule (3) of rule (9);<br>(ii) for each claim in addition to 10.<br>(iii) for each page of sequence listing of nucleotides and/ or amino acid sequences under sub-rule (3) of rule (9). | 2 | No fee<br>(i) 160<br>(ii) 320<br>(iii) 160 subject to a maximum of 24000 | No fee<br>(i) 800<br>(ii) 1600<br>(iii) 800 subject to a maximum of 120000 | No fee<br>(i) 180<br>(ii) 350<br>Not allowed | No fee<br>(i) 880<br>(ii) 1800<br>Not allowed |
| 3. | On filing a statement and undertaking under section 8. | 3 | No fee | No fee | No fee | No fee |
| 4. | i) On request for extension of time under sections 53(2) and 142(4), rules 13(6), 80(1A) and 130 (per month). | 4 | 480 | 2400 | 530 | 2600 |
| | ii) On request for extension of time under sub-rule (5) of rule 24B (per month). | 4 | 1000 | 4000 | 1100 | 4400 |
| | iii) On request for extension of time under sub-rule (11) of rule 24C (per month). | 4 | 2000 | 10000 | 2200 | 11000 |
| 5. | On filing a declaration as to inventorship under sub-rule (6) of rule 13. | 5 | No fee | No fee | No fee | No fee |
| 6. | On application for postdating. | - | 800 | 4000 | 880 | 4400 |
| 7. | On application for deletion of reference under section 19(2). | - | 800 | 4000 | 880 | 4400 |
| 8. | (i) On claim under section 20(1);<br>(ii) On request for direction under section 20(4) or 20(5). | 6<br>6 | 800<br>800 | 4000<br>4000 | 880<br>880 | 4400<br>4400 |
| 9. | (i) On notice of opposition to grant of patent under section 25(2);<br>(ii) On filing representation opposing grant of patent under section 25(1). | 7<br>7A | 2400<br>No fee | 12000<br>No fee | 2600<br>No fee | 13200<br>No fee |
| 10. | On giving notice that hearing before Controller shall be attended under rule 62(2). | - | 1500 | 7500 | 1700 | 8300 |
| 11. | On application under sections 28(2), 28(3) or 28(7). | 8 | 800 | 4000 | 880 | 4400 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 12. | Request for publication under section 11A(2) and rule 24A. | 9 | 2500 | 12500 | 2750 | 13750 |
| 13. | Application for withdrawing the application under section 11B(4), and rules 7(4A) and 26. | 29 | No fee | No fee | No fee | No fee |
| 14. | On request for examination of application for patent—<br><br>(i) under section 11B and rule 24(1);<br>(ii) under rule 20(4)(ii). | 18 | <br><br>4000<br>5600 | <br><br>20000<br>28000 | <br><br>4400<br>6150 | <br><br>22000<br>30800 |
| 14A. | On request for expedited examination of application for patent under rule 24C. | 18A | 8000 | 60000 | Not allowed | Not allowed |
| 14B. | Conversion of the request for examination filed under rule 24B to request for expedited examination under rule 24C. | 18 A | 4000 | 40000 | Not allowed | Not allowed |
| 15. | On application under section 44 for amendment of patent. | 10 | 2400 | 12000 | 2650 | 13200 |
| 16. | On application for directions under section 51(1) or 51(2). | 11 | 2400 | 12000 | 2650 | 13200 |
| 17. | On request for grant of a patent under sections 26(1) and 52(2). | 12 | 2400 | 12000 | 2650 | 13200 |
| 18. | On request for converting a patent of addition to an independent patent under section 55 (1). | - | 2400 | 12000 | 2650 | 13200 |
| 19. | For renewal of a patent under section 53— | | | | | |
| (i) | before the expiration of the 2nd year from the date of patent in respect of 3rd year; | - | 800 | 4000 | 880 | 4400 |
| (ii) | before the expiration of the 3rd year in respect of the 4th year; | - | 800 | 4000 | 880 | 4400 |
| (iii) | before the expiration of the 4th year in respect of the 5th year; | - | 800 | 4000 | 880 | 4400 |
| (iv) | before the expiration of the 5th year in respect of the 6th year; | - | 800 | 4000 | 880 | 4400 |
| (v) | before the expiration of the 6th year in respect of the 7th year; | - | 2400 | 12000 | 2650 | 13200 |
| (vi) | before the expiration of the 7th year in respect of the 8th year; | - | 2400 | 12000 | 2650 | 13200 |
| (vii) | before the expiration of the 8th year in respect of the 9th year; | - | 2400 | 12000 | 2650 | 13200 |
| (viii) | before the expiration of the 9th year in respect of the 10th year; | - | 2400 | 12000 | 2650 | 13200 |
| (ix) | before the expiration of the 10th year in respect of the 11th year; | - | 4800 | 24000 | 5300 | 26400 |
| (x) | before the expiration of the 11th year in respect of the 12th year; | - | 4800 | 24000 | 5300 | 26400 |
| (xi) | before the expiration of the 12th year in respect of the 13th year; | - | 4800 | 24000 | 5300 | 26400 |
| (xii) | before the expiration of the 13th year in respect of the 14th year; | - | 4800 | 24000 | 5300 | 26400 |
| (xiii) | before the expiration of the 14th year in respect of the 15th year; | - | 4800 | 24000 | 5300 | 26400 |
| (xiv) | before the expiration of the 15th year in respect of the 16th year; | - | 8000 | 40000 | 8800 | 44000 |
| (xv) | before the expiration of the 16th year in respect of the 17th year; | - | 8000 | 40000 | 8800 | 44000 |
| (xvi) | before the expiration of the 17th year in respect of the 18th year; | - | 8000 | 40000 | 8800 | 44000 |
| (xvii) | before the expiration of the 18th year in respect of the 19th year; | - | 8000 | 40000 | 8800 | 44000 |
| (xviii) | before the expiration of the 19th year in respect of the 20th year. | | 8000 | 40000 | 8800 | 44000 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 20. | On application for amendment of application for patent or complete specification or other related documents under section 57— | 13 | | | | |
| (i) | before grant of patent; | | 800 | 4000 | 880 | 4400 |
| (ii) | after grant of patent; | | 1600 | 8000 | 1750 | 8800 |
| (iii) | where amendment is for changing name or address or nationality or address for service. | | 320 | 1600 | 350 | 1750 |
| 21. | On notice of opposition to an application under sections 57(4), 61(1) and 87(2) or to surrender a patent under section 63(3) or to a request under section 78(5). | 14 | 2400 | 12000 | 2650 | 13200 |
| 22. | On application for restoration of a patent under section 60. | 15 | 2400 | 12000 | 2650 | 13200 |
| 23. | Additional fee for restoration under section 61(3) and rule 86(1). | — | 4800 | 24000 | 5300 | 26400 |
| 24. | On notice of offer to surrender a patent under section 63. | — | 1000 | 5000 | 1100 | 5500 |
| 25. | On application for the entry in the register of patents of the name of a person entitled to a patent or as a share or as a mortgage or as licensee or as otherwise or for the entry in the register of patents of notification of a document under sections 69(1) or 69(2) and rules 90(1) or 90(2). | 16 | 1600 (In respect of each patent) | 8,000 (In respect of each patent) | 1750 (In respect of each patent) | 8,800 (In respect of each patent) |
| 26. | On application for alteration of an entry in the register of patents or register of patent agents under rules 94(1) or rule 118(1). | — | 320 | 1600 | 350 | 1750 |
| 27. | On request for entry of an additional address for service in the Register of Patents under rule 94(3). | — | 800 | 4000 | 880 | 4400 |
| 28. | On application for compulsory license under sections 84(1), 91(1), 92(1) and 92A. | 17 | 2400 | 12000 | 2650 | 13200 |
| 29. | On application for revocation of a patent under section 85(1). | 19 | 2400 | 12000 | 2650 | 13200 |
| 30. | On application for revision of terms and conditions of licence under section 88(4). | 20 | 2400 | 12000 | 2650 | 13200 |
| 31. | On request for termination of compulsory licence under section 94. | 21 | 2400 | 12000 | 2650 | 13200 |
| 32. | On application for registration as a patent agent under rule 109(1) or rule 112. | 22 | 3200 | Not applicable | 3500 | Not applicable |
| 33. | On request for appearing in the qualifying examination under rule 109(3). | — | 1600 | Not applicable | 1750 | Not applicable |
| 34. | For continuance of the name of a person in the register of patent agents— | | | | | |
| | (i) for the 1st year to be paid along with registration; | — | 800 | Not applicable | 880 | Not applicable |
| | (ii) for every year excluding the 1st year to be paid on the 1st April in each year. | — | 800 | Not applicable | 880 | Not applicable |
| 35. | On application for duplicate certificate of patent agent under rule 111A. | -- | 1600 | Not applicable | 1750 | Not applicable |
| 36. | On application for restoration of the name of a person in the register of patent agents under rule 117(1). | 23 | 1600 (Plus continuation fee under entry number 34) | Not applicable | 1750 (Plus continuation fee under entry number 34) | Not applicable |
| 37. | On a request for correction of clerical error under section 78(2). | — | 800 | 4000 | 880 | 4400 |
| 38. | On application for review or setting aside the decision or order of the controller under section 77(1)(f) or 77(1)(g). | 24 | 1600 | 8000 | 1750 | 8800 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 39. | On application for permission for applying patent outside India under section 39 and rule 71(1). | 25 | 1600 | 8000 | 1750 | 8800 |
| 40. | On application for duplicate patent under section 154 and rule 132. | — | 1600 | 8000 | 1750 | 8800 |
| 41. | (i) On request for certified copies under section 72 or for certificate under section 147 and rule 133(1). | — | 1000 (up to 30 pages and, thereafter, 30 for each extra page) | 5000 (up to 30 pages and, thereafter, 150 for each extra page) | 1100 (up to 30 pages and, thereafter, 30 for each extra page) | 5500 (up to 30 pages and, thereafter, 150 for each extra page) |
| | (ii) On request for certified copies under section 72 or for certificate under section 147 and rule 133(2). | -- | 2400 (up to 30 pages and thereafter, 30 for each extra page) | 12000 (up to 30 pages and thereafter, 30 for each extra page) | 3300 (up to 30 pages and thereafter, 30 for each extra page) | 13200 (up to 30 pages and thereafter, 30 for each extra page) |
| 42. | For certifying office copies, printed each. | — | 800 | 4000 | 880 | 4400 |
| 43. | On request for inspection of register under section 72, inspection under rule 27 or rule 74A. | — | 320 | 1600 | 350 | 1750 |
| 44. | On request for information under section 153 and rule 134. | — | 480 | 2400 | 530 | 2650 |
| 45. | On form of authorisation of a patent agent. | 26 | No fee | No fee | No fee | No fee |
| 46. | On petition not otherwise provided for. | — | 1600 | 8000 | 1750 | 8800 |
| 47. | For supplying of photocopies of the documents, per page. | — | 10 | 10 | 10 | 10 |
| 48. | Transmittal fee for International application. | — | 3200 | 16000 | 3500 | 17600 |
| 48A. | Transmittal fee for International application (for ePCT filing). | — | No fee | No fee | Not applicable | Not applicable |
| 49. | For preparation of certified copy of priority document and for transmission of the same to the International Bureau of World Intellectual Property Organization. | — | 1000 (up to 30 pages and, thereafter, 30 for each extra page) | 5000 (up to 30 pages and, thereafter, 150 for each extra page) | 1100 (up to 30 pages and, thereafter, 30 for each extra page) | 5500 (up to 30 pages and, thereafter, 150 for each extra page) |
| 49A. | For preparation of certified copy of priority document and e-transmission through WIPO DAS. | — | No fee | No fee | Not applicable | Not applicable |
| 50. | On statement regarding working of a patented invention on a commercial scale in India under section 146(2) and rule 131(1). | 27 | No fee | No fee | No fee | No fee |
| 51. | To be submitted for claiming the status of a small entity or startup | 28 | No fee | No fee | No fee | No fee |
| 52. | Request for adjournment of hearing under rule 129A (for each adjournment). | - | 1000 | 5000 | 1100 | 5500 |
| 53. | Miscellaneous form under rule 8(2), to be used when no other form is prescribed. | 30 | As applicable | | | |

”

**4.** In the principal rules, for the proviso to sub-rule (5) of rule 24C, the following proviso shall be substituted, namely:-

"Provided that a request for expedited examination under this rule filed by a startup or small entity shall not be questioned merely on the ground that the startup or small entity, having filed an application for a patent, ceases to be a startup or small entity due to the lapse of the period during which it is recognised by the competent authority, or its turnover subsequently crosses the financial threshold limit as notified by the competent authority.".

**F.No.P-24027/4/2020-IPR-III**

*Ravinder, Joint Secretary, Department For Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, New Delhi,*

***Note:*** *The Principal Rules were published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-Section (ii) vide number S.O.493(E) dated the 2nd May, 2003 and last amended vide Notification Number G.S.R. 652 (E) dated the 19th October, 2020.*

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# NPPA fixes ceiling prices of 2 formulations under Drugs (Prices Control) Order, 2013 relating to 80th Authority meeting dated 26.10.2020 – reg.

**NPPA Notification No.S.O.3977(E), dated 3rd November, 2020**

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O.1394(E) dated the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the item specified at Sr.No.11 & 13 of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O.1214(E), dated 25th March 2020, in so far as it relates to formulation packs mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

**TABLE**

| Sr. No. | Name of the Scheduled Formulation | Dosage form & Strength | Unit | Ceiling Price (Rs.) |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 1. | Praziquantel | Tablet 600 mg | Per tablet | 34.63 |
| 2. | Sodium nitrite | Injection 30 mg/ml | Per ml | 25.91 |

**Note:**

*(a) All manufacturers of Scheduled formulation, selling the branded or generic or both the versions of Scheduled formulation at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulation downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.*

*(b) All the existing manufacturers of above mentioned Scheduled formulation having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.*

*(c) 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 mentioned in column (5) of the above said table.*

*(d) 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 in column (5) of the above table 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.*

*(e) 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.*

*(f) Where an existing manufacturer of Scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.*

*(g) The manufacturers of above said Scheduled formulation shall furnish quarterly return to the NPPA, in respect of production/ import and sale of Scheduled formulation in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said Scheduled formulation shall furnish information to the NPPA, in respect of*

*discontinuation of production and/or import of Scheduled formulation in Form-IV of Schedule II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.*

*(h) The manufacturers not complying with the ceiling price and notes specified hereinabove 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 Act, 1955.*

*(i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.*

**PN/212/80/2020/F/**
**F.No.8(80)/2020/D.P./NPPA-Div.II**

*Prasenjit Das, Asstt. Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.*

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# NPPA fixes ceiling prices of 6 formulations under Drugs (Prices Control) Order, 2013 relating to 80th Authority meeting dated 26.10.2020 – reg.

**NPPA Notification No.S.O.3976(E), dated 3rd November, 2020**

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O.1394(E) dated the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

**TABLE**

| Sr. No. | Name of the Schedule Formulation | Dosage form & Strength | Unit | Ceiling Price (Rs.) |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 1. | TD Vaccine | Each dose of 0.5ml contains: Diphtheria Toxoid ≤5Lf (≥ 2IU) Tetanus Toxoid ≥ 5Lf (≥ 40IU) | Each 0.5ml Pack | 18.69 |
| 2. | TD Vaccine | Each dose of 0.5ml contains: Diphtheria Toxoid ≤5Lf (≥ 2IU) Tetanus Toxoid ≥ 5Lf (≥ 40IU) | Each 5ml Pack | 175.59 |
| 3. | TD Vaccine | Each dose of 0.5ml contains: Diphtheria Toxoid ≤25Lf (≥ 30IU) Tetanus Toxoid ≥ 5Lf (≥ 40IU) | Each 0.5ml Pack | 16.02 |
| 4. | Tacrolimus | Tablet 0.5 mg | 1 Tablet | 18.68 |
| 5. | Tacrolimus | Tablet 1 mg | 1 Tablet | 34.31 |
| 6. | Tacrolimus | Tablet 2 mg | 1 Tablet | 67.77 |

**Note:**

*(a) All manufacturers of Scheduled formulation, selling the branded or generic or both the versions of Scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.*

*(b) All the existing manufacturers of above mentioned Scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.*

*(c) 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 mentioned in column (5) of the above said table.*

*(d) 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 in column (5) of the above table 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.*

*(e) 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.*

*(f) Where an existing manufacturer of Scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.*

*(g) The manufacturers of above said Scheduled formulations shall furnish quarterly return to the NPPA, in respect of production/ import and sale of Scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said Scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and/or import of Scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.*

*(h) The manufacturers not complying with the ceiling price and notes specified hereinabove 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 Act, 1955.*

*(i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.*

**PN/212/80/2020/F/**
**F.No.8(80)/2020/D.P./NPPA-Div.II**

*Prasenjit Das, Asstt. Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.*

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# NPPA issues Addendum to S.O.1215(E) dated 25.03.2020 relating to 80th Authority meeting dated 26.10.2020 – reg.

**NPPA Addendum Notification No.S.O.3974(E), dated 3rd November, 2020**

**1.** The National Pharmaceutical Pricing Authority's Order No. 1215(E) dated 25th March 2020, published in the Gazette of India, Extraordinary, related to ceiling price fixation of Scheduled formulation packs of I.V. fluids (non-Glass with special features) is hereby extended for the following manufacturer with the insertion of the Sr.No., Name of Manufacturers and Products/ Brand name, specified in column no.(1), (2) and (3) respectively in Table 'B' of S.O. No.1215(E) dated 25.03.2020, as detailed below:

**TABLE**

| Sr. No. | Name of Manufacturer | Product/Brand Name |
|---|---|---|
| (1) | (2) | (3) |
| 16 | M/s R.K. Laboratories Pvt. Ltd | Eurohead bottle |
| 17 | M/s Eurolife Healthcare Pvt. Ltd | Life port |

**2.** The ceiling prices specified in Table A of S.O.1215(E) dated 25th March 2020 are applicable to the manufacturers specified in Sr.Nos.16 & 17 above from the date of publication of this Order.

**3.** All the notes and other contents mentioned in the original order S.O.1215(E) dated 25th March, 2020 shall remain same and are applicable except that notes (a) and (c) are not applicable to the manufacturers specified in Sr.Nos.16 & 17 above.

**PN/212/80/2020/F**
**F.No.8(80)/2020/D.P./NPPA-Div.-II**

*Prasenjit Das, Asstt. Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.*

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# NPPA issues Addendum to S.O.1216(E) dated 25.03.2020 relating to 80th Authority meeting dated 26.10.2020

### NPPA Addendum Notification No.S.O.3975(E), 2020 dated 3rd November, 2020

**1.** The National Pharmaceutical Pricing Authority's Order No.1216(E) dated 25th March 2020, published in the Gazette of India, Extraordinary, related to ceiling price fixation of Ringer lactate injection in pack having special features is hereby extended for following manufacturers with the insertion of the Sr. No. and Name of Manufacturers, specified in column no. (1) and (2) respectively in Table 'B' of S.O. No.1216(E) dated 25th March 2020, as detailed below:

**TABLE**

| Sr. No. | Name of Manufacturer |
|---|---|
| (1) | (2) |
| 11 | M/s. R.K. Laboratories Pvt. Ltd |

**2.** The ceiling prices specified in Table A of S.O.1216(E) dated 25th March 2020 are applicable to the manufacturers specified in Sr.No.11 above from the date of publication of this Order.

**3.** All the notes and other contents mentioned in the original order S.O.1216(E) dated 25th March, 2020 shall remain same and are applicable except that notes (a) and (c) are not applicable to the manufacturers specified in Sr.No.11 above.

**PN/212/80/2020/F/**
**F.No.8(80)/2020/D.P./NPPA-Div.II**

*Prasenjit Das, Asstt. Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.*

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# In Lok Sabha & In Rajya Sabha

## In Lok Sabha

## Impact of COVID-19 on MSMEs

**Lok Sabha Unstarred Question No.856**

**Shri Balubhau (Alias Suresh Narayan) Dhanorkar:**

**Shri Kani K Navas:**

**Shri Parvatagouda Chandanagouda Gaddigoudar:**

**Shri Sudheer Gupta:**

**Shri Bidyut Baran Mahato:**

**Shri Shrirang Appa Barne:**

**Shri P K Kunhalikutty:**

**Shri Sanjay Sadashivrao Mandlik:**

**Q**. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether a number of Micro, Small and Medium Enterprises (MSMEs) have fallen into the debt trap, resorting to retrenchment and are on the verge of closure after the outbreak of COVID-19 and subsequent lockdown in the country;

(b): if so, the details thereof, State-wise particularly in the State of Karnataka and the major reasons for their closure;

(c): whether the Government has assessed the losses of the said MSME industries in this regard and if so the details thereof;

(d): whether the Government has proposed/unveiled any kind of assistance/ sops to assist the sick/closed MSMEs;

(e): if so, the details thereof and if not, the reasons therefor; and

(f): whether the Government has so far granted any incentive to industrial units in MSME sector to sustain during this pandemic period and if so details thereof?

**Answered on 17th September 2020**

**A.** (a) to (c): Taking into account the stress on the MSME sector after the outbreak of COVID-19 and the subsequent lockdown, Government of India and Reserve Bank of India has announced series of measures to revive the MSME sector after the outbreak of COVID-19.

This inter-alia includes:

(i) moratorium upto 31st August, 2020 on repayment of installments of term loans/cash credit/over draft.

(ii) reducing the Cash Reserve Ratio and Repo rate.

(iii) Special refinance facility of Rs.15,000 crore to SIDBI for on-lending/refinancing.

(iv) Special liquidity scheme for NBFCs, HFCs and MGIS worth Rs.30,000 crore.

(v) Emergency Credit Guarantee Line of Rs.3 lakh crore for Standard accounts and stressed accounts (SMA-0 and SMA-1).

(vi) Credit Guarantee Scheme for Subordinate Debt for SMA-2 and NPA accounts for infusing Rs.20,000 crore in MSME Sector.

(vii) Credit Guarantee scheme for Street Vendors (PM SVAnidhi) which also involves interest subsidy.

(viii) partial credit guarantee scheme for the liabilities of NBFCs and MFIs etc.

The above measures are applicable to the whole of India including the state of Karnataka.

(d) to (f): The Atma Nirbhar Package announced by the Government provides various kinds of assistance to the economy including units in the MSME Sector. The Emergency Credit Line Guarantee Scheme (ECLGS) being implemented through the National Credit Guarantee Trustee Company Ltd (NCGTC) which is under the administrative control of Department of Financial Services (DFS), Ministry of Finance of Rs.3 lakh crore for Standard accounts and stressed accounts (SMA-0 and SMA-1). The

State-wise details of Emergency Credit Line Guarantee Scheme including the State of Karnataka is at ***Annexure-I*.** Moreover, Credit Guarantee Scheme for Subordinate Debt is also being implemented for SMA-2 and NPA accounts for infusing Rs.20,000 crore in MSME Sector. The two schemes are demand driven. As per the approved scheme following the announcement under the Atma Nirbahr Package the ECLGS shall be in operation till 31.10.2020 or till an amount of Rs.3 Lakh crore sanctioned. However, the CGSSD shall be in operation for 10 years or till an amount of Rs.20,000 Crore of guarantee amount is approved. (***Annexure-I not reproduced here***).

**Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)**

## Interest Subvention Scheme for MSME Sector

### Lok Sabha Unstarred Question No.909

### Shrimati Gitaben Vajesingbhai Rathva:

### Shri Nayab Singh:

### Shri John Barla:

**Q.** Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether under "Interest Subvention Scheme", the Government has added provisions in the scheme through amendment for access of credit at low cost and to increase production in Micro, Small and Medium Enterprises (MSMEs) sector;

(b): the name of the MSMEs industries which are provided further incentives under the said scheme;

(c): the details of the arrangements made to expand coverage and access under above scheme for MSME sector; and

(d): the number of people in Haryana getting benefit under the scheme in MSME sector?

### Answered on 17th September 2020

**A**. (a) & (b): As a part of the initiative on support and outreach for MSMEs Hon'ble Prime Minister announced the "Interest Subvention Scheme for Incremental credit to MSMEs 2018" on 2nd November, 2018. The Scheme offers 2% interest subvention for all MSMEs on fresh or incremental loans to the extent of Rs.100 lakh. The Scheme aims at encouraging both manufacturing and service enterprises (including trading activities) in the MSME Sector through access of credit at lower cost and to increase production.

(c): In order to expand coverage, as per extant guidelines issued by RBI, all scheduled commercial Banks (including Regional Rural Banks) and RBI registered systemically important NBFCs are made eligible institutions under Interest Subvention Scheme for MSMEs. Further, to expand coverage, besides manufacturing and service enterprises covered under MSMEs, trading enterprises have also been included under interest subvention scheme. The scheme has also been modified and made very simple for eligible lending institutions to extend benefits to MSMEs in December 2019.

(d): In the State of Haryana 45,404 MSMEs have been benefitted from the scheme. An aggregate amount of Rs.27.08 crore was released to the above units in Haryana involving a loan of Rs.1354 crore till 12.09.2020.

**Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)**

## High import of Active Pharmaceutical Ingredients (APIs)

### Rajya Sabha Unstarred Question No.697

### Shri Rajeev Satav:

**Q**. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether Indian pharmaceutical companies import more than 70% of the Active Pharmaceutical Ingredients (APIs) used for manufacturing medicines in the country;

(b): if so, the details of the countries from which India imports APIs along with the reasons for high import of APIs;

(c): whether Government has taken any steps for setting up Bulk Drug Parks in the country and if so, the details thereof, State/UT-wise; and

(d): the other steps taken by Government to create a self-reliant ecosystem in the pharmaceuticals, health and hygiene sector by ramping up domestic production which would help in building *Atmanirbhar Bharat?*

### Answered on 18th September 2020

**A.** (a) & (b): Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2019-20. India imports bulk drugs largely for economic considerations. The following are major countries from which India imported APIs during 2019-20:

| S. No. | Country | Percentage share of import |
|---|---|---|
| 1 | CHINA P RP | 68.04 |
| 2 | U S A | 3.53 |
| 3 | ITALY | 3.02 |
| 4 | SINGAPORE | 2.88 |
| 5 | SPAIN | 2.17 |
| 6 | GERMANY | 1.85 |
| 7 | FRANCE | 1.56 |
| 8 | JAPAN | 1.53 |
| 9 | DENMARK | 1.26 |
| 10 | HONG KONG | 1.25 |

Source: DGCIS, Kolkata

(c):Under the scheme Promotion of Bulk Drug Parks; financial assistance will be provided to the State implementing agencies for creation of common infrastructure facilities to three Bulk Drug Parks to be developed by State Governments. States will be selected on the basis of scores obtained by the proposals submitted by the states on predefined selection criteria (given in the scheme guidelines available on the website of the department under the tab titled 'schemes').

(d): With a view to attain self-reliance and reduce import dependence in APIs/Bulk drugs, the department of pharmaceuticals has rolled two schemes viz:

(i): "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" and

(ii): "Promotion of Bulk Drug Parks". The guidelines of both the schemes were released on 27th July, 2020.

**Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)**

## Provision of medicines at cheaper price during COVID-19 pandemic

### Rajya Sabha Unstarred Question No.698

### Shri Harnath Singh Yadav:

**Q.** Will the **MINISTER OF CHEMICALS AND FERTILIZERS** be pleased to state;

(a): the details of steps being taken by Government for controlling the prices of medicines and providing medicines at cheap/fair rate to the poor particularly during the alarming times of COVID-19; and

(b): whether it is a fact that some medicines have been added and some removed by making changes at a large scale in the control list by Government for providing medicines at cheaper price, if so, the details thereof?

### Answered on 18th September 2020

**A.** (a): The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling prices of Scheduled medicines which are specified in National List of Essential Medicines (NLEM) and are included in Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The ceiling price fixed by the NPPA is applicable on all the branded and generic versions of such formulations alike. The Indian Council of Medical Research (ICMR) under Ministry of Health & Family Welfare has issued revised Clinical treatment protocol for COVID-19 on 13.06.2020. As per ICMR protocol Hydroxychloroquine, Paracetamol, Methylprednisolone, Enoxaparin, Dexamethasone medicines are included in Schedule-I of the DPCO 2013. The ceiling price of these medicines have been fixed/revised by NPPA vide S.O.No.1213(E) dated 25.03.2020. The detail of price Notification is available on the website of the NPPA i.e. **www.nppaindia@nic.in.**

In respect of non-scheduled formulations, no ceiling price is fixed by the NPPA, the manufactures fix the Maximum Retail Price (MRP) of their formulations at the time of their launching. However, after launching, the NPPA ensures that no manufacturer can increase the MRP of non-Scheduled drugs by more than ten percent of MRP during preceding twelve months as per provisions of the DPCO, 2013.

In order to ensure smooth availability of drugs, the NPPA has set up a 'Control Room' with Helpline No.1800111255 and issues like non-availability of medicines, masks, gloves, hand sanitizers etc and High price of medicines, masks, gloves, hand sanitizers, etc were resolved promptly. A COVID-19 dash board on NPPA website, which has controlled latest Office orders, circulars, helpline number, Email for sending grievances etc., was created for convenience of public and other stakeholders.

Further, on the intervention of the NPPA and the Drugs Controller General of India {DCGI},

manufacturers of Remdesivir have created a Helpline to make available the remdesivir. However, both these drugs are not part of COVID-19 Protocol and continue as under investigational therapy Drugs. The availability of key medicines is also monitored through regular survey conducted by the officials of the Central Drugs Standard Control Organisation (CDSCO) on chemist shops at various localities across the country.

In the wake of COVID-19 crisis, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) has been rendering essential services to the nation. The stores remained functional during the lock-down period and maintained operations as part of their commitment to ensure uninterrupted availability of essential medicines. It was ensured to make available adequate stock of generic medicines at PMBJP stores.

(b): No, Sir.

**Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)**

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INTERVIEW

# We had to make Favivent cost-effective for everyone

***Ashish Uttam Bhuta**, CMD, Jenburkt Pharmaceuticals Ltd*

**Jenburkt Pharmaceuticals was the second Pharma company in India to introduce the oral antiviral Favipiravir. Jenburkt's Favivent is being used to treat mild to moderate Covid-19 symptoms. At the time of its launch, it was the lowest-priced Favipiravir in the market at Rs.39 for a tablet.**

***Excerpts* from an interview with Ashish Uttam Bhuta, Chairman and Managing Director, Jenburkt Pharmaceuticals:**

**Do take us through Jenburkt's role during the pandemic;**

*Right from March, when the nationwide lockdown was announced, not many [effective] medicines were available. We had Hydroxychloroquine, but it was used on an experimental basis. It was a tough situation because we were learning from what was happening in Europe, especially in Italy and Spain.*

*In June, Remdesivir was introduced for severe Covid-19 infection and the tablet Favipiravir was prescribed for mild to moderate cases of Covid-19.*

*We launched Favivent, which is a broad-spectrum antiviral agent that selectively inhibits RNA polymerase of influenza virus and prevents replication.*

*Given the current scenario of health concerns and economic challenges surrounding Covid-19, if we as a pharmaceutical company cannot make a significant positive difference to society, our company's very existence is inconsequential.*

**Tell us more about Favivent;**

*Favipiravir was developed by a Japanese organisation for the treatment of influenza. Initial reports from China said that it was helping in the treatment of mild to moderate cases of Covid-19. Japan, the Middle East and Russia also accepted this as a drug for Covid-19. So, the Drugs Controller General of India gave an emergency approval, considering the (rising) number of cases.*

*Jenburkt Pharmaceuticals launched Favivent at Rs.39 per tablet. It is manufactured in Telangana, (in a plant) which is compliant with the standards of the US Food and Drug Administration and the European Directorate for the Quality of Medicines and Health Care.*

*Favivent will be available in a strip of 10 tablets… as a prescription-only drug, which is to be administered under the supervision of a doctor.*

**Jenburkt is new to the antiviral drugs segment;**

*In April, we were deciding whether to get into this [segment] or not because this was an antiviral, just like the drug for HIV. Around May, we decided to go for it. Tragically, a few colleagues had lost their close ones to Covid-19.*

*The idea is that if one [takes] Favivent quite early, when the symptoms are mild, then one can be treated at home. Some reputed doctors with whom we had sessions said that whenever [the treatment] starts very early, a normal patient will respond to the drug within seven to eight days. And hence, hospitalisation may not be required.*

**How did you bring down the cost for Favivent to Rs.39?**

*When it was launched in India, Favipiravir was available for Rs.75 per tablet. Now, the number of tablets one needs to take is quite high. On day one, a patient must consume 18 tablets of 200mg each (nine in the morning and nine in the evening). From day two, one must take eight—four tablets each in the morning and evening. This can be had for up to 14 days.... At Rs.75 per tablet, the total cost of the dosage turned out to be far expensive and so we brought it down to Rs.39.*

*We felt that when the disease would spread to smaller towns and would have to be contained at a mild to moderate stage, we had to make it cost-effective for everyone. At that point in time, anyone who would price the drug below Rs.40 a tablet would either lose money or break even. So, this was never a money-making prospect for us, to begin with.*

*Perhaps, later, if the prices of the raw material fall down, one may end up making a bit of money. But we never started out with a business plan for Favivent. Our position was very clear that we would encourage other organizations to price the product less than Rs.40 as a service to the nation. But then, we saw that this price drop from Rs.75 to Rs.39 had triggered a price war because there were many organizations who had their business plans in place.*

*Importantly, our low pricing of Favipiravir 200mg tablets not only encouraged many to join us to serve the nation but also set a trend to price all future Favipiravir tablets launched (of a higher strength) to be proportionately priced. Hence the cost of treatment was reduced and thousands benefitted.*

**What were the challenges you faced while bringing out Favivent?**

*It is very tough. When the Drugs Controller approved this, it came with a three-month expiry. So the challenge is that you cannot reach out to all the chemists within this time-frame. We have a tool on our website by which any person who has been prescribed Favivent can find stockists in the city. The demand is high and there is a scarcity of the drug; the logistical challenges only add to it further. There are eight lakh chemists in India and it is impossible to manufacture so much in a short time and make it available every where.*

*The challenges of transit within districts, people not being willing to come [out] and the danger of Covid-19 transmission are some of the challenges we faced at our production facilities. We hope Favivent's easy accessibility and affordable price point will offer our citizens a timely therapeutic solution.*

*Source: Pooja Biraia Jaiswal, The Week, 07.11.2020 (Excerpts)*

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NEW DEVELOPMENTS

## Scientists Diving for Drug Compounds off California's Coast

The scientists, led by oceanographer Lisa Levin, will probe for the microscopic organisms and minerals off Southern California's coast. Levin and her team, at UCSD's Scripps Institution, will hit nine sites along the Southern California Borderland (SCB). This region, characterized by fault lines, is rich in invertebrates, microbes, and mineral-rich substrates all worthy of exploration.

"The residents of the deep sea, and the minerals that compose its floor, are of growing importance to modern society for two reasons," Levin wrote in a recent blog post. "[They] offer significant biopharmaceutical and industrial promises and some of the minerals, such as

those in phosphorite and iron-manganese (Fe-Mn) crusts, are increasingly rare and in demand."

Levin and her team will explore the SCB aboard the Ocean Exploration Trust's Exploration Vessel Nautilus—a.k.a. the (E/V) Nautilus. The 211-foot-long Nautilus, which has allowed scientists to observe countless deep sea creatures before, offers a robotic submarine (immediately above) that Levin's team will use to collect samples.

In regards to biopharmaceutical potential, it seems the sky—or the mantle?—is the limit. Wired, for example, notes that federal regulators frequently approve pharmaceuticals developed from marine plants; pharmaceuticals such as cancer treatment drugs, cholesterol-lowering drugs, and even antiviral drugs.

Levin adds in her blog post that ocean sediments harbor bacteria useful in the treatment of cancers, and shallow-water sponges and soft corals have yielded compounds for treating chronic pain. Griffiths in, a protein isolated from red algae, may even be able to help with mitigating HIV and SARS-CoV-2 infections.

Aside from the focus on pharmaceuticals, Levin and her team will be looking to generally catalog the mineral-rich biomes. Beyond looking for cancer treatments, or antiviral-drugs compounds, the scientists also want to study the SBC's still mysterious ecology.

"The crucial questions, if we ever plan to use these resources wisely for economic gain, are what lives [in the SCB] and what ecosystems services do they Governments and Corporations to understand the tradeoffs involved in exploiting deep-sea resources. And that's critical, as destroying the ocean's ecosystems may itself be hazardous to humanity's health.

Source: Matthew Hart, Nerdist, 27.10.2020 (Excerpts)

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NATIONAL NEWS

## Indian Pharma Market registers 9.6% Growth in October 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 9.6 percent for the month of October 2020, after growing at 4.5 percent in September. According to AIOCD AWACS report, the IPM has recorded sales of Rs.1,43,999 crore for Moving Annual Total (MAT) basis during October 2020. Amongst the top 10 Corporates, Mankind exhibited the highest growth of 8.6 percent, followed by Torrent Pharma at 7.9 percent.

Amongst the 11 to 25 ranked Corporates, Himalaya exhibited highest growth of 14.8 percent followed by Glenmark Pharmaceuticals at 16.6 percent. Amongst the 26 to 50 ranked Corporates, Boehringer Ingelheim registered the highest growth of 19.9 percent followed by Medley at 15.6 percent. Amongst the 51 to 75 ranked Corporates, Danone registered the highest growth of 31.2 percent.

Amongst the 76 to 100 ranked corporates, Reckitt Benckiser exhibited the highest growth at 29 percent, followed by Llyod Hc at 20 percent. Cardiac registered a monthly growth of 19.5% in October as compared to 17.1% in September 2020, while anti-diabetic registered growth of 9.7% compared to 6.5% in September 2020. The respiratory medicines showed marginal improvement and are -6.6% in October 2020 as compared to -10.5% in September 2020.

Post unlock down since June 2020, the struggle for anti-infectives 1.4% in September 2020 continues positive trend 6.6% in October 2020. Associated therapy like gastro exhibits growth of 13.6% in October 2020 as against 5.5% in September 2020, while vitamins have bounced back has growth of 22.6% in October as against 16.3% September 2020.

The pain and analgesics are at 2.8% in October 2020 as against -4.3% in September 2020. The NLEM 2013 containing molecules market showed growth at 4 percent, whereas the non NLEM market registered growth of 3.9 percent.

Source: Yash Ved, Pharmabiz, 10.11.2020

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## IDMA urges DoP to relax Environmental Norms for better utilisation of surplus capacity of Brownfield units to boost API production

The Indian Drug Manufacturers Association (IDMA) has urged the Department of Pharmaceuticals (DoP) to give flexibility in the present environmental regulations for better utilisation of surplus capacity of the existing Brownfield

manufacturing units for self-reliance in domestic production of Active Pharmaceutical Ingredients (APIs).

This comes close on the heels of Centre's recent move to remove minimum investment criteria and the condition of domestic sales from the Production Linked Incentive (PLI) scheme to boost bulk drugs production in the country. In a representation to the DoP recently, the IDMA has recommended that reasonable time limits for grant of various permissions for additional production from pollution control authorities is needed for timely implementation of the projects and ultimate success of the PLI scheme. Many of the eligible products are intermediates or require intermediates to achieve value addition.

Although para 5(f) of Environment Impact Assessment (EIA) 2006 Notification mentions APIs and intermediates, the recent relaxation in Environment Clearance (EC) Rules by Union Environment Ministry with reference to Notification dated October 15, 2020 for treating all bulk drug projects as B2 category has omitted the word "intermediates". Even the draft 2020 EIA Notification, which is yet to be notified, also mentions under para 5 (f) for API and intermediates. Unless included, intermediates production under PLI scheme will get delayed as EC will be insisted upon.

Besides this, baseline is not defined in the revised PLI scheme. It has therefore been recommended to offer clarity on the matter. It has also been recommended that change of location may be permitted as long as the committed investment is achieved. It is also recommended to rethink carrying forward an unused incentive amount from the first year as it may not be possible to achieve 100% production due to certain problems.

Finally, since the criteria of minimum investment is now removed in the revised Guidelines, some of the clauses are no longer relevant or need minor alterations, which need to be relooked at as there is no longer an investment criteria.

The clauses which are no longer relevant are with reference to that however the investment already made in the ancillary facilities shall not qualify for the purpose of the committed investment to be made under the scheme. Expenditure on land shall not be considered. Similarly guest house, recreation, building, office building, residential accommodation etc shall not be considered as threshold investment. Investment as defined in the Guidelines shall be considered for determining the eligibility. The applicant shall submit a certificate by Chartered Engineer by Project Management Agency (PMA) for committed investment by the applicant and shall be relied upon by PMA.

Source: Shardul Nautiyal, Pharmabiz, 09.11.2020

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## Industry sees regulatory processes attaining Global Standards with CDSCO, MHRA pact

Indian Pharma industry is upbeat about the pact between the Central Drugs Standard Control Organisation (CDSCO) and the UK Medicines and Health Products Regulatory Agency (MHRA) for cooperation and exchange of information related to medicines and medical devices. According to the industry, this pact will ensure that regulatory processes are of global standards and will strengthen ties between companies of the two countries in the development of COVID-19 vaccine, medicines and devices during the ongoing pandemic.

With the ongoing pandemic leading to fast tracking approvals of medicines and medical devices, the MoU seeks to strengthen the two regulatory bodies for Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Distribution Practices and Good Pharmacovigilance Practices (GpvP) come to the fore.

According to Dr Viranchi Shah, Senior Vice President, IDMA, India plays an important role as a global pharmacy. Signing of MoU between CDSCO and UK MHRA reflects that we are a strategic partner to UK for their Pharma and devices supply chain. IDMA welcomes this development and shall continue to work closely with the government and CDSCO, and in helping Indian companies access the UK markets. The pact focuses on bolstering trade ties and capacity building to scale up production of medicines and medical devices, and encourage scientific conferences between India and the UK. Working in an increasingly global environment, the sharing of intelligence on medicines and medical devices would reinforce good practices internationally, and identify emerging safety trends to protect public health.

This is the beginning of a new era where India is getting closure to global regulatory bodies. The MoU with MHRA is the step in the right direction by CDSCO. The sharing of best practices in GMP, GLP and GVP will help India to strengthen its regulatory systems meeting global standards as well as support in exports. In the coming decade, we can visualize harmonization of regulatory Guidelines to some extent and MHRA will start accepting CDSCO approvals

for granting MHRA certification to Indian companies. This collaboration will also support India to be part of PIC/S and ICH which is a long-standing wish list of Industry, said Kaushik Desai, a Pharma Consultant.

Suresh Khanna, Designated Partner, Dossier Solutions and Services LLP, noted that this was indeed a very bold decision and will be very helpful to CDSCO to keep abreast with latest developments internationally in regulatory domain. This is one step towards harmonization of regulatory practices followed by CDSCO and UK MHRA which will be very beneficial in the long run to the Indian Pharma industry and other stake holders in the areas of Pharma services.

Source: Nandita Vijay, Pharmabiz, 09.11.2020

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## India has proactively engaged with partner countries in fight against Covid: MEA


India has proactively engaged with partner countries in the joint fight against the Novel Coronavirus since March, Ministry of External Affairs (MEA) spokesperson Anurag Srivastava said on Friday, 06.11.2020.

While speaking at his weekly press briefing, Srivastava said: "Since March 2020, India has been proactively engaged with partner countries in our joint fight against Covidc-19 and this includes the supply of medicines, diagnostic kits, and medical equipment."

He informed that India has organized various online training programmes for testing and case management, as part of vaccine development efforts."We have organised training programmes on Clinical Trials for neighbouring countries in which nearly 90 experts from eight countries have participated. We stand ready to expand these cooperation programmes with other interested countries," the MEA spokesperson said. Srivastava also highlighted the briefing of participants on India's management of COVID-19, vaccine development programmes, software and related issues of vaccine delivery system, and international cooperation in that regard.

"As regards the tour, it will be organised later this month. It is open for all heads of missions and representatives of international organisations, and the participants will be visiting institutions in Pune where they can see first-hand institutions engaged in Covid-19 related research and vaccine development programmes," he added. The Coronavirus cases in India crossed the 84-lakh mark after 47,638 new infections were reported in the past 24 hours, according to the Union Ministry of Health and Family Welfare's data on Friday, 06.11.2020.

Source: ANI, ET-Health World, 07.11.2020

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## ICMR says second virus wave likely if Rules are ignored

Senior epidemiologists from the Indian Council of Medical Research have warned that states should not disregard the threat from a possible Covid second wave and must focus on strengthening individual protection. The experts said with several regions unlocking and increase in inter-state movement, chances of spikes are now high if citizens ignore precautions. "States cannot, and should not, take it easy. Delhi is seeing its third wave. States such Maharashtra should be on the alert," said Chief Scientist and Senior Epidemiologist Dr Samiran Panda.

Dr Panda said regions that may have allowed relaxations without ensuring individual protection are bound to see a rise in cases. "Covid infection waves can be state-specific, considering the precautionary measures that are in place to prevent rise in cases," he said. Giridhara Babu, of Public Health Foundation of India, said pockets with susceptible people will see outbreaks. Population movement and effective testing are important determinants of detecting outbreaks, he said. A C Mishra, a former Director of the National Institute of Virology, said the virus is unique and its biology is yet to be completely understood.

Mishra was at the helm during the SARS and swine flu outbreaks. 'This is more severe than SARS and swine flu. The only way forward is to keep our public health infrastructure — including care facilities for serious cases — in place as we have to learn to live with it," he said. With unlocks on, Mishra said contact tracing or door-to-door surveillance would be practically impossible to keep up due to high inter-state movement.

Source: ET-Health World, 07.11.2020

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## To Boost Pharma investments, Modi Government sets up panel to revamp policies & draw up action plan

The expert panel, consisting of 5 members from the industry and a Government official, has highlighted archaic labour laws & flawed definitions of fast-tracking mechanisms as hiccups. The Modi Government has formed an expert committee to identify the bottlenecks in the pharmaceutical industry and design an action plan to attract investments, ThePrint has learnt.

In an Office Memorandum issued 2 November by the Department of Pharmaceuticals (DoP), six representatives were chosen by the Government to revamp the Pharma policies in India. Of them, five are members from the Pharma industry and one is a Government official. The DoP is an apex authority that designs policies related to medicines in India under the Ministry of Chemicals and Fertilizers.

The expert panel includes Dinesh Dua, Chairman of Pharmaceuticals Export Promotion Council of India (Pharmexcil); B R Sikri, President of Federation of Pharma Entrepreneurs (FOPE); Mahesh Doshi, National President, Indian Drug Manufacturers' Association; V V Krishna Reddy, President, Bull Drug Manufacturers of India; and Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliances (IPA). Dr Sumit Garg, Deputy Secretary, DoP, is the Government official on the panel. All these associations represent big Pharmaceutical companies, including Glenmark, Sun Pharma, Dr Reddy's, Lupin, Ipca Labs and others.

### Duties of the panel:

According to the office memorandum, seen by ThePrint, the Government has tasked the panel with three basic responsibilities. "Examine the number and type of approvals and compliances needed in the sector by investors for setting up operations and compare them with those of the best countries in the world," it said. The panel mist also "identify common hurdles and bottlenecks pertaining to the investments". The final directive is to "prepare an action plan for maximum process improvements" based on the bottlenecks identified.

### Labour laws, multiple window clearance & other impediments discussed:

The panel held its first meeting immediately after the rolling out of the Notification. From archaic labour laws to flawed definitions of fast-tracking mechanisms, the panel highlighted several hiccups. "The first meeting took place on 3 November where everyone was heard and their points were noted," a member of the committee told. "The members so far have highlighted the need to give incentives to the companies to manufacture in India. There is a need to bring policies which encourage the industry to manufacture the latest molecules in India," the member added. "Newer diseases like Covid have placed enough evidence on the table that India needs to revamp its manufacturing policies for pharmaceuticals' sector," Sikri, another panel member, told.

Labourers are a big hindrance in the growth of our industry. There are 1,248 different laws. There are 17 definitions of wages, 22 definitions of workers, and 19 definitions of Enterprise. These laws hurt more than help," he added. The amount of skilling which is required in the sector is not happening despite having a separate Union Ministry for skill development, Sikri noted. On the contrary, he said, one of the reasons for China's success in the Pharmaceutical sector is its technical strength in skill development. "We have highlighted the issue," he said.

The panel has also highlighted the need for a 'single-window clearance' concept on the lines of China. Instead of using a generic term of "expediting the process or fast tracking the approval mechanism", a stipulated time-frame should be decided for each clearance, the panel has suggested.

Source: The Print, 08.11.2020

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## Pharma Products worth Rs.358 crore sold via *Jan Aushadhi Stores* this Fiscal: Government

Pharma products worth Rs.358 crore were sold through Jan Aushadhi stores during the first seven months of the current fiscal year, the Government said on Tuesday, 03.11.2020. Minister for Chemicals & Fertilizers D V Sadananda Gowda held a comprehensive review meeting of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) on Tuesday, 03.11.2020 the Ministry said in a statement.

Sales of Rs.358 crore worth of Pharma products through Jan Aushadhi stores were achieved in seven months up to October 31, 2020, of the current fiscal year, and the sales are likely to surpass Rs.600 crore for the entire fiscal year, it added. Gowda said there is a need to work on increasing awareness amongst people regarding efficacy

and quality of Jan Aushadhi medicines, increasing coverage with a focus on remote and rural areas, and making sure availability of medicines at each of the Jan Aushadhi shops, the statement said.

He also asked the Bureau of Pharma PSUs of India (BPPI) to prepare and submit a detailed action plan to achieve this goal, it added. Gowda also asked BPPI to strengthen supply chains by adopting innovative measures, the statement said. BPPI is the implementing agency for PMBJP.

Source: Farhat Nasim, Medical Dialogues, 05.11.2020

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## Ban use of disinfectants, UV rays on humans for Covid: Supreme Court to Centre

The Supreme Court on Thursday, 05.11.2020 asked the Centre to issue directions for banning use of disinfectants and ultra violet rays on humans for Covid-19 management. A bench headed by Justice Ashok Bhushan asked the Government to do the needful in this regard within a month. The bench passed the verdict on a plea seeking directions to the Centre to forthwith ban the installation, production and advertisement of disinfection tunnels involving spraying or fumigation of chemical disinfectants on humans.

On September 7, the apex court had asked the Centre why it has not banned the use of tunnels for disinfecting people for Covid-19 despite taking the stand that spraying of chemical disinfectants is physically and psychologically harmful. Solicitor General Tushar Mehta had earlier informed the court that the Health Ministry has not issued any advisory or Guideline on the use of ultraviolet lights for disinfection of humans for Covid-19 management.

Mehta had said that spraying of any chemical disinfectant is also physically and psychologically harmful for humans. The top court was hearing a PIL filed by Gursimran Singh Narula who also sought forthwith a ban on spraying or fumigation of organic disinfectants and exposing humans to ultraviolet rays for the purposes of disinfecting them.

The Centre, in its affidavit, had submitted that as public health and hospitals are state subject, it is for the states/ Union Territories to implement the Guidelines issued by the Health Ministry, and the role of Government of India is limited to providing necessary Guidance and financial support. It had said that on June 9, an expert committee meeting was held under the Chairmanship of Director General of Health Service to review the use of disinfectant tunnels, various chemicals and spraying of disinfectants along with the efficacy of such use of spraying/fogging.

The Centre had said the committee has reiterated that spraying of individuals with disinfectants (such as tunnels, cabinets, cambers) is not recommended as it will not diminish the infected person's ability to spread the virus through droplets or contact.

Source: PTI, ET-Health World, 06.11.2020

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## Sugam portal approves 1,34,298 out of total 1,51,724 applications related to medical devices and drugs during lockdown period

The Central Drugs Standard Control Organisation (CDSCO)'s Sugam portal has approved 1,34,298 out of the total 1,51,724 applications during the lockdown period related to import and registration of drugs, medical device and diagnostics, test license, biologicals, veterinary, BA/BE for export, global clinical trial, new drug, investigational new drugs and Fixed Dose Combinations (FDCs), among others.

Out of the total 1,51,724 applications which included 343 new ones, 2,459 applications are undergoing regulatory protocols and processes. SUGAM is an e-Governance system to discharge various functions performed by CDSCO under Drugs and Cosmetics (D&C) Act, 1940. The software system developed is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions and approvals.

It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online and generate the permissions online and generate MIS reports. It contains step-by-step guidance to the applicants of the SUGAM portal with screenshots of the workflow for various application submissions.

Following sections which are detailed in Sugam are User Registration and Login, Applicant Dashboard, Managing Sub login Accounts, Form Submission for various processes and Post Approval Changes. Applications were made in hard copy dossier format to various divisions in CDSCO before the Sugam portal was introduced. The timelines for granting permissions or approvals for

applications were almost three times more than what is there in the current scenario.

Earlier the fees for applications were made in the respective bank and then the copy of challan/receipt was submitted to CDSCO office. But now in Sugam portal, fee is calculated according to the applications and can be paid online on the same portal in bharatkosh.gov.in. The receipt for payment is available on the portal which can be downloaded and submitted in the application. Due to the introduction of the Sugam portal, India is now in the state to compete with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) regions. A separate medical device online portal was also started in line with new Medical Device Rules-2017 (MDR-2017) for applications related to medical devices and in-vitro diagnostics (IVDs).

Source: Shardul Nautiyal, Pharmabiz, 05.11.2020

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## BIRAC invites applications from Indian biotech companies for funding R&D

The Biotechnology Industry Research Assistance Council (BIRAC), under its Small Business Innovation Research Initiative (SBIRI) scheme, has invited proposals from Indian biotech companies for funding of Research and Development in the field of biotechnology. Under this SBIRI scheme, the BIRAC will provide support for innovation research in biotech companies including start-ups, small and medium enterprises and other 'for-profit' private companies.

Under this flagship Public-Private Partnership (PPP) programme, BIRAC will provide support to the biotech companies for discovery; proof-of-concept and early stage innovations; and R&D aimed at affordable product development. BIRAC is a not-for-profit, public sector Company set up by Department of Biotechnology (DBT) to promote and nurture innovative research in biotech enterprises. The eligible companies can send their proposals till November 30, 2020. The key feature of the scheme is that it is an advanced technology scheme for high risk, transformational technology/process development from proof-of-concept to validation leading to high value product commercialization; it supports new and futuristic technology development with major social bearing but uncertain market driven demand; and it also supports start-ups SMEs and other biotech companies on cost sharing basis.

The SBIRI aims to strengthen those existing private industrial units whose product development is based on in-house innovative R&D; encourage other smaller businesses to increase their R&D capabilities and capacity; to create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs; and stimulate technological innovation. The objectives of this programme are to provide support for early stage, pre-proof-of-concept research in biotechnology by industry; to support new indigenous technologies particularly those related to societal needs in the healthcare, food and nutrition, agriculture and other sectors; and to nurture and mentor innovative and emerging technologies/entrepreneurs, to assist new enterprises to forge appropriate linkages with academia and government. A single or consortia of Indian companies, registered under 'The Indian Companies Act 2013' with minimum 51 percent of Indian ownership, and in-house R&D unit, are eligible apply for this programme, either alone or in collaboration with another company, institute or university.

Source: Neethikrishna, Pharmabiz, 07.11.2020

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## India tops Global Survey on Covid-19 vaccination intent; rising hesitancy in many countries

Indians are the keenest on getting vaccinated whenever a Covid-19 vaccine is available, even as people in 10 out of 15 countries showed a growing reluctance about getting vaccinated, according to a global survey. In the World Economic Forum/ Ipsos survey of 18,526 adults from 15 countries, 73 percent said they would get a Covid-19 vaccine if available, down from 77 percent in August.

While vaccination intent has remained unchanged at 87 percent in India since August, it has declined in 10 of the 15 countries surveyed, most of all in China, Australia, Spain and Brazil.

Globally, the two main reasons for not wanting to get a Covid-19 vaccine are concerns about side effects (cited by 34 percent) and concerns about Clinical Trials moving too fast (cited by another 33 percent). In India also, 34 percent

respondents said they are worried about side effects, while 16 percent are concerned about fast-moving trials.

Besides, one in ten persons globally said they are against vaccines in general (19 percent in India), while another 10 percent said they don't think a vaccine will be effective (14 percent in India), and 8 percent cited a low risk of getting Covid-19 (14 percent in India), as per the survey.

The World Economic Forum (WEF) said the latest survey has shown a growing reluctance to receive a vaccine, despite progress made by numerous pharmaceutical companies working on vaccine trials and international organisations like the World Health Organization (WHO), Gavi and CEPI working to ensure any future solution is available for those most in need.

Arnaud Bernaert, Head of Shaping the Future of Health and Healthcare at the WEF, said, "This drop in vaccine confidence is a remarkable and sad trend as we edge closer to a possible vaccine roll-out." "The numbers are significant enough to compromise the effectiveness of a Covid-19 vaccine to manage the disease and to see an end to the cycle of new lockdowns and restrictions. It is critical that Governments and the private sector come together to build trust in the next steps. It's important to know that when a vaccine is ready, it will make a difference," Bernaert added.

The survey also asked the respondents how soon after a vaccine becomes available would they get one. Nearly half of the adults globally said they would get vaccinated within three months after the Covid-19 vaccine is available to all (54 percent in India).

Globally, 72 percent said they would get vaccinated within a year (82 percent in India). The WHO had called 'public hesitancy towards vaccination' as one of the top-10 threats to global health in 2019, affecting not only public health but businesses and economies also.

The survey was conducted by leading market research company Ipsos from October 8-13, 2020, with a sample of 18,526 adults in the US, Canada, South Africa, Australia, Brazil, China, France, Germany, India, Italy, Japan, Mexico, South Korea, Spain, and the UK. The survey also put Indians as being the second most optimistic about availability of a Covid-19 vaccine soon -- 34 percent expecting it within three months and 72 percent within six months. China topped the chart with 37 per cent expecting a vaccine in three months and 75 percent in six months.

Globally, 16 per cent expect the first vaccine for general use in three months and 45 percent in six months. More than 4.8 crore people have tested positive for the virus so far globally, while more than 12 lakh have died. India's Covid-19 case load has crossed past 84 lakh, while nearly 1.25 lakh have died.

Source: PTI, ET-Health World, 07.11.2020

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## India needs 6 cr+ glass vials to pack vaccine in first 6 months

India would require around 6.10 crore glass vials to pack Covid-19 vaccines for the first six months once a vaccine is available and Pharma companies developing the shots have indicated they have sufficient stock to cater to the immediate demand.

There is also an additional capacity to manufacture 9.3 crore vials over next six months, while some of the vial-makers are also planning to further augment capacity, official sources said.

A Government sub-committee -- under the National Expert Group for Vaccine Administration for Covid-19 which is examining supply chain and logistics has prepared a blueprint with projected demand, inventory, spare capacity and the plans of companies to ramp up. This plan has been drawn after consultations with vaccine manufacturers and vial-makers to ensure there is full preparedness while expectations are rife that a vaccine against Covid-19 will be ready for rollout in early 2021, a senior official said.

"The three vaccine makers – Bharat Biotech, Serum Institute and Cadila – which are working on Covid-19 vaccines have indicated that they will together need around 6.10 crore glass vials to store the vaccine in the first six months and that they have sufficient stock with them to cater to this demand. We have also held meetings with vial-makers who have indicated their spare capacity to manufacture more," the official said. Major players in the vial manufacturing segment include Schott kaisha, Saint Gobain, Borosil Klasspack and Gerresheimer India. The Health Ministry has indicated that once the Covid-19 vaccine is approved, it will be administered to 20-25 crore people including healthcare and front-line workers by mid-2021. A two-dose vaccine would mean around 50 crore doses in the first phase.

Source: ET-Health World, 07.11.2020

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## Alembic Pharma gets US FDA nod for elevated intraocular pressure drug

Drug firm Alembic Pharmaceuticals on Monday, 02.11.2020 said it has received final nod from the US health regulator for its Timolol Maleate ophthalmic gel forming solution used for the treatment of elevated intraocular pressure. The company has received final approval from the US Food and Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA) Timolol Maleate ophthalmic gel forming solution, 0.25 percent and 0.5 percent, Alembic Pharma said.

The product is generic version of Bausch Health US' Timoptic-XE ophthalmic gel forming solution in the same strengths, it added. The company "has been granted a Competitive Generic Therapies (CGT) designation for this ANDA and it is eligible for 180 days of CGT exclusivity as it is the first approved ANDA," Alembic Pharma said. This application has been co-developed in partnership with Orbicular Pharmaceutical Technologies, it added.

According to IQVIA, Timolol Maleate ophthalmic gel forming solution, 0.25 percent and 0.5 percent has an estimated market size of USD 71 million for the 12 months ending June 2020, Alembic Pharma said. The product is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma, it added.

Source: PTI, ET-Health World, 26.10.2020 (Excerpts)

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## India's R&D Policy to bolster drug discovery

Indian drug companies have a new ally. The UAE Government is all set to provide incentives, including financial contributions, and will help create a full ecosystem to support Indian pharmaceutical companies having strong Research and Development facilities, reports The Pharma Letter's India correspondent. With the Department of Pharmaceuticals' (DoP) vision of developing India as a drug discovery and Pharma innovation hub, the Indian Government recently concluded a rapid assessment of India's opportunity in Global Pharma R&D.

The basis of the DoP's vision was a white paper shared by McKinsey, which outlined potential and key imperatives for the Indian Government, even as it described several opportune areas for developing excellence. It was pointed out that almost all the patented pharmaceutical products have come from Global Big Pharma, and their Research and Development (R&D) spend as a percentage of sales is around 20% of their sales turnover. In terms of highest R&D spending ratio to revenue for Indian drug companies, data showed Sun Pharma Advanced Research Company (SPARC) had 587% investment, followed by another drugmaker, Suven Life Sciences, which spent 304% of its revenues on R&D in FY20. Other Pharma companies also figured in the largest spenders of R&D in absolute terms.

Alembic Pharma and Unichem Labs spent between 14% and 31% of their revenues on R&D. Dr Reddy's Lab spent 11.3%, Cipla 8.9%, Aurobindo Pharma 6.3% and Sun Pharma 9.8%. In financial year 2020 in India, Lupin spent $225 million on R&D (14.3%). By contrast, the lowest was by Torrent with $57 million. On an average, Indian Pharmaceutical companies tend to spend less than 13% of their annual turnover on R&D.

### UAE opportunities:

At a recent event, The UAE-India Healthcare Conference 2020, organized jointly by the Embassy of India, Abu Dhabi, and Consulate General of India, Dubai, FICCI and Invest India, it was pointed out that higher R&D costs, a relatively dry pipeline for new drugs, increasing pressure from providers for reduced healthcare costs and a host of other factors are putting pressure on global pharmaceutical companies.

Speakers noted India's booming pharmaceuticals industry is not only a great source of innovation and employment generation, but also has become a global healthcare provider in need. During the Covid-19 pandemic, speakers said India has shown exemplary work on international cooperation by sending valuable medicines to many countries, and added India is now world renowned for its Pharma innovation and for producing high quality medicines at a low cost.

Pavan Kapoor, India's Ambassador to the UAE, drew attention to the close collaboration between the two countries during Covid times and stated the UAE Government is keen to explore ways to promote collaboration and partnerships and has shown a strong desire for setting up manufacturing facilities for vaccines and generic medicines by Indian companies that have strong R&D facilities.

Ambassador Kapoor asked Indian companies to look closely at the offer, aimed at providing an excellent opportunity to enter the Gulf Cooperation Council (GCC) as well as African markets in the entire Pharma supply chain ecosystem, and emphasized that there were huge

opportunities for the UAE to invest in India where seven mega drug parks have recently been announced. Almost $20 billion of India's Pharma output is exported, said speakers, with 40% of exports predominately to the US, the UK and other countries like South Africa though India remains a price sensitive market, speakers said the increased buying power and epidemiological changes prevalent in the country could spur dramatic growth in sales volumes.

Investment high:

Drugmakers Granules India and Laurus Labs are all set to invest in Genome Valley in Hyderabad. Granules India, a Hyderabad based company, announced a major investment of $53 million to set up a manufacturing facility with a capacity to manufacture 10 billion units of finished dosages. The proposed unit will generate employment for about 1,600 people. Granules India has manufacturing sites in eight locations and presence in 75 countries across the globe. The company already operates the world's largest commercial Pharmaceutical Formulation Intermediates (PFI) Facility at Gagillapur near Hyderabad. In a related development, Laurus Labs, a leading research driven drug maker, announced the setting up of a formulation facility with a unit capacity of 5 billion. The company plans to invest $40 million in two phases. Phase one of the plant is expected to provide employment to about 150 people. Laurus Labs has its R&D facility in IKP Knowledge Park, Hyderabad, and also operates six manufacturing facilities in Visakhapatnam in Andhra Pradesh. All these facilities have been certified and approved by WHO, US FDA, NIP Hungary, and other renowned agencies. Laurus Labs is one of the leading manufacturers of API for anti-retroviral (ARV), oncology, cardio-vascular, anti-diabetics, anti-asthma and gastroenterology.

Great Opportunities:

Even as the Indian Government is set to announce a R&D policy for the pharmaceutical sector as it looks to place India's Pharma on par with the USA and Europe, a new report has noted there are multiple opportunities for Indian vaccine manufacturing companies, considering the knowledge base, cost of production and skilled labour. India is looking at a great opportunity to ramp up investments and collaborate with global players in the Pharma and biotech domain to cater to global needs, states research agency JLL (Jones Lang LaSalle) in its latest report. "As the shift of major business would move to multiple countries, the infrastructure around manufacturing facilities on logistics, supply chain, cold chains, data integrity and security systems may lead to increased drug costs of APIs and finished Pharma products," said M V Harish, Managing Director, PDS - India and Sri Lanka, JLL. India is staring at a golden opportunity to ramp up its R&D, technology, manufacturing, and innovation and attracting larger investments, he added.

Source: The Pharmaletter, 03.11.2020

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## Industry appreciate Cabinet sanction of Rs.15000 crores for Pharma PLI scheme

***Stakeholders feel that it is a timely action towards making the industry self-reliant***

The industry has appreciated the cabinet's approval of Rs.15000 crores for the Production Linked Incentive (PLI) scheme in the Pharma sector. In an earlier move, the Government had approved Rs.6,940 crores for 53 Bulk Drugs. The industry feels that it is a timely action towards making the industry self-reliant.

B R Sikri, Chairman FOPE, and Vice President, BDMA, said, "As the Chairman of an industry association, I would like to appreciate the timely effort of the Government in bringing the PLI scheme to make the industry Aatma Nirbhar and more strong in the Global Pharma Market."

Mahesh Doshi, National President, IDMA commented, "As previously also we requested the Government authorities to incorporate the Brownfield projects in the PLI scheme, we continue in making the appeal to the concerned authorities to incorporate the request of incorporating the Brownfield projects as well. We urge to the Government bodies to look into it while formulating the policy for the recently announced PLI scheme. Overall, we appreciate the Government's move as it will benefit the industry in the long run."

The three categories which have been identified and included in the PLI scheme for Pharma are:

### Category 1:

1) Biopharmaceuticals;
2) Complex generic drugs;
3) Patented drugs or drugs nearing patent expiry;
4) Cell-based or gene therapy products;
5) Orphan drugs;
6) Special empty capsules;
7) Complex excipients.

Category 2:

Active Pharma Ingredients (APIs)/Key Starting Materials (KSMs) and /Drug Intermediaries (DIs).

Category 3:

1) Repurposed Drugs;
2) Auto-immune drugs;
3) Anti-cancer drugs;
4) Antidiabetic drugs;
5) Anti Infective drugs;
6) Cardiovascular drugs;
7) Psychotropic drugs;
8) Anti-Retroviral drugs;
9) In vitro Diagnostic Devices (IVDs);
10) Phytopharmaceuticals.

The Department of Pharmaceuticals (DoP) will be formulating the policies and the industry stakeholders anticipate that it will come by the end of the current Financial Year.

Source: Usha Sharma, Express Pharma, 11.11.2020

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GOVERNMENT COMMUNICATIONS

# Provision of fall clause quoted in tender documents for procurement of drugs - reg.

**DoP OM No.31026/1/2019-Policy, dated 12th November 2020**

**1.** The undersigned is directed to refer to the above subject and say that it has been brought to the notice of this department that many Government procuring agencies are quoting the provision of fall clause in their tender documents for procurement of drugs despite the fact that the Manual for Procurement of Goods, 2017 in para 8.1.14 of **Chapter-8** (copy enclosed)* on sale of goods such as drugs, which have an expiry date.

**2.** Accordingly, the Ministries/Departments which are involved in the procurement of drugs through agencies under their administrative control are requested to take into account that the provision of fall clause does not apply on the sale of drugs which have an expiry date, and to ensure that tenders are issued accordingly.

This issues with the approval of Secretary Pharmaceuticals.

*Byasadev Naik, Deputy Director, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.*

*(*Not reproduced here. Members-interested to have the **Chapter-8**, may kindly write to IDMA Secretariat at email:* actadm@idmaindia.com *so as to enable us to mail the soft copy of the same).*

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ed by a registered mobile number based One Time Password facility.

**ination:** For the purpose of this rule, a Nil return or Nil details of outward supplies or Nil stateme a return under section 39 or details of outward supplies under section 37 or statement under r tax period that has nil or no entry in all the Tables in **FORM GSTR-3B** or **FORM GSTR-1** or **FOR 08,** as the case may be".

said rules, in rule 80, in sub-rule (3), for the proviso, the following proviso shall be substituted, nar

ided that for the financial year 2018-2019 and 2019-2020, every registered person whose aggregate tu eds five crore rupees shall get his accounts audited as specified under subsection (5) of section 35 furnish a copy of audited annual accounts and a reconciliation statement, duly certified, in **FORM GS** e said financial year, electronically through the common portal either directly or through a Facilitation ed by the Commissioner."

# The Pandemic has provided the industry to recalibrate and leverage the use of Digital Technologies: Prof Bejon Kumar Misra

***Prof Bejon Kumar Misra,*** *Founder-Director, Patient Safety and Access Initiative of India Foundation*

***Indian Pharma products have passed several quality studies by various bodies such as US FDA, NIB, etc and have been found acceptable for patient usage***

Indian-manufactured generics and other drugs have significantly contributed to the growth of the Indian pharmaceutical industry through the decades and even more so during the pandemic. With immense manufacturing capacity and high export volume, the Pharma Industry not just contributes to the Indian economy but net foreign exchange for the country.

Having said that, the industry has promoted the betterment of the global public health outcomes by lowering the treatment costs of diseases such as Leukaemia and Hepatitis C through affordable therapeutics. The unceasing demand for Indian origin pharmaceutical products has enabled the industry to carve a niche for itself in the global ecosystem. In true sense, what 'Atmanirbhar Bharat' should be as a success model.

India contributed to one-fifth of the world's exports of generic drugs in 2019. The country also accounts for 26% of generic drug imports in European markets and 40% in the US. Despite this, there are several misconceptions regarding the quality of Indian generics, especially in the US, which is industry's largest market. A survey conducted by Web MD in collaboration with the US FDA suggested that close to 75% of the healthcare practitioners and patients in the US believe that the quality of drugs manufactured outside the US are of lower quality. There are several such studies instituted by organizations at more local scale, limited to individual countries. While necessary, such studies which consider limited variables and more specific sample sizes tend to project a skewed perspective. Taking cognizance of this, a couple of years ago the Government of India launched one of the largest qualitative studies to assess the quality of drugs manufactured in India. Spearheaded by the National Institute of Biologicals (NIB), the exhaustive study spanned over two years and a project report on 'Survey on the Extent of the Problem of Spurious and Not of Standard Quality (NSQ) Drugs in India' was released. India was one of the first countries in the world to institute such a large scale study with vast sample size.

In this context, it is extremely encouraging that the US has come forward to commission extensive and exhaustive studies to assess the quality of drugs imported. The US FDA's recently released study on 'Quality Testing of Difficult-to-Make Prescription Pharmaceutical Products Marketed in the US' is a step in the right direction. The US FDA's report concludes that the quality of drugs imported and legally marketed in the US are on-par with those manufactured domestically. With Indian generics accounting for 36% of the sampled products and 9% of finished formulations, the drugs were marked acceptable for patient usage.

Why do studies and statistics matter?

With patient centricity and quality as key tenets, the Indian Pharma industry manufacturers exports pharmaceutical products to more than 200 countries. India has been supplying life-saving drugs to most of the countries for decades. It is alarming for experts who work in the interest of patients to read media reports claiming India to be a hub of substandard and spurious medicines. The best way to address these misnomers is to conduct more qualitative and quantitative research studies at various capacities. Furthermore, as India is expanding and establishing its footprint in Pharma markets across the world, it is imperative to evidence the reality with academic research. The country passed the highest number of US FDA inspections between 2009 and 2016 with 840 FDA inspections in 2016. Such nuances ought to be highlighted to ensure elimination of dubious reports. This is only possible if global organizations like the World Health Organization collaborate with various regulatory authorities and work towards protecting the interests of countries with robust pharmaceutical ecosystems.

Bridging the necessary gaps:

The high volume of drugs exported by India is an evidence that countries around the world prefer Indian-

origin generics. This should also act as a trigger for the Indian Government to heavily invest in the pharmaceutical industry and foster an environment conducive to nurture R&D and innovation which would translate into creation of jobs. India's total healthcare spending stands at 3.6% of GDP which is significantly lower than that of other countries. There is a need to increase the spend to at least 5% of the GDP, in the near future. The Pandemic has provided the industry to recalibrate and leverage the use of digital technologies. This increasing penetration of digital technologies in the ecosystem has given a rise to online pharmacies. The Government should rethink the regulations Governing this growing market and ensure that online players come under the gambit of stringent laws and regulations the Pharma industry is subject to. The industry and Government should also work in tandem towards harmonizing the Drugs and Cosmetics Act of India with best global practices. These regulatory overhauls must be accompanied by incentivizing pharmaceutical companies venturing into new drug discovery and vaccine development with a focus on quality. Furthermore, there is a dire need for the development of a robust distribution system along with non-clone-able tracking and tracing mechanism in place to ensure that medicines are not subject to tampering, thus assuring quality. The industry must also look at an operational process wherein the safe disposal of expired medicines is addressed. The time is right for India to mobilize resources for manufacturing of Pharmaceutical products and reduce taxes on medicines, which are currently high. The country should also consider bringing rational competitiveness by using good marketing and ethical practices, keeping patient centricity and quality at the centre of all policies.

(Disclaimer: The views expressed are solely of the author and ETHealthworld.com does not necessarily subscribe to it. ETHealthworld.com shall not be responsible for any damage caused to any person/organization directly or indirectly.)

Source: ET Health World, 07.11.2020

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for all stakeholders have already been initiated and the task force at PvPI is also arranging online trainings and workshops for Market Authorization Holders (MAHs), NABH accredited hospitals and other stakeholders to ensure capacity building in Pharmacovigilance. Dr Gupta further added, "PvPI took prominent actions for reporting of ADRs on account of emergency use of different medicines in prophylaxis and treatment of COVID-19 infection. PvPI tools such as Toll free Helpline number - 1800-180-3024 and android mobile app 'ADR PvPI' made available for all stakeholders to report the safety issues of medicines."

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