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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

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# IDMA BULLETIN

**Vol. No. 51 Issue No. 43 15 to 21 November 2020**

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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 Pre-Union Budget 2021-22 Proposals – reg.

**ATTENTION MEMBERS**

***The Association has submitted the following suggestions on Direct Taxes and Indirect Taxes for the Union Budget 2021-22 Proposals on 12th November 2020 to Shri Navdeep Rinwa, IAS, Joint Secretary, Department of Pharmaceuticals, New Delhi in response to DoP Letter No.31019/1/2020-Policy, dated 5th November 2020. Similar submissions have also been made to Shri K C Varshney, IRS, Joint Secretary (TPL-1), Central Board of Direct Taxes, Ministry of Finance and Shri G D Lohani, IRS, Joint Secretary (TRU-1), Central Board of Indirect Taxes and Customs, Ministry of Finance, New Delhi in response to their letter No.334/4/2020-TRU, dated 23rd October, 2020 on the above subject:***

## IDMA Pre-Union Budget 2021-22 Recommendations: Direct Taxes

| Sr. No. | Issue | Issues | Recommendations |
|---|---|---|---|
| 1. | **Section 115BAA: Reduced rate of tax 22% not available to non-corporate assessee.** | ▪ The Ordinance covers only Domestic companies excluding non-corporate tax payers which is unfair as these tax payers also contribute equally to nation's exchequer | ▪ Majority of trade partners (e.g. distribution channel partners) operate on non-corporate entity structure and they play very important role in the overall business cycle and therefore, excluding them from the reduced tax benefit u/s. 115BAA is not only unfair on their part but also make them relatively less tax efficient.<br>We therefore, recommend that all the tax payers should be covered under the new ordinance and be granted the benefit of reduced rate of tax option. |
| 2. | **Dividend Tax in hands of shareholders should be at par with Buy back** | ▪ Buy back proceeds in the hands of shareholders is not taxable in the hands of shareholders of listed entities. However, Dividend received by the same shareholder is taxable at 10% if dividend received is above Rs. 10 lakhs. | ▪ We believe, this is an unintended anomaly. Both, dividend pay out and buy back of shares, are modes of distributing surplus cash to shareholders. With Dividend becoming taxable in the hands of shareholders, the whole purpose of distribution of surplus cash gets through this mode becomes tax inefficient *vis-à-vis* buy back.<br>▪ We therefore, recommend that the Dividend Tax in the hands of shareholders be withdrawn and the same be made exempt from tax in line with buy back provisions. |

| Sr. No. | Issue | Issues | Recommendations |
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| 3. | **Brought forward Minimum Alternate Tax (MAT) credit allowability** | ▪ Once the company exercises the option of paying reduced rate of tax, the brought forward MAT credit lapses. | ▪ MAT credit is nothing but tax payment by the taxpayer in addition to the normal tax which he is otherwise liable to pay and any such payment and credit thereof is promise given under the law to protect his future cash outflow.<br>We therefore, recommend that withdrawing the legitimate credit allowed (promised) under the law is uncalled for and unfair and should be allowed to be set off even when assessee exercise the option u/s. 115BAA. |
| 4. | **Depreciation on Medical/ Surgical/Pathological equipments** | ▪ In line with the roadmap for phasing out the deductions and incentives along with the corporate tax rate, the maximum rate of depreciation available from FY 2018-19 is 40%. The rate of depreciation continues to be 40% till date. Further the Depreciation rate of 40% continues to be in force from A.Y. 2004-05. However, in case of certain medical equipments the higher rate of depreciation currently available is on account of the obsolescence of the equipment and not on account of an incentive provided. | ▪ Depreciation rate for all medical/ surgical/pathological equipments including life-saving medical equipments should be increased to 60%. |
| 5. | **Section 37(1) - CBDT Circular No. 5/2012** | ▪ As per the said circular expenses incurred on freebies to doctors are inadmissible under Section 37(1) of the Income-Tax Act, 1961 ('Act'). However, the circular is unclear in its current form on the aspects of scope of expenses, it's applicability and manner of administration. | ▪ There is already a mechanism in Section 37(1) of the Act to disallow expenses which are personal or illegal in nature.<br>▪ Therefore, in no circumstances the AO should be left with the discretion to determine which expenses are in violation of the appropriate applicable code/law. To this effect, the disallowance should be made only where an adjudication has been done by an appropriate authority having jurisdiction or by AO where it is evidently clear from the facts. |

| Sr. No. | Issue | Issues | Recommendations |
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| | | | ▪ **Freebies should be clearly defined in terms of cost of such freebies or other gifts or providing a threshold for the allowance of such expenses.**<br>▪ As an another interim measure, the CBDT may consider to constitute a panel with adequate representation from the Revenue, Department of Pharmaceuticals and Trade to define which expenses would be considered as 'ethical'/ 'unethical' (eg. samples, conferences, etc) and Guidelines for implementation.<br>▪ Notwithstanding the above, the provisions of the Circular should be prospective in nature and not effective from the date of the Regulations (i.e. 10 December 2009).<br>▪ **Further, the Circular should be linked to violations of Uniform Code of Pharmaceutical Marketing Practices for Indian Pharmaceutical Industry ('UCPMP') as and when it becomes mandatory. Till such time Circular should be kept in abeyance. The UCPMP is a voluntary code of marketing practices for pharmaceutical companies in India and it was introduced in March 2012 by the Department of Pharmaceuticals. Further, Department of Pharmaceuticals is now in process to re-draft the UCPMP code and is engaged in discussions with the stakeholders from the pharma and medical device industry for their comments.** |
| **6.** | **Weighted deduction for Rural Health Infrastructure** | ▪ **Rural and semi-urban areas in India do not have basic healthcare infrastructure and the same needs to be augmented and strengthened.** | ▪ A weighted deduction of 200 percent of the amount spent on specified activities like investment in rural/semi-urban healthcare infrastructure.<br>▪ Even donations to institutions carrying out building of such an infrastructure should be qualified for weighted deduction. |

| Sr. No. | Issue | Issues | Recommendations |
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| | | | ▪ With special focus of the Government on scheme like Aayushman Bharat, such provisions will give big boost to the pharma players to contribute to success of the scheme. |
| 7. | **Special scheme/policy for Pharmaceuticals and allied industry** | ▪ Currently, Active Pharmaceutical Ingredients ('APIs') (raw material used to make bulk drugs) are majorly imported from China. India imports around 80%-90% of its raw material from China. Thus, India runs the risk of a severe shortage of medicines because of it's over dependence on China for sourcing raw material for drugs. | ▪ **There is a need for India to take immediate concrete steps to create adequate infrastructure to become self-sufficient for manufacturing medicines which are essential in nature. Therefore, it is recommended to formulate policy/scheme on a priority basis to boost manufacturing of APIs in India.**<br>▪ With introduction of new section 115BAB, the reduced tax rate of 15% is available to only those units which are set up on or after 01.10.2019. However, we suggest such progressive outlook be extended to any new investment even in an existing business with suitable safeguards and provisions of law. This will avoid potential litigation for those companies which plan to expand the business/mfg capacity without getting into the issues of splitting and restructuring as stated in the new section 115BAB.<br>From a tax point of view, investment based tax incentives can be declared to boost API manufacturing in India. Special zones may be notified for manufacture and export of APIs. Special package schemes, similar to Modified Special Incentive Package Scheme ('M-SIPS') or Electronics Manufacturing Cluster Scheme could also be considered for this purpose.<br>▪ With ongoing trade war between USA and China, there is a big opportunity for India to capture big share in global Pharma Export Market. |

| Sr. No. | Issue | Issues | Recommendations |
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| 8. | **In-house R&D expenditure [Section 35(2AB)]** | ▪ Section 35(2AB) of the ITA provides for weighted deduction of 150% on the expenditure incurred[1] on scientific research on in-house R&D facility approved by the prescribed authority – DSIR.<br>▪ Further, DSIR has issued Guidelines dated May 2014 which provides for approval of the R&D facility subject to fulfillment of certain conditions<br>▪ One of the conditions for granting approval of the R&D facility is that the company should not claim expenses which are specifically not permissible as per the DSIR Guidelines. Example of expenses which are not permissible as per the DSIR Guidelines is as under (please note that this is just an illustrative list):<br>• Lease rent, building maintenance and municipal taxes of the R&D facility;<br>• Clinical trials conducted outside the approved facilities;<br>• Interest on loan for R&D facility;<br>• Foreign patent filing expenditure and consultancy expenditure;<br>• Contract manpower/labour;<br>• Security charges;<br>• Salary paid to personnel not having degree/diploma in Science or Engineering discipline and above qualification;<br>▪ As per the erstwhile Rule[2], a company was required to audit | ▪ It is suggested that the existing provisions should be specifically clarified to allow weighted deduction in respect of expenditure incurred outside the R&D facility which are sometimes necessitated by the industry's business needs. Additionally, it could also be provided that where the risk of doing research is assumed by a company, the entire cost of R&D activities (whether outsourced or undertaken in-house) is eligible for weighted deduction in the hands of company undertaking the risk. |

[1] *Finance Act 2016 has restricted weighted deduction to 150% from FY 2017-18 till FY 2019-20. Consequently, from FY 2020-21, deduction u/s 35(2AB) is restricted to 100% of the expenditure incurred.*

[2] *Rule 6 and Forms 3CK, 3CL and 3CM*

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| | | the accounts of the R&D facility annually and submit a copy of the same to DSIR by 31st October of each succeeding year. No specific format of the auditor's report was prescribed in the rules.<br>▪ The DSIR Guidelines prescribed the format of the auditor's certificate wherein the auditor had to certify that the expenditure claimed by the company was in consonance with the DSIR Guidelines. However, practically the assessees used to claim weighted deduction of the said expenses and the auditors generally while issuing the certificate draw reference to such expenditure with appropriate caveats/basis of judicial precedents.<br>▪ Till now, the assessees used to claim weighted deduction u/s 35(2AB) in light of the following propositions:<br>- Section 35(2AB)(1) provides that the in-house R&D facility should be approved by DSIR. It does not provide that the approval from DSIR is required in respect of expenditure eligible for weighted deduction *i.e.* weighted deductions would not be restricted to the extent expenditure is quantified by DSIR. Further, the section refers to 'any' expenditure and weighted deduction is allowed to the expenditure 'so incurred'.<br>- Section 35(3) states that, a reference can be made to DSIR only to determine whether any activity constitutes scientific research | |

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| | | or any asset is or was being used for scientific research. However, Section 35(3) does not provide scope for referring to the DSIR the issue of determining the amount of expenditure eligible for deduction.<br>- Erstwhile Rule and Forms do not anywhere state that the approval granted by DSIR is with respect to the expenditure.<br>▪ In view of the above propositions, assessee's contended that DSIR is not the authority to decide the quantum of R&D expenditure u/s 35(2AB). It is the AO who has the right and jurisdiction to decide the quantum of R&D expenditure.<br>▪ There are several judicial decisions wherein it has been held that expenses such as Legal and professional fees, Clinical Trials, security charges, rent of R&D Labs, are permissible for weighted deduction u/s 35(2AB).<br>▪ Also, CAG in its report of 2015 had highlighted various cases where the income tax department has allowed weighted deduction on R&D u/s 35(2AB) without verifying the details of expenditure approved by DSIR in form 3CL/3CM.<br>▪ Recently, the Karnataka High Court[3] ('HC') considering the provisions of Section 35(3) of the ITA, held that DSIR is the final authority to determine the quantum of R&D expenditure eligible for weighted deduction u/s 35(2AB). | |

[3] *Tejas Networks Ltd [60 taxmann.com 309]*

| Sr. No. | Issue | Issues | Recommendations |
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| | | Further, Rule 6 of the ITR were amended on 28th April 2016[4] *inter alia* prescribing that DSIR shall furnish electronically its report in Form No. 3CL quantifying the expenditure incurred on in-house R&D facility and eligible for weighted deduction under Section 35(2AB) in Part B of Form No. 3CL.<br>▪ Further, the amended rules also provide for issuance of a new form 3CLA (Report from an Accountant to be furnished under section 35(2AB) relating to in-house R&D facility) which requires reporting of the following details:<br>- The accounts of in-house R&D centre have been audited and is approved u/s.35(2AB) by the DSIR;<br>- Separate accounts have been maintained for the R&D centre;<br>- The accounts have been satisfactorily maintained and expenditure certified is in consonance with DSIR Guidelines;<br>- The expenditure relating to in-house scientific R&D facility is in accordance with section 35(2AB).<br>**Issues for Consideration:**<br>***(a) Applicability of Section 35(2AB) of the Act on expenditure incurred on scientific research carried outside the in-house R&D facility approved by the prescribed authority.***<br>▪ In the pharmaceutical Sector, discovery is a lengthy, risky | ▪ It is suggested that DSIR Guidelines should not deal with the allowability or dis-allowability of any expenditure incurred on in-house R&D facility. There are sufficient provisions within the Act which provides powers to the Assessing Officer (AO) to examine the same. Further in case of doubt about the usage of asset for or activity constituting scientific research, the AO can always refer the question to CBDT under Section 35(3) of the Act, which in turn will refer the question to DSIR. Based on these feedback the AO should decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act.<br>▪ In other words, DSIR should not decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act. The AO should decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act. Accordingly, the provisions of Section 35(2AB), Rule 6 (including relevant forms) and DSIR Guidelines should be amended.<br>***Clarity needed on following issues:***<br>- If DSIR is the final authority, what is the alternate remedy available with the assessee?<br>- Whether the assessee can claim the expenditure disallowed by the DSIR in the return of income? |

[4] *The amended rules have come into force on 01st July 2016*

| Sr. No. | Issue | Issues | Recommendations |
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| | | and expensive proposition. In this business environment, necessitated by the current business needs, companies have to incur expenditure towards scientific research outside their Research & Development (R&D) facility for e.g. expenditure incurred outside the approved R&D facility towards Clinical Trials (including those carried out in approved hospitals and institutions by non-manufacturing firms), bioequivalence studies conducted in overseas CROs and regulatory and patent approvals, overseas trials, preparations of dossiers, consulting/legal fees for filings in USA for New Chemicals Entities (NCE) and Abbreviated New Drug Applications (ANDA) as approved by the Department of Scientific and Industrial Research (DSIR) which are directly related to the R&D, etc.<br><br>***(b) DSIR should not decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act:***<br><br>▪ A plain reading of Section 35(2AB) of the Act may suggest that the weighted deduction is not with respect to 'expenditure' on scientific research on in-house R&D facility as approved by the prescribed authority. However, the provision of Section 35(2AB) of the Act is not very happily worded. Thus the issue is approval by DSIR whether relates to 'expenditure' or 'in-house R&D facility'. | It is recommended to provide weighted deduction for expenditure incurred on internally developed intangible assets under Section 35(2AB) of the Act. It is also recommended that any initial cost paid for acquiring R&D related intangible assets, which are used in the R&D unit should also be allowed for weighted deduction under Section 35(2AB) of the Act.<br><br>▪ With a view to achieve a growth rate of 8 percent and put India on the growth trajectory and to ensure having a robust R&D database, it is suggested that the weighted deduction under Section 35(2AB) of the Act should be extended for a further period of 10 years. This would enable the country to be on par with the developed nations which have robust R&D centres fuelling growth in the economy. |

| Sr. No. | Issue | Issues | Recommendations |
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| | | ▪ Earlier, Rule 6 and Forms 3CK, 3CL and 3CM do not anywhere state that the approval granted by DSIR is with respect to the expenditure. Recently, Rule 6 has been amended vide Notification dated 28 April 2016, where it has been stated that DSIR shall furnish electronically its report quantifying the expenditure incurred on in-house R&D facility by the company during the previous year and eligible for weighted deduction under Section 35(2AB) in Part B of Form No. 3CL.<br>▪ Further DSIR has issued its own set of Guidelines which specifically states that certain expenditure are not permissible for claiming weighted deduction under Section 35(2AB) of the Act viz Clinical Trials conducted outside the approved facilities, lease rent, building maintenance and municipal taxes of the R&D facility, foreign patent filing expenditure and consultancy expenditure, interest on loan for R&D facility, etc.<br>***(c) Weighted deduction should be available on expenditure incurred on internally developed intangible assets:***<br>▪ The DSIR Guidelines provide that eligible capital expenditure on R&D will include expenditure on plant, equipment or any other tangible item only. It also provide that capital expenditure of intangible nature is not eligible for weighted deduction. | |

| Sr. No. | Issue | Issues | Recommendations |
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| | | ***(d) Extension of the weighted deduction under Section 35(2AB) of the Act for a further period of 10 more years:***<br>▪ The Finance Act, 2015, with a view to phase out weighted deduction under Section 35(2AB) of the Act, restricted the allowability of expenditure incurred on scientific research (other than expenditure in the nature of cost of any land or building) on in-house Research and Development facility incurred on and from 1 April 2020 to 100 percent from the existing 200 percent. | |

## IDMA Pre-Union Budget 2021-22 Proposals: Indirect Taxes

## GST

| Sr. No. | GST issue | SUGGESTIONS |
|---|---|---|
| 1. | **Manufacturers and marketers of hand sanitizers are facing regulatory challenges and tremendous pressure about applicability of GST rate 12% or 18%:** Classification of Alcohal based Hand Rubs (ABHR) - GST liability on Hand Sanitizer should be under Drug Category HSN Code 3004 @ 12%. – Request to examine the matter and issue a clarification as regards the applicability of GST.<br><br>Manufacturer and marketers in India are using HSN code 3004 with tariff of 12% as:<br>(i): Hand sanitizers manufactured by Pharma Manufacturers are drugs or Medicaments which are used to clean Hands and on regular basis.<br>(ii): The product contains pharmaceutical ingredients that have therapeutic or prophylactic properties.<br>It is claimed on the label that the ABHR 'kills' germs, as it would mean that the product is not for cosmetic application but for medicinal application as the product contains certain curative and preventive ingredients. | The product in question merits classification only under Chapter 30 for the following reasons:<br>(i): The products in question are manufactured under drug license in the capacity as a manufacturer of drug.<br>(ii): The different ingredients which go into the product are all clearly indicated in the label and the label also indicates the application of the product; the methodology with adequate caution symbols and also has the manufacturing license number.<br>(iii): The label clearly indicates that it has to be applied on the palm and the limited time at which it can be applied including the quantity that has to be taken when it is used as hand disinfectant and when it is used in surgical segment.<br>(iv): The fact that the product is effective against bacterial, virus, fungi, etc is also specified in the container.<br>(v): The product can be used only for the hands as indicated in the name of the product as well as in the usage instructions. |

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| | (iii): Hand sanitizers manufactured by Pharma manufacturing facilities are as DRUG like any other medicine in GMP environment after getting license from concerned drug department in Form 25.<br><br>(iv): Hand sanitizers manufactured by Pharma are as per the formulations recommended by WHO.<br><br>(v): Chapter 3808 does not cover Medicaments (Heading 3003 or 3004).<br><br>It has come to our notice that - The Government has opined that such manufacturers are wrongly classifying the said item under tariff heading 3004 whereas the said item is liable to be classified under tariff heading 3808 having 18% GST Rate. The opinion is based on classification opinion of World Customs Organisation wherein WCO has inferred that Alcohaol based Hand Sanitizers are correctly classifiable under heading 3808 of HSN (Precisely under sub-heading 3808.94).<br><br>Further, The GST intelligence in Chennai and Puducherry as well as from other parts of the country are of the view that the product attracts GST at the rate of 18% and based on this summons have been issued to various members and in some cases there is tremendous pressure exercise to make payment of the differential duty immediately. The position is apparently based on the view of the Department that the product falls under Chapter 3808 attracting GST at the rate of 18%. | Given the plethora of decisions on the issue including authoritative pronouncement of the Supreme Court on the issue, the classification of Pharma grade alcohol based hand sanitizer manufactured under Drug License issued under the Drugs and Cosmetics Act under Chapter 3808 for the purpose of 18% GST is incorrect and the correct classification would be Chapter 3004 which attracts GST at the rate of 12%.<br><br>**IDMA concerns/Requests:**<br><br>Members of the Association are manufacturing a product for the society at large at the time of Covid pandemic and thousands of people are risking their life in ensuring that the factory continues to work and the most important product for the society at large at this point of time is continuously available.<br><br>Further, the profits have dwindled on account of the MRP for the product being reduced and the MRP itself was fixed based on the GST at 12%. At this juncture, it is not possible for the members of the Association to bear any additional impact of GST or to face the pressure being mounted by GST Intelligence and the GST Department in seeking payment of the higher rate of GST.<br><br>Whereas, The authorities are incorrect in taking the term 'disinfectant' to mean one which is used for antiseptic purpose by human beings.<br><br>It is submitted that there is an urgent need for the Ministry of Finance/Central Board of Indirect Taxes and Customs to examine the matter and issue a clarification as regards the applicability of GST HSN 3004 or 3808.<br><br>Since the matter is of considerable significance and has implication on the mis-classification of product manufactured by vast section of the industry, it is earnestly requested to instruct the concerned authorities to kindly clarify the issues as early as possible. This would put an end to the prevailing confusion and uncertainty, reduce litigation and ensure uniformity of compliance. |
| **2** | **Government has recently made rule to restrict ITC of invoice, debit notes not reflecting in GSTR 2A of receiver to 10% of eligible ITC reflecting in GSTR- 2A.**<br><br>This newly inserted provision along with board circular has created lot of hue and cry amongst taxpayer. | It would have been proper in case Rule 36(4) was inserted after introduction of new return system which is scheduled to be applicable from 01.04.2020 as currently the system of matching is not operational.<br><br>Government must act pro-actively and its applicability be deferred along with new system of invoicing. |

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| | **Impact** :<br><br>Calculation of Rule 42/43 reversal will suffer a lot, since now all calculation will be based on ITC as per rule 36(4) rather than actual ITC.<br><br>**Working capital requirement**. Tax payer may require cash at earlier stage & accumulation of ITC at later stage<br><br>**Getting GSTR-2A on 11th of next month** is another challenge , as GSTR 2A has no option to take position as on some day, it is always as on date. Further GSTR 2A is dynamic document.<br><br>**Exporter may be big sufferers**. If ITC is delayed due to this rule, zero rated supply based on LUT will get lessor claim or in some cases excess claim (finally disproportionate claim) against actual eligible claim.<br><br>The provision for restriction in Input tax credit is stated to be incorporated for ensuring timely filing of statement of outward supplies. However for instilling discipline on the suppliers, the restriction of ITC in hands of the recipient seems to be unjustified.<br><br>Further it appears that Rule 36(4) is introduced to give effect to Section 43A of the CGST Act, 2017 which is yet to be notified and, accordingly, the Rule itself may get challenged for legal validity.<br><br>There is no doubt that Rule 36(4) has been implemented in a hasty manner without answers to the endless queries that may creep in during its implementation and even the Circular doesn't have much respite for the taxpayers. It creates more problems for the legitimate taxpayers than the purpose it serves and is a classic example of missing the woods for the trees in order to catch a few errant taxpayers.<br><br>In our view, implementing Rule 36(4) in terms of the circular is set to consume countless hours of manpower in the thankless reconciliation work every month and same will increase with each passing month as the recipient would have to keep track of the additional ITC month-wise and also ensure that the provisional ITC for a month does not exceed the actual ITC. | |

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| | Further, Circular has linked cut-off date to due date for filing GSTR-1 by the supplier and thereby punishes the recipient for the late filing by the supplier – a highly prevalent practice, which is outside the control of the recipient.<br><br>To conclude, the Circular has even surpassed our expectations that Rule 36(4) may prove to be a hard shove for the taxpayers – it is probably a shootout. | |
| **3** | **Marketing and distribution expenses - Promotional items or brand reminders – ITC not allowed**.<br><br>In today's world, every Pharma company in its business operations incurs various marketing and distribution expenses. The said expenses are incurred with a view to promote their brand/ products and enhance sales.<br><br>Under various schemes, these companies distribute different products among its trade channels as promotional items or brand reminders such as pens, notepad, key chains, etc with their name mentioned on it. The brand mentioned on these products serve as an advertisement tool and is a brand reminder or a brand recall. Such products act as reminder of the association with the brand so as to promote products of these companies.<br><br>Similarly, companies offer various sales promotion schemes such as staggered discounts to the distributors which are provided, basis the increase in sales volume. The distributors/wholesalers get promotional items such as watches, trips, etc based on the reward points earned on the basis of goods sold by them, etc.<br><br>The ambiguity in the above cases revolves around the argument of whether such brand reminders or promotional schemes offering rewards by way of watches, trips, etc can be termed as an expense in the furtherance of business and credit be allowed or the said expenses be considered as gift and credit on the same be denied.<br><br>On the said issue, recently, the Karnataka Authority for Advance Rulings ('AAR') has held that ITC on goods or services procured for giving as incentive to the dealers shall not be available considering | There should not be any restriction of input credit as long as the goods given are a brand reminder or a brand recall for business purposes. From a business standpoint, the cost of all such items are already factored in the sale price of products on which GST is paid. |

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| | the same as “gift”. In the state of Maharashtra also, the AAR has held that brand reminders and goods given to distributors for achieving sales target as part of marketing and sales promotion activities as not eligible for credit considering the same as “gift”, even though, in essence they are a marketing and promotion expense.<br><br>As per the AAR, credit on such goods will not be available as no GST is being paid on their disposal.<br><br>The above AARs have ignored the fact that these sales-linked schemes are purely for enhancement of company’s business. Further, it is the case that instead of discount, goods are provided. It is a known principle that “nothing comes free in business”. Each and every act done for business comes with a consideration, goods provided as incentive is consideration for the fulfilment of contractual obligation of achieving stipulated lifting or payment criteria and as soon as an obligation is attached, the commodity loses its identity as a “gift”. Also the GST law does not lay any condition of GST being paid on output for considering the input tax as eligible. The only condition laid down is that the goods or services should be used or intended to be used in the course or furtherance of business.<br><br>The Central Board of Indirect Taxes and Customs (CBIC) has also issued a clarification in relation to treatment of sales promotion schemes vide Circular No. 92/11/2019-GST dated 7 March, wherein they have provided clarification citing few examples such as free samples, buy one get one offer, discounts including ‘Buy more, save more’ offers. It is further clarified that the supplier shall be entitled to avail the credit for such inputs, input services and capital goods used in relation to the supply of goods or services or both on such discounts.<br><br>Drawing an analogy from the above circular, one can take a stand that the credit should be available on goods given to the customers as reward for achieving a particular target, as the same are for furtherance of business. Brand reminders and promotional schemes ensure brand loyalty and market loyalty which are | |

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| | important aspects of any business. Just because CBIC circular does not cover the above scenario, it does not mean that such business-related expenses shall be disallowed considering the same as a gift.<br><br>Is this the right approach? The denial of ITC on such expenses would affect the profitability of such companies and thus have a negative impact.<br><br>If we look at GST, its main objective is of removing cascading effect of taxes and bringing in seamless flow of credit. Denying such credit will defeat its purpose. In fact, even under international VAT laws, credit on such expenses is allowed.<br><br>Lastly, considering the confusion and ambiguity on availability of credit with regard to the above marketing and promotional activities, we hope that the CBIC provides further clarification so as to bring more clarity and justice. | |
| **4.** | **Physician Samples – ITC not allowed.**<br><br>**Section 17(5) (h) of the Central GST Act, 2017**- Input tax credit shall not be available in respect of goods lost, stolen, destroyed, written off or disposed of by way of **gift or free samples**;<br><br>Promotional schemes such as Buy one and get one or additional quantities for the same price etc are part of the pharma business marketing practice and is for furtherance of business.<br><br>Recently, The Law Review Committee has said in a report submitted to the GST Council that gifts and samples should not be denied input tax credit and an annual value cap may be fixed at 0.5% of turnover. | Ideally, there should not be any restriction of input credit as long as the goods given free of cost and Free Samples are for business purposes. From a business standpoint, the cost of all such items are already factored in the sale price of products on which GST is paid.<br><br>**We suggest and request through your office to GST Council to accept the proposals of The Law Review committee but there should be no cap as suggested by committee to be fixed at 0.5% of turnover.** |
| **5** | **Expiry Goods** – Similarly, In pharma, due to the peculiar nature of goods and the regulatory requirement, the goods have shelf life and if the goods are not sold till the expiry date, then the said goods are to be destroyed. This is applicable for stock lying not only with manufacturer, but also with distributors, retailers, etc. | It is the need of the hour to amend the exclusion clause of input tax credit and allow the credit w.r.t. goods destroyed due to expiry so that the credit can be availed w.r.t. the input taxes. |
| **6.** | **Annual Audit** – Every registered person whose aggregate turnover during a financial year exceeds two crore rupees shall get his accounts audited as specified under sub-section (5) of | We prepare Financial Statement of the company at one place. Hence, Audit for every Company having one PAN number but having units/Branches in many states should be done on all India basis at such place |

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| | section 35 and he shall furnish **a copy of audited annual accounts** and **a reconciliation statement, duly certified, in FORM GSTR-9C**, electronically through the common portal either directly or through a Facilitation Centre notified by the Commissioner.<br>It means that Every Company having one PAN number but having units/ Branches in many states will have to get its accounts audited in each state whose aggregate turnover during a financial year exceeds two crore rupees. | of business of the company where Annual Financial Statement is prepared. |
| **7.** | **Sale of Capital Goods:**<br><br>As per Section 18(6) of the CGST Act ,2017, in case of supply of capital goods or plant and machinery, on which input tax credit has been taken, the registered person shall pay an amount equal to the higher of the following;<br><br>1. input tax credit taken or availed on the said capital goods / plant and machinery as reduced by percentage points as prescribed; or<br>2. the tax on the transaction value of such capital goods or plant and machinery as determined under section 15 of the CGST Act, 2017<br><br>The taxes in respect of an inward supply of capital goods, where credit has been availed, would be paid by the recipient to the supplier, and consequently, remitted to the credit of the Government at the time of inward supply.<br><br>Moreover, one must appreciate that cases where capital goods are disposed of for a value that is significantly lower than the purchase price soon, after their receipt, upon availment of input tax credits, would be isolated transactions in respect of any business and would normally not be entered into with intent to evade or avoid taxes.<br><br>Now, the irony comes in when one looks for the machinery prescribed to determine the above stated ITC reversal. There are two separate machineries in the law in the form of Rule 40 and Rule 44.<br><br>Both these rules have independent procedure for computation of ITC for Section 18(6). | While it is an accepted fact that the GST law is an amalgamation of the erstwhile laws and where the erstwhile law so wisely catered to the above issue, the missing linkage for eligibility of availing of ITC by the recipient appears to be an unintentional omission in the GST Law.<br><br>Further, a divergence appears in the rules in respect of the same provision causing a dilemma for the taxpayers. Hence, a clarification is sought from the Board for the purpose of the divergent rules and to resolve the confusion for the taxpayers. In addition to that, a provision is required for the eligibility of ITC for the recipient where amount charged is higher than tax on Transaction value, the absence of which may cause unnecessary interruption in the flow of credit, the basic objective of the GST law.<br><br>It is suggested to levy taxes in such instances only on the transaction value. |

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| | **Q1.** Whether ITC reversal on supply of capital goods u/s. 18(6) is to be done as per Rule 40 or Rule 44?<br><br>**Q2.** Whether supplier can charge such ITC amount payable as per Section 18(6) from the recipient, if same is higher than tax on Transaction Value?<br><br>**Q3.** Whether the recipient can claim ITC of such amount charged instead of tax on Transaction value? | |
| **8.** | **Restriction of inverted duty structure refund for input services:**<br><br>Section 54 (3) provides for refund of "any unutilised input tax credit at the end of the tax period" in two situations.<br><br>**(i) zero rated supplies made without payment of tax;**<br><br>**(ii) where the credit has accumulated on account of rate of tax on inputs being higher than the rate of tax on output supplies (other than nil rated or fully exempt supplies), except supplies of goods or services or both as may be notified by the Government on the recommendations of the Council.**<br><br>Accordingly, where the rate of tax on inputs is higher than the rate of tax on output supplies, the situation is known as inverted duty structure and if there any accumulation of credit due to such inverted duty structure the "unutilised input tax credit" can be claimed as refund.<br><br>It may be observed from the above that once there is an inverted duty structure with reference to any input, then the entire unutilised input tax credit, including the credit availed on input service can be claimed as refund.<br><br>**The formula for claiming such refund had been prescribed in Rule 89 (5) of the CGST Rules, 2017** which was subsequently amended with retrospective effect vide Notification 26/2018 C.T. Dt.13.06.2018, with effect from 01.07.2017, as:-<br><br>Explanation for the purposes of this sub-rule states that , the expressions, **"Net ITC" shall** | It is suggested that:<br><br>• the word 'inputs' be replaced with the phrase 'inputs and input services'.<br><br>• Also, the word 'Output Supply' be replaced with the word 'Outward Supply'. |

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| | **mean input tax credit availed on inputs** during the relevant period other than the input tax credit availed for which refund is claimed under sub-rules (4A) or (4B) or both;<br><br>**Issue:**<br><br>A manufacturer or a service provider may have accumulated credit balances for the reason that he is availing input services which attract at higher rate of GST (say, 18% or 28%) whereas the final product or output service attracts GST rate of 18% or 28%. However, the authorities may deny refund on the ground that the provision allows refund benefits only if the input is subject to higher rate of GST and not in case where the input service attracts higher rate of GST. If a strict interpretation is taken that refund would be allowed only if the GST rate of input is higher without considering the rate of input service, then the very object of the provision would stand defeated.<br><br>**All those taxpayers who have already claimed refund of input tax credit in respect of input services have to pay back the same.** | |
| **9.** | **Cross charge** – Trade & Industry is in the panic situation, especially after Advance Ruling by Karnataka Advance Ruling Authority in the case of Columbia Asia Hospitals Private Limited.<br><br>Various representations have been received seeking clarification on the taxability of activities Performed by an office of an organisation in one State to the office of that organisation in another State, which are regarded as distinct persons under section 25 of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as 'the CGST Act') and of the supply of services between such distinct persons.<br><br>Various representations have been received to clarify the issues regarding distribution of input tax credit in respect of input services procured by the Head Office but attributable to the Head Office and /or various Branch Offices, treatment of expenses incurred by the Head Office on the procurement, Distribution and management of common input services, treatment of services provided by the Head Office such as common administration or common IT maintenance to its Branch Offices and its valuation thereof, etc. | It is suggested to clarify "Whether the activities performed by the employees at the Corporate Office in the course of or in relation to employment such as accounting, other administrative and IT system maintenance for the units located in the other states as well i.e. distinct persons as per Section 25(4) of the Central Goods and Services Tax Act, 2017 (CGST Act) shall be treated as supply as per Entry 2 of Schedule I of the CGST Act or it shall not be treated as supply of services as per Entry 1 of Schedule III of the CGST Act?".<br><br>There is a need to remove/rationalize Schedule-I provision of deemed supply for services done inter branch.<br><br>**Suggestion:**<br><br>In this regard better amend the law by giving clear cut provision relating to taxing of services. |

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| **10.** | **E Way Bill** - Eway bill is generated when there is a movement of goods in a vehicle/ conveyance of value more than Rs. 50,000.<br><br>Reliefs have been provided to people of few States by way of exempting them from Eway bill generation in case of monetary limits falling below threshold amount or certain specified items. For Instance, **Tamil Nadu** has exempted people of its State from the generation of eway bill if the monetary limit of the items falls below Rs. One Lakh. Similarly, Many other states have increased threshold amount to Rs.1 lakh. | GST being One Nation One Tax, Central Government should hike E-way bill threshold amount to Rs. 1 lakh throughout the country. |
| **11.** | **Exemption from filling of Return under form GSTR ITC 04 when Premises of "Loan Licensee" is registered as** Additional Place of Business for the purpose of movement of input materials and dispatch of the final product **by the Principal Manufacturer.** | The purpose of having Additional Place of Business in the GST Registration is in the view of practical challenges in the pharmaceutical industry is as under:-<br><br>Multiple usage of the raw and packing material (Common inputs) for different finished products having different strengths (for example: Paracetamol – 100 mg/200 mg/500 mg etc)<br><br>Temperature conditions (Sensitive category of inputs) for different type of inputs to avoid contamination.<br><br>Semi-Finished (work in process) mix of the inputs kept in the vessels/ Reactors/compression equipment's awaiting Quality Control Approval for final packing.<br><br>Multiple samplings for each receipt and removal mandatory as per Drugs Rules and Regulations.<br><br>Multiple input materials are supplied against delivery challan for getting the finished goods converted into different forms on continuous basis, the tracking, monitoring and/or reconciliation with each challan is practically impossible as the usage of input material may not be for any specific finished product.<br><br>We submit in the above scenario there should not be any requirement to follow job work procedure as prescribed under Section 143 of CGST Act read with allied Rules. |
| **12.** | **Rule 39 of CGST provides that:** An Input Service Distributor shall distribute input tax credit in the 'same month' in which credit is availed.<br><br>Further it also provides that Input Service Distributor shall separately distribute the amount in-eligible as input tax credit and the amount eligible as input tax credit. | The distribution of credit should not be restricted to same month. The limit of availment is already in place and hence there should not be any further restriction w.r.t. distribution of credit. At most the restriction should be limited to period upto due date for filing annual return.<br><br>Further, Requirement of distribution of ineligible credit should be done away with as the same also does not hold any significance. |

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| | The process of distribution of ineligible credit adds to the documentation, compliance and efforts of computation with no added benefit from GST perspective. As it is the company would have internal accounting processes which would take care of identification of costs for the respective units. | |
| **13.** | **Exemption for national calamities or Good cause:**<br><br>In order to fight against COVID-19 virus the purchases of masks, sanitizers and PPE kits for own use in the factory and for free distribution throughout country as social responsibility.<br><br>Input Tax Credit for the Masks, Sanitizers, PPE kits and essential medicines | Considering the gratuitous gesture by Pharma Companies, Exemption Notification should be granted, in regard to Medicines supplied free during National Calamities.<br><br>In order to fight against COVID-19 virus the purchases of masks, sanitizers and PPE kits for own use in the factory and at all registered premises has been made. Further, we have also purchased these items as well as medicines for free distribution throughout country as social responsibility. Under GST the ITC for such activity is not eligible. Our humble request that ITC for these items for self-consumption and for free distribution should not be questioned and ITC should be allowed. |
| **14.** | **Procedure for simplification of Advance Ruling:**<br><br>Present provisions of Sections 96 & 97 of the CGST Act, 2017 are procedurally complicated and would be out of reach of small & medium taxpayers. Advance ruling can only be filed by the "applicant" who is the registered person/ person intending to be a registered person but not an association representing the industry, or in the capacity as a member of such association/ industry. | **Suggestions:**<br><br>It is suggested that Advance Ruling provisions be extended for filing of application on behalf of an association representing its members (with a unanimous vote from the members), whereby the decision rendered by the Authority would mutatis mutandis apply to all the members of association representing such issue/industry. |
| **15.** | **As per Section 21 of CGST Act, 2017**: "Where the Input Service Distributor distributes the credit in contravention of the provisions contained in section 20 resulting in excess distribution of credit to one or more recipients of credit, the excess credit so distributed shall be recovered from such recipients along with interest, and the provisions of section 73 or section 74, as the case may be, shall, mutatis mutandis, apply for determination of amount to be recovered."<br><br>Each of the unit to whom the credit is distributed needs to rework the amount of credit to be reversed for each of the periods where error is occurred which will be time consuming and involve duplication of efforts. | The recovery of credit should be from the Input service distributor and not the recipient since the recipient is not responsible for errors done at distributor stage and it should not impact the recipient. Also, practically, it is from the books of the ISD that it can be established that it is incorrectly distributed. After identifying this, if recovery is to be made from each of the recipient, it would increase the administration cost and time involved in recovery since each of the jurisdictional authorities will have to initiate recovery. Further it will be cumbersome for each of the unit of the company to revise the workings and compute the reversible and interest. |

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| **16.** | **Time of supply of goods and services under RCM:**<br><br>Section 12(3) of the CGST Acts provides that in case of supplies of goods in respect of which tax is paid or liable to be paid on reverse charge basis, the time of supply shall be the earliest of the following dates, namely:<br><br>(a): the date of the receipt of goods; or<br><br>(b): the date of payment as entered in the books of account of the recipient or the date on which the payment is debited in his bank account, whichever is earlier; or<br><br>(c): the date immediately following thirty days from the date of issue of invoice or any other document, by whatever name called, in lieu thereof by the supplier:<br><br>However, as per section 13(3) of the CGST Acts provides that in case of supplies of services, the time of supply shall be the earlier of the following dates, namely:<br><br>(a): the date of payment as entered in the books of account of the recipient or the date on which the payment is debited in his bank account, whichever is earlier; or<br><br>(b): the date immediately following sixty days from the date of issue of invoice or any other document, by whatever name called, in lieu thereof by the supplier:<br><br>**Issue:**<br><br>The time period of 30/60 days from the date of issue of invoice by the supplier is quite short considering the time taken for delivery of goods with invoice and may create unnecessary interest liability if payment is not made within 30 or 60 days. | It is suggested that the time limit prescribed in both the cases be made 90 days. |
| **17.** | Inclusion of Interest, penalty etc in Value of Supply:<br><br>Section 15(2)(d) of CGST Act provides that the value of supply shall include interest or late fee or penalty for delayed payment of any consideration for any supply. | • It is suggested that clause d of section 15(2) be omitted.<br><br>• Alternatively, if it needs to be essentially included, it might be considered to shift this clause to section 31 as one of the circumstances requiring the issuance of debit note. |

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| | **Issue:**<br><br>In most of the cases the amount of interest or penalty is not known at the time of supply. Required to be included in the valuation at the time of supply is a cumbersome task. | |
| **18.** | **Reversal of Credit on non-payment of taxes:**<br><br>Second proviso to the Section 16(2) of the CGST Act provides that where a recipient fails to pay to the supplier of services, the amount towards the value of supply of services along with tax payable thereon within a period of 180 days from the date of issue of invoice by the supplier, an amount equal to the input tax credit availed by the recipient shall be added to his output tax liability, along with interest thereon, in such manner as may be prescribed. | We recommend that in case where, credit period is more than 180 days ITC should be allowed provided the supplier has made payment of applicable GST at the time of as per provision of the act.<br><br>It is proposed to remove the liability to pay interest in case where the recipient has been made liable to pay an amount equal to the ITC availed in case he fails to pay to the supplier of goods or services or both the amount towards the value of supply along with tax payable thereon within a period of 180 days from the date of issue of invoice by the supplier. Since upon payment of the due amount to the supplier, the recipient shall be eligible to avail ITC of the said amount, it is believed that liability to pay interest is too onerous and should be removed.<br><br>Section 16(2) (c) is to be amended to read:<br><br>Subject to the provisions of section 41 or 43A, the tax charged in respect of such supply has been actually paid to the Government, either in cash or through utilisation of input tax credit admissible in respect of the said supply; and Amendment to be made prospective.<br><br>A similar relaxation from payment of interest on the import invoices where GST is payable under reverse charge when the payment to the vendor is delayed beyond 60 days. |
| **19.** | **Exclusion of petroleum from GST:**<br><br>Currently, petroleum crude, high speed diesel, motor spirit, natural gas and aviation turbine fuel goods are kept outside the ambit of GST Laws.<br><br>Exclusion of petroleum products from GST adds to the cost of manufacture as excise duty on such products is not creditable under the GST regime. Petroleum products such as high speed diesel, are common fuels used in various manufacturing processes, as also for transportation of inputs and final products.<br><br>Businesses that consume such non-GST products, face issues like cascading of taxes, non availability of credit, maintaining separate books of accounts etc. | In order to maintain a level playing field, it is suggested that all petroleum products (petroleum crude, high speed diesel, motor spirit, natural gas and aviation turbine fuel) be brought into the purview of GST at the earliest, including petroleum, alcoholic liquor, and electricity. Other laws that govern the levy of taxes/duties on such non-GST goods be repealed.<br><br>Petrol & Diesel to be brought into GST, without placing any restriction on availing credit on the same used in the course or furtherance of business, to get significant impact. |

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| **20.** | **Huge Interest rate in case of default in payment or wrong availment of credit:**<br><br>By Notification No.13/2017 Central Tax — The Central Government, on the recommendations of the Council has fixed the rate of interest per annum, for the purposes of sub-sections (1) and (3) of section 50, sub-section (12) of section 54 and section 56 of the Central Goods and Services Tax Act, 2017 (12 of 2017).<br><br>**Issue:**<br><br>Comparing the notified interest rate of 18% or 24% with the present bank rate, which is not more than 7-8% per annum is too huge. | In the implement phase of GST, interest rate be notified equivalent to present bank rate only as due to lack of knowledge of new law, taxpayer may have made some error.<br><br>Even post 1 year, Interest rate should be not exceeding more than 12%. |
| **21.** | **Revision of GST returns.** | Revision of GST returns facility to be provided. |
| **22.** | **Settlement Commission [Omitted] – Should be restored:**<br><br>Settlement Commission provisions which existed under the Model GST Law has been omitted. | **Suggestion:**<br><br>The provisions relating to Settlement Commission as provided in Chapter-VIII of the Model GST Law should be reinserted as genuine mistakes may occur in the initial phases of the GST regime due to complexity of the Law. These provisions act as an alternate dispute resolution mechanism which is essential and therefore, the settlement commission provisions need to be restored.<br><br>**Justifications for the suggestions:**<br><br>The basic objectives of setting up of the Settlement Commission are:<br>1. To provide an alternative channel for dispute resolution for the taxpayer;<br>2. To expedite payment of GST involved in disputes by avoiding costly and time consuming litigation process;<br>3. To provide an opportunity to tax payers to come with clean who may have evaded payment of tax;<br>4. To service as a forum for the taxpayer to apply for settlement of their cases, on the basis of true and complete disclosure of their tax liability;<br>5. To encourage quick settlement of disputes and save the business from the worries of prosecution in certain situations. |
| **23.** | **Delinking of payment of dues with filing of return:**<br><br>Under the existing return system, a registered person cannot file the return unless all the dues | **Suggestion:**<br><br>It is suggested that returns should be allowed to be filed even without payment. The late payment of tax as per |

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| | Under the existing return system, a registered person cannot file the return unless all the dues as per the return are paid. This system will lead to noncompliance as well as make other provisions of law such as installment payments redundant. | the return is anyways liable to interest.<br><br>**Justifications for the suggestion:**<br><br>A registered person who is in financial difficulty may not be able to file the return even though he wants to comply the returns and apply for installment for payment of taxes as per the return. |
| **24.** | **Provision of flexibility in the GSTN.** | The GSTN is indispensable in India's GST journey, but there is little flexibility offered to users. For instance, there is no option to set off the excess tax paid by an entity under one registration in relation to another registration in a different state, even if it has the same PAN.<br><br>Further, In case of closure of one registration, there is no option to set off the balance Input tax credit of an entity under one registration in relation to another registration in a different state, even if it has the same PAN. |
| **25.** | **Section 10 of the IGST Act, 2017 provides for the place of supply for goods in various situations.**<br><br>The existing provision under Section 10 especially Section 10(1)(b) are difficult to apply in certain situations.<br><br>(b): where the goods are delivered by the supplier to a recipient or any other person on the direction of a third person, whether acting as an agent or otherwise, before or during movement of goods, either by way of transfer of documents of title to the goods or otherwise, it shall be deemed that the said third person has received the goods and the place of supply of such goods shall be the principal place of business of such person; | **Suggestion:**<br><br>It is suggested that place of supply for all B2B transactions may be made as registered place of business of the recipient. Specific rule may be amended for B2C transaction. In any case, the concept of "third person" may be explained in the legislature itself by way of an example to bring in uniformity in interpretation of Section 10(1)(b).<br><br>**Justifications for the suggestion:**<br><br>It is important to bring parity in place of supply rules between services and goods. Different treatment leads to confusions among the trade and also may increase the chances of litigation. |
| **26.** | **GST refund – Requirement of receipt of remittance:**<br><br>A new Rule 96B has been inserted in the Central Goods and Services Tax Rules, 2017 ('CGST Rules) w.e.f. 23 March 2020 which mandates an exporter of goods, to repay the GST refunded to him, proportionate to the export proceeds not realized within the time (or extended) period allowed under the Foreign Exchange Management Act, 1999.<br><br>The definition of export of goods under section 2(5) of the Integrated Goods and Services Act | Rule 96B restricting GST refund in case of non-receipt of export proceeds be withdrawn. Alternatively, in case of non-receipt of export remittances within the stipulated time period, re-credit of attributable GST may be allowed to the exporter. |

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| | 2017 ('IGST Act), lays down a simple condition to qualify as export - taking goods out of India to a place outside India. In line with the said provision, the undertaking which the exporter of goods provides, is merely to export goods within 3 months (or extended period) from the date of issue of the invoice for export, as per Rule 96A(1) of the CGST Rules. As against a statement of invoices and FIRC for export of services, an exporter of goods is required to provide a statement of invoices with details of shipping bills or bill of export, as the case may be, in terms of Rule 89(2) of the CGST Rules. Therefore, it is clear that for export of goods, physical movement to a place outside India has been the only condition for qualifying as export and claiming the refund.<br><br>This understanding was affirmed in CBIC Circular No.37/11/2018-GST dated 15 March 2018. At para 12 of the said Circular, it was emphasized that realization of consideration is not a pre-condition for export of goods and therefore, there should be no insistence for proof of realization of export proceeds by the refund authorities. The same understanding was carried forward through para 48 of the CBIC Circular No.125/44/2019-GST dated 18 November 2019 which superseded the circular dated 15 March 2018 mentioned above. Contrary to this settled position, the new rule indirectly saddles the condition of receipt of export proceeds on a legitimate refund for export of goods. This rule appears to travel beyond the scope of the IGST Act.<br><br>More importantly, this would tantamount to Input Tax Credit ('ITC') becoming a cost in case of non-receipt of export proceeds. Thus, in case of bad debts, besides the export value being written-off, the attributable GST would also have to be written-off. However, if an exporter chooses not to claim refund on exports, there would be no requirement to reverse ITC proportionate to export of goods where the export proceeds have not been received. This puts an exporter who claims refund of GST to disadvantage, *vis-a-vis* a exporter who does not claim export refund. This apparently would not be the intent of the legislature. | |

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| **27.** | **Restrictions on ITC refund claims – SEZ units.**<br><br>Vide the Notification No.16/2020-Central Tax dated 23 March 2020, the definition of 'Turnover of zero-rated supply of goods' has been amended as follows:<br><br>"(C) "Turnover of zero-rated supply of goods" means the value of zero-rated supply of goods made during the relevant period without payment of tax under bond or letter of undertaking or the value which is 1.5 times the value of like goods domestically supplied by the same or, similarly placed, supplier, as declared by the supplier, whichever is less, other than the turnover of supplies in respect of which refund is claimed under sub-rules (4A) or (4B) or both.<br><br>Apparently, the above amendment restricts the value of exports for the purpose of refund to 1.5 times of value of domestic supplies. As there is no change in the definition of 'Adjusted Total turnover', the said amendment would result in relatively lesser ITC refunds.<br><br>In case of SEZ units, the ISD ITC can be liquidated only by claiming refund under Rule 89 of the CGST Rules 2017, as mentioned. Post this amendment, SEZ units would not be able to liquidate the balance ITC which was claimed as refund before the said amendment. | This restriction should not apply to ITC refund claims filed by SEZ units. |
| **28.** | **GST refunds in SEZ units:**<br><br>In the pre-GST regime, the Service Tax provisions mandated a Head Office/ Corporate Office, which qualifies as an Input Service Distributor ('ISD'), to distribute CENVAT credit availed on input services to all its manufacturing units, including SEZ units. As SEZ units were outside the purview of Central Excise and there was no Excise duty chargeable on goods manufactured in SEZs, there was no mechanism to utilize such distributed CENVAT credit. Thus, the Government had prescribed a mechanism under the erstwhile Service Tax law by which the SEZ units could claim refund of the service tax distributed to them.<br><br>In the GST regime, the CGST Act 2017 has a similar provision which mandates a Head Office/ Corporate Office, which qualifies as an ISD, to | The SEZ online module should be enabled to permit exports on payment of GST and refunds can be sanctioned by the SEZ authorities. Ideally, the SEZ online module should communicate seamlessly with the GST Network (similar to how the Customs ICEGATE portal communicates with the GST Network portal), and the GST refund process should be automated. |

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| | distribute credit of GST availed on input services to all its business units, including a SEZ unit. The difference here *vis-à-vis* the previous pre-GST provisions is that the GST law extends to SEZs as well, unlike the Central Excise provisions which did not apply.<br><br>The GST law allows exporters, both in Domestic Tariff Area ('DTA') and in SEZs, to pay GST on exports and claim refund of the same. However, the SEZ online module presently does not provide a facility for exports from SEZ unit to be effected on payment of GST. At the time of preparation of Shipping Bill, an auto-generated declaration 'Supply meant for export by SEZ Entity under Bond or Letter of Undertaking without payment of Integrated Tax' gets printed in the Shipping Bill.<br><br>This significantly impacts the working capital of exporters. | |
| **29.** | **<u>ITC admissibility in GST in case of expenses booked towards CSR activities:</u>**<br><br>As per Section 135 of Companies Act, 2013, a company is required to spend at least 2% of its average net profit for the immediately preceding 3 financial years on Corporate Social Responsibility (CSR) activities subject to its turnover/net worth/ net profit crossing prescribed limits. Accordingly, the company incurs expenses for procurement of goods and services while undertaking CSR activities. Since such supplies are procured in course of business activities and as mandated by Statute, availment of ITC of GST charged on such supplies under Section 16(1) should not be in dispute. However, there is lack of clarity as to whether company will be called upon to reverse the ITC on the ground that the company has provided such goods and services to the recipient of such CSR activity without charging any consideration and thereby, using such goods and services in undertaking non-taxable supplies, which will be subject to provisions contained in Section 17(2) of CGST Act. | Given that CSR is mandated under Statute and also, in order to encourage CSR spends in excess of mandated limits, it would be appropriate if the taxpayers are not burdened with additional cost of input taxes while undertaking CSR activities. A suitable clarification in this regard and /or an amendment in the CGST Act, may be carried out as it may deem fit. |
| **30.** | **<u>Inverted Duty Structure:</u>**<br><br>Pharmaceutical Industry is suffering due to the inverted rate of tax. Wherein there is mismatch of GST on APIs (18 percent) and finished formulations (12 percent) though there is a | A simple mechanism is to be prescribed so that MSME do not suffer due to blockage of Input Tax Credit on account of inverted rate of duty.<br><br>1) GST on API/Bulk drug list should be reduced to 12% or if not possible GST on finished products should be |

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| | provision to get refund of GST under Rule 89 (5) of CGST Rules, 2017, to get refund on account of inverted duty structure, under which refund of input tax credit shall be granted as per the formula. The procedure is cumbersome and the MSME are finding it difficult to follow the same. Due to the huge amount of working capital stuck with the Government. | increased from 12% to 15% and in fact a new slab may be created for all items under 12% & 18% to be under 15% new slab. If at all not doable then increase GST of formulations (other than life saving covered under 5% may be continued unchanged to 18%). It will be a real ease of doing business besides direct benefit to all MSME sectors particularly in Pharma. |
| **31.** | **Under Rule 96 (10) of the CGST Rules, 2017, the persons claiming refund of integrated tax paid on exports of goods or services should not have:**<br><br>(a) : Received supplies on which the benefit of the Notification No.48/2017-Central Tax, dated the 18th October, 2017, except so far it relates to receipt of capital goods by such person against Export Promotion Capital Goods Scheme or Notification No.40/2017-Central Tax (Rate), dated the 23rd October, 2017, or Notification No.41/2017-Integrated Tax (Rate), dated the 23rd October, 2017, has been availed; or<br><br>(b): Availed the benefit under Notification No.78/2017-Customs, dated the 13th October, 2017, or Notification No.79/2017-Customs, dated the 13th October, 2017, except so far it relates to receipt of capital goods by such person against Export Promotion Capital Goods Scheme. | Due to the aforesaid restriction the MSME are unable to Export goods on Payment of IGST and avail refund. There is huge ITC credit surplus lying with MSME due to various reasons, mainly (1) Inverted duty structure whereas all inputs and services has 18% and above GST and finished products has 5% to 12% GST (2) Mostly MSME companies sells goods at a much competitive rates in market and so GST is levied on selling rates which leaves with them unutilized GST credit, so on the contrary where this sector is helping to supply medicines at a competitive rates, they are being punished by way of blocking of huge working capital and it is requested that such restrictions should be removed so that MSME can export goods under Rebate of duty. |
| **32.** | **Special Scheme/policy for Pharmaceuticals and allied industry:**<br><br>Currently, Active Pharmaceutical Ingredients ('APIs') (raw material used to make bulk drugs) are majorly imported from China. India imports around 65%-75% of its raw material from China. Thus, India runs the risk of a severe shortage of medicines because of it's over dependence on China for sourcing raw material for drugs. | With the ongoing trade war between USA and China, there is a big opportunity for India to capture a big share in the Global Pharma Export Market.<br><br>PLI scheme on the principle of proportionate basis recently introduced should be also available to Brownfield project also, however whatever new investment are done in existing plant atleast on weightage basis benefit can be given. Also, scheme should be available to Pharma excipients and key intermediates which are only used for making bulk drugs and formulations. |
| **33.** | **Input Tax Credit should be allowed for construction of an immovable property which is intended to be used for furtherance of business or commerce:**<br><br>As per Section 17(5)(c) and (d) of the CGST Act, 2017, input tax credit (ITC) shall not be available on (i) works contract services in respect of an | It is recommended that the provisions of section 17(5)(d) should be appropriately amended to allow ITC where the taxpayer is going to use the immovable property in the course or furtherance of business (e.g. real estate and hospitality sector). |

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| | immovable property or (ii) goods and services used for construction of an immovable property on his own account including when such goods and services are used in the course of furtherance of business.<br><br>ITC, though, is available when works contract service is an input service for further supply of works contract service. This exception to denial of ITC enables a developer to avail input tax credit of works contract services and charge tax on the output works contract service to the customer. Bit denial of credit when used for construction on own account even though the same are used in the course of furtherance of business is against the philosophy of the GST law which is aimed at reducing cascading effect of taxes.<br><br>Allowing ITC where building is used in the course or furtherance of business (generating income liable to GST) such as renting will keep the tax chain intact and serve the purposes of equity. | |
| **34.** | **<u>Mechanism for payment of GST under reverse charge:</u>**<br><br>Currently, GST under reverse charge is required to be discharged in cash and not by utilization of available input credit. The restriction adversely impacts the cash flow and is not in line with Global Practice. | GST payable under reverse charge should be allowed to be discharged by utilizing input credit in line with global practice. |

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# Court rejects AstraZeneca's plea on diabetes drug patent

The Delhi High Court has rejected Global Pharma major AstraZeneca's application seeking a restraining order against marketing of a blockbuster anti-diabetes drug Dapagliflozin by domestic companies, including Torrent, USV, Micro Labs, Eris LifeSciences and Zydus, thus paving the way for affordable diabetes drugs in the Indian market.

With nearly a dozen companies launching generic versions at competitive prices, the stage is set for a price war between the players to get a slice of the growing Rs.15,000-crore diabetes market. AstraZeneca had sued several generic companies for the infringement of patents covering Dapagliflozin. In a keenly watched court battle, the high court in a hearing on Wednesday, 18.11.2020 concluded that its patent is "prima facie invalid as it lacks inventive merit", legal sources told.

AstraZeneca holds two patents for Dapagliflozin in India — the first expired in October, while the second will expire in May 2023. Simply put, the second patent was not found to have inventive merit over what was already existing in prior art (earlier patent). The order by Justice Mukta Gupta, accessed by TOI, said "since the defendants have prima facie laid a credible challenge to the validity of suit patent on the ground of obviousness and for non-compliance of section 8(2) of the Act, this court finds that the plaintiffs have not made out a prima facie case for grant of interim injunction which is declined".

AstraZeneca's Dapagliflozin is sold under the brand Forxiga, and is part of a popular class of drugs called SGLT2 inhibitors, valued around Rs.4,500 crore (MAT October 2020), approved for use in type 2 diabetes. It is also distributed by Sun Pharma and Abbott Healthcare under the brands Oxra, Oxramet, Oxramet XR and Gledepa, Gledepa MET IR and Gledepa MET XR respectively.

Recently, certain generic versions have entered the market, nearly halving the therapy cost for patients. "The court also found that failure to share vital information under section 8 (2), with the Indian Patent office was a breach enough to deny an interim order to the patent holder", S Majumdar, Counsel on behalf of Torrent, said. The company has faced patentability objections in the US, which it failed to disclose. When contacted, an AstraZeneca spokesperson said, "The order contains several positive findings in its favour, especially on those issues which formed the main thrust of the attack.

AstraZeneca has been informed that findings mainly on two issues have been rendered against it. We are currently studying the order of the high court, and are committed to taking all steps which are necessary in law in order to protect and enforce its patent for Dapagliflozin, which it believes to be a world-class invention." Majumdar added, "For a suit patent to be revoked under section 64(1)(a) no prior publication is required.

However, if there is a prior patent for the same invention, no second patent can be granted. Even the definition of invention under section 2(1)(j), the Act provides that invention means a new product or process involving an inventive step and capable of industrial application."

*Source: Rupali Mukherjee, The Times of India, 19.11.2020*

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# WTO and IP Waiver

India and South Africa have recently knocked at the doors of WTO for waiver of IP rights and patents for COVID-19 medical products. By this IP waiver, under certain provisions of the TRIPS Agreement, both the countries wanted to ensure rapid access to affordable medical products like diagnostic kits, PPEs, ventilators, vaccines and other medicines to prevent, contain and treat Coronavirus disease. In the joint communication, both the countries wanted the waiver to continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity.

Both the countries' clarion call for the waiver is relevant as the outbreak has led to a swift increase in global demand for these medical products with many countries facing acute shortages. Shortages of these COVID-19 medical products have put the lives of health and other essential workers at risk and led to many avoidable

deaths. It is also threatening to prolong the pandemic. The longer the current global crisis persists, the greater will be the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak.

There are several reports about IP rights potentially hindering timely provisioning of affordable medical products to the patients. It is also reported that some WTO members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing Compulsory/Government use licences. Beyond patents, other IP rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the TRIPS Agreement.

A particular concern for countries with insufficient or no manufacturing capacity is the requirements of Article 31 *bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products. The Article 31 *bis*, which came into force on January 23, 2017, provides the legal basis for WTO members to grant special Compulsory Licences exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients. Unfortunately, the proposal has met with staunch opposition from a bloc of developed countries including the US, EU, UK, Switzerland, Norway, Australia, Canada and Japan, and later joined by Brazil. The US reiterated the importance of innovation during the COVID-19 pandemic for safe and affordable medical solutions, without looking into the issues raised by India and South Africa. The EU stated that it doesn't see IP as a barrier. The developed countries stated that suspending key protections of the TRIPS Agreement would send the wrong message to industry investors. They are of the view that IP has enabled collaboration between bio-pharmaceutical innovators and Governments, universities and other research partners to speed up progress on the most pressing unmet medical needs.

But, what these countries have conveniently forgotten is the fact that this pandemic has claimed more than one million lives across the world, and is still counting. Though the countries across the globe are taking extreme steps to contain it, the pandemic is raging ahead with no signs of abating. Before rejecting the proposal put forward by India and South Africa, these developed countries should have deliberated the fact that all IP covenants including Paris Convention, TRIPS and others including most National IP laws have provisions for overriding patents during pandemics and national emergencies. So, it would have been appropriate for the WTO to adopt a resolution for waiving IP rights and patents for COVID-19 medical supplies under these unprecedented medical emergencies like the one we are witnessing now.

*Source: Ramesh Shankar, Pharmabiz-Editorial, 11.11.2020*

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GOVERNMENT COMMUNICATIONS

# Requirement of Public Hearing for Violation cases: Clarification - reg.

**MoEF&CC Office Memorandum dated 12th November, 2020**

*To*

1. *Chairman of all the Expert Appraisal Committees,*
2. *Chairperson/Member Secretaries of all the SEIAAs/SEACs,*
3. *Chairpersons/ Member Secretaries of all SPCBs/UTPCCs,*
4. *Chairman, Central Pollution Control Board (CPCB),*
5. *All the Officers of IA Division.*

**1.** The Ministry vide OM dated 16.03.2018 directed that the projects/activities which are in violation, pertaining to all sectors, shall be considered as per the directions of Hon'ble High Court of Judicature at Madras vide Order dated 14th March, 2018 in WMP Nos.3361 and 3362 of 2018, and WMP No.3721 of 2018 in WP No.11189 of 2017.

**2.** It has been now brought to notice that pursuant to the Ministry's OM dated 16.03.2018, the EAC (Violation Sector) and certain SEACs are stipulating Public Hearing to projects and activities which are in violation across all sectors except for Building and

Construction projects covered under Schedule 8 (a) of the EIA Notification and as amended thereof.

3. The Ministry is in receipt of representations from various stakeholders requesting the Ministry to clarify that Public hearing shall be undertaken only in respect of those cases of violation, where the EIA Notification, 2006, as amended from time to time, so mandates.

4. After due consideration of the spirit of the Hon'ble Court's directions, the Ministry hereby clarifies that the purpose behind conduct of public hearing is not to determine the violation but only to assess the impact that the project may have on local environment and living. Therefore, if in the first place nature of the project does not call for public hearing, violation does not cast additional requirement of public hearing. Wherever, public hearing is required, it should be undertaken bringing out all facts before the public.

5. In this regard, while considering the applications for Environmental Clearance under the violation category as per the provisions of S.O. 804(E) dated 14.03.2017, the EACs/SEACs may insist upon public hearing to be conducted only for those categories of projects for which the EIA Notification, 2006 itself requires public hearing to be conducted.

6. This issues with the approval of the competent authority.

**F. No. 22-28/2020-IA.III**

*Sharath Kumar Pallerla, Scientist 'F'/Director, IA (Policy), Ministry of Environment, Forest and Climate Change, Impact Assessment Division, New Delhi.*

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CBIC MATTERS

# Proposal for allocation of funds for MEIS for FY 2019-20 and for 9 months of FY 2020-21 i.e. from 01.04.2020 to 31.12.2020 - reg.

**CBIC Office Memorandum F.No.605/58/2015-DBK-(Pt-II), dated 12th November, 2020**

*To*
*Directorate General of Foreign Trade,*
*(Kind Attn. Shri Amit Yadav, DGFT),*
*New Delhi.*

1. The undersigned is directed to refer to DGFT's requests vide OMs dated 04.06.2020, 26.08.2020, 01.09.2020 and 01.10.2020 from F.No. 01/61/180/288/PC-3 regarding allocation for MEIS of Rs.39,097 Crore for the FY 2019-20, Rs. 10,555 Crore for the period 01.04.2020 to 31.08.2020 and Rs. 5000 Crore for the period 01.09.2020 to 31.12.2020.

2. It is to inform that the Competent Authority has approved the allocation of an amount of Rs.39,097 Crore for MEIS benefits for exports made during the FY 2019-20. Further, allocation totaling Rs.15,555 Crore for MEIS benefits for exports made during the period 01.04.2020 to 31.12.2020 is conveyed with the approval of the Competent Authority.

3. It may be ensured that the aforestated allocations are utilized for issuance of duty credit scrips only for exports made during the respective periods i.e Rs.39,097 Crore for FY 2019-20, Rs. 10,555 Crore for the period 01.04.2020 to 31.08.2020 and Rs.5000 Crore for the period 01.09.2020 to 31.12.2020.

4. To ensure that MEIS allocations for FY 2019-20 and for FY 2020-21 (April to December, 2020) are not exceeded, DGFT should review the MEIS outgo periodically and share scrip issuance data on a regular basis with this Department.

5. Further, keeping in mind the ongoing stress on Customs revenues, it is suggested to limit the issuance of MEIS duty credit scrips in this financial year. Accordingly, DGFT is requested to issue MEIS scrips upto a total value of Rs. 16,000 Crore in FY 2020-21. Issuance of remaining scrips may be spread over the subsequent financial years through an appropriate mechanism.

*Gopal Krishna Jha, Director (Drawback), Central Board of Indirect Taxes and Customs, (Drawback Division), Department of Revenue, Ministry of Finance, New Delhi.*

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# Amendment to Industrial Policy Notification No.10(1)/2017-DBA-II/NER dated 05.10.2017 *re.* 'Scheme of Budgetary Support under GST Regime to units located in States of Jammu & Kashmir - reg.

**DPIIT Notification dated 12th November, 2020**

*(Published in the Gazette of India on 13th November, 2020)*

The Central Government hereby makes the following amendments in the Government of India Notification No.10(1)/2017-DBA-II/NER dated 05.10.2017, titled 'Scheme of Budgetary Support underGoods and Services Tax Regime to the units located in States of Jammu & Kashmir, Uttarakhand, Himachal Pradesh and North East including Sikkim as per "The Jammu and Kashmir Reorganisation Act, 2019" and will be applicable on and from the "appointed day".

**i) The subject title of the Scheme may be read as:-**

*The Scheme of Budgetary Support under Goods and Services Tax Regime to the eligible units located in States of Uttarakhand, Himachal Pradesh, North East including Sikkim,* ***Union Territory of Jammu & Kashmir and Union Territory of Ladakh.'***

**ii) Para 3.1 of the Scheme may be read as follows:-**

The Scheme shall be called 'The Scheme of Budgetary Support under Goods and Services Tax Regime to the eligible units located in States of Uttarakhand, Himachal Pradesh, North East including Sikkim, ***Union Territory of Jammu & Kashmir and Union Territory of Ladakh.'***. The said Scheme shall come into operation w.e.f. 01.07.2017 for an eligible unit (as defined in para 4.1) and shall remain in operation for residual period (as defined in para 4.3) for each of the eligible unit in respect of specified goods (as defined in para 4.2). The overall scheme shall be valid upto 30.06.2027.'

**iii)** The name of Jammu & Kashmir, wherever applicable in the Notification No.10(1)/2017-DBA-II/NER dated 05.10.2017 may be read as **Union Territory of Jammu & Kashmir and Union Territory of Ladakh.**

**F.No.10/2/2019-GSTSS**

*Rajendra Ratnoo, Joint Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce & Industry, New Delhi.*

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# In Lok Sabha & In Rajya Sabha

## In Lok Sabha

## Impact of COVID-19

### Lok Sabha Unstarred Question No. 923

### Shri Behanan Benny:

**Q.** Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): whether the Government is aware of the impact of the Covid-19 infection on India in comparison with other major countries, like USA, Russia, EU and Brazil;

(b): if so, the details thereof;

(c): whether any assessment of World Health Organization has been received by the Government in this regard, if so, the details thereof; and

(d): the details of assessment made by the Government regarding the end of Covid-19 pandemic?

**Answered on 18th September 2020**

**A.** (a) & (b): Government of India has been analysing the data on progression of disease in other major countries. As of now, India has performed fairly well as compared to global situation and major countries like USA, Russia, Brazil and the European Union. India has the lowest key performance indicators such as cases and deaths per million population and case fatality rates. Details are given in Annexure.

(c): World Health Organization provides on its website weekly epidemiological report on global, regional and country-wise situation of COVID-19 and key parameters like weekly, cumulative cases, newly reported deaths by region and by country. It also provides global and regional trends.

(d): The pandemic is declared by Director General, World Health Organization (WHO). The end of COVID-19 pandemic will also be declared by Director General, WHO based on global situation and recommendation of the Emergency Committee under International Health Regulations.

Annexure

| Sr.no | Country/Region* | Total cases | Total deaths | Cases per million | Deaths per million | CFR |
|---|---|---|---|---|---|---|
| 1 | United States of America | 64,26,958 | 1,92,612 | 19,295 | 579 | 2.9% |
| 2 | Russia | 10,68,320 | 18,635 | 7,283 | 127 | 1.7% |
| 3 | Europe Union** | 25,94,115 | 1,84,117 | 5896 | 418 | 7.1% |
| 4 | Brazil | 43,15,687 | 1,31,210 | 20,146 | 613 | 3.0% |
| 5 | India | 48,46,427 | 79,722 | 3,445 | 57 | 1.6% |
| 6 | World | 2,89,18,908 | 9,22,252 | 3,780 | 120 | 3.2% |

* Source: WHO COVID Dashboard; ** European Center for Disease Control

**The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)**

## Procurement of Medical Equipments for Corona

### Lok Sabha Unstarred Question No.961

### Shri Balubhau Alias Suresh Narayan Dhanorkar:

### Shri K Navaskani:

**Q.** Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): whether the Government had planned to procure adequate number of PPE kits, sanitation equipment and material to prevent contamination and safeguard the doctors, health workers and para-medical staff and others including police personnel deputed on the task of combating Covid-19 in the country, if so, the details thereof;

(b): whether there has been an acute shortage of such preventive equipment, all along leading to large scale spread of disease among these health personnel; and

(c): if so, the details thereof and steps taken to tackle the situation especially when cases are being reported in large number throughout the country?

### Answered on 18th September 2020

**A.** (a): Yes. The Ministry of Health & Family Welfare anticipating the spread of COVID-19 pandemic in India had planned to procure adequate number of Personnel Protective Equipment including coveralls and N-95 masks. By 31st May 2020 orders had been placed for 192 lakh coveralls and 459 lakh N-95 masks. As on 15.09.2020, 140 lakh coveralls and 344 lakhs N-95 masks have been distributed to the States/UTs and Central Institutions to enable them to equip their Covid related personnel.

(b) & (c): No. There are a large number of indigenous manufacturers of quality certified coveralls and N-95 masks in the country and these products are available on Government e-market place (GeM) also. States are being encouraged to procure the same from the (GeM), anticipating the demand for these products in their State.

**The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)**

## Monitoring of EIA

### Lok Sabha Unstarred Question No.1016

### Shri Vinod Kumar Sonkar:

### Dr Jayanta Kumar Roy:

### Shri Bhola Singh:

### Shri Raja Amareshwara Naik:

### Dr Sukanta Majumdar:

### Shrimati Sangeeta Kumari Singh Deo:

**Q.** Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state;

(a): whether the Ministry of Environment, Forest and Climate Change has issued the draft Environment

Impact Assessment (EIA) Notification 2020 recently;

(b): if so, the details thereof;

(c): whether Government has any mechanism to monitor the functioning of State Level Environment Impact Assessment Authorities;

(d): if so, the details thereof?

(e): whether there has been delay in environmental clearance causing inordinate time and cost over-run of projects;

(f): if so, the details thereof; and

(g): the further steps being taken for ensuring balance between environment and development?

**Answered on 18th September 2020**

**A.** (a) & (b): Yes Sir. The Ministry has used the draft Environment Impact Assessment (EIA) Notification, 2020, with an objective, inter alia, to promote environmental cause; removes redundancies; encourages modernization; brings defaulters into environmental regime with requisite action, penalty and remediation; introduces standardization and technology driven process; and consolidates 55 amendments and 229 Office Memoranda/circulars issued from time to time in the past 14 years since the issuance of Environmental Impact Assessment Notification, 2006. The draft EIA Notification 2020, has been issued for, inter alia, including integration of the amendments, office memoranda, circulars, guidelines issued from time to time; rationalization of categorization of projects; delegation of more projects or activities to the state level authority; fast tracking of environmental clearance for small projects or activities; strengthening of monitoring mechanism; standard operating procedures; explicit provisions; automation of the process; validity of environmental clearance at one-go; flexibility in data collection; provision for dealing with violation cases; provision for dealing with non-compliance of EC conditions; implementation of directions of Hon'ble Courts and Tribunal; rationalization of Public consultation process; integration of learning's in implementation of EIA, 2006; etc.

(c) & (d): The central online portal 'PARIVESH' has integrated the process of application, processing and grant of environmental clearances across the states since August, 2019. With on boards of States on PARIVESH, the status of pendency and output in respect of projects or category of projects with relevant agencies including State Level Environment Impact Assessment Authorities and State Level Expert Appraisal Committees of respective states is available on the PARIVESH dashboard.

(e) to (g): The EIA Notification, 2006 lays down detailed process for application, appraisal and grant of Environmental Clearances(EC). The said notification also specifies time period for processing and grant of ECs. In some of the cases the time period may be more because of additional studies desired by the expert committees or directions from the courts/Tribunal, etc. Several steps have been taken for ensuring balance between environment clause and development including the draft EIA Notification, 2020 that encourages modernization and provides mechanism for fast tracking of environmental clearance for small projects or activities on one hand; and strengthens the monitoring mechanism on other by bringing defaulters into regulatory regime with commensurate damages & costs.

**Answer Minister of State in The Ministry of Environment, Forest and Climate Change (Shri Babul Supriyo)**

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## Scientists identify synthetic mini-antibody to combat COVID-19

By screening hundreds of synthetic mini-antibodies called sybodies, a group of scientists has identified one that might stop SARS-CoV-2 from infecting human cell.

**Llama's mini-antibodies and their synthetic imitations:**

The ability of SARS-CoV-2 to infect cells depends on interactions between the viral spike protein and the human cell surface protein ACE2. To enable the virus to hook on to the cell surface, the spike protein binds ACE2 using three finger-like protrusions, called the Receptor Binding Domains (RBDs). Blocking the RBDs therefore has the potential to stop the virus from entering human cells. This can be done using antibodies.

Nanobodies, small antibodies found in camels and llamas, are promising as tools against viruses due to their high stability and small size. Although obtaining them from animals is time consuming, technological advances now allow for rapid selection of synthetic nanobodies, called sybodies. A technology platform to select sybodies from large synthetic libraries was recently developed in the lab of Markus Seeger at the University of Zurich, and made available for this study.

**In search of the best sybody against SARS-CoV-2:**

EMBL Hamburg's Christian Löw group searched through the existing libraries to find sybodies that could block SARS-CoV-2 from infecting human cells. First, they used the viral spike protein's RBDs as bait to select those sybodies that bind to them. Next, they tested the selected sybodies according to their stability, effectiveness, and the precision of binding. Among the best binders, one called sybody 23 turned out to be particularly effective in blocking the RBDs.

To learn exactly how sybody 23 interacts with the viral RBDs, researchers in the group of Dmitri Svergun at EMBL Hamburg analysed the binding of sybody 23 to the RBDs by small-angle X-ray scattering. In addition, Martin Hällberg at CSSB and Karolinska Institutet used cryo-EM to determine the structure of the full SARS-CoV-2 spike bound to sybody 23. The RBDs switch between two positions: in the 'up' position the RBDs poke out, ready to bind ACE2; in the 'down' position they are furled to hide from the human immune system. The molecular structures revealed that sybody 23 binds RBDs in both 'up' and 'down' positions, and blocks the areas where ACE2 would normally bind. This ability to block RBDs regardless of their position might explain why sybody 23 is so effective.

Finally, to test if sybody 23 can neutralise a virus, the group of Ben Murrell at Karolinska Institutet used a different virus, called a lentivirus, modified such that it carried SARS-CoV-2's spike protein on its surface. They observed that sybody 23 successfully disabled the modified virus *in vitro*. Additional tests will be necessary to confirm whether this sybody could stop SARS-CoV-2 infection in the human body.

**Scientific collaboration during lockdown:**

"The collaborative spirit has been enormous in these times, and everybody was motivated to contribute," says Christian Löw, one of the lead scientists in the study. The researchers started the project as soon as they received approval from EMBL leadership to reopen their laboratories during the COVID-19 lockdown. They managed to select the candidate sybodies and perform the analyses in just a few weeks.

"Getting the results so quickly was only possible because the methodologies we used had already been established for other research projects unrelated to SARS-CoV-2. Developing these tools would have taken significantly more time and resources," says Löw. The results of this project hold out the promise of a potential way to treat COVID-19. In future work, the scientists will perform further analyses to confirm whether sybody 23 could be an effective COVID-19 treatment.

*(Materials provided by European Molecular Biology Laboratory. Original written by Dorota Badowska. Note: Content may be edited for style and length).*

*Source: European Molecular Biology Laboratory, Science Daily, 04.11.2020 (Excerpts)*

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## Cancer treatment could be replicated for COVID-19

Beta-blockers could potentially be used to treat COVID-19, according to a new international study by Italian and Australian scientists. University of South Australia cancer researcher, Dr Nirmal Robinson, working with a team in Naples, has found evidence in animal models that the beta-blocker Propranolol helps suppress the spread of cancer in the lung which has an inflammatory profile very similar to COVID-19. The scientists have presented their findings in a paper published in Frontiers in Immunology, calling for Clinical Trials to support their research.

Dr Robinson, Head of the Cellular-Stress and Immune Response Laboratory at the Centre for Cancer Biology, says Propranolol is commonly used to treat heart conditions, anxiety and migraine. Recent Clinical Trials have shown its effectiveness for other conditions, including cancer. Patients with COVID-19 suffer from many abnormalities, including inflammation, because the SARS-CoV-2 virus disrupts the body's immune system. Beta-2 blockers could potentially reduce this inflammation and help rebalance the immune system," Dr Robinson says.

Beta-blockers including Propranolol are medicines that work by temporarily stopping or reducing the body's natural 'fight-or-flight' response. In return, they reduce stress on certain parts of the body, such as the heart and blood vessels in the brain. They have also been suggested as a treatment option for autoimmune diseases such as rheumatoid arthritis. "SARS-Cov-2 enters the human cells through the protein ACE2, infecting the lower respiratory tract, causing profound inflammation and multi-organ failure. Patients with comorbidities, such as high blood pressure, diabetes and heart disease, are at much higher risk," he says. Other inflammation suppressors, including Tocilizumab (an immuno-suppressive drug prescribed for arthritis) and Ruxolitinib (a drug used to treat the rare bone marrow blood cancer, myelofibrosis) have already been used to treat the more serious COVID-19 cases, the researchers say. "We believe the beta-2-adrenergic pathway should be more deeply investigated as a possible target to reduce the inflammatory symptoms related to COVID-19. The next step is to perform clinical trials to explore an alternative therapy to treat COVID-19, based on the lessons we have learned from cancer," Dr Robinson says.

*Source: University of South Australia, Ecancer News, 04.11.2020 (Excerpts)*

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INTERNATIONAL NEWS

## Sri Lanka Government to establish Pharma Manufacturing Zone

The Sri Lankan Government has decided to establish a Pharmaceutical Manufacturing Zone in the southern coast of Hambantota and will also invite global pharmaceutical companies to set up companies within the zone, local media reported on Wednesday, 11.11.2020. The Government information department, quoted in media reports said the Government planned to set up the Special Manufacturing Zone on a 400-acre land so that it could attract leading pharmaceutical companies in the world.

According to a statement by the information department, the proposal to set up the zone was made by Health Minister Pavithra Wanniarachchi, who proposed to establish 20 pharmaceutical manufacturing companies in 200 acres of land under the first phase of this project. The cabinet of Ministers approved this project, the statement said. Cabinet approval was also granted to establish another 20 pharmaceutical manufacturing companies in another 200 acres of land under the second phase of the project.

All infrastructure facilities will be supplied by the Sri Lanka Board of Investment, the statement said. Sri Lanka's Presidential Task Force for economic revival and eradication of poverty has identified the pharmaceutical manufacturing industry as one of the industries that can attract direct foreign investments as well as a field that has a potential for earning foreign exchange.

*Source: MD Bureau, Medical Dialogues, 13.11.2020 (Excerpts)*

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NATIONAL NEWS

## Industry awaits clarity on Category 2 stipulated APIs, KSMs, DIs under newly approved PLI scheme

The pharmaceutical industry is waiting for further clarity on the second category of Active Pharmaceutical Ingredients (APIs)/Key Starting Materials (KSMs) and Drug Intermediaries (DIs) under Cabinet's newly approved Production Linked Incentive (PLI) scheme in Pharma sector worth Rs.15,000 crore towards boosting existing Brownfield API units in country.

The new PLI scheme is envisaged to boost 3 categories of Pharma products under which Category 2 includes APIs, KSMs and DIs. Besides the clarity sought, industry is also awaiting notified Guidelines on the new PLI scheme of Rs.15,000 crore. It is also looking towards fulfilling

industry's long pending demand for having single window approval mechanism for faster environmental clearance and compliance. The Department of Pharmaceuticals (DoP) came out with a Notification of Rs.6,940 crore PLI scheme in July this year for promotion of domestic manufacturing of critical KSMs, DIs and APIs in India.

The Gazette Notification dated July 21, 2020 superseded the earlier Notification of DoP issued on this subject on June 2, 2020. Under the scheme, financial incentives shall be given for six years based on sales made by selected manufacturers for 41 products which cover all the identified 53 APIs. The tenure of the scheme is from FY 2020-21 to FY 2029-30.

The other two categories, first and third category, includes biopharmaceuticals, complex generic drug, patented drugs or drugs nearing patent expiry, cell-based or gene therapy products, orphan drugs, special empty capsules, complex excipients, repurposed drugs, auto-immune drugs, anti-cancer drugs, antidiabetic drugs, antiinfective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, in vitro diagnostic devices (IVDs) and phytopharmaceuticals.

Industry leaders are hopeful that the new PLI scheme will also include existing Brownfield API units in the country and will be instrumental in the production of priority 20 molecules thus overcoming the need for API imports from China. Industry experts have appreciated the second part of PLI scheme for incentivizing the Pharma sector amongst 10 key sectors of the country.

This would be a welcome change as 35% - 40% of existing Brownfield API units capacity need to be utilized. It has been learnt that around 20 molecules can be manufactured by synthetic chemistry within a period of two to three months. This can be done considering the fact that the earlier PLI scheme of Rs.6,940 crore announced in the month of July, 2020 will take minimum 2 years to fructify. Fermentation based units alone will take 3 to 4 years as setting up of Greenfield units generally entail a time period of 2 years.

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.

*Source: Shardul Nautiyal, Pharmabiz, 13.11.2020*

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## DoP issues revised Guidelines for procurement of Make in India Medical Devices

The Department of Pharmaceuticals (DoP) has issued revised Guidelines for implementing the provisions of public procurement (preference to Make in India) Order (PPO) - 2017 DPITT Guidelines for procurement of Make in India medical devices. The Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153 (iii) of the general financial rules 2017, had issued PPO - 2017 dated June 15, 2017 which was partially modified on May 28, 2018, May 29, 2019 and September 16, 2020.

According to Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD), "The Guidelines on PPO - 2017 are basically to align the PPO of DPITT with earlier Guidelines." This is envisaged to promote manufacturing and production of medical devices in India with a view to enhancing income and employment of local population. It is aimed to give maximum preference to local companies.

"This will be a big boost to Indian companies as earlier it was restricted till drugs with reference to Drugs and Cosmetics Act (D&C) Act. With the inclusion of New Medical Device Rules (2017) under the D&C Act, medical devices will also get preference as per the DoP and DPITT Guidelines," said All India Drug and License Holders Foundation (AIDLHF) President Abhay Pandey.

DPIIT in order to facilitate the implementation of the PPO 2017 dated August 14, 2017 has identified Department of Pharmaceuticals (DoP) as the nodal department for implementing the provisions of the PPO 2017 relating to goods and services related to pharmaceutical sector. DPIIT has now decided that the nodal department for product category medical devices shall be DoP.

DoP in supersession of the Guidelines issued earlier dated October 16, 2018 and December 12, 2019 has issued the revised Guidelines. The DoP move gives priority to bidders of Government contracts that use

more local content. The revised order has introduced a concept of Class-I, II and non-local suppliers, based on which they will get preference in Government purchases of goods and services. Class-I local suppliers will get the most preference in all Government purchases because their domestic value local content addition is 50 percent or more. They will be followed by Class-II suppliers, whose local content value addition range is more than 20 percent but less than 50 percent.

For verification of local content, the Class I and II suppliers shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement norms. Concept of Class-I supplier has been introduced so that in cases where local suppliers are to be given the order, even within that group we should give first preference to the ones whose domestic value addition is significantly high.

Under the revised Guidelines, it is envisaged that all Central Government departments, their attached or subordinate offices and autonomous bodies controlled by the Government of India should ensure that purchase preference will be given to domestic suppliers.

*Source: Shardul Nautiyal, Pharmabiz, 12.11.2020*

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## Medical devices industry seeks clarity on PLI scheme

The medical devices industry has sought clarity on the Central Government's claim that medical device sector has been adequately covered under the existing Production Linked Incentive (PLI) scheme unlike pharmaceutical sector for which the Union Cabinet has recently approved new PLI scheme worth Rs.15,000 crore to boost domestic manufacturing. The Department of Pharmaceuticals (DoP) notified the PLI scheme for the medical device sector through a Gazette Notification dated July 21, 2020. Total financial outlay for the PLI scheme is Rs.3,420 crore. The scheme is expected to see investment worth Rs.5,400 crore, as per Government estimates.

Medical device manufacturers had recently urged DoP to consider reducing the threshold investment limit in the range of Rs.75 to Rs. 90 crore from Rs.180 crore for domestic manufacturers in the Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices. This, according to the Association of Indian Medical Device Industry (AiMeD), will also widen the scope of eligibility to cover COVID-19 utility medical devices.

The Government of India through its flagship "Make in India" initiative envisages to meet the rising demand of essential healthcare equipment for the country pushing the Indian medical devices sector to become self-reliant especially for essential 39 COVID-19 medical devices. Besides this Government had earlier also announced, medical device park scheme, which has an outlay of Rs.400 crore for 4 medical device parks. This will offer world class testing facilities, lower cost of production and single window for regulatory approvals. It is expected to attract an investment of Rs.40,000 crore in this sector.

Medical devices covered under the PLI scheme target segments include cancer care or radiotherapy medical devices, radiology and imaging medical devices, nuclear imaging devices, anaesthetics and cardio-respiratory medical devices including catheters of cardio respiratory category and renal care medical devices.

Besides this, target segments also cover all implants including implantable electronic devices like cochlear implants and pacemakers. The PLI scheme is designed to attract investors in select 4 high technology target segments of medical devices where import dependence is very high. PLI scheme stipulates that the medical device company should be registered in India. There should be minimum Rs.180 crore investment by one unit. Minimum net worth of the company should be Rs.18 crore (30% of threshold investment of first year).

Applicants can apply multiple products within one target segment. Application window is 120 days and approval thereafter within 60 days. Applications can be made through the online portal of the Project Management Agency (PMA) and the maximum number of applicants to be selected is 28.

Under the PLI scheme, financial incentives shall be given to selected companies based on threshold investment and incremental sales (over Base Year) of medical devices covered under target segments. Under the Scheme, financial incentive shall be given to selected companies at the rate of 5% of incremental sales (over Base Year) of goods manufactured in India and covered under Target segments, for a period of five years i.e. from FY 2021-22 to FY 2025-26.

The scheme is applicable only for Greenfield projects. Financial incentive under the scheme shall be provided

only to companies engaged in manufacturing of goods covered under target segments in India. Eligibility shall be subject to thresholds of investment and incremental sales of manufactured goods (covered under Target Segments) over Base Year. An applicant must meet all the threshold conditions to be eligible for disbursement of incentive. Eligibility under Production Linked Incentive scheme shall not affect eligibility under any other Scheme and vice-versa. The tenure of the scheme is from FY 2020-21 to FY 2026-27.

*Source: Shardul Nautiyal, Pharmabiz, 16.11.2020*

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## Life Sciences Advisory Committee advocates 3-pronged approach to make Telangana a hub for Clinical Trials

The Life Sciences Advisory Committee, headed by K Satish Reddy, Chairman of Dr Reddy's Laboratories, has called upon the state Government of Telangana to make the industrial policy initiatives more liberal and encouraging so as to make Telangana a hub for Clinical Trials in India.

While releasing a vision document for Telangana life sciences for the year 2030 recently, the Telangana Life Sciences Advisory Committee said that as already the state Government has initiated the largest integrated Pharma city project in the state. There is need to scale up infrastructure to aid start-ups in graduating to commercialization stage; augment current sources of funding for existing and emerging innovations as well as establish technology sharing and transfer linkages within and between industry and academia, observed the committee.

"Apart from boosting the existing formulations, bulk drugs and biotechnology industry, it is also important to nurture a conducive environment to breed an integrated healthcare ecosystem, including the need to boost equipment manufacturing, along with boosting the innovators in biotechnology segment and give a pushup for the Clinical Trial sector in the state," observed Satish Reddy.

As part of the new life sciences policy initiative, the advisory committee has advocated three-pronged development approach including giving a boost to innovation, development of infrastructure and creating a sustainable growth path for the life sciences sector.

In fact, as per the new life sciences report released by the Telangana Government by 2030, the state Government had set a target of increasing the value of Pharma, biotechnology and healthcare sector to reach Rs.7.45 lakh. For which the state industries department lead by K T Rama Rao, Minsiter for IT and Industries has sought suggestions and advise from the life sciences committee to achieve the set targets.

In view of this, the advisory committee has suggested the Government to provide financial incentives to foster fresh investments. It had also advised setting up of an investment promotion body for the State's life sciences sector. It highlighted the need to devise training and finishing programmes to bridge the State's talent employability gap.

*Source: A Raju, Pharmabiz, 16.11.2020*

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## DCGI bans manufacturing, sale, distribution of ulipristal acetate tablets 5 mg

The Drugs Controller General of India (DCGI) has directed the State Licensing Authorities (SLAs) to direct manufacturers to suspend the manufacturing, sale or distribution of ulipristal acetate tablets 5 mg based on the recommendation of European Medicines Agency (EMA).

SLAs have also been directed to recall the stock in respect of the subject product from the market. The action taken in the matter may be communicated to this directorate at the earliest, as per DCGI directive. Ulipristal acetate (Fibristal) (5 mg tablets) has been widely used for treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age who are eligible for surgery.

There are reports from EMA regarding liver failure associated with the use of ulipristal acetate tablets 5 mg. In May 2018, Pharmacovigilance Risk Assessment Committee (PRAC) in EMA finalised a review of the benefit risk balance of ulipristal tablets 5 mg initiated due to three cases of liver injury leading to liver transplantation.

Meanwhile, health activists have also urged state FDAs to urgently follow DCGI directive to suspend the manufacturing, sale, distribution of ulipristal acetate. All

Food and Drug License Holders Foundation (AFDLHF) President Abhay Pandey has also reported the matter to Maharashtra Food and Drug Administration (FDA) in the interest of patient safety.

DCG(I) directive is also based in the light of a report of serious liver injury in European Union (EU) and recommendation of PRAC in EMA for suspension of ulipristal tablets 5 mg until a definitive conclusion is arrived. Esmya tablet 5 mg (ulipristal acetate) has also been directed to be voluntarily recalled in Philippines, Thailand, Malaysia, Singapore, Ireland and Dubai.

The drug was approved by DCGI on March 14, 2018 for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The PRAC reviewed the new cases of serious liver injury leading to liver transplantation reported with ulipristal acetate 5 mg and concluded a probable causal association with the drug.

The PRAC also noted that a progression in the development of hepatic failure leading to liver transplantation could not be prevented despite the risk minimisation measures implemented previously.

*Source: Shardul Nautiyal, Pharmabiz, 17.11.2020*

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## Public cautioned against use of fake drugs

The Pharmacovigilance Centre of Ayurveda, Siddha, Unani and Homoeopathy (AYUSH) Drugs has asked the public to remain cautious about use of counterfeit drugs or drugs prescribed by quacks, as they may cause Adverse Drug Reaction (ADR).

They can report any issues related to fake medicines and ADR in AYUSH system to the centre without delay. The centre functions at the Siddha Wing of the Perundurai Government Hospital.

D Venkatachalam, Centre Coordinator, and S Yamini Priyadharsini, Programme Assistant, told that during the COVID-19 pandemic people were not only using Allopathic medicines, but also Siddha and Ayurvedic medicines.

The State Government had established separate facilities for Siddha treatment and had introduced special health care scheme "Arogyam". It is also distributing Siddha medicines like Kabasura Kudineer as immune modulators for COVID-19.

However, there are lot of counterfeit medicines in the market, they said. Original medicines will have manufacturing license number from the State Licensing Authority (IM), batch number, manufacturing date, expiry date and contact address or customer care support numbers.

Whereas fake medicines will only have FSSAI, cottage industry and Small Scale Industry Licenses and women self-help group manufacturing details.

Similarly, Practitioners list can be accessed at the Tamil Nadu Siddha Medical Council portal www.tnsmc.com, they said. The Peripheral Pharmacovigilance Centre at Erode can be reached at **ppvcayusherode@gmail.com**. Complaint forms and more details are available in **www.ayushsuraksha.com** or contact 011-26950401/402.

*Source: The Hindu, 29.10.2020 (Excerpts)*

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FEATURE

# How To Vaccinate A Nation

***Sachidananda Murthy***

Even as laboratories and Pharma companies are announcing varying stages of success in developing a Covid-19 vaccine, an Inter-Ministerial Group in Delhi has carved out a universal vaccination plan. The Health Ministry and the state Governments were the Nodal Agencies for mega vaccination campaigns in the past. This time in view of the size, scale and timeline of the programme, the Government has also brought in other Ministries — Home, Finance, Pharmaceuticals, Biotechnology, Railways, Agriculture, Consumer Affairs, Education, Civil Aviation and even Defence — for consultations and input on their expertise.

As the Government has promised free vaccination for all, the operation would be much bigger than other countrywide operations like the annual polio vaccination, the census or the General Elections. The Government wants to get the vaccine administered within 12 to 18 months from the date the Drugs Controller General of India certifies a Covid-19 candidate vaccine as viable. There is hope that India can be declared free of Covid-19 when the nation celebrates its 75th Independence Day in August 2022. The task becomes even more gigantic in the light of the Prime Minister's promise to the international community — that India would not only take care of its citizens, but also help humanity by exporting huge quantities of vaccine produced in India.

Finance Minister Nirmala Sitharaman has assured that there will be no dearth of funds for the programme. The official task force is, however, not in favour of recommending vaccines developed in the west, which could be priced at 300 to 500 per dose. The Health and Pharmaceuticals Ministries are checking whether there are enough drug companies in the country which could conform to the World Health Organisation's Good Manufacturing Practice code — a prerequisite for being permitted to manufacture the highly sensitive drug.

There are also suggestions on capacity augmentation for RNA-based vaccines for which the manufacturing base is insufficient. The challenge of supplying enough syringes is also being addressed, as the present thinking is that the vaccine has to be administered twice, with a gap of at least three weeks. The temperature at which the vaccine has to be made, transported and stored is also a big challenge as most of the vaccine candidates require cold-storage facilities.

The Agriculture Ministry has been sounded out on the capacity of cold storages in the country. The Transport Ministries are being asked whether it would be easier to shepherd the recipients to a Single Urban Centre and administer the vaccine, rather than take the whole operation to every village. There is also hope for availability of a vaccine that would not require refrigeration and can remain effective in normal temperature.

The Inter-Ministerial Group has also worked out the sequence of the population segments that would get vaccinated first. These include health workers, associated Covid-19 warriors in police, sanitation, transportation and connected areas, and all high officials like Ministers, Judges, MPs, MLAs and Bureaucrats. Next in priority would be Senior Citizens and those having specific health conditions.

The group feels the more widespread and penetrative the design of the programme, the faster the entire population would be covered. But the plans would remain on paper, until the specifications of the approved vaccine are known.

*Source: The Week, 21.11.2020*

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## INDIAN DRUG MANUFACTURERS' ASSOCIATION

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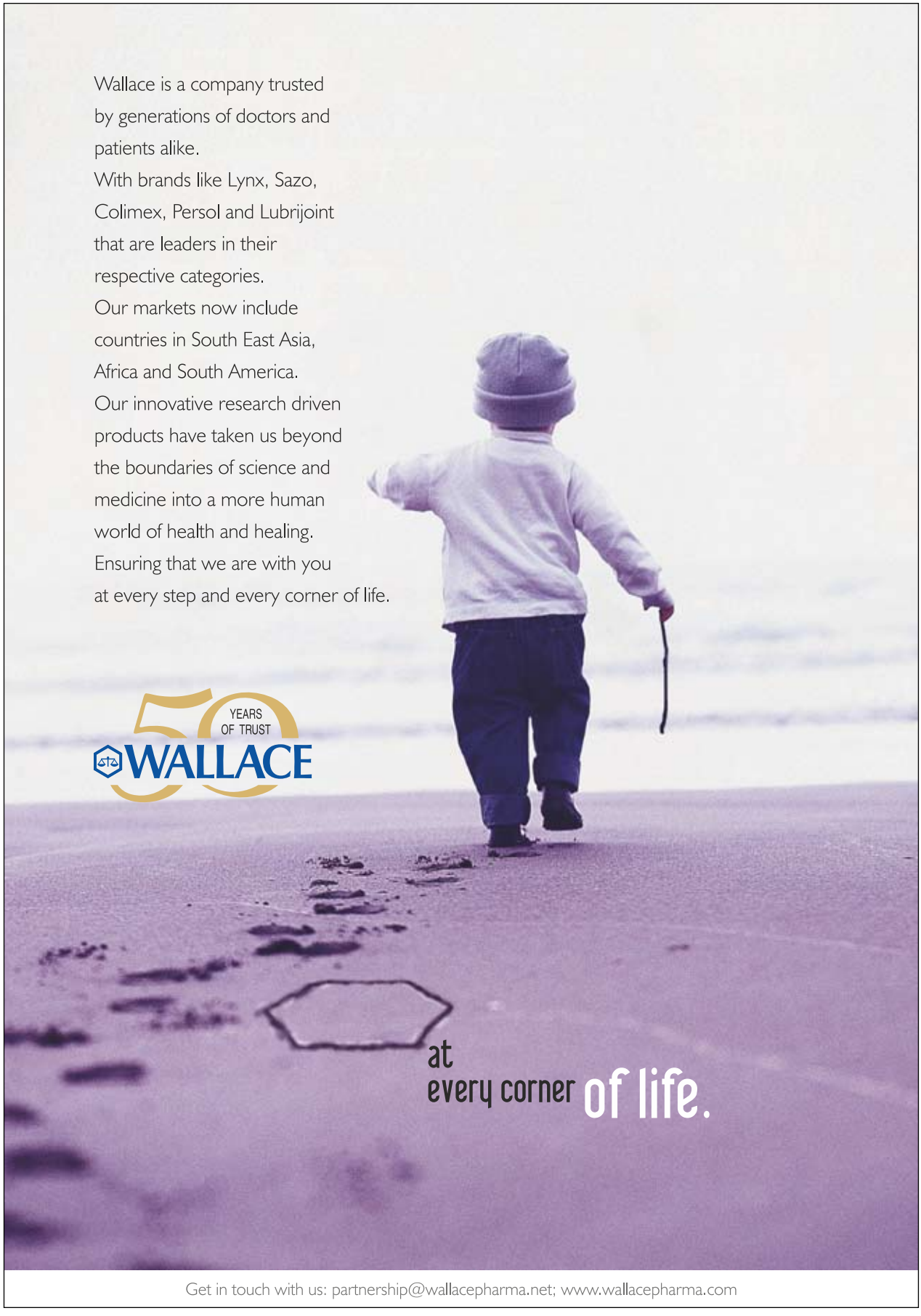

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