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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 **Issue No. 29** **01 to 07 August 2020**

IDMA ACTIVITIES:

CBIC NOTIFICATIONS:

CUSTOMS MATTERS:

DGFT MATTERS:

GOVERNMENT PRESS RELEASE:

NEW DEVELOPMENTS:

NATIONAL NEWS:

IDMA-Invest India joint Interactive VC meeting with Shri Mansukh Mandaviya, Hon'ble Minister of State for Chemicals & Fertilizers

An Interactive Virtual Conference with Hon'ble Minister of State for Chemicals & Fertilisers and Shipping Shri Mansukh Mandaviya with IDMA was organised by Invest India on 14 July 2020. The theme was ***"Strengthening India's Pharmaceutical Industry Post COVID-19".*** Invest India is a Government organisation working in Ministry of Commerce as the National Investment Promotion and Facilitation Agency of India and acts as the first point of reference for investors in India. Invest India focuses on sector-specific investor targeting and development of new partnerships to enable sustainable investments in India. Mr Mahesh Doshi, National President, Mr Daara Patel, Secretary-General, Past Presidents, Chairmen of various Committees, domain experts and IDMA Secretariat participated as listed below:

1. **Mr Mahesh Doshi** – National President, IDMA & Managing Director, Dy-Mach Pharma.
2. **Dr George A Patani** – Hon General Secretary, IDMA & Director, INGA Laboratories P Ltd.
3. **Mr Daara B Patel** – Secretary General, IDMA.
4. **Mr Deepnath Roy Chowdhury** – Immediate Past National President, IDMA & Managing Director, Strassenburg Pharmaceuticals Ltd.
5. **Mr Yogin Majmudar** – Past President & Chairman-Bulk Drug Committee, IDMA and Managing Director, Bakul Aromatics and Chemicals Ltd.
6. **Mr Manish Doshi** – Past President, IDMA & Managing Director, Umedica Laboratories Ltd.
7. **Mr S V Veerramani** – Past President, IDMA & Chairman and Managing Director, Fourrts (India) Laboratories Pvt Ltd.
8. **Mr Bharat Shah** – Vice President (Western Region) & Managing Director, S Kant Heathcare Ltd.
9. **Dr Viranchi Shah** – Senior Vice President, IDMA & Director, Saga Laboratories Ltd.
10. **Mr S M Mudda** – Chairman, Regulatory Affairs Committee, IDMA.
11. **Mr Sandeep Bambolkar** – Joint Managing Director, Indoco Remedies Ltd.
12. **Mr Mehul Shah** – Chairman, Contract Manufacturing Committee, IDMA & Managing Director, Encube Ethicals Pvt Ltd.
13. **Dr Amit Rangnekar** – Chairman – Pricing /Consumer Committee, IDMA & Vice-President, Centaur Pharmaceuticals Pvt Ltd.
14. **Mr B G Barve** – Chairman, Excise and Taxation Committee, IDMA and Joint Managing Director, Blue Cross Laboratories Pvt Ltd.
15. **Mr Ashok Madan** – Executive Director, IDMA Delhi Office.

A number of issues were discussed. The key points discussed and deliberated are listed below, broadly relating to promotion of (a) API industry in India, replacing imports; (b) Exports of API and Formulations from India, further strengthening the position; (c) R&D helping the industry to add value to its operations; (d) investments in Indian Pharma industry, through path breaking steps such as Regulatory simplification, decriminalization of Drugs & Cosmetics Act and Rules as well as Environment Act, easing of Price Control measures, Financing issues, and other ease of doing business initiatives. National President delivered a brief welcome address as published below. Secretary-General provided a brief outline of IDMA and its activities as below; and also facilitated the discussions. A Note seeking the Hon'ble Minister's further support required to boost ease of doing business in API industry is also published. A detailed Note to explain in depth issues relating to Regulatory and Quality matters was forwarded earlier to the Minister. The Hon'ble Minister provided a summary of the vision and mission of the Government in further boosting Pharmaceutical Industry in India and acknowledged our points. He informed that he had already initiated action on many of the issues with other concerned Ministries. Mr Ashok Madan, Executive Director, IDMA Delhi Office delivered the Vote of Thanks.

IDMA BRIEF PROFILE AND ACTIVITIES:

Brief Profile:

- Founded in 1961.
- Premier association of the Indian Pharmaceutical Industry.

- Regarded in Government, Media and Industry circles as the *Voice of the National Sector.*
- Secretariat Head Office in Mumbai.
- 20 Committees, headed by experts.
- Works with the Government on the industry's development plans and various public matters.
- Represents the industry on important issues such as Pricing, Regulatory Issues, Drug Act amendments and other policy matters.
- Plays crucial role in keeping opinion leaders, Press and public informed about industry issues.
- IDMA Membership has been growing from strength to strength with over 1000+ members at present.
- At present we have State Boards in Tamil Nadu, Kerala & Puducherry, Gujarat, West Bengal, Haryana, Himachal Pradesh & Uttarakhand, Madhya Pradesh, Telengana and Karnataka.
- We propose to open State Boards in all States.

Publications:

- ***IDMA Bulletin***: Weekly - continues to be successfully published for the past 51 years providing up to date information on IDMA Activities and other relevant issues.
- ***Indian Drugs:*** Monthly Scientific and Research publication covering original papers and Review articles of current interest to pharmaceutical industry – now in its 57th year. Has a dedicated website: **www.indiandrugsonline.org**
- ***IDMA Annual Publication:*** provides statistical and other relevant data and released annually at Annual Celebrations – completed 58 Editions.

Awards on Annual Day:

- **IDMA Quality Excellence Awards**: instituted in 1984 for Bulk Drugs and Formulation manufacturing units.
- **IDMA Margi Memorial Best Patent Awards:** best original Patents - India & Global.
- **IDMA ACG-SCITECH Research Paper Awards:** best original papers published in ***Indian Drugs*** in various disciplines.
- **IDMA J B Mody Best Student Awards:** to outstanding top ranking students of B Pharm of various universities
- **IDMA Corporate Citizen Award**: for excellence in CSR activities.

Awards at IDMA-APA-PAC:

- **IDMA-APA Eminent Analyst Award**; in recognition of life-time contribution and expertise in the field of Quality Assurance/Quality Control.
- **IDMA-APA Young & Outstanding Analyst Awards** - to encourage and promote young professional analysts of promise.

Seminars and Training Programs:

- Various Seminars/Workshops on Regulatory, Technical, Medical, GST, Marketing etc have been organised to keep Members updated about latest manufacturing practices, technical developments and harmonisation of various Pharmacopoeias.
- **IDMA and Department of Pharmaceuticals have been jointly organizing Seminars and Workshops for the past 3 years to train SMEs on upgradation to WHO-GMP and beyond.**
- **IDMA – CDSCO & FDA have jointly organized Ten workshops pan India in regards to SUGAM Portal.**
- **IDMA-APA Pharmaceutical Analysts' Convention (PAC) – held successfully for the past 21 years.**
- **Successfully conducting Advanced Program in Pharmaceutical Quality Management (APPQM) jointly with NSF, UK.**

WELCOME REMARKS BY MR MAHESH DOSHI, NATIONAL PRESIDENT, IDMA (*EXCERPTS)*:

Shri Mansukh Mandaviyaji, Hon'ble Minister of State for Shipping (IC) and Chemicals & Fertilisers, Government of India, Mr Deepak Bagla, MD & CEO, Invest India and my IDMA Colleagues;

It is my pleasure to welcome you all to this Interactive Session with Hon'ble Minister Shri Mansukh Mandaviya organised by Invest India with IDMA.

The theme of this Interactive Session is aptly named *"Strengthening India's Pharmaceutical Industry Post COVID-19", w*hich I understand is being organised by Invest India as a series.

Hon'ble Prime Minister Shri Narendra Modiji speaking at a Global Meet recently said:

"The pandemic has once again shown that India's Pharma Industry is an asset not just for India but for the entire world. It has played a leading role in reducing the cost of medicines especially for developing countries."

The large number of manufacturers, the intense competition and the ability to produce a number of different drugs and formulations has ensured that quality medicines are produced and the prices are kept affordable.

For many years, the Pharma industry was growing on its own, tackling various requirements of regulatory, logistic and other issues.

Now Industry is really pleased and encouraged by the Government's active support and guidance in the last years, especially witnessed during the COVID-19 pandemic

Sir, your support in allowing Pharma manufacturing units to restart production soon after the nationwide lockdown announced was remarkable.

At our request the Department of Pharmaceuticals, under your guidance also supported in getting the supply and distribution chain activated to ensure continuous supply of medicines to the market.

The day-to-day interaction with us in resolving immediate issues, interacting with State authorities to address local issues etc was an eye-opener.

The recent examples of Government and Industry joint initiative such as our Members supplying Hydroxychloroquine medicines on demand to the world at very short notice, mass producing Favipiravir tablets and Remdesivir injections for our COVID-19 positive patients, fast tracking Clinical Trials for indigenously researched vaccines etc would surely have not been possible without the Government jointly working with industry.

We really appreciate such support and guidance and request that such thing continues to be extended to us at all times.

We will be taking up a few issues which require your indulgence and support in getting them addressed and resolved.

I appreciate and congratulate Invest India for organising such Interactive Sessions for strengthening the Indian Pharma Industry. I am sure these excellently organised Government to Business Webinars will go a long way in attracting huge investments, both domestic and FDI, to the Pharma industry.

The Indian Pharma Industry is already being recognised as the "*Pharmacy of the World*".

The PLI scheme for enhancing domestic production of KSMs, Intermediates and APIs and the setting up of bulk drug parks that your Ministry has initiated, the fiscal incentives for growth of MSMEs etc announced by Government will ensure that we are totally self-reliant in API production and formulations.

Sir, with your directions and continued support, we will become the Number 1 manufacturers of the world in APIs and formulations and only the sky will be the limit for the Indian Pharma Industry.

DISCUSSIONS AND DELIBERATIONS *(EXCERPTS):*

IDMA is aligned with the Government's vision of making Indian Pharma industry a USD 120 Billion industry by the year 2030. We believe that the following points are critical to prepare the Industry towards this elevation:

1) Promotion of API industry in India, replacing imports.
2) Promotion of Exports of API and Formulations from India, further strengthening the position.
3) Promotion of R&D helping the industry to add value to its operations.
4) Promotion of investments in Indian Pharma industry, through path breaking steps such as Regulatory upgradation in line with practices followed in the advanced markets, decriminalization of Drugs & Cosmetics Act and Rules as well as Environment Act, and other ease of doing business initiatives.

1. Regulatory matters:

- Urgent need for holistic changes to Drugs & Cosmetics Act. There is a need to simplify the laws.

1.1 **Manufacturing and Quality Standards:**

- Criminal proceedings to be pressed ONLY in case of Spurious drugs & adulterated drugs.
- Decriminalise minor violations and unintentional errors for better compliance.

- To add the provision of *mens rea* in the D&C Act, in order to distinguish criminal intent and negligence, from technical non-compliances.
- In case of product batch failures (other than spurious/adulterated), the same to go through investigation, validated effective recalls, followed by CAPA for addressing the GMP root cause. Production of relevant products be commenced only after effective CAPA has been conducted. In such cases criminal court proceedings to be done away with and to be replaced by above actions and backed by financial penalties in case of repetitive failures.

1.2 **GMP compliance:**

- Important to distinguish GMP compliance from Product quality compliance.
- GMP Compliance through proposed revision of Schedule M to be redrafted to adopt global practices. This could be framed with minimal Rules and detailed Guidelines to encourage objectivity in compliance, as done in the advanced regulated markets. The guidelines can be updated regularly by working committee formed on each major GMP subject.
- GMP Guidelines have force of law but are not mandatory.
- Non-compliance to guidelines to be handled through CAPA in order to improve GMP compliance.
- Non-compliance to GMP can be the reason for withdrawal of GMP Licence, cessation of manufacturing/testing activities of affected areas/ products, etc unless rectified or corrected within reasonable time through effective CAPA.

2. Financing issues:

2.1 Promotion of R&D:

2.1.1 Weighted Deduction of 200% under Income Tax needs to be continued for at least next 10 years

2.2 Government should revive Investment Allowance Reserve for better utilisation of fund

2.3 BA/BE expenses incurred on studies carried out at independent bioanalytical laboratories should be eligible for deduction as R&D expenses.

2.4 50% of the Registration expenses incurred for international registrations to be reimbursed to exporter (widen the scope of current policy under MoC to include both plant registration fees and product registration fees).

2.5 API Industry must be identified as a priority industry and offered a lower rate of interest by all banks and loan-disbursing institutions.

2.6 Financial Incentive Package may be considered for all Bioequivalence Studies carried out for registration in the domestic market.

3. Support required by API Industry:

3.1 In light of the new definition of MSMEs, fees payable to PCBs needs to be rationalized and PCB definitions of MSMEs have not been revised.

3.2 Urgent need for providing flexibility in Environment Clearance (EC) Guidelines for API manufacturers.

3.3 Consider API and intermediate manufacturing as a group and "Consent" can be given in this general category instead of individual products, as provided in other advanced countries for ease of doing business.

3.4 Need for EC has been rightly dispensed with by MoE&F for expansion up to 50% when there is no increase in overall pollution load.

3.5 Procedure of obtaining "no increase in pollution load certificate" at State level takes anywhere between 4 to 6 months. Hence, a cap of maximum 30 days needs to be put on clearance time and it must be deemed as approved if there is no reply from State PCB. A check must be put in place to prevent the practice of minor queries being sent at the end of the time-limit.

3.6 In case of emergencies such as COVID-19 pandemic, even 30 days' time for granting permission will be too long and just a declaration of "no increase in pollution load" from the API manufacturer should be the way forward.

3.7 Indian API industry is mature and must be allowed to self-regulate and not have to await such approvals and licenses every time. Concerned Regulatory and Environment Authorities have online monitoring data of air and water effluents. Hence any increase in load will be detected.

3.8 All old cases of alleged "violation" of Consent Terms need to be compounded and closed to allow API manufacturers to concentrate on meeting the urgent need of increased demand.

3.9 Most so called "violations" have been for exceeding production quantities beyond the Consent, or manufacturing 'non-consented' products; in both cases without any change in effluent quality or quantity.

4. Boost to Export Industry:

4.1 Formulation Exports:

- ➢ Track and Trace:
  - Track and trace of Pharma packs is being taken up by Departments of Commerce, Health/CDSCO and Pharmaceuticals at various levels. It is high time that the status-quo be declared as the final status rather than extending it year by year as this is a self imposed trade barrier.
  - As an exporting country, Track and Trace may be made optional until an internationally acceptable harmonious system is evolved. Aggregation is not mandatory in US/Europe. Moreover, implementation of Track & Trace will depend on the requirements of the importing countries.
- ➢ MRA (Mutual Recognition Agreement):
  - Enter into MRAs (not MoU) for recognition of WHO GMP issued by Indian regulators by all RoW (Rest-of-World) (Other than regulated world) countries.
  - Basically this means that WHO GMP issued by India is accepted as GMP evidence by regulators of such importing countries with whom India has MRA. This can be done with all countries that adopt WHO GMP Guidelines as GMP requirements.
  - This helps in avoiding duplication of Plant GMP inspections by several international auditors looking for GMP evidence to the WHO GMP standards.
  - This could give a huge boost to Pharma exports from India to such markets.
  - This could also substantially reduce the registration time line for Indian Pharma products in RoW markets, thereby speeding up the exports to such markets.
- ➢ BA/BE for Product License for products meant for Exports should not be mandatory and left to the need of the importing country regulations.
- ➢ 50% of the Registration expenses incurred for international registrations to be reimbursed to exporter (widen the scope of current policy under MoC to include both plant registration fees and product registration fees).
- ➢ Advance License – delay in approvals and penalties for non-compliance – request that timeline be extended to 2 years from the present 18 months for ease of doing business.
- ➢ Provide additional support of 3% on Exports under Remission of Duties or Taxes on Export Products (RoDTEP) /MEIS scheme.

5. DPCO Issues:

- Need to revamp price control mechanism as it discourages investment:

  India has the lowest drug prices in the world, yet many Indians are deprived of life-saving drugs. Instead of price controls, other mechanisms like promoting competition among manufacturers, bulk procurement of generic drugs by public institutions for distribution, increase in public spending on healthcare etc will deliver better outcomes.

- Price Revision must be from Prospective batch only:

  Price increase or decrease should be from prospective batch only as industry requires sufficient time to implement price revision.

- Price control and approval mechanisms must be restricted to medicines falling under essentiality criterion as per NLEM. It must be for specific dosage form and strength that is essential.

  'Essentiality' should be the main criterion for inclusion in the NLEM and not the market size, sales data or span of control. All strengths and dosages are not required by majority of patients. Hence the most popular dosage may be specified and put under price control. This will also comply with the objective of limited span of control.

- It can be further filtered to apply to only those essential formulation/strength that has monopolistic status;

  Controlling price of monopoly formulation will ensure access to that essential formulation at affordable price.

- Keep any formulations with large number of manufacturers out of price control;

  Indian Pharma industry is mature and competition in any formulation ensures prices are kept under check. Market forces will promote self-regulation without Government intervention.

- Introduce mechanism or institutionalise system for automatic adjustment for high prices of raw materials under Para 19;

  A formula or mechanism needs to be introduced under para 19 to automatically revise prices of the formulations to adjust for steep hike in prices of APIs. Manufacturers do absorb some fluctuations in prices of APIs. However a huge increase impacts production costs if the API becomes unviable and may lead to shortages or non-availability of the medicines.

6. Boost to R&D efforts:

- Weighted Deduction of 200% under Income Tax needs to be continued for at least next 10 years.
- Same incentives to be provided for R&D carried-out outside own premises.
- Freeing the R&D and Innovation activities and centres from multiple approval requirements/ controls.
- New Product approval system must be revamped.
- Incremental Innovation to be recognised and supported.
- Research in FDCs to be recognised as an opportunity to create Intellectual Property and supported.
- National Biodiversity Rules and Regulations have prevented innovation in the field of Natural products. The regulations must facilitate the use of natural resources for the benefit of the local population by the local companies.

7. Aligning the Administrative Controls:

- Currently the industry is regulated through statutes from Ministry of Chemicals and Fertilisers, Ministry of Health & Family Welfare, Ministry of Environment and Forest, Department of Revenue and many others.
- Therefore, a single window be created under DoP to handle all issues related to Pharma industry

8. Protect the Indian Manufacturers and encourage "Make In India":

- Higher duty to be imposed on import of formulations (as compared to rate of duty for APIs).
- Increase the period of registration of APIs and Formulations of "Me Too" products from other countries on a reciprocity basis.
- Membership of PICs will provide easy access to the Indian Market to Manufacturers in the other 52 Country PICs Members and hence will be a detriment to "MAKE in INDIA".

9. Reforms for overall growth:

- Ease labour law and other related regulations with respect to working hours and overtime hours.
- Strengthen Central Drug Authority: Single-window clearance mechanism, incentivise automation of Pharma plants and digitalization of data for faster approvals and ease of doing business.
- Improve the talent, attitude and support the Pharma R&D ecosystem,
- Incentivise innovation for patients with Unmet Needs more than generics.

10. Overall plan for the growth of the Indian Pharma Industry:

- Need for wider consultation with industry on any change in Rules - should be transparent and industry's views need to be perceived to be considered.
- Proper Guidelines must be established, with training programs, to ensure that State Governments implement the regulations in the true spirit that they were formulated**.**
- Our priority must be to focus on India and leveraging Indian market of 1.37 billion people for enabling them access to affordable quality medicines.

NOTE SEEKING HON'BLE MINISTER'S FURTHER SUPPORT TO BOOST EASE OF DOING BUSINESS IN API INDUSTRY:

(Mr Y R Majmudar, Chairman, Bulk Drugs Committee)

1. At the outset let me congratulate you Hon'ble Minister Mansukhbhai for your vision in being one of the first to recognise the need for India to be self-reliant in APIs and constituting the Task Force for APIs as far back as April, 2018. I feel privileged to be a Member of the same.

2. Next milestone from your side is the PLI Scheme where initially 41 molecules have been selected. Our suggestion is that Government should start the exercise for identifying more such products for Phase II of the Scheme, as 41 is just the tip of the iceberg.

3. Incidentally, IDMA & BDMA have done an internal exercise and our Members have identified 20 of the 41 molecules which can be produced in existing facilities with minimal investment. So if the investment

criteria is removed we can have production of these 20 in just a few months instead of waiting for couple of years needed by green field units. Achieving production should be more important than creating investment when already spare capacities are available.

4. Although, you are already aware of most of the current issues facing the API manufacturers, for sake of record I would like to touch upon few important ones.

5. Main issue as you know is with environmental controls. In fact due to your proactive support, Ministry of Environment has been adequately sensitised. With just a junior officer as attendee in last Task Force Meeting in February, 2 weeks back in the Video Conference arranged by Secretary, Department of Pharmaceuticals Dr P D Vaghelaji, Additional Secretary from Ministry of Environment had also joined in. In fact last week even the Secretary himself was part of another VC, which had to be postponed due to technical issues with presentation from his Ministry.

6. No one disputes need to protect the environment. So the need of the hour is to simplify procedures and cut down on unnecessary expenses and time in lengthy paperwork in getting permissions from Pollution Control Boards. Also some out of the box thinking is needed.

7. Aligning with the West, over the years India has been tightening environment standards. This has led to increase in cost of treatment which now is just next to the Raw Material cost in overall cost of manufacture – as much as 20%.

8. Against this, our main rival China provides variety of subsidies because of which our API industry finds difficult to compete with the Chinese.

9. Let me now list a few of specific issues for Min of Environment:

- Instead of reducing restrictions, STANDARDS for treated effluent are being proposed for just Pharma industry. With no other developed country having fixed such norms, India wants to be the first to fix norms for Antibiotic residue. The proposed norms are based on international study which recommends achieving the same over a period of 8 years, but for us they have to be adhered to with immediate effect. With Antibiotics constituting hardly 5% of total Pharma Industry, the norms are to be applicable across the board to entire Pharma industry.
- New Environment Impact Assessment (EIA) Policy is being drafted to subsume earlier one, including all amendments. It is a 83 page document, which is beyond the comprehension of average MSME manufacturer. Need for external consultant with consequent costs will be necessary. Instead of simplification, life will be more complicated. We suggest a simplified format separately for just Pharma removing numerous layers of permission required before one can produce an API.
- Exemption from need of Environment Clearance (EC) for up to 50% increase in production has not led to expected benefit at ground level, as State Bodies still take time up to 6 months to issue "No increase in pollution load certificates". Need to fix time limits (30 days), even for raising query (7 days) beyond which deemed approval. Better still issue all permissions in general category of "API & Intermediates" and/ or allow "self-certification".
- As I said earlier need is for out of the box thinking.
  - i) Why control production/utilities when need is to control only the effluent being discharged thereby giving total flexibility to the manufacturer for quick product changes.
  - ii) In 1994 when the current Environment Controls were conceived for the first time, individual units used to discharge directly into water bodies. Since last 10 years concept of CETP has been introduced with individual units sending effluent to CETPs for further treatment, who in turn discharge into water bodies. So why continue to control / monitor individual units? – Change in mind-set needed.

I would like to go a step further, let manufacturers be free to produce what API and the quantity they wish as long as CETP has the capacity to treat the generated effluent. After all API manufacturer specialises in Chemistry and has expertise in manufacture of chemicals. Effluent treatment is a different activity and there are other experts operating CETPs. Why not consider the two as separate activities? Another out of the box thinking.

Finally, need is to decriminalise minor offenses under EIA Guidelines, if necessary by even going to the Parliament. USA and other countries have only fiscal penalties. At the same time there are a number of pending old cases which need to be compounded so that manufacturers can concentrate of producing rather than taking rounds of courts.

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Need for Essential Medicines for Rare Diseases

Mr Mahesh Doshi, National President, IDMA

(Delivered the following address at the Webinar on 'Need for Essential Medicines for Rare Diseases' on 1 August 2020. The webinar brought together six Associations - IORD, BDMA, IPA, IDMA, FOPE and OPPI - on the same platform to address this vital issue):

- ***Dr V G Somani,*** *DCG(I),*
- ***Mr B R Sikri,*** *Chairman, FOPE,*
- ***Dr Ramaiah Muthyala,*** *President & CEO, IORD,*
- ***Mr Sudarshan Jain,*** *Secretary General, IPA,*
- ***Mr K G Ananthakrishnan,*** *Director General, OPPI,*
- ***Mr V V Krishna Reddy,*** *National President, BDMA,*
- ***Mr Venkat Jasti,*** *Managing Director, Suven Life Sciences,*
- ***Dr Viranchi Shah,*** *Sr Vice-President, IDMA;*

Ladies and Gentlemen;

Thank you for the kind introduction and warm welcome.

It gives me great pleasure to join you all at this Webinar on '***Need for Essential Medicines for Rare Diseases'*** hosted jointly by IORD, BDMA, IPA, IDMA, FOPE and OPPI.

Since 1977, the WHO Model List of Essential Medicines has provided advice to Member States to decide which pharmaceutical technologies should be provided to patients within their public health systems.

An incentive system has been put in place by various Governments for the development of medicines for rare diseases, often referred to as "orphan drugs".

India has taken the lead in focussing on R&D in this neglected area and is one of the top global funders of R&D in neglected diseases.

With a promising scientific base built on the foundation of an expanding Science and Technology workforce, the country is well placed to make a substantial contribution to innovation in neglected tropical diseases.

A third of new drugs (six out of 18) and two thirds of new vaccines (six of 10) for neglected diseases registered since 2000 have had Indian involvement. Nearly 12% of drug, diagnostic, and vaccine candidates for neglected diseases in the R&D pipeline are from India. The world's first leprosy vaccine was developed in India in 2016 and will accelerate eradication efforts.

India has successfully eliminated certain infectious diseases—such as guinea worm, trachoma, and yaws—in recent years.

Yet, neglected diseases such as leishmaniasis, filariasis, leprosy, snakebite, and soil transmitted worm infections still pose a challenge.

A draft National Policy for Rare Diseases has again been released for public comments by Ministry of Health and Family Welfare in February 2020.

The Policy provides for lowering the incidence of rare diseases based on an integrated preventive strategy encompassing awareness generation and screening programmes and enable access to affordable health care to patients of rare diseases which are amenable to one-time treatment.

The policy has noted that number of persons suffering from diseases considered rare globally, is lacking in India and accordingly provides that for the purpose of the policy the term rare diseases shall construe three Group of disorders identified and categorised by experts based on their clinical experience.

Considering the limited data available on rare diseases, and in the light of competing health priorities, the focus of the policy is on prevention of rare diseases as a priority for all the three groups of rare diseases identified by experts.

The Policy includes infectious tropical diseases and identifies a need to support research on treatments for rare diseases.

It has not yet prioritised diseases and areas for research funding or how innovation would be supported. In India, all medicines are essential, as 'drugs' as a category are included in Essential Commodities Act.

Moreover, the National List of Essential Medicines forms the basis for DPCO since 2013, and hence all drugs included there are price controlled.

Neglected diseases predominantly affect poor and marginalised populations and do not constitute a market that is attractive enough to stimulate private sector investment.

As such, the Indian Government must step in with appropriate policies and investments to support innovation.

The Department of Pharmaceuticals proposed to amend DPCO 2013 to exempt Orphan Drugs from purview of DPCO 2013.

This provision is intended to increase and improve accessibility, especially of drugs for treating orphan diseases.

In the short term, affordability may be hit unless alternate medicines are put in place.

However, accessibility and affordability could improve substantially in the long term.

We have recommended that the amendment should be extended to include rare and tropical diseases to encourage R&D and manufacture of drugs for such essential requirements.

In this regard, we must note that Pharmaceutical R&D is very expensive and time consuming as compared to other industrial research, on account of regulatory requirements of safety, efficacy and quality.

Sustained R&D efforts by Indian companies have enabled the Government to address India's needs on tropical/country specific diseases like TB, Kala Azar, dengue and other life-threatening inflictions like cancer, asthma, diabetes etc.

India is the fourth largest Government funder of neglected diseases research, and the largest among middle income countries.

Yet, funding falls far short of requirements.

Few public agencies disburse R&D grants for neglected diseases in India.

Hence R&D activity expenses should be continued under weighted deduction of 200% under the Income Tax laws for at least another 10 years.

It is time for India to notify the National Policy for Rare Diseases to pave the way for greater funding and mechanisms to support R&D innovation.

Creating an enabling environment for research and innovation will be crucial if India is to achieve the target set in Sustainable Development Goal 3.3 to end epidemics of neglected tropical diseases by 2030. Thank you.

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IDMA representation in response to draft Rules published under GSR 999(E) dated 05.10.2018 to substitute existing Schedule M of the Drugs and Cosmetics Rules, 1945

The Association has submitted the following representation on 3rd August 2020 to Shri Rajesh Bhushan, IAS, Secretary, Ministry of Health and Family Welfare with copy to Dr Mandeep K Bhandari, Joint Secretary, Ministry of Health & Family Welfare, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We sincerely thank you for providing an opportunity to IDMA in the Zoom Call on the 16th July 2020 for presenting our views on the proposed Notification to amend Schedule M to the Drugs & Cosmetics Rules.

IDMA appreciates the Government proposal to upgrade the regulatory requirements for ensuring availability of safe, standard and efficacious medicines to the Indian public as well as to the international community. This will also serve as a first important step towards achieving the long term objective of India becoming the member of PIC/S and will help in improving our image as quality manufacturers across the globe.

IDMA has submitted a detailed representation on January 17, 2019 expressing our concern that while upgrading the existing Schedule M, the guidelines published by WHO have been included as a part of the regulations and added that adoption of guidelines as regulations will lead to difficulties in interpretation and implementation of the requirements since unlike the non-mandatory nature of the WHO GMP guidelines, the proposed Schedule M is mandatory in nature. We have strongly suggested to differentiate the mandatory requirements from the guidelines in the proposed Schedule M. While we are enclosing a copy of our representation, we would like to reiterate the reasons for our suggestion in some detail below for your kind consideration:

Drugs and Cosmetics Act, 1940 and Rules, 1945 have been enacted to regulate manufacture, sale and distribution of drugs and cosmetics with a view to ensure availability of safe, standard and efficacious medicines and standard, safe cosmetics. The Act and Rules provide exhaustive regulations to the manufacturers, distributors and retailers and expect strict compliance from all concerned. Every requirement under the Act and Rules assumes mandatory nature and thus the Act imposes the concept of absolute liability.

Further, in the absence of defense of *mens rea* (not considering the intention behind the non-compliance), any unintentional, minor departure from the practices for the manufacture of medicines is considered as an offence and such manufacturer or dealer or any person is exposed to stringent penalty under the Act.

In view of this, any new change/requirement to be introduced under the Act or Rules by way of amendment should be done very cautiously and after properly appreciating the difficulties likely to be faced by the stakeholders in implementation of new regulations. Add to this is the misinterpretation of the provisions by few regulatory officers and the penal approach adopted during implementation which leads to unavoidable harassment to the manufactures, especially, the Medium scale and Small scale manufacturers.

We would like to present only one example of harassment caused due to misinterpretation of the provisions of the Act 26 of 2008 substantiating the above view. The amended Act has provided for enhanced punishment for the offenders involved in manufacture, sale and distribution of adulterated and spurious drugs. The Act has also introduced the provisions whereby getting bail has been made extremely difficult. While the idea was right about providing deterrent punishment to the offenders, we had expressed our apprehension about unintended consequences of the amended provisions for the licensed bonafide manufacturers. Our apprehensions were found to be correct when the regulatory officers started categorizing not of standard quality drugs failing in assay as spurious and adulterated drugs. Few manufacturers have already been convicted and stringent punishment has been imposed by the Trial Court. In some cases, charges have been framed against the manufacturers by the Trial Court. It is true that the Government tried to provide relief by issuing guidelines under Section 33P of the Act for taking action on NSQ reports. However, despite these guidelines, the manufacturers are still facing harassment due to misinterpretation as referred above.

The global guidelines are framed to serve as an advice and are required to be written in a manner that allows flexibility in the approach to be adopted for compliance with the principles of GMP. Therefore, by design the guidelines are open to different interpretations even while serving the objective of compliance with the regulation. With this background, adopting the guidelines as regulations themselves will inevitably lead to contentious misinterpretation and make compliance extremely challenging. Therefore the implementation of the proposed Schedule M in the current format will lead to serious issues of interpretation and compliance and consequently will hamper the growth of the industry.

In order to deal with these issues we request to distinguish the principles of GMPs from the Guidelines proposed to be included in Schedule M, in line with the framework adopted by European Union, that are aligned with PIC/s.

The EU framework has Directives and Regulations that are mandatory in nature and include the Principles of GMP. These are supported by GMP Guidelines, that are not mandatory requirements. These guidelines help in the interpretation of the principles of GMP and also provide guidance for implementation.

We, therefore urge that the requirements of GMP shall be amended to include the principles and concepts in the Act & Rules, while the details shall be in the form of guidelines and advisories. The guidelines shall be dynamic and may be updated as per the prevailing situations and developments. The power to issue the guidelines and changes shall be with DCGI.

The guidelines offer the flexibility to the manufacturers for complying with legal requirements and will remove the fear of legal actions. This framework will encourage all sectors, including MSME, to comply with the upgraded GMP requirements. The new framework will also help in decriminalization of minor errors, departures from good practices.

If our suggestions are considered, we are willing to prepare and submit a draft of the suggested Schedule M in two parts, the first one dealing with high level principles of the GMPs and the other in the form of a Guideline with detailed instructions to comply with the principles along with technical Annexures, where necessary.

In this system, compliance with the requirements of the GMP guidelines is achieved through regulatory inspections. The guiding principle followed in the developed countries to provide the manufacturer an opportunity to explain and implement appropriate Corrective and Preventive Actions (CAPA) on the observations or non-compliances are required to be followed.

This is vital for reducing the impact of the frequent regulatory changes on the industry especially on MSMEs and to increase the level of compliance of the dynamic changes happening in the science and technology of manufacture of pharmaceuticals as well as in the GMP guidelines. Present provisions under the Drugs and Cosmetics Rules, 1945 do not provide any scope for the same.

We therefore strongly feel that there is an urgent need to empower the regulators to take a judicious decision and give adequate discretion, in-built in Rule 85. Therefore, following amendment is suggested;

"Where any Licensee fails to comply with any provision of the Act and these rules, the Licensing Authority may issue the notice for improvement at the first instance of inspection and ascertaining the nature of the observations in the periodic inspections. On verification, if the compliance is not found to be satisfactory, after giving an opportunity to explain and that of being heard, the Licensing Authority by order in writing, may take one or more of the following actions, namely: -

(i) Issue warning in writing describing the deficiency or non-compliances observed during the inspection, including compliance verification inspection.

(ii) Suspend the licence of the concerned product on which there is an impact on the quality for the period as considered appropriate.

(iii) Cancel the licence of the concerned product on which there is impact on the quality.

The pharmaceutical industry is a highly technical and knowledge-based industry. Before introducing any changes to the provisions of the Act and Rules as well as to guidelines, a serious review with all stakeholders and particularly the industry stakeholders is necessary to add value and make such changes beneficial to the patients while making them easy to comply with by the industry.

There are several global examples of such active and objective collaborations. There is an ample scope to simplify the requirements for better patient compliance. IDMA has submitted a detailed proposal on this topic. This practice must be encouraged, and a wide consultation should be done before the changes are notified. Thanking you and with regards".

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Format/Schema for e-Invoices - reg.

ATTENTION MEMBERS

CBIC has notified registered person whose aggregate turnover in a financial year exceeds 500 crore rupees, as a class of registered person who shall prepare e-invoice w.e.f. 1st October 2020.

Also CBIC has Substituted a new Format/Schema for e-Invoice through FORM GST INV-01 vide CBIC Notification No. 60/2020 - Central tax dated 30th July 2020. (Copy of the same is reproduced below for your reference).

We have analysed Invoice Schema to be implemented with our present Invoice pattern and have observed that we need to include the following aspects in our all types of Invoices with immediate effect:

1. ***Invoice Reference Number***
2. ***Document Type to be INV/CRN/DBN instead of Regular***
3. ***Supplier Place***
4. ***Place of Supply (State Code)***
5. ***Recipient Place***
6. ***Is Service - Y/N***

Courtesy. Mr B G Barve, Chairman, Excise & Taxation Committee, IDMA.

Gazette Notification No. 60/2020–Central Tax [G.S.R. 480(E)], dated 30th July 2020

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on the recommendations of the Council, hereby makes the following rules further to amend the Central Goods and Services Tax Rules, 2017, namely: -

1. (1) These rules may be called the **Central Goods and Services Tax (Ninth Amendment) Rules, 2020.**

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

2. In the Central Goods and Services Tax Rules, 2017, for **FORM GST INV-01,** the following form shall be substituted, namely:-

FORM GST INV – 1

(See Rule 48)

Format/Schema for e-Invoice

Note 1: Cardinality means whether reporting of the item(s) is mandatory or optional as explained below:

0..1: It means that reporting of item is optional and when reported, the same cannot be repeated.

1..1: It means that reporting of item is mandatory but cannot be repeated.

1..n: It means that reporting of item is mandatory and can be repeated more than once.

0..n: It means that reporting of item is optional but can be repeated more than once if reported. For example, previous invoice reference is optional but if required one can mention many previous invoice references.

Note 2: Field specification Number (Max length: m, n) indicates 'm' places before decimal point and 'n' places after decimal point. For example, Number (Max length: 3,3) will have the format 999.999

Schema (Version 1.1)							
Sr. No.	**Technical name of the field**	**Cardinality (0..1/ 1..1/ 0..n/ 1..n)**	**Brief Description of the field**	**Whether Mandatory/ Optional**	**Technical Field Specification**	**Sample Value of the field**	**Explanatory Notes**
1.	**Basic Details**	**1..1**		**Mandatory**			**Header for Basic Details**
1.0	Version	1..1	Version Number	Mandatory	String (Max. Length:6)	1.1	This is version of the e-invoice schema. It will be used to keep track of version of Invoice specification.
1.1	IRN	1..1	Invoice Reference Number	Mandatory	String (Length: 64)	a5c12dca80e7433217…..ba4013750f2046f229	This will be a unique reference number for the invoice. **<u>However, the supplier will not be populating this field.</u>** The registration request may not have this field populated. The Invoice Registration Portal (IRP) will generate this IRN and respond to the registration request. e-invoice is valid only when it has the IRN. Hence, this is marked as mandatory field.
1.2	Supply_Type_ Code	1..1	Code for Supply Type	Mandatory	Enumerated List	B2B/B2C/SEZWP/SEZWOP/EXPWP/EXPWOP/DEXP	This will be the code to identify type of supply. ***B2B:*** *Business to Business* ***B2C:*** *Business to Consumer* ***SEZWP:*** *To SEZ with Payment* ***SEZWOP:*** *To SEZ without Payment* ***EXPWP:*** *Export with Payment* ***EXPWOP:*** *Export without Payment* ***DEXP:*** *Deemed Export*
1.3	Document_Type _Code	1..1	Code for Document Type	Mandatory	Enumerated List	INV / CRN / DBN	Type of Document: **INV** for Invoice, **CRN** for Credit Note, **DBN** for Debit note.
1.4	Document_Num	1..1	Document Number	Mandatory	String (Max Length:16)	Sa/1/2019	This is as per relevant rule in CGST/SGST/UTGST Rules.
1.5	Document_Date	1..1	Document Date	Mandatory	String (DD/MM/YYYY)	21/07/2019	The date on which the Invoice was issued. Format "DD/MM/YYYY"
1.6	Additional_ Currency_Code	0..1	Additional Currency Code	Optional	Enumerated List	USD, EUR	The field is for reporting additional currency, if any, in which all invoice amounts can be given, along with INR. One such additional currency may be used in the invoice, as per list published under **ISO 4217** standard.

							List published and updated from time to time at https://www.icegate.gov.in/Webappl/CUR_ENQ
1.7	Reverse_Charge	0..1	Reverse Charge	Optional	String (Length:1)	Y	Whether the tax liability payable is under Reverse Charge.
1.8	IGST_Applicability_despite_Supplier_and_Recipient_located_in_same_ State/UT	0..1	IGST Applicability despite Supplier and Recipient located in same State/UT	Optional	String (Length: 1)	N	To report the scenarios where the supply is chargeable to IGST despite the fact that the Supplier and Recipient are located within same State/UT
2.	**Document_Period**	**0..1**		**Optional**			**Header for Document Period**
2.1	Document_ Period_Start _ Date	1..1	Document Period Start Date	Mandatory	String (DD/MM/YYYY)	21/07/2019	This is the start date of the document period (delivery/invoice period). *(This field is mandatory only if this section is selected)*
2.2	Document_ Period_End_ Date	1..1	Document Period End Date	Mandatory	String (DD/MM/YYYY)	21/07/2019	This is the end date of the document period (delivery/invoice period). *(This field is mandatory only if this section is selected)*
3.	**Preceding Document / Contract Reference**	**0..1**		**Optional**			**Header for Preceding Document / Contract Reference**
3.1	**Preceding Document Reference**	**0..n**		**Optional**			**Sub-header for Preceding Document Reference**
3.1.1	Preceding_ Document_ Number	1..1	Preceding Document Number	Mandatory	String (Max length:16)	Sa/1/2019	This is the reference of original document/invoice to be provided optionally in the case of debit or credit notes. Credit/Debit notes, against invoices can also be referred here. *(This field is mandatory only if this section is selected)*
3.1.2	Preceding_ Document_ Date	1..1	Date of Preceding Document	Mandatory	String (DD/MM/YYYY)	21/07/2019	Date of preceding document/invoice. *(This field is mandatory only if this section is selected)*
3.1.3	Other_ Reference	0..1	Other Reference	Optional	String (Max length:20)	KOL01	This field is to provide any additional reference e.g. specific branch, their user ID, their employee ID, sales centre reference etc.
3.2	**Receipt / Contract References**	0..n		**Optional**			**Sub-header for Receipt / Contract References**
3.2.1	Receipt_Advice_ Reference	0..1	Receipt Advice Reference	Optional	String (Max length:20)	CREDIT30	This reference is kept for user to provide number of their receipt advice to their customer, in lieu of advance.
3.2.2	Receipt_Advice _Date	0..1	Date of Receipt Advice	Optional	String (DD/MM/YYYY)	21/07/2019	Date of issue of receipt advice for advance.

3.2.3	Tender_or_Lot_ Reference	0..1	Tender or Lot Reference	Optional	String (Max length:20)	TENDERJAN 2020	This reference is kept for mentioning number or details of Lot or Tender, if supplies are made under such Lot or tender.
3.2.4	Contract_ Reference	0..1	Contract Reference	Optional	String (Max length:20)	CONT23072019	This reference is kept for mentioning contract number, if supplies are made under any specific Contract
3.2.5	External_ Reference	0..1	External Reference	Optional	String (Max length:20)	EXT23222	An additional field for provision of any additional/external reference number for the supply.
3.2.6	Project_ Reference	0..1	Project Reference	Optional	String (Max length:20)	PJTCODE01	This reference is kept for mentioning project number, if supplies are made under any specific project
3.2.7	PO _Ref_Num	0..1	PO Reference Number	Optional	String (Max length:16)	Vendor PO /1	This is the reference number of Purchase Order
3.2.8	PO_Ref_Date	0..1	PO Reference Date	Optional	String (DD/MM/YYYY)	21/07/2019	This is the date of Purchase Order.
4.	**Supplier Information**	**1..1**		**Mandatory**			**Header for Supplier Information**
4.1	Supplier_Legal_ Name	1..1	Supplier Legal Name	Mandatory	String (Max. length:100)	XYZ Ltd.	Legal Name, as appearing in PAN of the Supplier
4.2	Supplier_Trade_ Name	0..1	Trade Name of Supplier	Optional	String (Max length:100)	ABC Traders	A name by which the Supplier is known, i.e. Business Name, other than legal name
4.3	Supplier_ GSTIN	1..1	GSTIN of Supplier	Mandatory	String (Length:15)	29AADFV7589C1ZX	GSTIN of the Supplier
4.4	Supplier_ Address1	1..1	Supplier Address 1	Mandatory	String (Max length:100)	# 1-23-120, Flat No. 3, Nalanda Apartments, MG Road, Vasanth Nagar	Address 1 of the Supplier (Building/Flat no., Road/Street, Locality etc.)
4.5	Supplier_ Address2	0..1	Supplier Address 2	Optional	String (Max length:100)	# 1-23-120, Flat No. 3, Nalanda Apartments, MG Road, Vasanth Nagar Nagar	Address 2 of the Supplier (Building/Flat no., Road/Street, Locality etc.), if any
4.6	Supplier_Place	1..1	Supplier Place	Mandatory	String (Max length:50)	Bangalore	Location of the Supplier (City/Town/Village)
4.7	Supplier_State_ Code	1..1	Supplier State Code	Mandatory	Enumerated List	29	State Code of the Supplier as per GST System List published and updated from time to time at https://www.icegate.gov.in/Webappl/STATE_ENQ
4.8	Supplier_Pincode	1..1	Supplier PIN Code	Mandatory	Number (Length: 6)	560087	PIN Code of the Supplier Locality
4.9	Supplier_ Phone	0..1	Supplier Phone	Optional	String (Max length:12)	9999999999	Contact number of the Supplier
4.10	Supplier_Email	0..1	Supplier e-mail	Optional	String (Max length:100)	supplier@abc.com	e-mail ID of the Supplier, as per REGEX (Regular Expressions) pattern
5.	**Recipient Information**	**1..1**		**Mandatory**			**Header for Recipient Information**
5.1	Recipient_Legal_ Name	1..1	Recipient Legal Name	Mandatory	String (Max. length:100)	PQR Pvt. Ltd.	It will be legal name of recipient, as per PAN.
5.2	Recipient_Trade _Name	0..1	Recipient Trade Name	Optional	String (Max length:100)	Adarsha	It will be trade name of recipient, if available.

5.3	Recipient_ GSTIN	1..1	GSTIN of Recipient	Mandatory	String (Length:15)	29ABCCR1832C1ZX, URP	GSTIN of the Recipient, if available. URP: In case of exports or if supplies are made to unregistered persons
5.4	Place_Of_Supply _State_ Code	1..1	Place of Supply (State Code)	Mandatory	Enumerated List	29, 96	Code/State Code of Place of Supply as per GST System. List published and updated from time to time at https://www.icegate.gov.in/Webappl/STATE_ENQ
5.5	Recipient_ Address1	1..1	Recipient Address 1	Mandatory	String (Max length:100)	# 1-23-120, Flat No. 3, Nalanda Apartments, MG Road, Vasanth Nagar	Address 1 of the Recipient (Building/Flat no., Road/Street, Locality etc.)
5.6	Recipient_ Address2	0..1	Recipient Address 2	Optional	String (Max length:100)	# 1-23-120, Flat No. 3, Nalanda Apartments, MG Road, Vasanth Nagar	Address 2, if any, of the Recipient (Building/Flat no., Road/Street, Locality etc.), if any
5.7	Recipient_Place	1..1	Recipient Place	Mandatory	String (Max length:100)	Mysore	Location of the Recipient (City/Town/Village)
5.8	Recipient_State_ Code	1..1	Recipient State Code	Mandatory	Enumerated List	29	Code/State Code of the Recipient. List published and updated from time to time at https://www.icegate.gov.in/Webappl/STATE_ENQ
5.9	Recipient_Pin code	0..1	Recipient PIN Code	Optional	Number (Length: 6)	560002	PIN code of the Recipient locality. In case of export, Pincode need not be mentioned.
5.10	Country_Code_ of_Export	0..1	Country Code of Export	Optional	Enumerated List	AN	Code of country of export as per ISO 3166-1 alpha-2 / Indian Customs EDI system. List published and updated from time to time at https://www.icegate.gov.in/Webappl/COUNTRY_ENQ
5.11	Recipient_Phone	0..1	Recipient Phone	Optional	String (Max length:12)	0802223323	Contact number of the Recipient
5.12	Recipient_email_ ID	0..1	Recipient e-mail ID	Optional	String (Max length:100)	billing@xyz.com	e-mail ID of the Recipient, as per REGEX (Regular Expressions) pattern
6.	**Payee Information**	**0..1**		**Optional**			**Header for Payee Information**
6.1	Payee_Name	0..1	Payee Name	Optional	String (Max length:100)	Ramesh K	Name of the person to whom payment is to be made
6.2	Payee_Bank_ Account_ Number	0..1	Payee Bank Account Number	Optional	String (Max length:18)	386850174726 2	Bank Account Number of Payee
6.3	Mode_of_ Payment	0..1	Mode of Payment	Optional	String (Max length:18)	Direct Transfer	Mode of Payment: Cash/Credit/Direct Transfer etc.
6.4	Bank _ Branch_ Code	0..1	Bank Branch Code	Optional	String (Max length:11)	SBIN9876543	Indian Financial System Code (IFSC) of Payee's Bank Branch

6.5	Payment_Terms	0..1	Payment Terms	Optional	String (Max length:100)	Text	Terms of Payment, if any, with the Recipient can be provided.
6.6	Payment_ Instruction	0..1	Payment Instruction	Optional	String (Max length:100)	Text	Instruction, if any, regarding payment can be provided
6.7	Credit_Transfer_ Terms	0..1	Credit Transfer Terms	Optional	String (Max length:100)	Text	Terms to specify credit transfer payments.
6.8	Direct_Debit_ Terms	0..1	Direct Debit Terms	Optional	String (Ma x length:100)	Text	Terms, if any, to specify a direct debit.
6.9	Credit_Days	0..1	Credit Days	Optional	Numeric (Max length:4)	30	Number of days within which payment is due.
7.	**Delivery_ Information**	**0..1**		**Optional**			**Header for Delivery Information**
7.1	***Ship_To_Details***	***0..1***	***Ship To Details***	***Optional***	***Refer A 1.0***		***Details of location to which the supply has to be delivered.***
7.2	***Dispatch_From_ Details***	***0..1***	***Dispatch From Details***	***Optional***	***Refer A 1.1***		***Details of location from where Supply has to be dispatched.***
8.	**Invoice Item Details**	**1..n**		**Man datory**			**Header for Invoice Item Details**
8.1	***Item_List***	***1..n***	***Item List***	***Mandatory***	***Refer A 1.2***		***Provides information about the goods and services being invoiced.***
9.	**Document Total**	1..1		**Man datory**			**Header for Document Total Details**
9.1	***Document_Total _Details***	***1..1***	***Document Total Details***	***Mandatory***	***Refer A 1.3***		***Details of document total including taxes.***
10.	**Extra Information**	0..1		**Option al**			**Header for Extra Information**
10.1	Tax_Scheme	1..1	Tax Scheme	Mandatory	String (Max length: 10)	GST	To specify the tax/levy applicable – GST *(This field is mandatory only if this section is selected)*
10.2	Remarks	0..1	Remarks	Optional	String (Max length: 100)	New batch Items submitted	A textual note that gives unstructured information that is relevant to the Invoice as a whole e.g. reasons for any correction or assignment note in case the invoice has been factored etc.
10.3	Port_Code	0..1	Port Code	Optional	Enumerated List	Alpha numeric	In case of export/supply to SEZ, port code can be mentioned as per Indian Customs EDI System (ICES), if applicable and available at the time of reporting e-invoice. Lists published and updated from time to time at below URLs: EDI Port Codes: https://www.icegate.gov.in/Webappl/LOCATION_ENQ Non-EDI Port Codes: https://www.icegate.gov.in/Webappl/nonlocation_det_all.jsp
10.4	Shipping_Bill_ Number	0..1	Shipping Bill Number	Optional	String (Max length: 20)	Alpha numeric	In case of export/supply to SEZ, shipping bill number as per Indian Customs EDI System (ICES), can be mentioned, if applicable and available at the time of reporting e-invoice.
10.5	Shipping_Bill_ Date	0..1	Shipping Bill Date	Optional	String(DD/M M/YYYY)	03/12/2020	Date of Shipping Bill as per Indian Customs EDI System

10.6	Export_Duty_ Amount	0..1	Export Duty Amount	Optional	Number (Max Length: 12,2)	1200000.50	Amount of Export Duty in INR, if any, applicable (in case of invoices for export)
10.7	Supplier_Can_ Opt_Refund	0..1	Supplier Can Opt Refund	Optional	String (Length: 1)	Y / N	In case of deemed export supplies, this field is for mentioning whether supplier can exercise the option of claiming refund or not.
10.8	ECOM_GSTIN	0..1	e-Commerce Operator's GSTIN	Optional	String (Length: 15)	29ABCCR1832 C1CX	GSTIN of e-commerce operator, if supply is made through him/her.
11.	**Additional_Supporting_Documents**	**0..n**		**Optional**			**Header for Additional Supporting Documents**
11.1	Additional_ Supportin g_Documents_ URL	0..1	Additional Supporting Documents URL	Optional	String (Max length: 100)	http://www.xyz.com/abc	This is to enter URL reference of additional supporting documents, if any.
11.2	Additional_ Supporting _ Documents_ base64	0..1	AdditionalSupporting Document in base64	Optional	String (Max length: 1000)	Base 64 encoded Document	This is to add any additional document in PDF/Microsoft Word in Base64 encoded format.
11.3	Additional_ Information	0..1	Additional Information	Optional	String (Max length: 1000)	Free text, remarks, identifiers, etc.	Any additional information, names, values, data etc. that is specific for the Supplier-Recipient transaction e.g. CIN, trade-specific information, Drug Licence Reg. No., FOB/CIF etc.
12.	**E-way Bill Details**	**0..1**		**Optional**			**Header for e-way Bill Details**
12.1	Transporter_ID	0..1	Transporter ID	Option al	String (Length: 15)	29AADFV7589 C1ZO	Registration / Enrolment Number of the transporter *(This field is required if Part-A of E-waybill has to be generated)*
12.2	Trans_Mode	0..1	Mode of Transportation	Optional	Enumerated List	1/2/3/4	Option to be provided based on mode of transport available on e-Way Bill Portal 1 for Road; 2 for Rail; 3 for Air; 4 for Ship *(This field is required if Part-B of e-way bill is also to be generated)*
12.3	Trans_Distance	1..1	Distance of Transportation	Mandatory	Number (Max length: 4)	200	Distance of Transportation *(This field is mandatory only if this section is selected)*
12.4	Transporter_Name	0..1	Transporter Name	Optional	String (Max length: 100)	Sphurthi Transporters	Name of the Transporter
12.5	Trans_Doc_No.	0..1	Transport Document Number	Optional	String (Max length: 15)	As/34/746	Transport Document Number *(This field is mandatory if mode of Transport is Rail or Air or Ship)*
12.6	Trans_Doc_Date	0..1	Transport Document Date	Optional	String (DD/MM/YYYY)	21/07/2019	Date of Transport document. *(This field is mandatory if mode of Transport is Rail or Air or Ship)*
12.7	Vehicle_No.	0..1	Vehicle Number	Optional	String (Max. length: 20)	KA12KA1234 or KA12K1234 or KA123456 or KAR1234	Vehicle Registration Number *(This field is mandatory if mode of Transport is Road)*

12.8	Vehicle_Type	0..1	Vehicle Type	Optional	Enumeration List	O / R	To mention nature of vehicle: O: Over-Dimensional Cargo R: Regular *(This field is mandatory if Part-B of e-way bill is also to be generated)*
A 1.0	**Ship To Details**	**0..1**		**Optional**			**Header for Annexure A 1.0: Ship To Details**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether optional or mandatory**	**Field Specifications**	**Sample Value**	**Explanatory Notes**
A.1.0.1	ShipTo_Legal_ Name	1..1	Ship To Legal Name	Mandatory	String (Max length: 100)	ABC-1 Ltd.	Legal Name of the entity to whom the supplies are shipped to. *(This field is mandatory only if this section is selected)*
A.1.0.2	ShipTo_Trade_ Name	0..1	Ship To Trade Name	Optional	String (Max length: 100)	XYZ-1	Trade Name of the entity to whom the supplies are shipped to.
A.1.0.3	ShipTo_GSTIN	0..1	Ship To GSTIN	Optional	String (Length: 15)	36AABCT2223 L1ZF	GSTIN of the entity to whom the supplies are shipped to.
A.1.0.4	ShipTo_Address1	1..1	Ship To Address1	Mandatory	String (Max length: 100)	Flat No. 2, Priya Towers, Omega Road, Srinivasa Nagar	Address 1 of the entity to whom the supplies are shipped to *(This field is mandatory only if this section is selected)*
A.1.0.5	ShipTo_Address2	0..1	Ship To Address2	Optional	String (Max length: 100)	Flat No. 2, Priya Towers, Omega Road, Srinivasa Nagar	Address 2, if any, of the entity to whom the supplies are shipped to
A.1.0.6	ShipTo_Place	1..1	Ship To Place	Mandatory	String (Max length: 100)	Bangalore	Place (City/Town/Village) of entity to whom the supplies are shipped to. *(This field is mandatory only if this section is selected)*
A.1.0.7	ShipTo_Pincode	1..1	Ship To Pincode	Mandatory	Number (Max length: 6)	560001	PIN code of the location to which the supplies are shipped to. *(This field is mandatory only if this section is selected)*
A.1.0.8	Ship_To_State_ Code	1..1	Ship To State Code	Mandatory	Enumerated List	29	Code/State Code (as per GST System) to which the supplies are shipped to. List published and updated from time to time at https://www.icegate.gov.in/Webappl/STATE_ENQ *(This field is mandatory only if this section is selected)*
A 1.1	**Dispatch From Details**	**0..1**		**Optional**			**Header for Annexure A 1.1: Dispatch From Details**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether mandatory or optional**	**Field Specific ations**	**Sample Value**	**Explanatory Notes**
A.1.1.1	DispatchFrom_Name	1..1	Dispatch From Name	Mandatory	String (Max length:100)	XYZ-2	Name of the entity from which goods are dispatched.

A.1.1.2	DispatchFrom_ Address1	1..1	Dispatch From Address1	Mandatory	String (Max length: 100)	Building No. 4/2, Flat No. 3, Kakatiya Apartments, Vasanth Nagar	Address 1 of the entity from which goods are dispatched. *(This field is mandatory only if this section is selected)*
A.1.1.3	DispatchFrom_ Address2	0..1	Dispatch From Address2	Optional	String (Max length: 100)	Building No. 4/2, Flat No. 3, Kakatiya Apartments, Vasanth Nagar	Address 2 of the entity from which goods are dispatched.
A.1.1.4	DispatchFrom_ Place	1..1	Dispatch From Place	Mandatory	String (Max length: 100)	Bangalore	Place (City/Town/Village) of the entity from which goods are dispatched. *(This field is mandatory only if this section is selected)*
A.1.1.5	DispatchFrom_ State_Code	1..1	Dispatch From State Code	Mandatory	Enumerated List	29	Code/State Code of the entity (as per GST System), from which goods are dispatched. List published and updated from time to time at https://www.icegate.gov.in/Webappl/STATE_ENQ *(This field is mandatory only if this section is selected)*
A.1.1.6	DispatchFrom_ Pincode	1..1	Dispatch From Pincode	Mandatory	Number (Length: 6)	560087	Pincode of the locality of entity from where goods are dispatched. *(This field is mandatory only if this section is selected)*
A 1.2	**Item Details**	**1..n**		**Mandatory**			**Header for Annexure A 1.2: Item Details**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether mandatory or optional**	**Field Specifications**	**Sample Value**	**Explanatory Notes**
A.1.2.1	Sl_No.	1..1	Serial Number	Mandatory	String (Max length: 6)	1,2,3	Serial number of the item
A.1.2.2	Item_Description	0..1	Item Description	Optional	String (Max length: 300)	Mobile	Description of the item
A.1.2.3	Is_Service	1..1	Service	Mandatory	String (Length: 1)	Y/N	Specify whether supply is service or not.
A.1.2.4	HSN_Code	1..1	HSN Code	Mandatory	String (Max length: 8)	1122	To enter applicable HSN / SAC Code of Goods / Service
A.1.2.5	***Batch Details***	***0..1***		***Optional***	***Refer A 1.4***		***Some manufacturers may mention batch details (in Section A 1.4)***
A.1.2.6	Barcode	0..1	Barcode	Optional	String (Max length: 30)	b123	Barcode, if any, of the item.
A.1.2.7	Quantity	0..1	Quantity	Optional	Number (Max length: 10,3)	10	The quantity of items to be mentioned in the invoice. *This is mandatory only in case of goods.*
A.1.2.8	Free_Qty	0..1	Free Quantity	Optional	Number (Max length: 10,3)	99	Quantity of item(s), if any, given free of charge (FOC)
A.1.2.9	Unit_Of_ Measurement	0..1	Unit of Measurement	Optional	String (Max length: 8)	Box	The Unit of Measurement (UOM), if any, applicable on invoiced goods.
A.1.2.10	Item_Price	1..1	Item Price	Mandatory	Number (Max length : 12,3)	500.5	Price per unit item.

A.1.2.11	Gross_Amount	1..1	Gross Amount	Mandatory	Number (Max length : 12,2)	5000	The gross price of an item (cost multiplied by quantity - rounded off to 2 decimal), exclusive of taxes.
A.1.2.12	Item_Discount_ Amount	0..1	Item Discount Amount	Optional	Number (Max length: 12,2)	10.25	Discount amount, if any, for the item.
A.1.2.13	Pre_Tax_Value	0..1	Pre-Tax Value	Optional	Number (Max length: 12,2)	99.00	If pre-tax value is different from taxable value, mention the pre-tax value and taxable values separately. In some cases, the pre-tax value may be different from taxable value. For example, where old goods are exchanged for new ones (e.g. new phone supplied for INR 20,000 along with exchange of old phone, then pre-tax value would be INR 20,000 and taxable value would be INR 24,000, assuming exchange value of old phone is 4,000. Another example is in the case of real estate where pre-tax value may be different from taxable value.
A.1.2.14	Item_Taxable_ Value	1..1	Item Taxable Value	Mandatory	Number (Max length: 12,2)	5000	This is the value on which tax is computed. Value cannot be negative.
A.1.2.15	GST_Rate	1..1	GST Rate	Mandatory	Number (Max length: 3,3)	5	The GST rate, represented as percentage that applies to the invoiced item. It will be IGST rate or sum of CGST & SGST Rates.
A.1.2.16	IGST_Amt	0..1	IGST Amount	Optional	Number (Max Length: 12,2)	999.45	Amount of IGST payable per item (rounded off to 2 decimals). If IGST is reported, then CGST & SGST/UTGST will be blank. For taxable supplies, either IGST or CGST &SGST/UTGST should be reported.
A.1.2.17	CGST_Amt	0..1	CGST Amount	Optional	Number (Max Length: 12,2)	650.00	Amount of CGST payable per item (rounded off to 2 decimals). If CGST is reported, then SGST/UTGST has to be reported and IGST will be blank.
A.1.2.18	SGST_UTGST Amt	0..1	SGST/UTGST Amount	Optional	Number (Max length: 12,2)	650.00	Amount of SGST/UTGST payable per item(rounded off to 2 decimals). If SGST/UTGST is reported, then CGST must be reported and IGST will be blank.
A1.2.19	Comp_Cess_Rate _Ad_valorem	0..1	Compensation Cess Rate, Ad_Valorem	Optional	Number (Max length: 3,3)	2.5%	*Ad valorem* Rate of GST Compensation Cess, applicable, if any
A1.2.20	Comp_Cess_Amt _ Ad_Valorem	0..1	Compensation Cess Amount, Ad Valorem	Optional	Number (Max length: 12,2)	56.00	GST Compensation Cess amount, ad valorem (rounded off to 2 decimals) *(based on value of the item)*
A1.2.21	Comp_Cess_Amt _Non_Ad_ Valorem	0..1	Compensation Cess Amount, Non ad valorem	Optional	Number (Max length:12,2)	23.00	GST Compensation Cess amount, computed on the basis other than value of item *(i.e. specific cess amount computed based on quantity, number etc.)*
A1.2.22	State_Cess_Rate _ad_valorem	0..1	State Cess Rate, Ad Valorem	Optional	Number (Max length: 3,3)	1.5 %	*Ad valorem* Rate of State/UT Cess, applicable, if any

A1.2.23	State_Cess_Amt _Ad_Valorem	0..1	State Cess Amount, ad valorem	Optional	Number (Max length: 12,2)	43.00	State/UT Cess amount, ad valorem *(based on value of the item)*
A1.2.24	State_Cess_Amt _Non_Ad_ Valorem	0..1	State Cess Amount, *non ad valorem*	Optional	Number (Max length: 12,2)	12.00	State/UT Cess amount, computed on the basis other than value of item *(i.e. specific cess amount computed based on quantity, number etc.)*
A.1.2.25	Other_Charges_ Item_Level	0..1	Other Charges (item level)	Optional	Number (Max length: 12,2)	874.95	Any other charges applicable at item level. These may not be part of taxable value, e.g. in case of pure agent reimbursement.
A.1.2.26	Purchase_Order_ Line_Reference	0..1	Purchase Order Line Reference	Optional	String (Max length: 50)	746/ABC/01	Reference of Purchase Order Line
A.1.2.27	Item_Total_Amt	1..1	Item Total Amount	Mandatory	Number (Max length: 12,2)	5000	The item total value that includes all taxes, cesses, as well as other charges. However, this value excludes discount, if any.
A.1.2.28	Origin_Country_ Code	0..1	Code of Country of Origin	Optional	Enumerated List	DZ	This is to specify country of origin of the item, e.g. mobile phone sold in India could be manufactured in other country; Code of country of export as per ISO 3166-1 alpha-2 / Indian Customs EDI system (ICES). List published and updated from time to time at https://www.icegate.gov.in/Webappl/COUNTRY_ENQ
A.1.2.29	Unique_Serial_ Number	0..1	Unique Serial Number	Optional	String (Max length: 20)	553	Serial number, in case of each item having a unique number.
A.1.2.30	***Product_ Attribute_Details***	***0..n***	***Optional***	***Refer A 1.5***			***Attribute details of product***
A 1.3	**Document Total Details**	**1..1**		**Mandatory**			**Header for Annexure A 1.3: Document Total Details**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether mandatory or optional**	**Field Specific ations**	**Sample Value**	**Explanatory Notes**
A.1.3.1	Taxable_Value_ Total	1..1	Total Taxable Value	Mandatory	Number (Max length: 14,2)	768439.35	This is the sum of the taxable values of all the items in the document.
A.1.3.2	IGST_Amt_Total	0..1	Total IGST Amount	Optional	Number (Max length : 14,2)	265.50	Total IGST amount for the invoice. Appropriate taxes based on rule will be applicable. For example, either of CGST & SGST/UTGST or IGST will be mandatory. *As this is conditional mandatory, it is marked as 'optional'*
A.1.3.3	CGST_Am_ Total	0..1	Total CGST Amount	Optional	Number (Max length: 14,2)	65.45	Total CGST amount for the invoice. Appropriate taxes based on rule will be applicable. For example, either of CGST & SGST/UTGST or IGST will be mandatory. *As this is conditional mandatory, it is marked as 'optional'*

A.1.3.4	SGST_UTGST_ Amt_Total	0..1	Total SGST/UTGST Amount	Optional	Number (Max length : 14,2)	65.45	Total SGST/UTGST amount for the invoice. Appropriate taxes based on rule will be applicable. For example, either of CGST & SGST/UTGST or IGST will be mandatory. *As it is conditional mandatory, it is marked as 'optional'*
A.1.3.5	Comp_Cess_ Amt_Total	0..1	Total Compensation Cess Amount	Optional	Number (Max length : 14,2)	24.95	Total GST Compensation Cess amount for the invoice *(ad valorem as well as non-ad valorem)*
A.1.3.6	State_Cess_Amt _Total	0..1	Total State Cess Amount	Optional	Number (Max length : 14,2)	5.45	Total State cess amount for the invoice *(ad valorem as well as non-ad valorem)*
A.1.3.7	Discount_Amt_ Invoice_Level	0..1	Invoice Level Discount Amount	Optional	Number (Max length: 14,2)	100.00	This is Discount Amount, if any, applicable on total invoice value
A.1.3.8	Other_Charges_ Invoice_Level	0..1	Other Charges (Invoice Level)	Optional	Number(Max length: 14,2)	200.00	This is Other charges, if any, applicable on total invoice value
A.1.3.9	Round_Off_ Amount	0..1	Round Off Amount	Optional	Number (Max length: 2,2)	31.21	This is round off amount of total invoice value
A.1.3.10	Total_Invoice_ Value_INR	1..1	Total Invoice Value in INR	Mandatory	Number (Max length: 14,2)	745249678.50	The total value of invoice including taxes/GST and rounded to two decimals maximum.
A.1.3.11	Total_Invoice_ Value_FCNR	0..1	Total Invoice Value in FCNR	Optional	Number (Max length: 14,2)	$5729.65	The total value of invoice in Additional Currency
A.1.3.12	Paid_Amount	0..1	Paid Amount	Optional	Number (Max length:14,2)	8463.50	The amount, if any, which has been paid in advance. It must be rounded to maximum 2 decimals.
A.1.3.13	Amount_Due_	0..1	Amount Due	Optional	Number (Max length:14,2)	98789.50	The outstanding amount due for payment. It must be rounded to maximum 2 decimals.
A 1.4	**Batch Details**	**0..1**		**Optional**			**Header for Annexure A 1.4: Batch Details**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether mandatory or optional**	**Field Specific ations**	**Sample Value**	**Explanatory Notes**
A.1.4.1	Batch_Number	1..1	Batch Number	Mandatory	String (Max Length: 20)	673927	Certain set of manufacturers may mention batch number details. *(This field is mandatory only if this section is selected)*
A.1.4.2	Batch_Expiry_ Date	0..1	Batch Expiry Date	Optional	String (DD/MM/YYYY)	21/11/2019	Expiry Date of the Batch, if any
A.1.4.3	Warranty_Date	0..1	Warranty Date	Optional	String (DD/MM/YYYY)	21/11/2019	Warranty date for the Item, if any.
A 1.5	**Attribute Details of Item**	**0..n**		**Optional**			**Header for Annexure A 1.5: Attribute Details of Item**
Sr. No.	**Parameter Name**	**Cardinality**	**Description**	**Whether mandatory or optional**	**Field Specific ations**	**Sample Value**	**Explanatory notes**
A.1.5.1	Attribute_Name	0..1	Attribute Name	Optional	String (Max Length: 100)	Colour	Attribute Name of the item.
A.1.5.2	Attribute_Value	0..1	Attribute Value	Optional	String (Max Length: 100)	Red, green, etc.	Attribute Value of item.".

F. No. CBEC-20/13/01/2019-GST

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note : *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification No. 3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R. 610(E), dated the 19th June, 2017 and last amended vide Notification No. 58/2020 - Central Tax, dated the 01st July, 2020, published vide number G.S.R. 426(E), dated the 01st July, 2020.*

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e-Invoice under GST must for turnover above ₹500 crore, SEZ exempted – reg.

Gazette Notification No. 61/2020–Central Tax [G.S.R. 481(E)], dated 30th July 2020

In exercise of the powers conferred by sub-rule (4) of rule 48 of the Central Goods and Services Tax Rules, 2017, the Government, on the recommendations of the Council, hereby makes the following amendments in notification of the Government of India in the Ministry of Finance (Department of Revenue), No.13/2020 – Central Tax, dated the 21st March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.196(E), dated the 21st March, 2020, namely:–

In the said notification, in the first paragraph,

(i) before the words —"those referred to in sub-rules", the words —**"a Special Economic Zone unit and"** shall be inserted;

(ii) for the words —"one hundred crore rupees", the words —**"five hundred crore rupees"** shall be substituted.

F. No. CBEC-20/13/01/2019-GST

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note : *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i) vide Notification No. 13/2020-Central Tax, dated the 21st March, 2020, published vide number G.S.R. 196(E), dated the 21st March, 2020.*

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Prohibition of selling of Health Supplement containing PABA (Para Amino Benzoic Acid) a banned ingredient - reg.

Instruction No.16/2020-Customs, dated 24th July, 2020

To,

All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),

All Principal Chief Commissioners/Chief Commissioners of Customs & Central Taxes, GST,

All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),

All Principal Commissioners/Commissioners of Customs & Central Taxes, GST.

1. Kind attention is drawn to the advisory dated 16.07.2020 on the mentioned subject issued vide File No.4(12) 2017/Gujarat/RCD/FSSAI by the Joint Director (RCD), Food Safety & Standard Authority of India, Ministry of Health and Family Welfare, Regulatory Compliance Division enclosing FSSAI Order No.Stds/Nutr(DGCI)/FSSAI-2017 (Pt.I) dated 29-06-2018 (copy enclosed)*. The operative para 2 of the advisory is reiterated below for ease of reference:

"2. FSSAI vide Order No.Stds/Nutr(DGCI)/FSSAI-2017 (Pt.I) dated 29-06-2018 (copy enclosed) has banned the use of PABA (Para Amino Benzoic Acid) in the products covered under Nutraceuticals Regulations due to safety concerns with immediate effect. Para No.2 (c) of the said order also directs the FBOs that no further manufacturing of products using this ingredient is allowed. Any product containing such ingredient which is already manufactured/ imported shall be withdrawn from the market immediately. However, it has come to the notice that several health supplements and nutraceutical products containing PABA are still being sold on e-commerce platform."*

2. The advisory has been issued with a request to circulate Order dated 29-06-2018 to all Customs Officials working as Authorized Officers to comply and to ensure that imported products containing banned ingredient shall not be cleared through their respective point of entries.

3. Suitable instruction may be issued for mandatory compliance by the departmental officers and the trade.

4. Any issues faced in implementation of this instruction may be brought to the notice of the Board.

Babu Lal Meena, Deputy Commissioner, Single Window Project, Cus. III, Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

*(*Not reproduced here)*

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CBIC specifies the jurisdiction of Commissioner (Appeals) to assessment orders passed by Faceless Assessment Groups - reg.

Notification No.63/2020-Customs (N.T.), dated 30th July, 2020

In exercise of the powers conferred by sub-section (1) of section 4 and sub-section (1) of section 5 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.92/2017-Customs (N.T.), dated the 28th September, 2017, namely:-

In the said notification, in paragraph 1, for the provisos, the following provisos shall be substituted, namely:-

"Provided that the Commissioner of Customs (Appeals), Bengaluru, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against the serial nos. 1, 5, and 6 of the Table above, in respect of the bill

of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.7 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act :

Provided further that the Commissioner of Customs (Appeals-1) Chennai and the Commissioner of Customs (Appeals-II) Chennai, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against serial no.1 and 7 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial nos. 5 and 6 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act:

Provided further that the Commissioner of Customs (Appeals), Delhi, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against the serial nos.5, 6, and 7 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.1 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act:

Provided further that the Commissioner of Customs (Appeals) Mumbai-I shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against serial no.3 and 4 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.2 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act:

Provided further that the Commissioner of Customs (Appeals) Mumbai-II shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against serial no.2 and 4 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.3 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act:

Provided further that the Commissioner of Customs (Appeals) Mumbai-III, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against serial no.2 and 3 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.4 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act".

F.No.437/48/2014-Cus.IV

Ananth Rathakrishnan, Deptuy Secretary (Customs), Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note: *The Principal Notification No.92/2017-Customs (N.T.), dated the 28th September, 2017, was published in the Gazette of India, Extraordinary, vide number G.S.R. 1210(E), dated the 28th September, 2017, and was last amended by Notification No.51/2020-Customs (N.T.), dated the 5th June 2020, published in the Gazette of India, Extraordinary, vide number G.S.R.353(E) dated the 5th June, 2020.*

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Issuance of Preferential Certificate of Origin for India's exports to Thailand under ASEAN-India FTA - reg.

DGFT Trade Notice No. 23/2020-2021, dated 31st July 2020

To,

1. All Exporters/Members of Trade,

2. All Designated Issuing Agencies under FTAs/PTAs.

1. Reference is invited to Trade Notice No. 12/2020-2021 dated 22.05.2020 and subsequent Trade Notice No.15/2020-2021 dated 21.06.2020, regarding issuance of CoO for India's exports under ASEAN-India FTA.

2. It is informed that w.e.f. 01.08.2020, the CoO applications for exports from India to Thailand under ASEAN-India FTA should be submitted through the e-COO Platform by the exporters to the designated issuing agencies i.e. EIA, MPEDA and Textile Committee. No physical/manual application for a CoO would need to be submitted from this date. However, manual applications submitted prior to the given date may be processed and CoOs issued by the designated agencies.

3. In line with the CoOs issued for other ASEAN Countries, the e-CoO platform will generate one additional copy i.e. electronic copy along with the set of 4 copies. The electronic copy shall bear the image signature of the officer and stamp of the issuing agency. The exporter may however get the set of printed certificates (in quadruplicate) duly ink-signed by the officer along with the stamp from the designated issuing office, by post or in person, for submission to the Thai authorities.

4. This issues with the approval of the Competent Authority.

File No. 01/02/82/AM-19/EDI

Md. Moin Afaque,
Deputy Director General of Foreign Trade,
Directorate General of Foreign Trade,
Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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GOVERNMENT PRESS RELEASE

Department of Biotechnology provides seed funding for Gennova Biopharmaceuticals Ltd's novel mRNA based COVID-19 Vaccine candidate-HGCO19

The vaccine is likely to go to Clinical Trial before the year ends

Vaccine Discovery Programme supported by the Department of Biotechnology, Government of India under Ind CEPI, implemented by BIRAC will soon move into Clinical Trials

Ministry of Science & Technology Press Release dated 24th July 2020

DBT-BIRAC has facilitated the establishment of 'first-of-its-kind' mRNA-based vaccine manufacturing platform in India. DBT has provided seed funding for the development of Gennova's novel self-amplifying mRNA-based vaccine candidate for COVID-19.

In collaboration with HDT Biotech Corporation, Seattle, USA, Gennova has developed an mRNA vaccine candidate (HGCO19), with demonstrated safety, immunogenicity, neutralization antibody activity in the rodent and non-human primate models. The company is

working aggressively to ensure first human injection by the end of the year, subject to Indian regulatory approvals.

Dr Renu Swarup, Secretary, DBT and Chairperson, BIRAC, speaking on the subject said that "diseases emanating from unknown and new pathogens require novel ideas for effective mitigation. Gennova's m-RNA platform supported by DBT utilizes the advances in nucleic acid vaccine and delivery systems. This vaccine candidate that makes use of nanotechnology has shown promise to be effective in animal models. With the kind of capacities Gennova has, I am confident that this vaccine candidate can be rapidly scaled up, once proven effective in human Clinical Trials."

Speaking on the development, CEO of Gennova Biopharmaceuticals Ltd, Dr Sanjay Singh said, "Bold moves are necessary to create globally competitive and sustainable solutions. Gennova appreciates DBT-BIRAC's initiative, guidance, and financial support towards the development of mRNA based next-generation vaccine. Our partnership is poised towards creating an eco-system for cutting-edge technology, providing solution towards making a cost-effective vaccine that can reach to the masses in a pandemic situation like COVID-19."

About HGCO19:

The novel mRNA vaccine candidate, HGCO19, has all the necessary arsenal to guide the host cells to make the antigen-spike protein of the virus, reported to interact with host cells receptor, and supported by 'lipid inorganic nanoparticle (LION)' as a delivery vehicle.

The neutralizing antibody response of the vaccine in mice and non-human primates was comparable with the sera from the convalescent patients of COVID-19, above the US FDA recommended titre of 1:160 for neutralizing antibodies.

Further, advantages of HGCO19 are its mRNA platform design and delivery vehicle. HGCO19 uses a 'self-replicating mRNA platform' that ensures the low injectable dose (dose-sparing effect) and sustained antigen release for a longer duration. 'LION delivery system' used for HGCO19 has adjuvanting property, enhanced storage stability, reduced adverse effects, improved permeability and bioavailability.

About DBT:

The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the development of biotechnology in India, including growth and application of biotechnology in the areas of agriculture, healthcare, animal sciences, environment and industry.

About BIRAC:

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

About Gennova:

Gennova Biopharmaceuticals Ltd., headquartered in Pune, India, is a biotechnology company dedicated to the research, development, production, and commercialization of biotherapeutics to address life-threatening diseases across various indications. To find out more visit **https://gennova.bio**

or Further Information: Contact Communication:

Cell of DBT/BIRAC
@DBTIndia@BIRAC_2012
www.dbtindia.gov.in www.birac.nic.in

Source: PIB, MoS&T Press Release, 24.07.2020

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A plot twist in Pharmaceuticals: Single nanoparticles could pave the way for medicines on demand

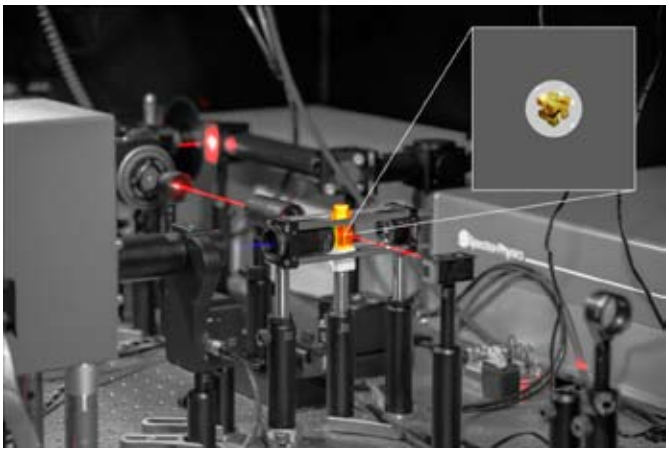

IMAGE: We can now 'see' the twist of a single nanoparticle, floating freely in a liquid. view more Credit: Ventsislav Valev and Joel Collins

For the first time, a single, twisted nanoparticle has been accurately measured a characterised in a lab, taking scientists one vital step closer to a time when medicines will be produced and blended on a microscopic scale.

Physicists at the University of Bath who study materials on the nanoscale - that is, molecules 10,000 smaller than a pinhead - made their groundbreaking observations using a new method for examining the shape of nanoparticles in 3D. This technique, called the hyper-Rayleigh scattering optical activity (HRS OA) technique, was used to examine the structure of gold (among other materials), resulting in an exceptionally clear image of the 'screw thread' twist in the metal's shape.

Understanding the twists within a material (known as its chirality) is vital in industries that produce medicines, perfumes, food additives and pesticides, as the direction in which a molecule twists determines some of its properties. For instance, a molecule that twists clockwise will produce the smell of lemons while the identical molecule twisting anticlockwise (the mirror image of the lemon-smelling molecule) smells of oranges. "Chirality is one of the most fundamental properties of nature. It exists in sub-atomic particles, in molecules (DNA, proteins), in organs (the heart, the brain), in bio-materials (such as seashells), in storm clouds (tornadoes) and in the shape of galaxies (spirals hurling through space)." said Professor Ventsislav Valev, who led the project.

Until now, physicists have relied on 200-year-old optical methods for determining the chiral properties of molecules and materials, but these methods are weak and require large amounts of molecules or materials to work. Through their use of a technique based on powerful laser pulses, Professor Valev and his team at Bath's Centre for Photonics and Photonic Materials have produced a far more sensitive probe for chirality, one that can detect a single nanoparticle as it floats freely in a liquid.

This discovery was made by Bath's Department of Physics in collaboration with the Department of Chemistry. The researchers' findings are published in *Nano Letters*. "This is both a record and a milestone in nanotechnology," said Professor Valev. "Pursuing this line of research has been one of the most rewarding achievements in my career."

"The observation by Valev's group is historic, and scientifically it inspires us in our work to synthesise new chiral 3D nanomaterials," said study co-author Professor Ki Tae Nam from Material Science and Engineering at the Seoul National University in Republic of Korea.

The potential applications for ultra-sensitive chiral sensing are many. For instance, many pharmaceuticals are chiral. Local pharmacists will be able to harness the technology to mix substances in a completely new way, producing pharmaceuticals from minute droplets of active ingredients rather than from large beakers of chemicals.

"You'll be able to go to the chemist with a prescription and instead of receiving a medicine that has to be mixed from bottles of chemicals and then stored in the fridge for several days, you'll walk away with pills that are mini-labs. Upon cracking the pill, a precise number of micro-droplets will flow through microchannels to mix and produce the needed medicine." said Professor Valev.

"For these mini-labs to produce chiral drugs, you'll need to know the number of molecules and catalysts within each micro droplet, as well as their chirality." said Ph.D., student Lukas Ohnoutek, who is the first author on the paper. "This is where our result is really important. We can now aim to produce microdroplets containing a single chiral nanoparticle, to use as catalysts in chemical reactions."

Professor Valev added: "Looking ahead, we can imagine building up chiral materials and even machines, one nanoparticle at a time, from such microdroplets. To do so would be amazing."

(AAAS and EurekAlert! are not responsible for the accuracy of news releases posted to EurekAlert! by contributing institutions or for the use of any information through the EurekAlert system).

Source: EurekAlert Science News, 20.07.2020

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New drug targets for lethal brain cancer discovered

Researchers have discovered more than 200 genes with novel and known roles in glioblastoma - the most aggressive type of brain cancer that offer promising new drug targets. Researchers from the Wellcome Sanger Institute, Addenbrooke's Hospital and their collaborators engineered a new mouse model to show for the first time how a mutation in the well-known cancer gene, EGFR initiates glioblastoma and works with a selection from more than 200 other genes to drive cancer. The results, published in *Genome Biology* present the first mouse model of its kind, which is available for the research community to advance new treatments for this lethal form of brain cancer. Glioblastoma is an aggressive form of brain cancer. It is treated with surgery followed by chemotherapy or radiotherapy, however, glioblastoma cells can evade treatment and tumours return. The prognosis is poor - the average patient survives for 12-18 months following diagnosis.

New, targeted treatments and immunotherapies are currently being developed to help glioblastoma patients. It is still not known exactly why glioblastomas begin to grow. In a new study, researchers from the Wellcome Sanger Institute and their collaborators created a new mouse model with glioblastoma to investigate which genes were implicated in cancer. The model showed that the well-known cancer gene, EGFR (Epidermal Growth Factor Receptor) can alone initiate the brain tumours to grow in mice, resulting in tumours that were highly representative of human glioblastomas. Dr Imran Noorani, a corresponding author previously from the Wellcome Sanger Institute, and now based at Addenbrooke's Hospital and the University of Cambridge, said: "We have created a new mouse model for studying the lethal human brain cancer, glioblastoma. For the first time, we showed that the familiar cancer gene, EGFR is capable of initiating glioblastoma and we identified new driver genes, whose potential for therapeutic targeting deserves further exploration." To identify which genes help EGFR to drive cancer, the team used the PiggyBac transposon technique - a small section of DNA inserted into different parts of the genome to introduce mutations. This revealed more than 200 known and novel mutations in tumour suppressor genes that were working with EGFR to drive brain tumour growth, many of which present new drug targets. The team compared the results with human genome sequences from glioblastoma patients and uncovered many genetic mutations found in both humans and mice. Human genomic data contains many mutations implicated in glioblastoma, without a clear indication of which specific mutations drive cancer. With the new mouse model, the team were able to narrow down on which mutations drive glioblastoma, which will focus on future drug development.

Professor Allan Bradley, previously Director of the Wellcome Sanger Institute, and now Chief Scientific Officer of Kymab and Professor in the Department of Medicine, University of Cambridge, said: "Glioblastoma patients urgently require new, targeted therapies. Unfortunately, glioblastoma tumours can become highly resistant to therapies that target specific molecules, as there are many other genetic drivers that can 'take over' progressing cancer. This new mouse model provides the missing link to translate findings from new potential treatments tested on mice to Clinical Trials."

Source: ANI, ET-Health World, 30.07.2020

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Pharma industry seeks Financial Assistance from Government for rare diseases

With an aim to drive Research and Development activities in the rare diseases segment and encourage orphan drug development in India, industry stakeholders have sought Government support in terms of sustainable research funding, tax exemption in orphan drug development, unified definition of rare disease etc.

Recently, five national Pharma associations i.e. BDMA, IPA, IDMA, FOPE and OPPI, along with a patient group called Indian Organization for Rare Diseases (IORD), conducted a webinar on the need for essential medicines for rare diseases. During the virtual conference, regulatory experts, industry stakeholders and the patient group discussed steps which need to be taken to make orphan drugs accessible and affordable in the country. This year in February, the Ministry of Health and Family Welfare had released the draft national policy for rare diseases for public comments.

Commenting the need to ensure that rare diseases get equal focus from all fronts and stakeholders, Dr V G Somani, Drug Controller General (India) stated, "The draft Guidelines for compassionate use of medicines will be getting finalised soon. And to provide regulatory assistance to patients affected by rare diseases, the authority is in touch with different research groups and patient groups. It is also working in a direction to ensure Indian population also gets participation in global clinical trials so that the country will have its own data for research understanding."

He also appreciated the fact that all the associations have jointly come forward to discuss the issue in detail with a single objective of creating treatment avenues for rare diseases. Dr Ramaiah Muthyala, President & CEO, Indian Organization for Rare Diseases, gave an overview of rare disease scenarios, not only in India but across the globe.

He pointed out that the definition of rare disease differs between ICMR and CDSCO and stressed on the unification of 'rare disease' definitions to assist the policymakers in drafting the document describing incentives for the Pharma industry.

Dr Ramaiah also informs that due to a small number of rare diseases patients, public health professionals do not include rare diseases into public health programs. However, he argues that because the burden of rare diseases far exceeds the combined burden of tuberculosis and malaria, and besides, they are lifelong diseases, rare diseases should be a public health priority.

Dr Ramaiah mentioned that the call for creating a model essential medicine list for rare diseases came from Rare Diseases International, a global alliance to ensure the achievement of Universal Health Care that includes rare diseases and leaves no one behind. During his presentation, he raised the challenges that would face the expert committee recommending orphan medicines in the WHO model list of essential medicines, considering their smaller population, lack of accessibility of inexpensive medications for low-and-middle-income countries.

Dr Ramaiah states that rare disease patients have equal rights and opportunities in the area of the diagnosis, treatment, and social services, which are enjoyed by patients with common diseases. He urges the Government of India to acknowledge the challenges faced by people living with a rare disease, on the top of the misery caused by the COVID-19 pandemic and the unfairness within the current system towards rare diseases patients.

Mr Sudarshan Jain, Secretary-General, IPA highlighted, "There is a need to create a corpus fund, which will support the Research and Development activities of rare disease. Along with this, there is also a need to create a patient registry, which will give the exact number as well as help in conducting the research."

He also added, "We need to have a centre of excellence dedicated to rare diseases. Understanding the amount of Research and Development work required in this segment, to begin with, a minimum four such centres should be created. Also, considering several aspects which have a direct impact on patients affected by rare diseases like social stigma, economic burden, etc., there is also a need to create a rare disease cell in the Health Ministry which will dedicatedly work in this area. Besides, there is an immense requirement to create awareness programmes at the doctors' level as well as including them in medical education.

B R Sikri, Chairman, FOPE, suggested, "Considering the amount of research work as well as capital cost which is required in carrying the Research and Development activities for developing orphan drugs, the industry looks

for support from the Government and proposes that it should consider exempting such drugs, R&D activities from different tax structures. The industry is of the opinion that it will encourage companies to carry out R&D under their CSR activities and help society."

Mr Venkat Jasti, Managing Director, Suven Life Sciences, emphasised, "To encourage the Pharma industry to carry out research activities pertaining to rare diseases, the Government needs to bring a policy assisting the industry financially. Along with this, the Government also needs to come forward with some mechanism which will ensure free treatment as well as diagnosis of rare diseases." He also felt that there is a need to create robust awareness programmes as well as genetic testing to deal with rare diseases in the early stages itself.

Highlighting the challenges in this arena and recommending a few measures to increase access to orphan drugs in the country, Dr Viranchi Shah, National Vice President, IDMA, mentioned, "There is a need to create a fast track approval system for handling of orphan drugs applications. Along with this, if the office of CDSCO makes a provision in the Clinical Trial rule, especially for volunteers of orphan drug Clinical Trials to get access to those drugs from the innovator company, it will help the community in a much larger context."

He continued, "Besides, if the drug approving authority can also frame Guidelines and give the approval to the orphan drug manufacturing company to launch the product within a stipulated timeline or allow compulsory licensing to other companies, it will certainly reduce the burden and benefit the patient significantly." "Considering the data availability of rare disease patients' in open source platforms, if the IT and Pharma industries work together, with Government support, in generating the data for research purposes, then the joint efforts will lead in the right direction with positive outcomes," expressed Shah.

Mr K G Ananthakrishnan, Director General, OPPI urged, "To understand the depth of requirements in each and every aspect related to rare diseases, there is a need for multi-stakeholder partnerships between the Pharma industry, academia, medical professionals as well as diagnostic players. Along with this, there is also a need to create sustainable funding to increase R&D activities along with early diagnosis."

He said that ambiguity related to the definition of rare diseases in India also should get cleared. He also suggested that an ICMR-initiated patient registry should be made live and updated regularly. Another recommendation was that drugs related to the treatment of rare diseases should be exempted from all kinds of duty and tax structure.

Mr V V Krishna Reddy, National President, BDMA also opines if the Pharma industry gets financial assistance from the Government to carry out research for rare diseases segment, then many companies will come forward to bring new drugs for the treatment of these diseases.

Mr Mahesh Doshi, National President, IDMA said, "We have recommended that the amendment should be extended to include rare and tropical diseases to encourage R&D and manufacture of drugs for such essential requirements. In this regard, we must note that Pharma R&D is very expensive and time-consuming as compared to other industrial research, on account of regulatory requirements of safety, efficacy and quality. Sustained R&D efforts by Indian companies have enabled the Government to address India's needs on tropical/ country-specific diseases like TB, Kala-azar, dengue and other life-threatening inflictions like cancer, asthma, diabetes etc."

Thereafter, he added, "It is time for India to notify the national policy for rare diseases to pave the way for greater funding and mechanisms to support R&D innovation. Creating an enabling environment for Research and Innovation will be crucial if India is to achieve the target set in Sustainable Development Goal 3.3 to end epidemics of neglected tropical diseases by 2030."

The draft national policy for rare diseases provides for lowering the incidence of rare diseases based on an integrated preventive strategy encompassing awareness generation and screening programmes and enables access to affordable healthcare to patients of rare diseases are amenable to a one-time treatment. The policy has also noted that the number of persons suffering from diseases considered rare globally, is lacking in India and accordingly provides that for the purpose of the policy the term 'rare diseases' shall be construed to three groups of disorders identified and categorised by experts based on their clinical experience.

Considering the limited data available on rare diseases and in the light of competing health priorities, the focus of the policy is on prevention of rare diseases as a priority for all the three groups of rare diseases identified by experts. The policy includes infectious tropical diseases and identifies a need to support research on treatments for rare diseases.

Source: Usha Sharma, Express Pharma, 02.08.2020

Indian Pharma may gain under Trump drug price reform plan

Indian pharmaceutical companies may be able to benefit from US President Donald Trump's plan to reduce the prices of drugs that would allow individuals to import prescription medications directly. This provision was one of several executive orders Trump has signed to lower the prices of medicines in the US, which are the highest in the world.

Under the order issued last week, individuals can get waivers to import prescription medications "provided such importation poses no additional risk to public safety and results in lower costs to American patients". Health Secretary Alex Azar explained that under the "personal importation" provision, the Food and Drug Administration will set up a system to allow the safe import from countries that have regulatory regimes comparable to the US.

The FDA has a presence in India to ensure that medicines made there "meet FDA's safety and quality requirements", according to the agency. The order is scheduled to come into effect on August 24 and in the meanwhile, Pharmaceutical companies can come up with proposals to cut costs of medications.

Azar suggested that a model for allowing individuals to import medicines would the system set up by Florida and some Native American tribes' administrations for getting Pharmaceuticals from Canada under previous Trump initiatives. He said that injectible medicines and controlled drugs such as opioids would not be allowed under the personal importation programme. India exports Pharmaceuticals worth about $5.8 billion to the US every year, making it the single largest market.

Unveiling his order, Trump said, "For decades, our citizens have paid the highest prices for drugs - prescription drugs - anywhere in the world, and it's not even close." The same medicines are sold with a much higher markup in the US. "A pill that would cost $1 could be $7, $8 in our country. The same pill," Trump said, mentioning Germany and Canada in particular.

A major step he has taken is requiring Medicare, the federal health insurance programme for seniors, to pay the lowest prices other countries pay. Explaining its impact, Trump said that if some other country pays $1 and the US was paying $5, it will now pay only $1. In reality "what's going to happen is their number will go up, our number will come very substantially down, and we'll all agree at two and a half or two or whatever the final number is," he said.

One effect of this on countries like India is that prices of medications sold by multinationals could be increased if the US brings it into how the pricing mechanism is determined. However, India does not have a similar centralized Government mechanism for drugs purchase like the US Medicare or those of some European countries.

Trump was mainly aiming at European countries through this provision, derisively calling their systems "socialist healthcare". "We incredibly and foolishly bear the full cost of all Research and Development, which is massive, in all fairness to the drug companies." "It also means that the US taxpayers are effectively subsidizing the socialist healthcare systems of foreign welfare states and many other countries."

Source: Arul Louis, IANS, daijiworld.com, 30.07.2020

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Brazil's acceptance of GMP certificates issued by PIC/S countries for drug registration augurs well for Indian exporters

The Brazilian health regulatory agency ANVISA's acceptance of GMP certificates issued by member countries of PIC/S for registration of Active Pharmaceutical Ingredients (APIs) and drugs; and also the relaxation in requirements for the presentation of Certificates of Origin during COVID-19 pandemic have augured well for Indian drug exporters.

India is a leading exporter of pharmaceutical products to the Latin American country. In 2019-20, India exported pharmaceuticals worth US$ 297 million to Brazil. Given the gravity of the current situation, Brazilian National Health Surveillance Agency (ANVISA) has adopted alternative certification procedures based on remote inspection or reliance on data from other health authorities.

As per the resolution of the Collegiate Board (Resolucao da Diretoria Colegiada – RDC) of ANVISA dated March 13, 2020, Brazilian health regulatory agency will accept GMP certification, based on reports issued by member countries of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) even in cases where the company is not based

in a country which is part of the scheme, for registration and post registration of APIs, drugs and health products in the country.

The March 13 resolution established extraordinary and temporary criteria and procedures for GMP certification for registration and post registration of APIs, drugs and health products in Brazil during COVID-19 pandemic. For the certification of healthcare products, information from the Medical Device Single Audit Program (MDSAP) is accepted by ANVISA.

MDSAP allows a single audit of a medical device manufacturer's quality management system which satisfies the requirements of multiple regulatory jurisdictions such as Australia, Brazil, Canada, Japan and the United States. Audits are conducted by Auditing Organizations (AO), such as Bureau of Indian Standards (BSI), authorized by the participating regulatory authorities (RA) to audit under MDSAP requirements.

For certifications related to pharmaceutical inputs (APIs), the resolution has allowed the acceptance of results from the "Program to rationalize international GMP inspections of API manufacturers". The programme has been implemented as an international cooperation among regulators in order to improve efficiency and effectiveness of GMP inspections. In addition to these alternatives, the resolution also allowed certification based on remote audits carried out by ANVISA.

With regard to acceptance of studies of safety, efficacy and quality for drug registration, ANVISA has informed that the resolution dated March 17, 2020 established special procedures for drug registration that has specific therapeutic indication for the prevention or treatment of COVID-19 and the drug can be useful in the clinical management of the disease or contribute to lessen the burden on the national health system.

Such special procedures include flexibility of evidence and prioritization of analysis. The resolution also allowed registration of anti-COVID drugs marketed in member countries of PIC/S in Brazil prior to bioequivalence study of the medicine in the country.

With reference to the requirement for printed documentation to import goods into Brazil, the Ministry of Economy has eased the requirements for the presentation of certificates of origin during emergency situations, state of public calamity or a pandemic declared by the WHO, extending the deadline for the presentation of the certificate to 60 days after the import declaration is registered. The flexibility was determined by means of the Normative Instruction No.1936, dated April 15, 2020.

Pharmexcil has sensitized member exporters to above alternate procedures adopted by ANVISA in the wake of Coronavirus to help them continue exports to Brazil seamlessly. Welcoming the alternative certification procedures adopted by ANVISA for product registration amid COVID-19 pandemic, Sahil Munjal, Vice Chairman, Pharmexcil said "India has a significant number of drug plants approved by UK Medicines and Healthcare Products Regulatory Agency (UK MHRA) which is a member of PIC/S. Thus Brazil's acceptance of GMP certificates issued by member countries of PIC/S will be beneficial to Indian exporters."

Munjal further stated that the ANVISA has fast tracked registration of COVID-19 drugs. The waiver of bioequivalence study for registration of COVID-19 drugs marketed in the US and Europe with ANVISA has augured well for Indian exporters. Earlier it was mandatory for drug exporters to conduct BE study on drugs in Brazil to register them with ANVISA. With the relaxation in norms, the exporters can register COVID-19 drugs with ANVISA provided that the BE study of the drugs has been conducted in the US and Europe. Later they can submit local BE study data to ANVISA.

Source: Laxmi Yadav, Pharmabiz, 31.07.2020

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Health Ministry exempts sale license for Hand Sanitizers under D&C Act to ensure its availability

In order to ensure easy availability of hand sanitizers in the interest of public and patient safety, the Union Health Ministry has exempted hand sanitizers from the requirement of sale licence under the provisions of Chapter IV of the Drugs and Cosmetics (D&C) Act, 1940 and the provisions of the D&C Rules, 1945.

As per the Ministry's Notification, several representations requesting to exempt hand sanitizers from the requirement of sale licence under the provisions of Chapter IV of the D&C Act, 1940 and the provisions of the D&C Rules, 1945 for stocking or sale of the drug have been received.

The Central Government considers it necessary that hand sanitizers are required to be made widely available to the public at large.

The Maharashtra Food and Drug Administration (FDA) had earlier sent a letter to the Central Drugs Standard Control Organisation (CDSCO) to allow exemption of sale license for hand sanitizers. "Exemption of sale license for hand sanitizers will not only make it available but also will offer competitiveness to the manufacturers in producing sanitizers at an affordable price. More so, as there is now no price control on hand sanitizers as the Government had capped the Maximum Retail Price (MRP) of hand sanitizer at Rs. 500 per lite bottle till June 30, 2020," according to a senior FDA official.

In view of COVID-19 pandemic, hand sanitizers were either not available with most of the vendors in the market or were available with great difficulty at exorbitant prices. Now, therefore, in exercise of the powers conferred by section 26B of the D&C Act, 1940 (23 of 1940), the Central Government, hereby directs that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, subject to the condition that provisions of condition (17) of Rule 65 of the said Rules are complied with by the person stocking or selling hand sanitizers.

Government had notified an order under the Essential Commodities (EC) Act to declare hand sanitizers as essential commodities up to June 30, 2020 by amending provisions of EC Act, 1955. It had also issued an advisory under the Legal Metrology (LM) Act. Under the EC Act, after discussions with the manufacturers, states could ask manufacturers to enhance production capacity of hand sanitizers, to make the supply chain smooth, while under the LM Act, the States could ensure sale of both the items at Maximum Retail Price.

The states were also advised to give publicity of state helplines for registering complaints by the consumers of hand sanitizers. The consumers could also register their complaints in this matter with the national consumer helpline number 1800-11-4000, online complaints at **www.consumerhelpline.gov.in,** department's website **www.consumeraffairs.nic.in**, **dsadmin-ca@nic.in** and **dirwm-ca@nic.in, secy.doca@gov.in.**

Source: Pharmabiz, 30.07.2020

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Pharma firms commit 815,000 doses of Remdesivir supply in August

Remdesivir is a Gilead Sciences, Inc drug being made by Indian players under license agreements with the innovator. In the wake of shortage of critical drugs used to treat Covid patients, the Centre has stepped up pressure on pharmaceutical companies to ramp up production of injectables like Remdesivir.

According to sources, 365,000 doses of Remdesivir are scheduled for supply in July. In August, the makers have committed to supply 815,000 doses. Remdesivir is a Gilead Sciences, Inc drug being made by Indian players under license agreements with the innovator. The drug, originally developed for Ebola, has been repurposed for Covid-19, and is being given to patients under the compassionate-use programme. Leading Pharmaceutical players like Cipla, Hetero Drugs, Jubilant Life Sciences, Mylan, Dr Reddy's Laboratories, and Cadila Healthcare have tied up with Gilead for making and marketing the antiviral drug here along with other countries. So far, Hetero, Mylan, and Cipla have launched their respective brands of Remdesivir priced between ~4,000 per vial and ~5,400 per vial.

The drug has been selling at six to seven times its Maximum Retail Price as it was also in short supply in the black market. The Department of Pharmaceuticals held meetings with manufacturers and has asked them to scale up production. The process of production is not simple — it involves 14 Active Pharmaceutical Ingredients and over 20 different steps to make the injectable drug. This makes manufacturing time-consuming as well as expensive. Makers, too, are fighting shy of making the drug in bulk as it has a three-month shelf life. "We are steadily ramping up supplies. Since the drug got emergency authorisation from the drug regulator in the wake of the pandemic, it has been granted three-month shelf life until further data is submitted. Making huge volumes in one go is fraught with risk," said one drug maker.

The Government, however, has held multiple meetings with the makers and is taking action to clamp down on black-market activities. "This drug is also being prescribed indiscriminately by many clinicians. Private hospitals, nursing homes, and a clutch of doctors have found this to be a lucrative business. The affluent also stock it, fearing

shortage," said a senior Government official, adding the Government has been collating data on profiteering.

He asked, "What is the point of stocking a drug with a three-month shelf life?" The official further explained that the supplies scheduled in July are 365,000 doses. "Considering each patient gets six doses, this should ideally cater to 50,000 patients. Are there 50,000 people in ICUs now?" he asked.

In August, the official added that manufacturers have promised around 815,000 doses and this would take care of the demand in the market. He clarified that the July supplies do not include Jubilant's numbers as the integrated global pharmaceutical recently got the nod. The prices of Remdesivir, too, are expected to come down further. While Hetero launched it for ~5,400 per vial, Cipla has launched it for ~4,000 per vial. Cadila Healthcare and Dr Reddy's are expected to price their brands competitively after the Drug Controller General of India's go-ahead.

Source: Business Standard, 30.07.2020

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BIRAC invites research proposals for supporting biotechnological products under PACE scheme

The Biotechnology Industry Research Assistance Council (BIRAC) has invited proposals for supporting biotechnological product/technology development from academia and industry under Promoting Academic Research Conversion to Enterprise (PACE) scheme through Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Programme (BIPP). PACE Scheme aims to support academic collaborations for development of products and technologies up to proof of concept for validation of products/technologies towards commercialization and to stimulate technological innovation.

The thrust areas of these proposals focus on development of devices & diagnostics such as rapid antigen detection test for COVID-19, high-through assay to measure SARS-CoV-2 neutralizing antibodies, virtual distant measurement of temperature, BP, pulse rate, tele auscultation, POCD, development of medical grade high resolution cameras relevant to COVID-19 and intensive care equipment for life support and emergency resuscitation in the context of COVID-19. Other areas of focus include drugs & drug delivery, biopharmaceuticals, biosimilars and regenerative medicine, vaccines and Clinical Trials for development for repurposing of drugs and novel therapeutics for COVID-19, new methods/ technologies for drugs and vaccines delivery in the context of COVID-19, development of *in vitro*, *ex vivo* and *in vivo* assay models for screening and evaluation of potential candidate drugs and vaccines relevant to COVID-19 and novel technologies for production of monoclonal antibodies for therapeutic applications and diagnostics in the context of COVID-19.

It also includes biomedical waste treatment including waste generated due to used protective gear in the context of COVID-19. It is cost effective production technologies for (microbial route) API needed for COVID-19 drugs and production of enzymes (microbial production) used in COVID-19 diagnostics kits. Other area of these proposals includes healthcare and veterinary sciences like development of new drugs for combating viral infections and newer adjuvants for animal vaccine development.

Under the scheme, academia (public or private institute, university, NGO, or research foundation) having a well-established support system for research shall be the primary applicant is eligible. The last date for submitting the application is August 31, 2020.

Source: Neethikrishna, Pharmabiz, 30.07.2020

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Monitoring Cell for APIs

For the last several years, the Indian pharmaceutical industry has periodically been facing headwinds because of the gyrating prices of Active Pharmaceutical Ingredients (APIs) for which the country has long been over-dependent on China. Whenever there is any supply disruption from China, it will have a direct bearing on the price of APIs.

If there is any sharp rise in the prices of APIs imported from China, it would send shock waves through the spine of Indian pharmaceutical industry, especially the Small and Medium Industries, as the SMEs in the country have been heavily dependent on the APIs imported from China to produce the drug formulations. Ever since the Chinese Government started crackdown on polluting industries, including producers of APIs some years back, the Indian Pharma industry has been under tremendous pricing pressure as the prices of APIs had then gone through the roof, affecting the financial viability of many of the formulations being produced by the Indian companies. More recently, the prices of APIs imported from China have fluctuated from 20% to even more than 100% from the beginning of this year because of the COVID-19

pandemic which had its origin in the Hubei region where several of the API units are located. The prices of anti-infective APIs such as tinidazole, amoxicillin, ceftriaxone, clav avicel, diclofenac sodium, ofloxacin, clav syloid, clotrimazole, ciprofloxacin as well as anti-inflammatory API-dexamethasone sodium have hiked by 24% to 38% from January to April this year. The prices of erythromycin thiocyanate which is the raw material for preparing erythromycin derivative products, such as azithromycin, clarithromycin and roxithromycin have spiked by 20% from pre-COVID period till now. Besides, the prices of four APIs-paracetamol, ornidazole, azithromycin and nimesulide have risen from 62% to 189% from January to April.

The price of paracetamol has increased from Rs.262 a kg in January to Rs.425 per kg in April. Para Amino Phenol (PAP) used as a key starting material for manufacturing paracetamol has also witnessed 27% rise in prices. Taking advantage of situation, some of the traders in India would also hike the prices of APIs. India, at present, does not have a mechanism to check rising prices of APIs on the lines of National Pharmaceutical Pricing Authority (NPPA) which regulates prices of drug formulations. It was under this background that the experts in the industry had earlier put forward a proposal to establish an 'API Monitoring Cell' to curb the malpractices in APIs and excipients business in the country. That the Government was also seized of the issue was evident from the fact that the Union Health Ministry, at the Indian Pharmaceutical Association Forum meet held at CDSCO headquarters in New Delhi on August 28, 2018, had declared that the Government will establish an API Monitoring Cell to control the twin issues of poor quality of APIs and overcharging of APIs by the importers taking advantage of the situation arising out of the disruption in its supply from China.

At an Indian Drug Advisory Forum meeting held on September 25, 2018, the Indian Pharma industry experts had also submitted a proposal for establishing an API Monitoring Cell in the country. Unfortunately, as is the case with several other proposals, this proposal has also been gathering dust in the shelves of the Department of Pharmaceuticals for the last about two years. As the API prices and its quality will have a direct bearing on the Pharmaceutical industry, the Government should not waste further time as an API Monitoring Cell will ensure stability of API prices and will help industry get genuine APIs from importers as well as domestic manufacturers.

Source: Ramesh Shankar, Pharmabiz-Editorial, 22.07.2020

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		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

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