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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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# IDMA BULLETIN

**Vol. No. 51 Issue No. 35 15 to 21 September 2020**

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## FEATURE:

# IDMA Representation to Finance Minister on Classification of Alcohol Based Hand Rubs and a detailed analysis on GST applicability on Hand Sanitizers – reg.

***The Association has submitted the following representation on 11th September 2020 to Smt Nirmala Sitharaman, Hon'ble Minister of Finance & Chairman, GST Council, Government of India with copies to Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, Shri Ajit Kumar, IRS, Chairman, Central Board of Indirect Taxes & Customs, Ministry of Finance and Dr Ajay Bhushan Pandey, IAS, Revenue Secretary & Ex-Officio Secretary to the GST Council, New Delhi re. regulatory challenges faced by Manufacturers and Marketers of hand sanitizers and tremendous pressure about applicability of GST rate 12% or 18% - Classification of Alcohol Based Hand Rubs (ABHR) - GST liability on Hand Sanitizer should be under Drug Category HSN Code 3004 @ 12% and to request to examine the matter and issue a clarification as regards the applicability of GST etc:***

**"Greetings from Indian Drug Manufacturers' Association.**

IDMA was formed in the year 1961 and is the only Association in India with Membership strength of over 1000 wholly-owned Indian Small, Medium and Large scale Pharmaceutical manufacturers situated throughout the length and breadth of our country. IDMA, as the premier National Association, has successfully completed 58 glorious years of providing support to its members who have provided affordable quality medicines, not only to the people of India, but also to people all over the world.

Many members of our Association have taken manufacturing/marketing of Hand Sanitizers containing ethanol or isopropyl alcohol as an active ingredient following the urgent and sudden need for hygiene products due to COVID-19 virus pandemic from March 2020. These Manufacturers and Marketers of Hand Sanitizers are facing regulatory challenges about applicability of GST rate 12% or 18%.

Our Members are using HSN code 3004 with tariff of 12% as:

(i) Hand sanitizers manufactured by Pharma Manufacturers are drugs or Medicaments which are used to clean Hands and on regular basis.

(ii) The product contains pharmaceutical ingredients that have therapeutic or prophylactic properties, and it is claimed on the label that the ABHR 'kills' germs. It would mean that the product is not for cosmetic application but for medicinal application as the product contains certain curative and preventive ingredients.

(iii) Hand sanitizers manufactured by Pharma manufacturing facilities are as DRUG like any other medicine in GMP environment after getting license from concerned drug department in Form 25.

(iv) Hand sanitizers manufactured by these Pharma companies are as per the formulations recommended by WHO.

(v) Chapter 3808 does not cover Medicaments (Heading 3003 or 3004)

It has come to our notice that the Government has opined that such manufacturers are wrongly classifying the said item under tariff heading 3004 whereas the said item is liable to be classified under tariff heading 3808 having 18% GST Rate. The opinion is based on classification opinion of World Customs Organisation wherein WCO has inferred that Alcohol based Hand Sanitizers are classifiable under heading 3808 of HSN (Precisely under sub-heading 3808.94).

Further, The GST intelligence in Chennai and Puducherry as well as from other parts of the country are of the view that the product attracts GST at the rate of 18% and based on this summons have been issued to various members and in some cases there is tremendous pressure exercise to make payment of the differential duty immediately. The position is apparently based on the view of the Department that the product falls under Chapter 3808 attracting GST at the rate of 18%.

From the settled legal principles as detailed in **Annexure A**, the product in question merits classification only under Chapter 30 for the following reasons:

(i) The products in question are manufactured under drug license in the capacity as a manufacturer of drug.

(ii) The different ingredients which go into the product are all clearly indicated in the label and the label also indicates the application of the product; the methodology with adequate caution symbols and also has the manufacturing license number.

(iii) The label clearly indicates that it has to be applied on the palm and the limited time at which it can be applied including the quantity that has to be taken when it is used as hand disinfectant and when it is used in surgical segment.

(iv) The fact that the product is effective against bacterial, virus, fungi, etc is also specified in the container.

(v) The product can be used only for the hands as indicated in the name of the product as well as in the usage instructions.

Given the plethora of decisions on the issue including authoritative pronouncement of the Supreme Court on the issue, the classification of Pharma grade alcohol based Hand Sanitizer manufactured under Drug License issued under the Drugs and Cosmetics Act under Chapter 3808 for the purpose of 18% GST is incorrect and the correct classification would be Chapter 3004 which attracts GST at the rate of 12%.

**IDMA Concerns/Requests:**

Members of the Association are manufacturing a product for the society at large at the time of Covid pandemic and thousands of people are risking their life in ensuring that the factory continues to work and the most important product for the society at large at this point of time is continuously available.

Further, the profits have dwindled on account of the MRP for the product being reduced and the MRP itself was fixed based on the GST at 12%. At this juncture, it is not possible for the members of the Association to bear any additional impact of GST or to face the pressure being mounted by GST Intelligence and the GST Department in seeking payment of the higher rate of GST.

Whereas, the authorities are incorrect in taking the term 'disinfectant' to mean one which is used for antiseptic purpose by human beings.

It is submitted that there is an urgent need for the Ministry of Finance/Central Board of Indirect Taxes and Customs to examine the matter and issue a clarification as regards the applicability of GST HSN 3004 or 3808.

We had made a submission on 8 July 2020 to CBIC Chairman and others requesting for clarification on this matter. A copy of our submission is enclosed as **Annexure B***.

Since the matter is of considerable significance and has implication on the mis-classification of product manufactured by vast section of the industry, it is earnestly requested to instruct the concerned authorities to kindly clarify the issue as early as possible. This would put an end to the prevailing confusion and uncertainty, reduce litigation and ensure uniformity of compliance. We look forward to a favourable response. Thanking you".

***(*Annexure B is not reproduced here as the same was already published in IDMA Bulletin Issue dated 14 July 2020)***

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**Annexure A**

## GST applicability on Hand Sanitizers - A detailed analysis

**1. Background:**

1.1 Indian Drug Manufacturers Association (IDMA) has members who manufacture drugs and pharmaceutical products under a Drug License issued under the Drugs and Cosmetics Act, 1940. These companies are also engaged in the manufacture and distribution of alcohol based pharma grade sanitizer which contains pharmaceutical ingredients that have prophylactic properties. The main ingredients in these alcohol based drug grade hand sanitizer are Indian Pharmacopeia chemical matters such as alcohol, hydrogen peroxide glycerol, etc. It is represented that the hand sanitizer are anti-bacterial formulation drugs (medicaments). It is represented that these products are manufactured as per WHO authorized formula.

1.2 The members of the Association who are manufacturers of the aforesaid products under drug license have been charged GST at the rate of 12% by classifying the goods under the category 3004 9087 from inception.

1.3 The GST intelligence in Chennai and Puducherry as well as from other parts of the country are of the view that the product attracts

GST at the rate of 18% and based on this summons have been issued to various members and in some cases there is tremendous pressure exercise to make payment of the differential duty immediately. The position is apparently based on the view of the Department that the product falls under Chapter 3808 attracting GST at the rate of 18%.

1.4 The point for consideration is with reference to the legal position.

**2. Relevant Statutory Provisions:**

2.1 Notification No.01/2017-CTR dated 28.06.2017 w.e.f. 01.07.2017 provides for applicable rate of CGST with matching Notifications being issued under SGST and IGST. The relevant entries in the Notification are given below:

| Schedule-II - 6% | | |
|---|---|---|
| **Sr. No.** | **Chapter/ Heading/ Sub-heading / Tariff item** | **Description of Goods** |
| 63. | 3004 | **Medicaments** (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale, including Ayurvaedic, Unani, Homoeopathic Siddha or Bio-chemic systems medicaments, put up for retail sale |
| **Schedule-III - 9%** | | |
| 87. | 3808 | Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products and plant-growth regulators, disinfectants and similar products other than bio-pesticides mentioned in Sr. No.78A of Schedule-II. |

2.2 The Explanation to the Notification No.1/2017 is of importance and (iii) and (iv) read as under:

*(iii) Tariff item, sub-heading, heading and chapter shall mean respectively a tariff item, sub-heading, heading and chapter as specified in the First Schedule to the Customs Tariff Act, 1975.*

*(iv) The Rules for the interpretation of the First Schedule to the Customs Tariff Act, 1975 including the Section and Chapter Notes and the General Explanatory Notes of the First Schedule shall, so far as may be apply to the interpretation of this Notification.*

**3. Analysis:**

3.1 The members of the Association manufacture pharma grade alcohol based hand sanitizer under the Drug License issued by the Drug Controller in Form 25 under the Drugs and Cosmetics Act.

3.2 Chapter 30 deals with pharmaceutical products and Chapter 38 deals with miscellaneous chemical products. The hand sanitizer manufactured has a composition of iso propyl alcohol and other Indian Pharmacopeia ingredients. The product packing material or container indicates the composition and also provides for an instruction for use on the hand as well as for surgical use. The time frame for application of the sanitizer to the body is also indicated. It is identified as strictly for external use and marketed as hand disinfectant for sanitizing of hand surfaces and acts as a disinfectant effective against bacteria, fungi, including TB, HIV, etc.

3.3 The ostensible reasons for the Revenue to harbor the view that the product attracts GST at 18% as against 12% are twofold. The first is the Press Release dated 15.07.2020 and the second is the Notification issued by the Ministry of Health and Family Welfare dated 27.07.2020.

3.4 In so far as the Press Release is concerned, it states that sanitizers are disinfectant like soaps, anti-bacterial liquids, Dettol, etc which attracts GST at the standard rate of 18%. The Press Release is issued in the context of representation seeking lower rate for sanitizers and similar items. The object of the Press Release was to express the position that a lower rate of GST on the output would result in an inverted duty structure and put the domestic manufacturer at a disadvantage vis-à-vis importers.

3.5 In so far as the Press Release is concerned with reference to rate of tax, the same does not had any legal effect for the following reasons:

(i) Classification of goods under the GST law has to be done in terms of the relevant notification read with the Rules for interpretation of Schedule to the Customs Tariff Act.

(ii) There is no power to issue press releases on classification of goods or to indicate applicable rate of GST.

(iii) If classification is in doubt, the law contemplates issue of a show cause notice; adjudication and an appellate mechanism.

(iv) Press Releases are not binding on the assessee or on the tax authorities.

(v) The Supreme Court in the case of ***CIT Vs. Anjum Ghaswala (2001) 252 ITR 1*** has held that a clarificatory note or press release issued by the Board does not have any statutory force.

3.6 In so far as the Notification issued by Ministry of Health and Family Welfare is concerned, the same does not have any bearing on GST for the following reasons:

(i) Only the Notifications issued under the CGST Act can determine the rate of tax applicable for a product subject to the interpretation of the relevant entries under the Customs Tariff Act.

(ii) The Notification by Ministry of Health was in the context of making available hand sanitizers to the public at large and hence the objective was to exempt the product, from the requirement of sale license under the provisions of Chapter V of the Drugs and Cosmetics Act, 1940 and the provisions of the Drugs and Cosmetics Rules, 1945 for stocking or sale of the drug.

(iii) The Notification itself provides that the Central Government *hereby directs that the* ***drug*** *namely hand sanitizer shall be exempted from the requirement of sale license…..*

(iv) The exemption from sale license for dealing with the drug does not change the character or nature of the product. In fact, the Notification itself identifies the product as a drug and there ends the matter.

(v) The relaxation for sale under another law does not mean that the classification of the product would also change.

3.7 It is also relevant to note that the Director General of Foreign Trade acting under the Foreign Trade (Development and Regulation) Act, 1992 had amended the Export Policy and in terms of Notification No.53/2015-2020 dated 24.03.2020, sanitizers which were free for export under the Policy where brought under the prohibited category. While doing so, the ITC HS Code was identified as 3401; 3402; **3004 9087**; and 3808 94.

3.8 Subsequently, Notification No.4/2015-2020 dated 06.05.2020 was issued amending the earlier Notification and the prohibition is now confined to alcohol based hand sanitizer and the ITC HS Code referred are **3004**; 3401; 3402; 3808 94. These Notifications clearly demonstrates that the Government is aware that certain hand sanitizers are medicaments falling under **3004**.

3.9 In so far as classification of hand sanitizer is concerned, it is relevant to note that the product in question is manufactured under a license issued by the Drug Licensing Authority under the Drugs and Cosmetics Act to manufacture specific drugs. The drug license number issued in Form 25 is displayed as the manufacturing license number by the pharmaceutical manufacturers on the label affixed on the hand sanitizer containers.

3.10 Chapter 3004 of the Customs Tariff Act covers *medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured dose (including those in the form of transdermal administration systems) or in forms or in packing for retail sale.*

3.11 Chapter 3004 90 covers 'other' and 3004 90 87 covers *anti-bacterial formulation not elsewhere specified or included*.

3.12 Entry 181A, Notification No.1/2017 was inserted by Notification No.34/2017 dated 13.10.2017 and reads as under:

Medicaments (including those used in Ayurvedic, Unani, Siddha, Homeopathic or Bio-chemic systems), manufactured exclusively in accordance with the ***formulae*** described in the authoritative books specified in the First Schedule to the ***Drugs and Cosmetics Act, 1940*** (23 of 1940) or Homeopathic Pharmacopoeia of India or the United States of America or the United Kingdom or the German Homeopathic Pharmacopoeia, as the case may be, and sold under the name as specified in such books or pharmacopoeia.

3.13 The Supreme Court in the case of ***BPL Phamaceuticals Ltd Vs CCE (1995) 77 ELT 485*** explained the difference between drugs and

cosmetics and Chapter 30 and Chapter 33. The Court held that merely because 3305 uses the word 'preparation for use on the hair' it does not mean that the product in question can be brought under the said heading. The product in question is intended as a medicine for curing diseases. The label gives warning, precaution and direction for use which make a difference from that of an ordinary shampoo which will not contain such warning or precautions for use. The Court ultimately held that '**selsun'**, an anti-dandruff preparation manufactured under Drugs License is understood as a medicine falling under Chapter 3003 and not under Chapter 3305.

3.14 When warnings were given on the label and precautions for use and suggestion to use once a week, the Supreme Court in the case of ***CCE Vs. Sarvotham Care Ltd (2015) 322 ELT 675*** held that the shampoo with 2% anti-fungal agent as an active ingredients is to be used like medicine and not used for cleaning hair. Thus it falls under Chapter 3003 and not Chapter 3305.

3.15 The Supreme Court in the case of ***Naturalle Health Products Pvt Ltd (2003) 158 ELT 257 (SC) – Vicks Medicated Cough Drops*** has held that held that Vicks Medicated Cough Drops and Vicks Vaporub Throat Drops manufactured as per license under the Drugs and Cosmetics Act have ingredients of natural herbs and extracts and can be considered as Ayurvedic Medicaments. An item can be an ayurvedic medicament even if it is patented as a medicine in USA.

3.16 The Supreme Court in the case of ***Puma Ayurvedic Herbal Pvt Ltd (2006) 196 ELT 3 (SC)*** has held that **neem facial pack**, anti-pimple herbal powder, herbal facial pack, herbal remedy for facial blemishes, hair tonic powder, etc. are all medicinal products intended to treat certain medical conditions of the human body and therefore are classifiable as medicaments and not as cosmetics. On the other hand, herbal massage oil, scalp tonic powder has no medicinal properties and is only in the nature of cosmetics. The Supreme Court held that:

(i) What is relevant is the primary use of the product.

(ii) Baldness is a medical problem and if by use of a product a person is able to grow hair on his head, his ailment of baldness is cured.

(iii) The product used for this purpose cannot be described as a cosmetic merely because it has ultimately led to improvement in appearance of the person.

(iv) The extent or quantity of medicament used in a particular product is not a relevant factor.

(v) In order to be a medicinal preparation or a medicament it is not necessary that the item must be sold under a Doctor's prescription.

(vi) Availability of product across the counter in shops is not relevant as it makes no difference either way.

3.17 In the case of ***Dabur India Ltd. (2002) 146 ELT A311***, when **Hajmola** contained 85% sugar and 15% medicine, the Supreme Court held that it has the necessary ingredients as per ayurvedic textbooks and that it is an ayurvedic medicine and not candy.

3.18 In the case of ***Sharma Chemical Works (2003) 154 ELT 328 (SC),*** **Banphool oil** contains 98% of till oil and other ayurvedic ingredients like amla, chandan, camphor etc. The Company contended that the product should be classified as 'Ayurvedic medicaments' since the product can be used for headache, eye problem, night blindness, weak memory, hysteria, blood pressure etc. Further the dosage required to be used was also mentioned in the label. The Department contended that the product was sold across the country without a prescription of a Doctor and the content of ayurvedic ingredients was less. The Supreme Court held that merely because the product is sold without Doctor's prescription, does not by itself lead into a conclusion that it is not a medicament. Further a less percentage of ayurvedic content does not ipso facto means that the product is not a medicament.

3.19 The Supreme Court in the case of ***CCE Vs. Ishaan Research Lab Pvt Ltd (2008) 230 ELT 7 (SC)*** has held that **bio-aloevera**, bio-bhringraj, bio-cucumber, bio-coconut, bio-kelp, bio-costes, bio-milk, bio-margosa, bio-peach, bio-wheat, bio-saffron, bio-walnut, etc contain elements having ayurvedic medicinal value and have been produced under drugs license issued under Drugs and Cosmetics Act, 1940 and the labels of the product clearly shows the medicinal properties of the product. The items have to be considered as medicinal product classifiable under Chapter 30 and not as cosmetics classifiable under Chapter 33.

3.20 The Chennai Bench of CESTAT in the case of ***CCE Vs. Pee Gee Pharma (2003) 155 ELT 341*** has held that **Krithika Hair Vitalizer** is manufactured under licence issued by the Drugs Controller and the product is a siddha drug as defined in Section 3(a) of the Drugs and Cosmetics Act. The fact that it is available in supermarkets or general stores cannot affect the classification since there is no requirement that a medicament should be sold only in a medical shop or should be prescribed by a medical practioners. Even medical shop sells chocolates and cosmetics. ***The license is specific for manufacture of drugs, the ingredients indicate the herbal content.*** The label and literature and common commercial parlance understanding establishes that the product falls under Chapter 3003 and not under Chapter 3005.

3.21 The Ahmedabad Bench of the Tribunal in the case of ***Commissioner Vs. Ban Labs Pvt. Ltd. (2009) 236 ELT 542*** has held that '**rootz oil**' with ingredients specified in authoritative ayurvedic books and manufactured with license from Drugs Control Authorities and used to cure hair diseases and having therapeutic and prophylactic value is classifiable under ayurvedic medicine under Chapter 3003 and not as hair oil under Chapter 3305.

3.22 **The product in question merits classification only under Chapter 30 for the following reasons:**

(i) The products in question are manufactured under drug license in the capacity as a manufacturer of drug.

(ii) The different ingredients which go into the product are all clearly indicated in the label and the label also indicates the application of the product; the methodology with adequate caution symbols and also has the manufacturing license number.

(iii) The label clearly indicates that it has to be applied on the palm and the limited time at which it can be applied including the quantity that has to be taken when it is used as hand disinfectant and when it is used in surgical segment.

(iv) The fact that the product is effective against bacterial, virus, fungi, etc is also specified in the container.

(v) The product can be used only for the hands as indicated in the name of the product as well as in the usage instructions.

3.23 In the case of ***CCE Vs. Wockhardt Life Sciences Ltd (2012) 277 ELT 299***, the Company was manufacturing '**povidone iodine cleansing solution USP**' and '**wokadine surgical scrub**' and contended that the items are 'medicaments' falling under Chapter 3003 and the revenue contended that the products are 'detergent' falling under 3402. The Supreme Court held that:

(i) Factors to be considered are composition, literature, label, character and user.

(ii) Medicaments are products which can be used either for therapeutic or prophylactic usage.

(iii) The contention that the product is primarily used for cleansing and hence cannot be considered as a medication is not acceptable.

(iv) It is not in dispute that the product is used by the surgeons for the purpose of cleaning or degerming of their hands and scrubbing the surface of the skin of the patient that portion is operated upon. The purpose is to prevent the infection or disease. The product can be safely classified as medicament.

3.24 The Supreme Court in the case of ***CCE Vs. Hindustan Lever Ltd (2015) 323 ELT 209*** has held that '**vaseline intensive care heel guard**' is marketed as a solution for cracked heel and it is claimed that it is a solution specially developed by scientists at vaseline research. The Supreme Court held that the product is a medicament since it was formulated and essentially used for treatment of cracked heels, protection from further cracks in the human heels; the product was manufactured ***under a drug license as drug authorities had treated the same as a medicament.***

3.25 As stated in the earlier part of the opinion, Notification No.1/2017 clearly provides that the tariff item, sub-heading, heading and chapter shall mean the respective tariff item, sub-heading, heading and chapter specified in the First Schedule to the Customs Tariff Act. Chapter 38 of the Customs Tariff Act deals with miscellaneous chemical products and it clearly provides that the

Chapter does not cover *medicaments (heading 3003 or 3004)*.

**3.26 Apart from a number of decisions on 'medicaments' falling under Chapter 30 where the dispute was between Chapter 30 and Chapter 33 dealing with cosmetic, there are also direct decisions in the context of classification dispute between Chapter 30 and Chapter 38**.

3.27 The Supreme Court in the case of ***ICPA Health Products Pvt Ltd Vs. CCE (2004) 167 ELT 20*** has held that as per the Concise Oxford Dictionary 9th Edition, the term '*prophylactic*' could mean intending to prevent diseases, a preventive medicine or a course of action. The appellant's products are used as a cleanser for cleaning the wounds and abrasion and minor cuts and to ***disinfect the skin prior to surgery.*** As the products have therapeutic properties and prophylactic uses they are ***medicaments falling under Chapter 30 and will not fall under Chapter 3808.***

3.28 In the case of ***Suganil Chemo Industries Vs. CCE (2006) 181 ELT 206 (SC)***, the company was manufacturing a product known as 'licel'. The company had classified the product under Chapter 3808 whereas the Department contended that the product falls under Chapter 3003. The Supreme Court did not accept the classification under Chapter 3808 and held that *the product is for killing lice in human hair. We are unable to accept the submission that killing lice does not amount to therapeutic or prophylactic use.* ***Any medicine or substance which treats diseases or is a palliative or curative is therapeutic.*** *It is also prophylactic in as much as it prevents disease which will follow from infestation of lice.* ***It would thus be a 'medicament' and get excluded from Chapter 38.*** *The Court also held that even if a product is an insecticide, if the product has any therapeutic or prophylactic use then for the purposes of classification that product cannot fall under Chapter 38.*

3.29 In the case of ***Medreich Sterlab Ltd. Vs. CCE (2005) 188 ELT 487***, the company was manufacturing '**ITEOL-3**' under Drug Control Act and under the license granted by the Drug Control and claimed that the item is a medicament under Chapter 30 and cannot be classified as a disinfectant under Chapter 3808. The Tribunal held that identical products have already been classified by the Supreme Court as medicaments. The product is being used by Doctors for the purpose of sterilization of their hands prior to surgery as well as for disinfecting the skin prior to surgery. As the products have therapeutic and prophylactic use they are manufactured under Drug License, they are medicaments.

3.30 In the case of ***Sarvotham Care Ltd. Vs. CCE (2004) 173 ELT 93***, the Tribunal held that the item is used for disinfection of surgeon hands as well as disinfection of instruments beside being used as a spray and disinfectant for sick rooms, floors, etc. The item has medicaments which are of IP standards. The use of both the items is for antiseptic purposes and they are not used for plant for disinfecting the plants as insecticides, rodenticides, fungicides, etc. The item cannot be considered as falling under 3808. It is a medicament as all the ingredients are of IP standards meant to destroy infectious gems or to destroy microorganism. ***The description of disinfectant has to be read along with other items in the said heading 3808 which are used for plant and the same product used in the disinfection itself indicate that it has to be products of similar nature.*** **Therefore the authorities are incorrect in taking the term 'disinfectant' to mean one which is used for antiseptic purpose by human beings.**

3.31 All the decisions of the Government in the context of reducing the MRP or facilitating the sale of the drug without a sale license by way of relaxation are all decisions in the context of Covid-19 pandemic and has no implications whatsoever with reference to GST or classification of goods under GST. The Press Release in the context of inverted duty structure has no relevance in determining the applicable rate of tax for goods in GST. Rate of tax for goods is notified through Notification No.1/2017-CTR which is issued in exercise of powers conferred by Section 9(1) of the CGST Act. All aspects of classification will have to be determined in terms of the Customs Tariff as per the Explanation to Notification No.1/2017. The hand sanitizers have been rightly classified under Chapter 30 in the light of the various decisions referred to above and the position adopted by the Revenue to the effect that the product would fall under Chapter 38 is not correct.

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# IDMA Swatchhata Pakhwada Day Celebrations 2020 Webinar on 'Disposal of Expired Medicines' - A Report

Indian Drug Manufacturers' Association (IDMA) celebrated Swatchhata Pakhwada Day on Thursday, 10th September 2020 between 5 PM – 6.15 PM. An email was sent to Government officials, CDSCO, FDA, OPPI, CII, IDMA Member companies to participate in the webinar to make awareness on "***Disposal of Expired Medicines***". The Webinar was graced by the presence of two eminent Speakers Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, Mumbai and Shri Atul Nasa, Head of Office/Controlling Authority/ Licensing Authority/Deputy Drugs Controller, New Delhi and the Indian Pharma Leaders at this memorable event which had a presence of 517+ people pan India.

**Mr Mahesh Doshi**, National President, IDMA & MD, Dy-Mach Pharma & Avesta Pharma in his Welcome Address said *(Excerpts)* that "It gives me great pleasure to welcome you all to the IDMA Webinar on "***Disposal of Expired Medicines".*** As an annual exercise, the Department of Pharmaceuticals requests us, as an active participant, to create awareness on various topics during the Swachhata Pakhwada fortnight which is from 1st September to 15th September 2020. In support of the Department's campaign, I am happy to mention the initiative taken by our Secretary-General, Mr Daara Patel in organising this Webinar on '***Disposal of Expired Medicines'***. It is my pleasure to inform you that IDMA is the first recipient of the Swachhata Pakhwada 2018 Award bestowed by Department of Pharmaceuticals at the 4th India Pharma Awards, Bengaluru in February 2019.

Pharmaceutical products assure potency and safety of the contained medicine till the expiry date which is mentioned on the medicine pack.

At the time of expiry, the medicine is expected to have at least 90% of its original potency, under recommended storage conditions. The Drugs and Cosmetics Act and Rules specify under Schedule M that the "shelf life of formulation product shall not exceed that of active raw materials used", which then determines the expiry date. The expiry date does not necessarily indicate that the medicine will lose its potency completely and will be no longer effective or become harmful after the expiry date.

Usually, expiry date for medicines is 2–3 years from the date of production. If the medicines are stored under optimal conditions, many retain 90% of their potency for up to 5 years after the declared expiry date, and in some cases even longer. The expired medicines cannot be recommended for human consumption since there will be no legal support for compensation of any side effect or adverse drug reaction occurring as the manufacturer cannot be blamed for it. Hence expiry dates are in benefit of the medicine consumers.

The disposal of the expired and unused medicines is a vital issue because it has direct impact on environment, on all life forms, including humans. The inappropriate disposal of expired medicines in rivers and other water bodies raises the possibility of contaminating drinking water source. Disposal of non-biodegradable antibiotics and disinfectants into the sewage system may kill bacteria necessary for treatment of sewage.

Burning of expired medicines at low temperature or in open containers results in release of toxic pollutants to the air. There have been instances of date expired or rejected medicines being recycled by unscrupulous elements posing a threat to the health and safety of patients. Similarly, pilfering from a stockpile of waste drugs may result in expired drugs being diverted to the market for resale.

State FDAs and CDSCO as the Regulatory agencies are expected to monitor and deal with such improper practices as required by law. IDMA has always been socially conscious and as early as in the year 2002, published Guidelines on Disposal of Date Expired, Damaged, Rejected Medicines. In the Guidelines, IDMA formulated a three-tier plan to help in prevention and control of such bad practices and provided SOPs to be followed at the three key locations - at Manufacturing sites, at Distribution/Sales locations and by Consumers.

The World Health Organisation, in 1999, had also released 'Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies'. While the expired medicines may not cause serious health hazard

to the public or to the environment, their improper disposal could be serious. We have expert regulators Dr Rubina Bose and Shri Atul Nasa today who will speak in detail on proper '*Disposal of Expired Medicines'*. We look forward to hearing them and understand the Regulatory and health issues involved and suitable solutions to deal with this vital issue.

**Mr Daara B Patel**, Secretary General, IDMA in his Opening Remarks said *(Excerpts)* that "It gives me great pleasure to welcome you all to the IDMA Webinar on "***Disposal of Expired Medicines"*** on the occasion of Swatchhata Pakhwada, an initiative of Department of Pharmaceuticals, Government of India.

Medicines play a very significant role for treating many diseases and conditions, but at the end of the treatment it is very important to dispose them of properly. Hence, the knowledge and awareness of proper drug disposal are essential for safe environment. Lack of knowledge and practice can lead to various problems like environmental pollution and various health hazards directly or indirectly. The World drug industry sold drugs worth $ 1250 billion (1.25 trillion US Dollar) in 2019 and this figure was in 2001 $ 390 Bn US Dollar. High usage rate invariably corresponds to more drug wastage.

Excessive buying of over-the-counter (OTC) drugs (53%); self-discontinuation (17%), and expiration of drugs (24%) resulted in possession of unused/leftover medications at home.

As the analytical techniques continue to improve in precision and accuracy, the number and frequency of detection of trace of organic chemicals in the environment, including pharmaceutical products are increasing. All these raised concerns about potential exposure of humans to these chemicals through the drinking water, and to living organisms in surface waters as the pharmaceuticals are difficult to remove with conventional wastewater treatment processes.

The discovery of diclofenac residues in cattle carcasses as the cause for the vulture population collapse in India and the discovery of oestrogens in sewage effluents as a cause of the feminization of fish (sex-reversal of males to females) and 12 Year Investigation of Minamata Disease in Japan in the 20th Century sparked an exponentially increased interest in the environment. Sewage effluents and receiving rivers were thereafter the prime focus for ecotoxicologists who were interested in pharmaceuticals.

The Guidelines for disposal for medicines are prescribed by World Health Organization (WHO), United States Food and Drugs Administration (US FDA) and our own Drugs & Cosmetics Act has laid down Guidelines for the disposal of expired Medicine for the Manufacturer. Some of the methods suggested to dispose date expired and unused medicines include returning to manufacturer, landfill, and waste immobilization: encapsulation/inertization, flushing it down the Sewer and incineration.

In India, the knowledge regarding disposal of date expired and unused medicines is lacking among common people. A conceptual framework to dispose date expired and unused medicine has been devised.

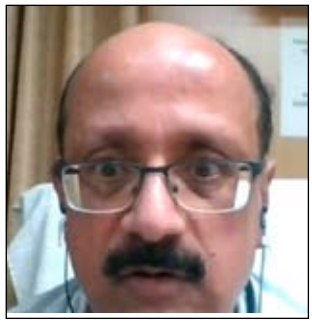
Pharmacies interested in program would be identified wherein patients visiting these pharmacies would be asked to register with pharmacy and return the unused/ date expired medicines to participating pharmacies. The unused and date expired medicines collected in pharmacies shall be segregated into various types by participating volunteers. The segregation would include various dosage forms and packing material. The recovered contents will be sent to a specialist company that uses specific procedures in order to recycle and collect reusable components and safely dispose of chemical components based on prescribed procedures. The reusable components shall be collected and properly treated for reuse. This concept would not only sensitize people but also community pharmacists and would be advantageous to protection of environment.

I am glad to inform you that one of our member Mr Sachin Gandhi is engaged in responsible disposal of expired Medicine by the patient and pharmacies.

Educating, promoting and implementing adequate disposal methods can limit potentially damaging environmental effects.

This Webinar would create an awareness to bridge the gaps between knowledge, practice of proper and

environmental safe methods of disposing expired/ unused drugs and biomedical waste generated during Covid-19 like mask, gloves and PPE kits among healthcare professionals and also the common man, who is the end user.



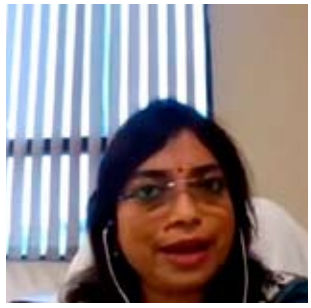
**Shri Atul Nasa**, made a presentation on "***Government Initiatives and Expectation from Pharma Industry on Disposal of Expired Medicines"***. In his presentation he explained the definition of expired medicine as per the Drugs and Cosmetics Rule. He discussed about the issue relating to the inappropriate disposal of expired medicines. He informed how the Disposal of non-biodegradable antibiotics, anti-neoplastics and disinfectants into the sewage system may kill bacteria necessary for treatment of sewage. Burning of the expired medicines at low temperature or in open containers results in release of toxic pollutants to the air.

He further discussed about the Major Disposal methods recommended by the International Authorities, like Returning to the manufacturer, Landfill, Waste immobilisation, Sewer, Chemical decomposition and Incineration which is the most accepted disposal method. He said Return to Manufacturer or Donor is the most feasible and it should be the first choice because the manufacturer is likely to have good disposal method at its disposal and It can also help in preventing the recycling of drugs at other sources.

He explained SOP for proper disposal of Expired Drugs, Solids, semi-solids and powders, Liquids, Ampoules, Aerosols and Statutory requirements for disposal of expired drugs. He also explained Bio-Medical Waste management Rule and disposal in detail.

He informed about the new Draft Guidelines on Good Distribution Practices for Pharmaceutical Products. CDSCO has published the draft Guideline on Good Distribution Practices for Pharmaceutical Products, wherein following points were mentioned with respect to disposal of expired or rejected medicines. The rejected pharmaceutical products and those returned to a distributor shall be appropriately identified and handled in accordance with a procedure which involves at least:- the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or other equivalent (e. g. electronic) segregation. Destruction of pharmaceutical products shall be done in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment.

He thanked IDMA and Department of Pharma to provide the platform to nation-wide awareness on the ill effects of unsafe and inappropriate disposal of Mechanisms.



**Dr Rubina Bose**, Deputy Drugs Controller (India), CDSCO West Zone, Mumbai spoke on "***Responsible Disposal of Expired Medicines".*** In her speech she informed about initiatives taken to draft the new Guidelines about the disposal of expired medicines. The Guideline explains how to deal with the expired medicines. She highlighted some of the points on expired medicines. She explained in detail Rule 65 of the Drugs and Cosmetics Rule.

The draft Guideline explains how to dispose of the expired medicines and how household expired medicines can be returned to the pharmacists or the designated authority to dispose off as per the Rules. She also explained how to dispose the medicine when it is in the small quantity at home so that it should not end up being accidentally consumed..

The Question & Answer Session was very ably conducted by **Dr Viranchi Shah**, Sr Vice President, IDMA

and **Mr T Ravichandiran**, Vice President (Southern Region) IDMA.

Presenting Concluding Remarks and vote of thanks, **Dr George A Patani**, Hon General Secretary, IDMA thanked all delegates for their active and lively participation. He also thanked Daara Patel and his team for their support in successfully organising the Webinar. He specially thanked Shri Atul Nasa and Dr Rubina Bose for their spontaneous acceptance at short notice to address the Webinar and making detailed presentation and expert remarks and in ensuring that the participants have very knowledgeable takeaways and making the event a grand success.

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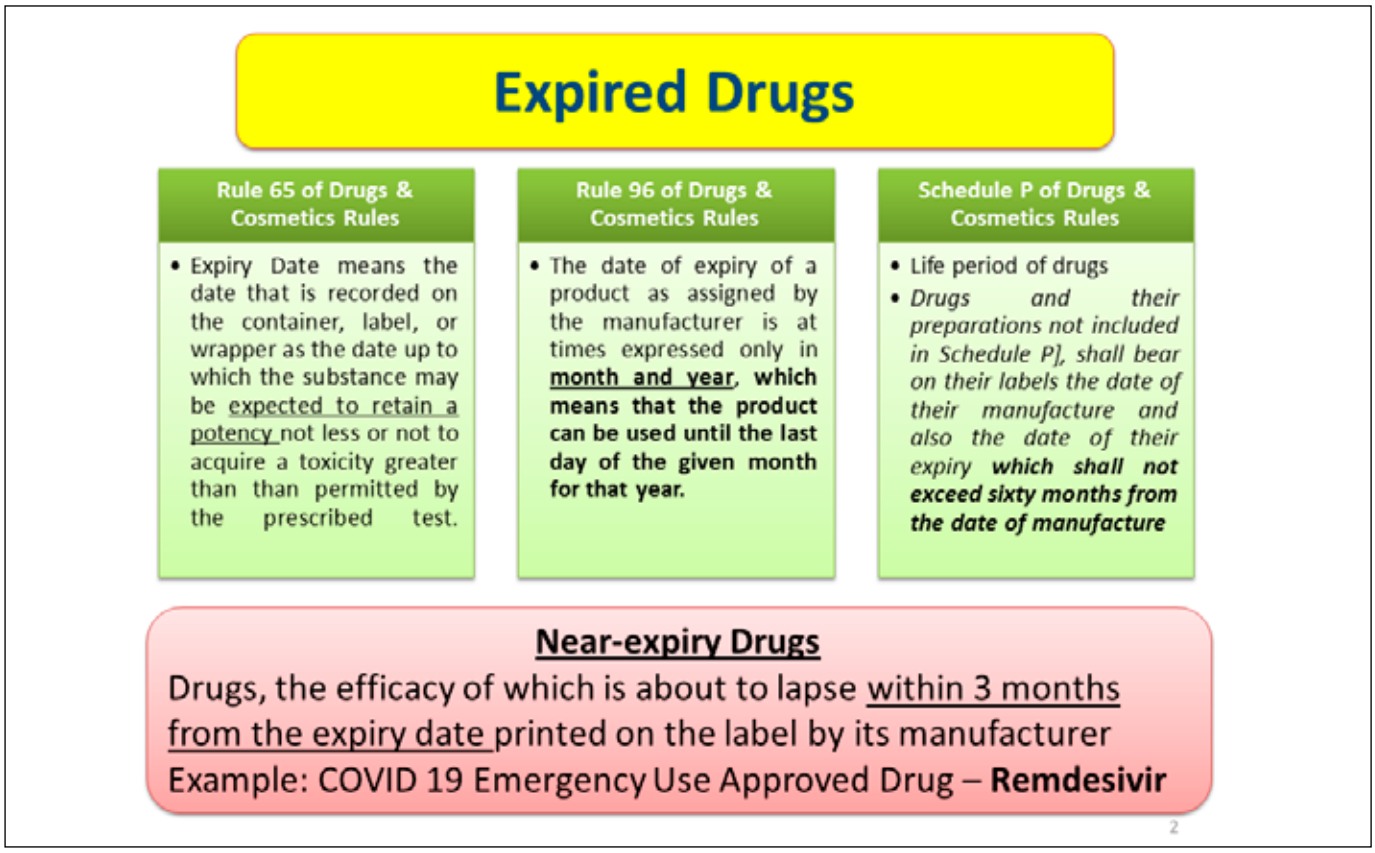
PRESENTATION

# 'Government Initiatives and Expectation from Pharma Industry on Disposal of Expired Medicines'

***by Shri Atul Nasa,*** *Head Office, Controlling & Licensing Authority, Deputy Drugs Controller, Drugs Control Department, New Delhi*

***[Presented at the Webinar on "Disposal of Expired Medicines" organized by IDMA as part of the celebration of Swatchhata Pakhwada Day on 10th September 2020]***



## Issues relating to the inappropriate disposal of expired medicines

- Possibility of contaminating drinking water source or supply
- Disposal of non-biodegradable antibiotics, anti-neoplastics and disinfectants into the sewage system may kill bacteria necessary for treatment of sewage

  ***(May lead to cause of Antimicrobial Resistance)***
- Burning of the expired medicines at low temperature or in open containers results in release of toxic pollutants to the air
- Inefficient and insecure disposal may lead to recycling of the expired medicines.

  ***(This is true especially when they are disposed in original containers)***

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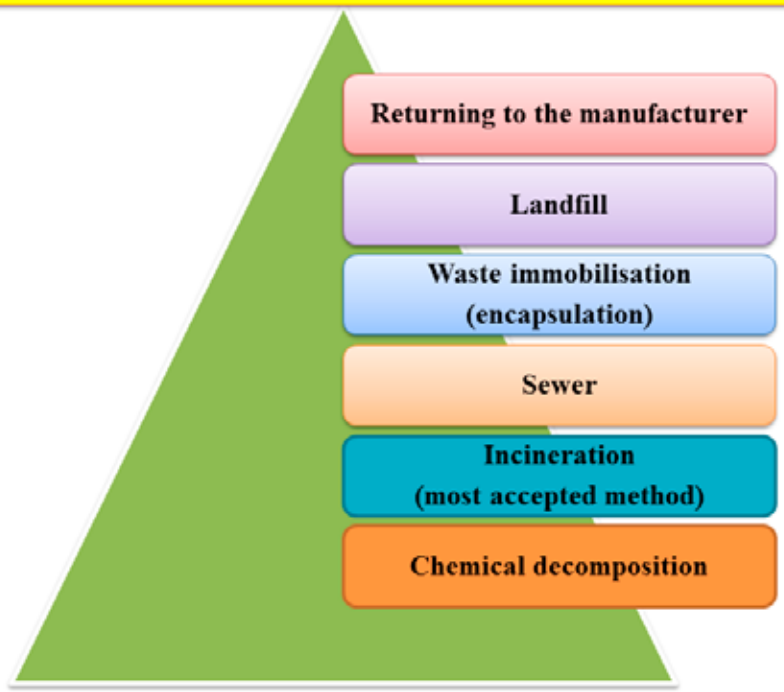
## Major Disposal methods recommended by the International Authorities



## Return to Manufacturer or Donor

- Returning unusable drugs / expired drugs for safe disposal by the manufacturer.
- For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date, it may be possible to return them to the donor for disposal
- Wherever feasible this should be the first choice because the manufacturer is likely to have good disposal method at its disposal
- It can also help in preventing the recycling of drugs at other sources

## Landfill

- Place waste directly into a land disposal site without prior treatment or preparation.
- Oldest and the most widely practiced method of disposing of solid waste.
- Untreated waste must be rapidly covered with other municipal waste to prevent scavenging.

## Waste Immobilisation (Encapsulation)

- Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum.
- They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam
- Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity.
- Steel drum lids should then be bent back and sealed, ideally by seam or spot welding.
- The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste.

## Sewer

- Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids etc., can be diluted with water
- Then, flushed into the sewers in small quantities over a period of time without serious public health or environmental affect.
- Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics

## Incineration

- Medium and high temperature incineration devices require a capital investment, operation and maintenance budget.
- Medium temperature incinerators operate at a medium temperature combustible process (800-1000°C), while high temperature incineration works at a temperature above 1000°C

***Expired or Discarded Medicines:***
***Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc***

## Chemical decomposition

- If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill.
- Chemical inactivation is a Tedious and time consuming process and stocks of the chemicals used in treatment must be made available at all times.
- For disposal of a small quantity of anti-neoplastic drugs this method may be practical


## Sorting categories

- The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as:

✓ controlled substances (e.g. narcotics),
✓ antineoplastic (cytotoxic-anti cancer) drugs
✓ any other hazardous non-pharmaceutical products

- The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets etc.)

- **Special disposal is needed for the following**

✓ Controlled substances; e.g. narcotics, psychotropic substances
✓ Anti-infective drugs
✓ Anti-Neoplastics
✓ Cytotoxic anti-cancer drugs, toxic drugs
✓ Antiseptics and Disinfectants

## SOP for proper disposal of Expired Drugs

- Intimation given by store department to State Pollution Control Board or Pollution Control Committee along with application stating the details of products (name of Product, Batch no., Expiry Date and Qty. to be disposed off)
- Stocks will be transferred from unrestricted area to rejected area
- After getting approval from State Pollution Control Board, destruction note shall be prepared
- Disposal will be carried out in presence of Store person & QA Department
- Expired finished goods is disposed as per **SOP FOR DISPOSAL OF MATERIALS (Tablets/capsules, Powders, Liquid dosage forms etc.)**
- Original copy of destruction note sent to the concerned Department for their record

## Recommended disposal methods for some of the formulations

### Solids, semi-solids and powders

- If it is not possible to return these to the manufacturer or adequate incineration is unavailable then encapsulation or inertization is recommended before discharge to a landfill
- Anti-infective drugs and anti-neoplastics drugs are encapsulated to delay release to the environment and avoid high concentrations.
- Controlled drugs (e.g. Narcotics etc.) should be immobilized under supervision of the pharmacist, the police or a judicial representative, depending on the Local regulations/State Regulations

### Liquids

❖ **Pharmaceuticals with no or low toxicity**

- Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer.
- Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers.
- If there are no sewers first diluted with large volumes of water and poured into large watercourses, providing they are immediately dispersed and diluted by the flowing river water.

# Ampoules

- These can be crushed on a hard impermeable surface using a stout block of wood or a hammer.
- The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill.
- The liquids released from the ampoules should be diluted and disposed.
- Ampoules should not be burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator. Melted glass will also clog up the grate of a furnace or incinerator if the operating temperature is above the melting point of glass.


**Ampoules of anti-Neoplastics or anti-infective drugs must not be crushed and the liquid discharged to sewers.**

## Anti-infective drugs

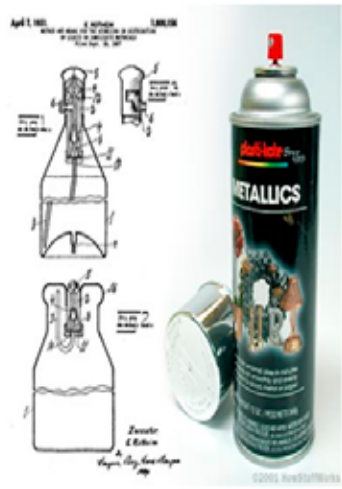
- Anti-infective drugs should not be discarded in an untreated form.
- They are unstable and are best incinerated, and if that is not possible encapsulated or inertized.
- Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.

## Controlled substances

- Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations.
- Such substances must not be allowed into the public domain as they may be abused.
- They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

## Aerosols

- Disposable aerosol and inhalers should not be burnt or incinerated
- High temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator.
- Provided they do not contain poisonous substances they should be disposed off in a landfill, dispersed among municipal solid wastes.




## Statutory requirements for disposal of expired drugs

**Drugs and Cosmetics Act, 1940 and Rules, 1945**

- **As per clause 1.4 of Part I of Schedule M, the disposal of waste by** manufacturing plants should be as per the requirements laid thereunder:
- The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of **Environment Pollution Control Board.**
- **All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste Management Rules, 2016.** Additional precautions shall be taken for the storage and disposal of rejected drugs.
- As per the Schedule L1, All bio-medical laboratory waste shall be destroyed as per the provisions of the **Bio-Medical Waste Management Rules, 2016**
- State Licensing Authorities appointed by the respective State Governments are empowered to take action in case of any violation of above requirements.

## Biomedical Waste Management (BMWM)

- In Drugs & Cosmetics Act, 1940 and Rules, 1945, earlier Industry has to follow Bio-Medical Waste (Management and Handling) Rules, 1998, which is now amended to Bio-Medical Waste Management Rules, 2016

- In exercise of the powers conferred by section 6, 8 and 25 of the **Environment (Protection) Act, 1986 (29 of 1986),** and **in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998,** Central Govt. makes the Bio-Medical Waste Management Rules, 2016

| Previous Legislation | Current Legislation |
|---|---|
| **Bio-Medical Waste (Management and Handling) Rules, 1998** | Bio-Medical Waste Management Rules, 2016 |

## Highlights of Bio-Medical Waste Management Rules, 2016

- These rules are effective from 28th March, 2016

- These rules shall apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form.

- ***bio-medical waste"*** *means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules;*

- "prescribed authority" means the **State Pollution Control Board** in respect of a **State** and **Pollution Control Committees in respect of an Union territory**

| Cat. | Type of Bag/ Container used | TYPE OF WASTE | Treatment /Disposal options |
|---|---|---|---|
| Yellow  | non-chlorinated plastic bags<br><br>Separate collection system leading to effluent treatment system | a) **Human Anatomical Waste**<br>b) **Animal Anatomical Waste**<br>c) **Soiled Waste**<br>d) **Expired or Discarded Medicines**<br>e) **Chemical Waste**<br>f) **Micro, Bio-t and other clinical lab waste**<br>g) **Chemical Liquid Waste** | Incineration or Plasma Pyrolysis or deep burial* |
| Red  | non-chlorinated plastic bags or containers | **Contaminated Waste (Recyclable)**<br>tubing, bottles, intravenous tubes and<br>sets, catheters, urine bags, syringes (without needles) and gloves. | Auto/ Micro/Hydro and then sent for recycling. not be sent to landfill |
| White  | (Translucent) Puncture, Leak, tamper proof containers | **Waste sharps including Metals** | Auto or Dry Heat Sterilization followed by shredding or mutilation or encapsulation |
| Blue  | Cardboard boxes with blue colored marking | **Glassware** | Disinfection or auto/ Micro/hydro and then sent for recycling. |

**Schedule I**

**Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options**

| Category | Type of Waste | Type of Bag or container used | Treatment and Disposal options |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| **Yellow** | d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc. | Yellow coloured non-chlorinated plastic bags or containers | Expired `cytotoxic drugs and items Contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 $^0$C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200 $^0$C Or Encapsulation or Plasma Pyrolysis at >1200 $^0$C.<br><br>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration. |

SCHEDULE IV

[See rule 8(3) and (5)]

Part A

LABEL FOR BIO-MEDICAL WASTE CONTAINERS or BAGS


HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL

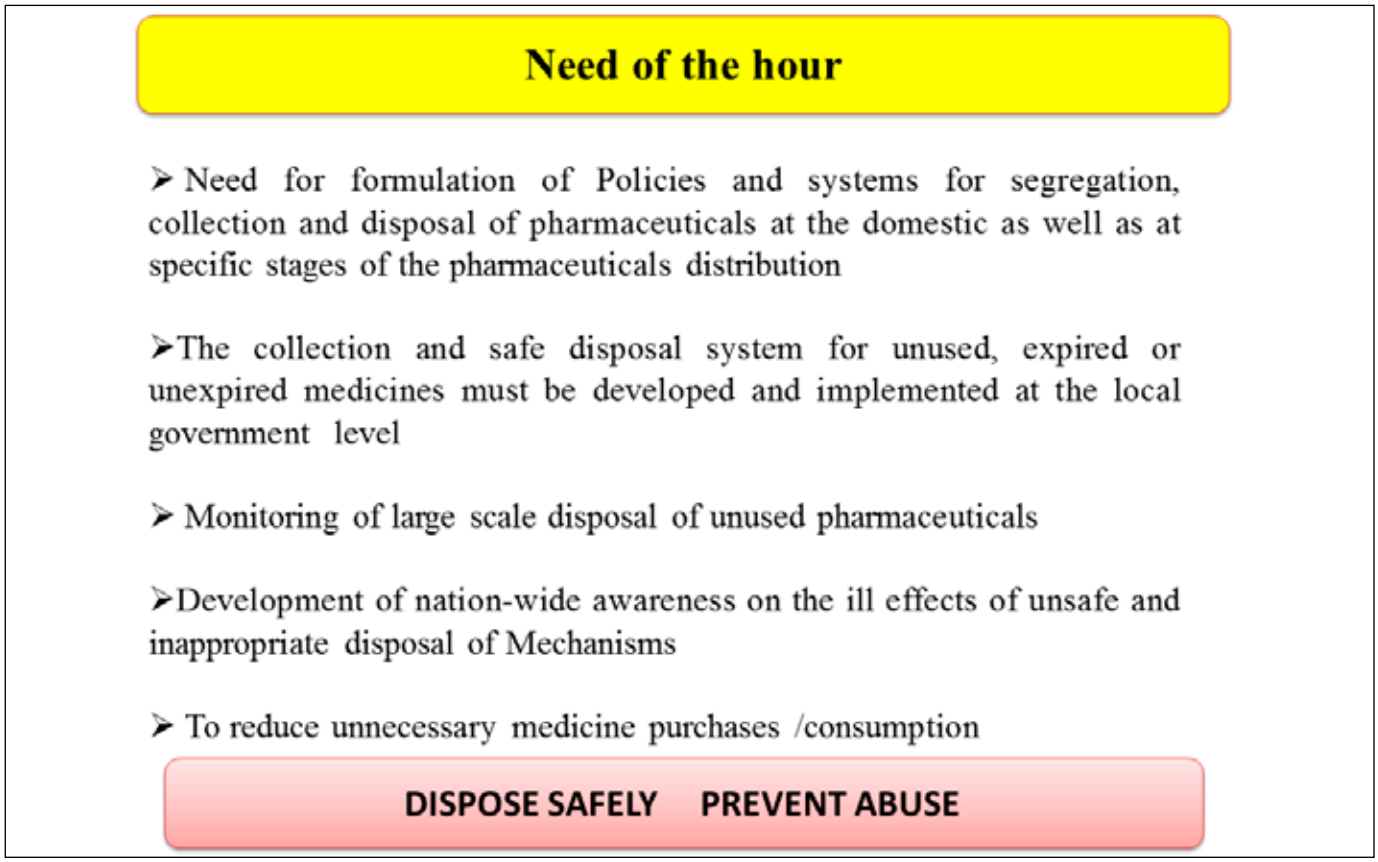

HANDLE WITH CARE

## Draft Guidelines on Good Distribution Practices for Pharmaceutical Products

The implementation of Good Distribution/storage practices were deliberated in 54th meeting of Drugs Consultative Committee held on 30.07.2018

- It was suggested to take necessary provisions to impart legal sanctity to the suggested guidelines as Schedule to Drugs & Cosmetics Rules, 1945 to penalise the offenders
- In view of above, CDSCO has published the draft guideline on Good Distribution Practices for Pharmaceutical Products, wherein following points were mentioned with respect to disposal of expired or rejected medicines.

- ***Rejected pharmaceutical products and those returned to a distributor shall be appropriately identified and handled in accordance with a procedure which involves at least:- the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or other equivalent (e. g electronic) segregation***
- ***Destruction of pharmaceutical products shall be done in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment.***




# IDMA Guidelines on Disposal of Date Expired/Damaged/ Rejected Medicines

Reported instances of date expired/damaged/ rejected medicines being recycled by unscrupulous elements pose a threat to the health & safety of patients. This activity needs to be eliminated urgently.

Regulatory agency (Food & Drug Administration) is expected to monitor and trace these unscrupulous elements & deal with them as required by law.

Indian Drug Manufacturers' Association has formulated a three-tier plan to help in prevention & control of such bad practices at three separate locations.

**Tier-one: Manufacturing locations:**

1. Intensify actions to destroy all on-line product rejects at the earliest.
2. Destroy all on-line or redundant printed packing materials.
3. Intensify security arrangements for all printed packing components.
4. Suitably reconcile stocks of all printed packing components.
5. Select only the trusted & reliable printers for obtaining printed packing components.
6. Ensure that these printers do not supply the company's printed packing materials to any unauthorized individuals.
7. Ensure that any defective or surplus printed materials remaining with the printer are effectively destroyed.
8. Destroy all surplus finished products remaining unsold/undistributed at the time of date of expiry. Similarly destroy all control samples & samples used for Stability Studies immediately after their intended purpose is served.

9. Ensure that the field sales representatives return all the stocks of date expired samples for destruction to the manufacturing locations.
10. Regularly monitor sales outlets to ensure that date expired medicines are not being sold/distributed.

**Tier-two: DistributionlSales locations:**

1. Ensure that all date expired medicines are segregated and securely stored and the manufacturer is promptly advised about the same.
2. Manufacturing locations will check their records & instruct for the return of such stocks duly identified. After due verification, the stocks will be suitably destroyed.
3. Alternatively, the management will depute a designated individual to ensure effective destruction at the distributor's location.

**Tier-three: Consumers:**

1. Manufacturers guarantee the safety & efficacy of medicines if these are stored as prescribed & used before the date of expiry. The use of date expired medicines can cause harm.
2. Verify that the medicines purchased or used are not date expired.
3. Use the medicines as directed by the doctor.
4. Remove & destroy any surplus medicines immediately on the date of expiry.
5. To prevent any misuse of surplus medicines or their containers, remove & destroy the medicines and then destroy the containers.

**Destruction:**

Suitable Standard Operating Procedure will be followed for all destruction. Management will designate a responsible individual under whose supervision destruction will be done. This individual will record all details & certify the destruction activity.

***(The Guidelines was prepared by late Shri G R Asrani in year 2002. It was discussed with the Commissioner, FDA Maharashtra and submitted to him for perusal and consideration at the meeting on 21 November 2002. The Guidelines was first published in IDMA Bulletin Issue dated 21 December 2002).***

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# Streamlining of Unit Quantity Codes (UQCs) in DGFT's EDI System and Customs' ICEGATE - reg.

## ATTENTION MEMBERS

***We are pleased to inform the quick action taken by DGFT as below in response to IDMA urgent Representation on 11 September 2020 highlighting the issues in export due to the JNCH Public Notice suddenly specifying limited UQCs and our request for immediate redressal. DGFT has allowed exports to continue based on the UOMs as practiced by Pharma Industry till 30.10.2020. Our Representation was published in IDMA Bulletin Issue dated 14 September 2020.***

**DGFT Trade Notice No.26/2020-21 dated 14th September, 2020**

*To*
*Members of Trade, Export Promotion Councils and all RAs.*

**1.** It has been observed that the usage of harmonized standard UQC (Unit Quantity Codes) at the time of filing of Shipping Bills and Bills of Entry in ICEGATE is being mandated through various public notices issued by customs formations during the month of August 2020. This is in continuation to the efforts being made by both DGFT as well as Customs Department over last few years to ensure standardization in the data collection for the purpose of clean data reporting and analysis. It also has been noted that use of Nonstandard and Non-convertible UQCs lead to poor quality of data capture and related consequences.

**2.** However, the Public Notice No.101 sated 18.08.2020 issued by JNCH Mumbai customs has resulted in difficulties for some members of the trade and Industry in complying with the standard UQCs in their old Advance and EPCG authorizations which have been issued with quantity units that do not match with the standard UQCs being adopted/available now.

**3.** In order to address this issue, following has been decided:

i) No new authorizations mentioning Non-standard units such as BoU, packs, Boxes cartons and bottles etc would be issued by RAs. For this necessary changes are being carried out in the DGFT EDI system also.

ii) In order to ensure that exports do not suffer in the meanwhile, for the authorizations already issued and carrying any Non-standard units such as BoU, packs, Boxes cartons and bottles etc, Customs have been requested to allow exports against such authorizations till 30.10.2020 by accepting exporter's shipping bills in the UQCs provided in ICEGATE. After 01.11.2020, exports/ imports without standard UQCs will not be permitted.

iii) In the meanwhile, such authorization holders are requested to approach concerned RA and get the non-standard units indicated in their authorizations in the import and export quantities, converted to standard quantity units. In case RAs face any difficulty in carrying out these amendments, they will get in touch with the concerned Norms Committee (NC) in Hqrs.

**4.** Difficulty in implementation of these instructions, if any, may be brought to the notice of this directorate at **policy4-dgft @gov.in immediately.**

**5.** This issues with the approval of the Competent Authority.

**File No.01/94/180/438/AM20/PC-4**

*Vijay Kumar, Additional Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.*

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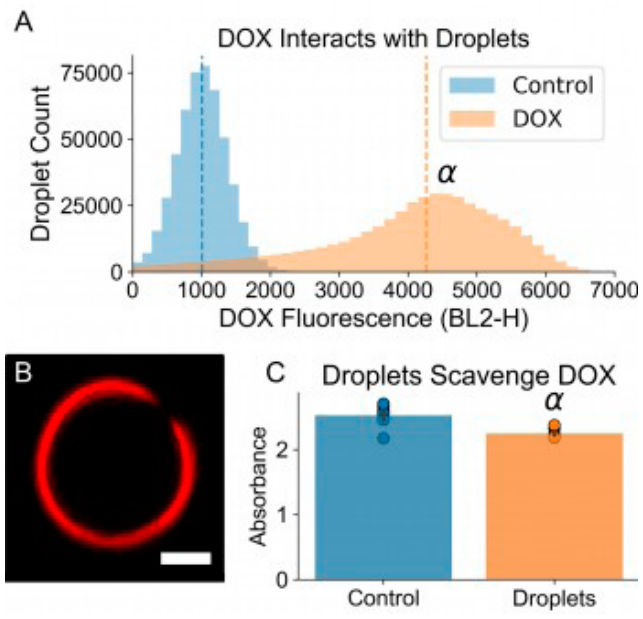
## Chemotherapy Drug more effective when combined with Microbubbles

***Administering a smaller, less toxic dose of DOX, along with intravenous perfluocarbon, shows tumor regression, reduces recurrence, and is less invasive than common treatments***

Hepatocellular carcinoma is a particularly stubborn form of cancer with few treatments and a high mortality rate. It is usually treated by blocking the flow of blood to the tumor to induce cancer cell death. The common treatment, transarterial chemoembolization, is invasive and too imprecise to be a local drug delivery method.




*An increase in fluorescence of droplets incubated with DOX indicates the drug's reaction with the droplet shell (top). The confocal microscopy image (left) shows DOX localizing to the droplet shell. Quantifying absorbance of DOX by droplets showed the total systemic dose was reduced by 11.4% (right).*

Aiming to increase the precision, researchers at Tulane University created a combination treatment that involves vaporizing tiny droplets of perfluorocarbon, a common organic material composed of carbon and fluorine that is used in pharmaceuticals, anesthetics, and industrial fluids.

The method of gas embolization, published in APL Bioengineering, by AIP Publishing, is relatively new, and it is the authors' specialty. "By changing the treatment parameters in this paper, we were able to achieve tumor regression, and by combining our method with chemotherapy, we were able to reduce regrowth following treatment," author Joseph Bull said. "Gas embolization has never been used in patients. Demonstrating that it can induce tumor regression is really new. We're very excited about the work in this paper." Their study tested gas embolization alone and in combination with two common cancer drugs, doxorubicin (DOX) and tirapazamine. Gas embolization stops blood flow to the tumor, and it was highly effective used in combination with DOX.

In the gas embolization method, perfluorocarbon liquid is administered intravenously, and it interacts with DOX that has been administered in the body. DOX binds to the surface of the droplets of liquid, which are small enough to travel through capillaries and do not cause blood vessel blockage until they are vaporized, so treatment can be applied at the specific site of the tumor.

To turn these tiny liquid droplets into microbubbles and cut off the blood flow to the tumor, ultrasound is applied from outside the body. The fluid mechanical interface of the droplet focuses the ultrasound in a cavitationlike event, in which gas bubbles inside the liquid droplet grow due to a drop in pressure, until the droplet turns completely into microbubbles. The drug DOX binds to the shell of the droplet, and the medicine becomes available to diffuse into the tumor, while the microbubbles cut off blood supply to the tumor. The combination of gas embolization and DOX was so effective that, on average, tumors shrank to 2.9% of their initial size, while using DOX alone slowed tumor growth but still allowed them to grow to 300% of their initial size.

*Source: Jonah S Harmon, www.newswise.com, 08.09.2020 (Excerpts)*

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## Peer reviewed studies show COVID-19 has long term side effects predominantly on heart, lungs and brain: Experts

Though the people above 60 years old are vulnerable to COVID-19 particularly those with co-morbidities like diabetes and cardiovascular diseases, experts have

corroborated peer reviewed studies substantiating that besides lung damage, COVID-19 can also damage other organs like the heart, kidneys and brain. COVID-19 virus can make blood cells bound to get together and form clusters. While enormous clusters can cause Coronary failures and strokes, a significant part of the heart failure due to COVID-19 is found to come from little clots that block small veins or vessels in the heart muscle.

"Side effects or damages of COVID-19 may also show years after getting over the disease. COVID-19 can likewise hamper veins which lead to possibly chronic ailments involving liver and kidneys," informed Dr Ajay Kaul, Chairman & HOD, Cardiothoracic and Vascular Surgeons (CTVS), BLK Super Speciality Hospital. Research done in JAMA Cardiology suggests that in numerous patients, COVID-19 could lead to cardiovascular damage, an incessant, dynamic condition in which the heart's capacity to pump blood all through the body decreases. It is too early to state if the harm in patients recovering from COVID-19 is transient or chronic, however cardiologists are worried that it may lead to permanent organ damage.

JAMA Cardiology is a monthly peer-reviewed medical journal covering cardiology published by the American Medical Association (AMA). JAMA Cardiology found that 78 of 100 individuals who had COVID-19 also had cardiac variations coupled with inflammation in the heart muscle when their heart imaging was done in a gap of 10 weeks from the first diagnosis. A significant number of participants in that study review were strong and physically healthy.

"The imaging tests have indicated enduring side effects to the heart muscle, even in individuals who experienced just mild COVID-19 side effects. This may build the danger of cardiovascular failure or other heart problems in the future," Dr Kaul explained. One such research in Italy found that 87% of patients who recovered from COVID-19 were still battling health issues two months later. Information from the COVID Symptom Study, which utilizes an application into which many individuals in the United States, United Kingdom and Sweden have shared their symptoms, recommend 10% to 15% of individuals—including some "mild" cases—don't rapidly recover.

"Current therapies for COVID-19 may interact with cardiovascular medications. COVID-19 and its adverse effects on different body systems is an evolving science. Daily, some impact on body organs is reported in different scientific journals from different countries. Surely, as time passes, we will come across newer challenges in diagnosis and management of COVID-19. It is reported in journals that cardiovascular system is affected with complications including myocardial injury, myocarditis, acute myocardial infarction, heart failure, dysrhythmias and venous thromboembolic events," stated Ahmedabad based Pharmaceutical Consultant Dr Sanjay Agrawal.

"Early this year, numerous specialists dreaded the infection would lead to extensive and permanent lung failure for many survivors since the other two variations of the Coronavirus, namely SARS and MERS, had the ability to damage the lungs. As per the American College of Cardiology (ACC), there were likewise instances of intense cardiovascular failure, heart attack and cardiac arrest after the infection," Dr Kaul explained.

Specialists have stated that being put in a medical clinic's emergency unit, brings about post-intensive care syndrome, which includes decreased physical capacities and psychological disability. Additionally, the COVID-19 could even impact a part of the brain associated with breathing and circulation having lesser known side effects.

*Source: Shardul Nautiyal, Pharmabiz, 16.09.2020*

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## SCTIMST develops Chitra Acrylosorb for safe handling of respiratory secretions

The Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIST), Thiruvananthapuram, has developed the 'AcryloSorb' canister bags, lined with super-absorbent material containing an effective disinfectant for the safe management of infected respiratory secretions. The device is expected to help health workers who have to handle patients suffering from highly contagious diseases such as COVID-19, tuberculosis, or influenza, as it helps reduce the risk of getting infected through the unsafe handling of respiratory secretions of patients.

"The canister bags can absorb 500 ml of secretions and solidify it immediately", said the statement issued by SCTIMST. When the patient is admitted to hospital, secretions are sucked into bottles or canisters using vacuum line and discarded through the waste fluid disposal system after subjecting to decontamination process. There is a high risk of contamination during the handling, and the disposal needs well-equipped sluice rooms with disinfection facilities. The safety threat and manpower issues will be

manifold in less equipped hospitals or temporary isolation wards setup during pandemics.

The know-how of the AcryloSorb suction canister liner (CL Series) bags is transferred to Romsons Scientific and Surgical Pvt Ltd for manufacture and immediate marketing. The approximate cost will be Rs.100 for each canister liner bag, said the statement. In addition to that the whole system will be decontaminated within no time because of the presence of disinfectant.

The liner structure has a patented design which allows the progressive absorbent availability upwards. Solidification and immediate disinfection occur inside these bags eliminate risk of secondary infections by avoiding spilling, and aerosol formation, and thereby protect healthcare workers and promote safe work place management. Canister bags are enclosed in a customizable sealer bag which can pack it as spill-proof decontaminated biomedical waste disposable through incineration. The product has been tested as per the International standards.

*Source: Neethikrishna, Pharmabiz, 16.09.2020*

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## New portable instrument can diagnose Coronavirus using a smartphone in 30 minutes

Scientists, including one of Indian-origin, have developed a prototype of a rapid COVID-19 test using a simple-to-use portable instrument for reading the results with a smartphone in 30 minutes, an innovation that may enable point-of-care diagnosis without needing to send samples to a lab.

*In approximately 30 minutes, a positive result will emit fluorescent light. (Representative Image)*

According to the study, published in the journal *PNAS*, the new technology may help overcome bottlenecks in supplies and laboratory personnel which have led to long waiting times for COVID-19 test results in several parts of the world amidst the ongoing pandemic.

"If such a device and test were available, we could test for COVID-19 at public events, auditoriums, large gatherings and potentially even at home for self-testing. The results could be sent back to the appropriate public health system for coordination," said Rashid Bashir, a Professor of Bioengineering at the University of Illinois, Urbana-Champaign in the US.

In one of the common methods to test for the novel Coronavirus SARS-CoV-2, healthcare workers take a sample from patients with a long nasopharyngeal swab, which is put into a substance called viral transport media, and send to a lab for extracting, isolating, and multiplying the viral genetic material, the scientists said.

This viral RNA multiplication process, called RT-PCR, requires several temperature fluctuation cycles, specialised equipment, and trained personnel, said Brain Cunningham, another co-author of the study. In the current research, the scientists used a simpler process to analyse the viral transport media, called LAMP, which bypasses the RNA extraction and purification steps.

"LAMP only needs one temperature -- 65 C -- so it is much easier to control," said Anurup Ganguli, the first author of the study. "Also, LAMP works more robustly than PCR, especially when there are contaminants in the test sample. We can just briefly heat the sample, break open the virus, and detect the genetic sequence that specifically identifies SARS-CoV-2," Ganguli said.

When the researchers compared the LAMP assay with PCR, they found the results were in agreement, following which they documented the sensitivity and specificity of the LAMP test. The scientists then incorporated the assay onto a small 3D-printed cartridge that has two input slots for syringes -- one for the sample-containing viral transport media, one for the LAMP chemicals.

Once the two syringe components are injected, they react within the cartridge, the study noted. "We use modern, high speed additive manufacturing to make these cartridges. The entire thing can be quickly scaled up to hundreds of thousands of tests," said Bill King, another co-author of the study from the University of Illinois.

"Production scale-up is typically the biggest obstacle for commercial applications of microfluidic cartridges, and we can overcome that obstacle using this new approach. Modern additive manufacturing is elastic and scalable, and it can be ramped up very quickly compared with legacy manufacturing technologies," King said.

According to the researchers, the cartridge can be inserted into a hand-held portable instrument with a heating chamber, which heats the cartridge to 65 degrees Celsius for the duration of the reaction, and a smartphone cradle is in place for reading the results. In approximately 30 minutes, a positive result will emit fluorescent light, they said. "The reader illuminates the liquid compartments with light from blue LEDs, while the phone's rear-facing camera records a movie of the green fluorescent light being generated," Cunningham explained. The scientists noted that they are currently assessing whether the assay would work with saliva samples to eliminate the need for nasopharyngeal swabs.

*Source: PTI, ET-Health World, 02.09.2020 (Excerpts)*

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NATIONAL NEWS

## Finance Minister Nirmala Sitharaman says India lost dominant position in bulk drug export market due to 'predatory pricing'

India is trying to regain its leadership position in the Active Pharmaceutical Ingredient (API) market which it lost to a particular country due to 'predatory pricing', Finance Minister Nirmala Sitharaman said. In a webinar address on the 'Aatmanirbhar Bharat' organised by the Shyama Prasad Mookerjee Research Foundation, Sitharaman, without naming China, said that the particular country had eaten into India's bulk drug exports market.

"In bulk drug export, India has led the way for the last 10 years. India used to produce its own API. Gradually, through predatory pricing, this API production slipped out. Because of just one country, we lost the bases we had. Today, nearly 68 percent is dependent on one country from where we bring in APIs," she said, adding that India would be looking to restore the API production capacity.

Other than APIs, the Government would also look at increasing the manufacturing of basic diagnostics and medical testing equipment domestically, she said. "We have made sure incentives are given to people who will come and set up business to produce APIs and to manufacture such diagnostic equipment also," Sitharaman said.

Bulk drugs are the ingredients that give a drug its therapeutic effect. With the Narendra Modi Government pushing for self-reliance in Pharmaceuticals, the Government has in the last few months announced measures to incentivise production of various essential drug ingredients. This includes calls to set up bulk drug parks as well as a Production-Linked Incentive (PLI) scheme to build self reliance in over 50 critical Active Pharmaceutical Ingredients, including penicillin G, vitamin B1, dexamethasone, meropenem, atorvastatin and aspirin.

Other options, like a potential hike in import duties on some of these Active Pharmaceutical Ingredients (APIs), were also being studied to help domestic bulk drug firms compete with cheaper imports. To fuel the economy and get it back on track, public spending on infrastructure will need to increase in addition to a hike in rural area agriculture and non-agriculture spend, the Minister said.

*Source: ENS (Economic Bureau), The Indian Express, 12.09.2020 (Excerpts)*

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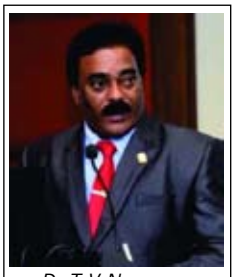
## Dr T V Narayana re-elected National President of Indian Pharmaceutical Association (IPA)


*Dr T V Narayana*

Dr T V Narayana has been re-elected as the National President of the Indian Pharmaceutical Association (IPA), the oldest and largest association of Pharmaceutical Professionals in the country, for the term 2020-2022. Dr T V Narayana has been the Vice President & Chairperson of Education Division of IPA since 2008. He is currently the Director & Principal of the Vikas Institute of Pharmaceutical Sciences, Rajahmundry and also the General Secretary of the Indian Pharmaceutical Congress Association (IPCA). With a brilliant stint of over three decades in academia, Dr Narayana brings with him an assorted mix of skill sets and capabilities that are essential for leading IPA.

The other office bearers for the term 2020-2022 include, Mr Suresh Khanna as National Honorary General Secretary, Dr Hemant Mondkar as Honorary Treasurer, Dr Alka Mukne as Editor – Pharma Times, Dr Divakar Goli as Editor - Indian Journal of Pharmaceutical Sciences,

Mrs Manjiri Gharat as Chairperson, – Community Pharmacy Division, Dr S Vidyadhara as Chairperson – Education Division, Dr R N Gupta as Chairperson –Hospital Pharmacy Division, Mr J Jayaseelan as Chairperson – Industrial Pharmacy Division and Dr Subhash Mandal as Chairperson – Regulatory Affairs Division.

*Source: IPA Press Release dated 11.09.2020*

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## COVID-19 vaccine likely by March 2021, will take it first if people have a 'trust deficit': Vardhan

*Union Health Minister Harsh Vardhan*

Union Minister Harsh Vardhan said that while there has been no date fixed on the availability of a potential Covid-19 vaccine, chances are it may be ready by the first quarter of 2021. He assured the vaccine will be first made available to those who need it the most, irrespective of their paying capacity. Vardhan further stated that the Government is taking full precautions in conducting the human trials of the vaccine and the officials are drawing up a detailed strategy on how to immunize majority of the population.

"Issues like vaccine security, cost, equity, cold-chain requirements, production timelines etc., are also been discussed intensely," he stated. On the availability of the vaccine and its authorization, Vardhan informed that Centre is considering emergency authorization of COVID-19 vaccination especially in the case of Senior Citizens and people working in high-risk settings. "This shall be done after a consensus has been reached", he said, according to an official statement.

To allay fears regarding the safety aspect of the vaccines, he said, "I shall be the first to offer myself for receiving COVID vaccine, if people have a trust deficit." He also noted that a safe and effective vaccine will help in establishing immunity to COVID-19 at much faster pace as compared to the natural infection.

It is hoped that a consensus will emerge in next few months over the desired level of protective herd immunity in any community, he stated. Elaborating on the vaccine candidates and their development in India, Vardhan added that Department of Bio Technology (DBT) as well as Indian Council of Medical Research (ICMR) have been pro-active in responding to the emerging situation to support advancement of vaccine candidates. India is actively partnering with Coalition for Epidemic Preparedness Innovations (CEPI) and trials at different phases are ongoing with respect to several vaccines in Indian laboratories (Private or Public) and hospitals.

The Health Minister was interacting and answering questions posed by his social media followers on the *'Sunday Samvad'* platform. Currently, India has three vaccine candidates, including country's first indigenous vaccine candidate Covaxin, which are in different phases of the clinical study, top ICMR scientist (Prof) Balram Bhargava informed earlier.

"So at the present moment, we have three Indian vaccine candidates which are in different phases of a clinical study. Studies for Phase 1 and 2 are to determine the safety and very early efficacy." The Covid-19 vaccine candidate Covaxin, developed by ICMR and Bharat Biotech, is currently in Phase I/II Human Trials and is being tested at 12 institutes across India.

For the vaccine candidate developed by AstraZeneca and Oxford University, Pharma major Serum Institute of India (SII) said it will resume the trials in India once Drugs Controller General of India (DCGI) gives it requisite permission. AstraZeneca PLC had on September 6 paused the trial of Coronavirus vaccine (recombinant) as a volunteer developed an unexplained illness.

It was also reported that the Clinical Trials had been put on hold in other countries including USA, UK, Brazil and South Africa. The third is a DNA vaccine of Pharma giant called Zydus Cadila. It has completed the Phase 1 study in India and has begun Phase 2 study at 11 sites and progressing well.

*Source: Livemint, 13.09.2020 (Excerpts)*

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## IDMA urges Finance Ministry to clarify on GST rate on Hand-Sanitizers and Alcohol-Based Hand-Rubs

The Pharmaceutical companies manufacturing hand-sanitizers and Alcohol-Based Hand-Rubs (ABHR), after obtaining drug licences from various State Drugs

Control departments, are being forced by the GST Intelligence wing to pay 18% GST for the products which, the manufacturers claim, are classified as drugs and covered under HSN code 3004 with a tariff rate of 12%.

In a communication to Nirmala Sitharaman, the Union Finance Minister and Chairman of the GST Council, the Indian Drug Manufacturers' Association (IDMA) has petitioned that the officials of the GST Intelligence wing in Chennai, Pondicherry and other parts of the country orally want them to pay GST at a rate of 18% claiming that the products fall under the HSN code 3808 which attracts 18% GST.

The association wanted urgent clarification from the Finance Minister on the applicability of GST rate, whether it is 12% or 18%, for hand sanitizers and ABHR. Further they sought the clarity of the HSN code under which the products are covered. The IDMA, the premier association of drug makers in the country, went on to say that the offices of the GST Intelligence wing are issuing summons to the sanitizer makers and putting tremendous pressure on them to make the payment at 18% saying that the products are classified as 'disinfectants' and not as 'medicament' to attract a lower rate of 12%. The drug makers informed the Minister that the departmental officials are of the view that hand sanitizers fall under chapter 3808 and it attracts 18% GST.

While briefing Pharmabiz about their grievances due to the regulatory challenges that they face during this pandemic situation, sources from the industry sector said hand sanitizers are manufactured under drug licences, hence they are medicament. The letter sent to Nirmala Sitharaman says that hand sanitizers contain pharmaceutical ingredients which have therapeutic and prophylactic properties. Further, the label of the product appears with the claim that the product 'kills germs' which means that the product is meant for medicinal purpose and not for cosmetic application. The product contains curative and preventive ingredients.

When contacted the Commissioner of the Central Board of Indirect Taxes and Customs (CBIC) in Chennai, N Padmashri the Commissioner said as per Government norms, the sanitizers have been classified into three categories, normal sanitizer, medical grade sanitizer and sanitizer disinfectant.

The first one (normal) comes under the HSN code 3402 2090 and 18% GST is charged. The second one (medical grade) falls under the GST tariff of 12% and its HSN code is 3004 9099. Third classification (disinfectant) is also charged a GST at a rate of 18% and it is the one that comes under the category of 3808 9400.

From the explanation of the Commissioner it is learnt that 18% GST is charged only for disinfectants and for the normal sanitizers. But sanitizers classified as 'medicament' are charged only 12%. IDMA's complaint to the Finance Minister is that the drug manufacturers in the country are manufacturing sanitizers under drug licences and the ingredients are having therapeutic and prophylactic properties, so the products come under the drug category and the applicability of GST is only 12%.

When asked about the alleged oral threat of GST Intelligence Wing to sanitizer makers asking for 18% GST, the Commissioner said she did not have any information on that hence unable to comment on it. To ensure whether sanitizers come under medicament or disinfectant, M Sivabalan, the Director of Drugs Control in Chennai, said manufacturing licence for sanitizers are given under drug category, so it comes under medicament.

*Source: Peethaambaran Kunnathoor, Pharmabiz, 15.09.2020*

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## India's Serum Institute says will resume COVID-19 vaccine Trials after DCGI nod

Serum Institute of India will resume Clinical Trials of AstraZeneca's COVID-19 vaccine candidate after getting the permission from the Drugs Controller General of India (DCGI), the Pune-based vaccine maker said on Saturday, 12.09.2020. Pharma giant AstraZeneca on Saturday, 12.09.2020 said that Clinical Trials for the AstraZeneca Oxford Coronavirus vaccine, AZD1222, have resumed in the UK following confirmation by the Medicines Health Regulatory Authority (MHRA) that the trials were safe.

"Once DCGI will give us the permission to restart the trials in India, we will resume the trials," Serum Institute of India (SII) said in a statement. In a tweet, SII CEO Adar Poonawalla said: "As I'd mentioned earlier, we should not jump to conclusions until the trials are fully concluded. The recent chain of events is a clear example why we should not bias the process and should respect the process till the end.

Good news, @UniofOxford." The human trials resumed days after a pause had been announced in the trials after an adverse reaction in one of the participants. Following the suspension, the DCGI directed Serum Institute of

India to suspend till further orders new recruitment in phase 2 and 3 Clinical Trials of the vaccine candidate. AstraZeneca and the University of Oxford, as the trial sponsor, on Saturday, 12.09.2020 said that they cannot disclose further medical information but confirmed that independent investigations concluded that the trials were safe to restart.

*Source: PTI, wionews, 12.09.2020 (Excerpts)*

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## NCISM Bill gets Parliament nod, Government appoints 10 Members to Board of Governors

The National Commission for Indian System of Medicine (NCISM) Bill 2019 has got the Parliament's nod which will strengthen and streamline the Profession of Practice in Ayurveda, Siddha and Unani (ASU) in the country, and will make the higher education in ASU streams into world class level. With the passage of the bill in Lok Sabha on Monday, 14.09.2020 last, the Indian Medicine Central Council Act 1970 has ceased to exist and the Central Council of Indian Medicine (CCIM) set up under IMCCA in 1971 is replaced by the National Commission.

Along with, the Parliament also passed 'The National Commission for Homoeopathy (NCH) Bill 2019'. On the lines of NCISM, the national council for homoeopathy will replace the Central Council of Homoeopathy (CCH) established by the Government in 1973 to supervise homeopathy education. Rajya Sabha had passed both the Bills on March 19 during the budget session this year.

According to the NCISM Bill 2019, the primary objective of the National Commission is to function for the development and regulation of all aspects relating to education, medical profession and medical institutions of Indian system of medicine in the country. Further, the commission should form Advisory Council to advise and make recommendations to the Commission. This clause is applicable to NCH also. The Government has appointed 10 persons to the Board of Governors for the NCISM including one as its Chairman. More members from different parts of the country will be selected to the National Commission later. Vaidya Jayanth Dev Pujari from Nagpur in Maharashtra is the Chairman of the Board of Governors.

While talking to Pharmabiz, the Chairman of the Board said besides further nomination of a few more members, three members are likely to be elected from national level. He said with the constitution of NCISM, the total structure of regulatory system of ISM education in the country will get a change and it will be par with international level. The higher education in Indian systems will encourage for increase in quality and boost researches in each stream.

Referring to the Bill, Vaidya Pujari said, "Although both the houses of Parliament have shown green signals for the constitution of NCISM, it will further take some time to form the full-fledged commission to come into force. Till then the already appointed 10 members will function. Government will incorporate people from different levels to the commission. However, it is a wise decision from the Government to form the NCISM as change was required to the total system of the Central Council of Indian Systems. The hitherto existed regulatory body, CCIM, was 50 years old. Now all is going to change," he told.

Dr K K Dwivedi Sampurnanand, a Member of the Board of Governors from Uttar Pradesh said the first meeting of the Board is likely to be held in this week and it will discuss the Rules and Regulations of the NCISM, after that only a uniform system of functioning will come into being. As per the Bills, NCISM and NCH, both the Commissions will constitute Advisory Councils which will have representations from each State and Union Territories. The councils will suggest ways for change of standards for medical education in each stream.

The Bill says that, on the lines of admission to modern medical education, there should be a uniform National Eligibility-cum-Entrance Test for admission to the degree and PG programs. Similarly, the Commission should hold a National Exit Test for granting licence to practice as Medical Practitioner of ISM. Vaidya Jayanth Pujari said all the Rules and Regulations were there already and they will continue without any change, but the structure of the regulatory mechanism is only going to be changed.

*Source: Peethaambaran Kunnathoor, Pharmabiz, 16.09.2020*

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## NPPA to roll out dashboard with helpline numbers of COVID-19 vaccine makers to facilitate its smooth supply & curb black marketing

In a bid to ensure smooth supply of COVID-19 vaccines and curb their black marketing, the National Pharmaceutical Pricing Authority (NPPA) is set to launch a dashboard containing the helpline numbers of vaccine

manufacturers. Once the vaccines get regulatory clearance, their manufacturers' helpline numbers will be uploaded on the dashboard which has been developed recently, said sources.

Taking a cue from black marketing of COVID-19 drugs namely Remdesivir and Tocilizumab in the wake of their short supply, the NPPA has initiated steps to put in place a mechanism to ensure hassle-free supply of COVID-19 vaccines and rein in unethical marketing practices of the vaccines. It has already put in place a dashboard containing helpline numbers of manufacturers of Remdesivir and Tocilizumab to ensure patients' access to the drugs.

COVID-19 vaccine 'Sputnik V' which was released by Russia into public recently is likely to be available in India if it clears all the safety and regulatory compliance in the country. By then the central Government needs to be equipped with requisite facilities and supply channels to protect people from overcharging. The NPPA's move is in that direction, sources added.

The Government of India is considering Russia's offer to conduct phase-3 trials and manufacture its COVID-19 vaccine. Russia's both offers are under consideration, said Dr V K Paul, Member (Health) Niti Aayog, who also chairs the national expert group on COVID-19 vaccine administration. He said that Indian scientists have looked at the data on Phase 1 and phase 2 Clinical Trials of Sputnik V. "We are looking at Phase-3 trial or bridging studies, as per requirements of the regulatory system, to be facilitated by the Government of India," added Dr Paul.

A number of Indian firms are looking into Russia's proposal. It is a win-win situation for India and the world as the county has capability to manufacture high quality vaccines in large quantities, he stated. The Russian vaccine developed by Gamaleya Research Institute of Epidemiology and Microbiology and the Russian Direct Investment Fund (RDIF) has triggered a strong immune response during phase 1 and phase 2 Clinical Trials. Russia has submitted comprehensive data on COVID-19 vaccine's safety and efficacy to Indian authorities for analysis.

Besides this, three COVID-19 vaccines are currently in phase II trials in the country. Bharat Biotech is set to start phase II trials of its COVID-19 vaccine candidate 'Covaxin' this week. Covishield by University of Oxford-AstraZeneca has entered phase II Clinical Trials in India on August 26. Serum Institute of India is conducting the vaccine trial on 1,600 participants at 17 sites across the country. 'ZyCov-D' by Zydus Cadila also moved to the second phase of Clinical Trials on August 6. Zydus is considering building a capacity to produce 100 million doses if phase II trials are successful. It is learnt that the Government is in talks with stakeholders to enhance access to COVID-19 vaccines, reduce their costs and ease their supply.

Commenting on the NPPA's preparedness to smoothen vaccine supply, Dr Om Shrivastav, Director, infectious diseases, Jaslok Hospital & Research Centre said "The NPPA is going to need to take stringent measures for the plan it has in having mechanisms ready to ease COVID-19 vaccine supply while it may appear to little bit premature to prepare for vaccine supply. Whenever the vaccine is available, it must be given to ones who are most deserving such as elderly people, armed forces, healthcare workers and those who are more prone to get infection because of systemic illnesses. They are the ones who deserve to get the first shot of the vaccine. There needed to be a mechanism so that unethical practices may not be employed in the distribution of the vaccines."

Talking about Indian Immunologicals' preparedness in making COVID-19 vaccine accessible and affordable, Dr Prasanna Deshpande, Deputy Managing Director, Indian Immunologicals Ltd said, "Since the beginning, the mission of Indian Immunologicals has always been to develop safe and effective vaccines for human and animal health and to supply them at an affordable price. In the case of COVID-19 vaccine development also, Indian Immunologicals and Griffith University are jointly developing a live attenuated vaccine using codon de-optimisation technology. Live attenuated vaccines are more likely to provide long-term immune protection."

*Source: Laxmi Yadav, Pharmabiz, 12.09.2020*

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## A Responsible Move on CSR

The Union Ministry of Corporate Affairs has recently amended the Corporate Social Responsibility (CSR) Rules under the Companies Law to provide the much needed fillip for funding for developing new vaccines, drugs and medical devices related to the Coronavirus pandemic. With the latest amendments, companies engaged in Research and Development activity of new vaccines, drugs and medical devices in their normal course of business have been allowed to undertake these R&D activities related to COVID-19 under the CSR ambit.

The provision will be available for the next three fiscal years from 2020-21 to 2022-23. This means that

money spent on R&D activities related to COVID-19 will be considered as CSR spending under the Companies Act, 2013. Under the Act, certain categories of profitable companies are required to shell out at least 2 percent of their three-year annual average net profit towards CSR activities in a particular financial year. The companies are required to carry out R&D in collaboration with any of the institutes or organizations mentioned in item (ix) of Schedule VII to the Act.

The item (ix) of Schedule VII includes public funded Universities, Indian Institute of Technology (IITs), National Laboratories and Autonomous Bodies established under the auspices of Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), Department of Atomic Energy (DAE), Defence Research and Development Organisation (DRDO), Department of Biotechnology (DBT), Department of Science and Technology (DST), Ministry of Electronics and Information Technology. This is not the first time the CSR Rule is being amended.

In fact, CSR rules were modified last year also to support research in publicly funded institutions and incubators. But Pharmaceutical companies in the country could not fund Pharma R&D under the CSR ambit as the CSR support was extended to organizations working in areas outside companies' 'normal course of business'. Of course, the Central Government's latest initiative will expedite R&D activities in finding a cure for COVID-19 pandemic as the amended law will allow Pharmaceutical and medical device companies to support COVID-19 R&D, collaboratively, in publicly funded institutions.

The latest amendments will definitely prove to be an encouragement to medical research and pharmaceutical industry in India which is engaged in the Research and Development of vaccine or drugs for the treatment of COVID-19 which is spreading like wildfire in the country. This initiative will surely boost the funding requirements for developing COVID-19 vaccines or drugs domestically. At a time when the country is reeling under the rage of this highly infectious disease, the Central Government's initiative is in right direction to boost India's efforts to find effective medicines and vaccines against COVID-19 which has taken a toll of more than 70,000 precious lives, and still counting.

*Source: Ramesh Shankar, Pharmabiz-Editorial 09.09.2020*

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## MSF urges Government authorities to include Patented Drugs in upcoming NLEM

The Médecins Sans Frontières (MSF) has asked Government authorities to consider the inclusion of patented as well as non-patented drugs in the upcoming National List of Essential Medicines (NLEM) at the Stakeholders National Consultation meeting, held on August 17, 2020, for the revision of NLEM 2015. Besides, the organisation has also proposed the following points to be considered for inclusion in upcoming NLEM:

**1) Inclusion in NLEM should not be linked to patent status:**

Essentiality of the medicine for the health system cannot be determined by its patent status, and there is no co-relation (linkage) between the two. The selection criteria of WHO's EML provides Guidance to the Member States on prioritising medicines for National Health Systems and has evolved since its inception. Since 2015 onwards, we have seen a shift in the WHO's policy. Patented medicines for Hepatitis C, several cancers and tuberculosis were included in the WHO EML by the Expert Committee on the Selection and Use of Essential Medicines, which recommends and should be included on the EML. New medicines added to the EML in May 2015 presented a key opportunity to exercise the EML as a tool for access.

**2) Exclusion of patented drugs from Price Control undermines right to affordable lifesaving essential medicines under Article 21:**

According to the 2019 DPCO amendment, Pharma Corporations can enjoy their monopoly by merely importing the patented medicine and setting a price as high as the richest people in India will pay, without the necessary checks on pricing to make them affordable for all patients and the health system. The amendment weakens the public health safeguards laid out under the Patents Act and further violates the right to affordable medicines under Article 21 of the Constitution of India.

**3) Example of patented drugs that should be included in the NLEM but would be exempt from Price Control:**

The two new antibiotics for drug-resistant tuberculosis (DR-TB) – bedaquiline and delamanid as they are part of WHO's EML. These medicines are also included in the Programmatic Management of Drug-Resistant

TB Guidelines (PMDT), 2019 under the National Tuberculosis Elimination Program (NTEP) of the Government of India. Due to the inclusion of these new TB drugs in WHO and national Guidelines, DR-TB patients are entitled to an injection-free regimen, and if available, can be treated in the safety of their homes amidst COVID-19 without the devastating side-effects such as hearing loss from amino glycosides (injectables).

Considering the unmet medical needs of DR-TB patients, these new DR-TB medicines should be included in India's NLEM and brought under Price Control and or/Compulsory Licensing. Divulging more information about the meeting, Leena Menghaney, Head-South Asia, MSF Access Campaign, said, "The representative of the Organisation of Pharmaceutical Producers of India (OPPI) went on to argue that 'patented drugs serve only a small proportion of the patient population, so, don't include them.

However, we strongly feel that this approach needs to be revisited. The decision to exclude patented medicines as a category/class from the NLEM may have a detrimental impact on the right to health. 15 years into the World Trade Organisation's (WTO) mandated product patent regime in India, new essential medicines are being patented in India every year and are priced out of reach for individual patients."

She commented, "In terms of additions to the upcoming NLEM, the Government should take into consideration of facilitating the administration of insulin as well. Along with this, different formulations of insulin should be added in the upcoming NLEM, for e.g. pen devices, and insulin in cartridges. The newer generation of analogue insulin has been submitted twice to the WHO EML (2017, 2019).

They could not be added as there is a lack of evidence for therapeutic or safety benefit above the human insulin, especially in low resourced and humanitarian settings. We strongly encourage the Government of India to participate in the generation of such evidence, to help enable both the WHO Expert Committee as well as India's Standing National Committee on Medicines (SNCM) to take an informed decision on their inclusion as essential medicines in the coming years."

"Understanding the unmet medical need in India, we hope that our recommendations will be taken on board and raised concerns will be addressed by the MoH&FW and the SNCM. And we hope for continued engagement with the committee as the revision of NLEM progresses." However, Government representatives mentioned that in the upcoming policy 'patented medicines are not considered for NLEM unless there is a strong/compelling reason to do so'.

*Source: Express Pharma, 15.09.2020*

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## Indian Pharma calls for Guidance document on disposal of expiry dated Drugs

The Union Government will need to formulate a Guidance document on disposal of unused and expiry dated drugs as there is a pressing need for a system of collection, segregation and disposal of Pharmaceutical products at the domestic as well as specific stages, said Atul Nasa, Deputy Drugs Controller, Controlling Authority & Licensing Authority, Delhi Drugs Control Department.

The collection and safe disposal system for unused and expired medicines must be developed and implemented at the local Government level, he added. Further there should be monitoring of large scale disposal of unused pharmaceuticals, Nasa said at an IDMA webinar on 'Disposal of Expired Medicines,' on the occasion of *Swatchhata Pakhwada* Fortnight Programme being conducted from September 1 to 15, 2020.

Development of a nationwide awareness on the ill-effects of unsafe and inappropriate disposal mechanism of drugs needs to be addressed. Moreover, consumers should be responsible to reduce unnecessary medicine purchase or consumption. The need of the hour is to dispose safe and prevent abuse, noted Nasa. Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, Mumbai, said, "India had taken up this initiative and brought about Guidelines in 2005. There are international norms on drugs that could be flushed to prevent accidental consumption. It is time for India to have a 'drug take back' programme for the industry."

**In a telecon post the webinar, Daara B Patel, Secretary General, IDMA told that there is awareness among consumers on medicine disposal. During the pandemic lockdown, households had stocked up on medicines and are now apprehensive about how to dispose of unused drugs. Therefore, there is need for a Guidance for consumers.**

**NGOs and like-minded individuals have plans to source large, tamper-proof boxes sponsored by Pharma companies**

**or other organisations. These will be placed across all healthcare centres and pharmacy outlets enabling users to discard unused and expiry drugs. These can be dispatched to any Pharma distributor who could in turn send them to drug manufacturers. IDMA members are already toying with this concept and will support this initiative, said Patel.**

Kaushik Deasi, Pharma Consultant who was not part of the event noted that there is no specific Guidance in the D&C Act on handling of expiry dated drugs, except that companies normally keep the expiry dated products in controlled temperature for year as a retention sample and then destroy it. In order to bring in a system for disposal of such drugs, Pharma companies have drafted their own internal processes, he added.

Currently, only WHO has issued Guidelines to handle expiry drugs during any epidemic where large quantity of medicines are procured by the Government. It has highlighted that drugs will have to be incinerated ensuring no impact on environment, humans, animals and contamination of soil. But now, COVID-19 is a pandemic. There is definitely a need for WHO to provide a global Guidance on the management of unused and date expiry drugs. Often, poor drug storage practices lead to its spoilage and they require to be discarded, said Desai.

*Source: Nandita Vijay, Pharmabiz, 14.09.2020*

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## Pharma MSMEs raise concern as Government begins anti-dumping probe into imports of Chinese foil stock among other Aluminium flat rolled products

The Union Commerce Ministry has initiated anti-dumping investigation into imports of certain Chinese flat rolled products of aluminium including foil stock which is used in Pharmaceutical packaging following a domestic manufacturer's appeal for imposition of levy. The probe was initiated by the Commerce Ministry's investigation arm Directorate General of Trade Remedies (DGTR) following a complaint by Hindalco Industries, alleging injury to the domestic industry due to the dumped goods.

The DGTR will investigate dumping from fiscal year 2016-17 to fiscal year 2019-20. The complainant stated that imports are causing threat of material injury, considering significant increase in imports as compared to base year, significant surplus capacities in subject country, high export orientation of producers in subject country, and ability to scale up production in short span. All these factors go on to show that imports are causing threat of material injury to the domestic industry.

"There is sufficient prima facie evidence of injury being caused to the domestic industry by dumped imports of subject goods from China. Hence the authority has initiated investigation to determine the existence, degree and effect of alleged dumping in respect of the product under consideration originating and exported from China and to recommend the amount of anti-dumping duty, which if levied, would be adequate to remove the injury to the domestic industry," stated DGTR in a Notification.

Earlier on May 17, 2017 the Finance Ministry had imposed anti-dumping duty ranging from US$ 0.69 per kilogram to US$ 1.63 per kilogram on aluminium foil imports from China for five years.

Commenting on the anti-dumping probe into import of aluminium foil among other flat rolled products of aluminium from China, Amit Chawla, Director of McW Healthcare said "The aluminium foil is significantly used in Pharmaceutical packaging. The anti-dumping duty on import of aluminium foil from China is in force since May 2017. The recent anti-dumping duty probe may lead to extension of levy on imported Chinese aluminium foil. Though we are supporting the Government's move, the extension of anti-dumping duty on imported foil may have consequences for Pharma MSMEs of the country who are mostly exporting low value products in the wake of the liquidity crisis faced by them since the COVID-19 outbreak."

He said the prices of PVC used in Pharma packaging have gone up by Rs.15 a kg since last few months. Earlier it used to cost Rs.105 a kg, now it has increased to Rs.120 a kg. The further increase in prices of aluminium foil is expected after DGTR comes out with an anti-dumping probe report thus causing a double whammy to the industry especially MSME players. The increase in prices of packaging materials will lead to rise in cost of formulations. It will put MSME exporters at disadvantage in the global market thus affecting Pharma export in the long run, he concluded.

*Source: Laxmi Yadav, Pharmabiz, 14.09.2020*

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## Pharma sector offers potential for high exports but India overly relies on China for Drug Ingredients

RBI Governor Shaktikanta Das said that the Drugs and Pharmaceuticals sector is among the sunrise sectors that offer the potential for higher exports in the post-COVID period. With strong drug manufacturing expertise at low cost, India is one of the largest suppliers of generic drugs and vaccines and some Indian manufacturers have already entered into new partnerships with Global Pharma companies to produce vaccines on a large scale, Shaktikanta Das added.

However, India heavily depends on China for raw materials required in drug manufacturing, which is severely affected due to the lockdowns and supply chain disruptions. There are 58 Active Pharmaceutical Ingredients (APIs) for which the country is heavily dependent on China, D V Sadananda Gowda, Minister of Chemicals & Fertilizers, said in a reply to a question in Lok Sabha.

In FY 2017-18, 68.62 percent of raw materials were imported from China, while the percentage remained 66.53 percent and 72.4 percent in the next two fiscal years, according to the Parliament papers. Also, the restrictions on movement of people and lockdown enforced in various places, logistic issues, etc, are believed to have impacted the supply of raw materials from China.

Further, the Central Drugs Standard Control Organisation (CDSCO) is reviewing all such applications for the import of APIs in an expeditious manner for which India is highly dependent on China. However, in an effort to overcome the over-dependence on China, the Government has approved an investment package for the promotion of bulk drug parks and a Production-Linked Incentive scheme is in place to enhance domestic production of drug intermediates and Active Pharmaceutical Ingredients.

Meanwhile, in order to establish India as a global leader in Pharma, efforts should be made to create a supportive regulatory set-up with a simplified pricing/drug approval process and expedited investment approvals, Arvind Sharma, Partner, Shardul Amarchand Mangaldas & Co, had told Financial Express Online. The immediate focus of India's Pharma sector is to boost domestic capacities and capitalize on any opportunities which come in its way in case global players shift their base from China to India, he had added

*Source: Samrat Sharma, Financial Express, 17.09.2020*

## Union Health Secretary, Industries & Internal Trade Secretary and Secretary Pharmaceuticals urge 7 Big States to ensure adequate Oxygen availability in all Healthcare Facilities

The Union Health Ministry held a virtual meeting where Union Health Secretary, Secretary DPIIT and Secretary Pharmaceuticals participated. State Health Secretaries and Industries Secretaries of Maharashtra, Andhra Pradesh, Karnataka, Telangana, Gujarat, Rajasthan and Madhya Pradesh also participated in the meeting. The aim of the meeting was to ensure adequate Oxygen availability in all healthcare facilities in these States & unrestricted intra as well as inter State movement of oxygen.

In the end, all the participants were addressed by the Union Minister for Commerce & Industry, and Railways Shri Piyush Goyal.

The States were specifically advised to:

1. Ensure facility-wise/hospital-wise oxygen inventory management and advance planning for timely replenishment so that there are no stockout.
2. Ensure that no restriction is imposed on the movement of Medical Oxygen between States/UTs.
3. Provision of "Green Corridor" for Liquid Medical Oxygen (LMO) Tankers within the cities.
4 Hospitals and institutions have long term tender/ contract agreement for supply of Oxygen with oxygen manufacturers, which need to be honoured. Hence, States must not impose restrictions on free movement of Oxygen.
5. Ensure timely payment of the **due bills** to the manufacturers and supplier to maintain uninterrupted supply of oxygen.
6. Improve power supply infrastructure and ensure uninterrupted supply to Oxygen Manufacturing Units.
7. Ensure proper disinfection of Oxygen cylinders as per protocols while sending cylinders to fillers of Oxygen.
8. Effective coordination with steel plants for Oxygen procurement since steel plants provide approx 550 MT/day oxygen in addition to oxygen manufacturers who provide 6400 MT.

*Source: PIB, Union Health Ministry Press Release, 13.09.2020*

## Raw materials crisis hit Pharma Production in Bangladesh

The disruption of supply of raw material amid the Coronavirus pandemic has already been hit the drug manufacturing Pharmaceutical factories throughout the country, which may hike price of the life saving drugs. The crisis was originated due to dependency on import of the raw materials from some countries like India, China and South Korea, said the sources of the Directorate General of Health Services (DGHS).

According to the Bangladesh Association of Pharmaceutical Industry (BAPI), over 97 percent of raw materials for manufacturing drugs are import-dependent. Some 40 percent comes from China, 30 percent from India, 10 percent from Korea and the rest is imported from Europe, the United States and Japan. Earlier, the countries have issued bar to export of generic drugs for the ongoing Coronavirus pandemic, BAPI mentioned. Some medicine manufacturing companies are facing the severe crisis of raw materials in last two couple of months after decreasing the previous stocks, said insider sources of the Pharmacuticals industry. Even many companies to follow the policy of refrain to produce the medicines for Hepatitis, blood pressure and acidity, they said. The owners of drug manufacturing companies feared that the Coronavirus crisis lingers, the Pharma industry will stop the production of drug due to the raw material crisis that may hit the international drug market.

The cheapest home of raw materials is China, India and South Korea. But being an epicentre of the Coronavirus, the domestic medicine businesses with the rest of the world have almost closed. If we bound to import from alternative sources by paying of the high cost, then we have no alternative to hike the cost of medicine, they said. M Shafiuzzaman, General Secretary to the BAPI, told the Daily Industry, "We will opt to alternative way to run the business if India and China do not release the bar to export their raw materials of drug production amid the ongoing Coronavirus outbreak. Even the companies may hike the price of medicines to carry out the cost of production and marketing." Moreover, raw materials for all medicines might not be available in the European market then the medicine business face severe crisis, he continued. It has been known to that some companies have refrained to produce for some drugs due to lack of raw materials, he added. "If the standoff in exporting countries to continue for two or three more months, there will be a shortage of Pharma raw materials, said Major General Mahbubur Rahman, Director General of the Directorate General of Drug Administration.

The drug manufacturers had been asked to look for alternatives regarding the import of Pharma raw materials to face the ongoing crisis, he said. Mohammad Mohsin, General Manager at ACI Pharmaceuticals, said, "Maximum companies have stocks of raw materials that may not possible to run the production for all types of drugs. As imports from China and India remain suspended, we are looking for alternative markets such as the US and European countries. However, there is uncertainty over those markets too due to Coronavirus outbreak." Abdur Rouf Khan, Managing Director of Opsonin Pharma Limited, said, "From till now, we are facing much crisis of raw materials for running the production." Mizanur Rahman, Executive Director (Operation) of the Square Pharmaceuticals, said, "We are trying to import the raw materials from European countries as alternatives to China and India". Many companies also are trying to reach out to different European sources for the import of some items. But it will cost more to bring raw materials from Europe, he said.

*Source: Md Joynal Abedin Khan, Daily Industry News, 15.09.2020*

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# How to fix Indian Pharma's Chinese import problem


*Satish Reddy, Chairman of Dr Reddy's Laboratories, and President, Indian Pharmaceutical Alliance Image: Harsha Vadlamani for Forbes India*

A Global phenomenon that the Covid-19 pandemic exposed was the world's reliance on China for various manufactured goods and raw materials. For India, its dependence on its eastern neighbour for numerous goods—electronics and electricals, automobile components and even Personal Protective Equipment (PPEs)—was a stark reminder of the country's lack of manufacturing prowess.

One of the sectors in which this was acutely felt was the Pharma industry, which imports almost 70 percent of its requirement of APIs (Active Pharmaceutical Ingredient)—also known as bulk drugs, they are the active ingredient in medicines—from China. India imports APIs from the US (4 percent), Italy (3 percent) and Singapore and Hong Kong (2 percent each) as well.

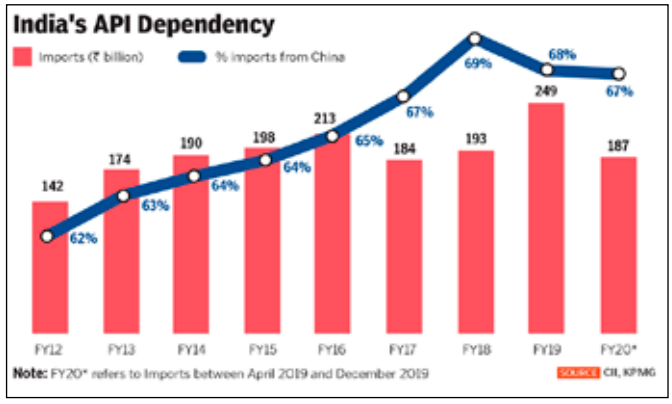
This, despite India contributing 20 percent of the world's generic medicines in terms of volume, and supplying more than 60 percent of the Globe's demand for various vaccines and antiretroviral drugs. India meets 25 percent of the UK's demand for medicines, and one in three pills consumed in the US. And yet, India's import of APIs has only kept rising: It has increased by a CAGR of 8.3 percent between 2012 and 2019.

This, however, was not always the case. In the Indian Pharma industry, the movement to be *atmanirbhar*, or self-reliant, began decades ago with visionaries who are responsible for making Indian Pharma an industry to reckon with globally. These include K Anji Reddy, who founded Dr Reddy's Labs in 1984, and Yusuf Hamied under whom Cipla took shape in the same year (although it was nationalist father Khawaja Abdul Hamied who founded The Chemical, Industrial & Pharmaceuticals Labs pre-Independence). Then, there was inventor and chemist A V Rama Rao, who founded Avra Labs in 1995, to make APIs.

Making medicines locally and for India's millions were the Goals of these Pharma futurists. And their efforts have paid off. In the early 1970s, for instance, the multinationals controlled over two-thirds of the Indian Pharma market. Today, it's the Indian companies that call the shots locally, thanks to the early efforts to make APIs. Dr Reddy's, for instance, started by producing methyldopa API, and by 1990 had become the first Indian company to export Norfloxacin and Ciprofloxacin to Europe and East Asia.

In a presentation on the Indian Pharma industry in 2005 to commemorate Rama Rao's 70th birthday in Hyderabad, Hamied said: "When I joined the Pharma industry in 1960, the label 'Made in India' was not acceptable internationally." He then went on to outline how the API industry took shape in India: "In 1960 itself, I was influenced by a publication in 1959 of Prof R N Chakravorthy, who discovered the existence of Diascoria species in Northern India, which yielded Diosgenin, the precursor to steroids.

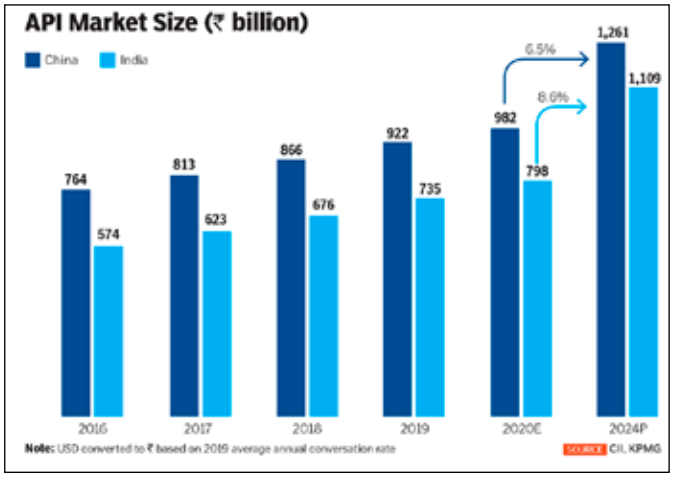
As some of these, such as testosterone and progesterone, were not covered under existing patents, they could be produced within the country. Thus started the synthetic API manufacture in my company."




The big leg-up, though, came in the early 1970s when the Patents Act was modified, abolishing product

patents, and allowing the Indian Pharma industry to manufacture and market in India almost any drug available internationally. And that set the ground for Indian Pharma players to move, over the decades, from APIs to finished doses, complex generics and biosimilars. There have, of course, been setbacks, particularly in new drug discovery, raps from the US FDA for inadequate manufacturing facilities, and a couple of huge Corporate Governance blowouts. And then there was China's big move into APIs sometime in the 1990s.

As China began to invest in its manufacturing capabilities, it began to gain a dominant position in the API market as well. Government policies and incentives led to the ease of doing business in the country, and the setting up of facilities to manufacture medicines in bulk. "Once China entered the API market, it was able to rapidly attain better cost structures through Government funding, tax incentives and economies of scale," says Satish Reddy, Chairman of Dr Reddy's Laboratories, and President of the Indian Pharmaceutical Alliance (IPA).




"China started encouraging and helping its API industry by giving economic incentives and building large-scale plants, making its manufacturers significantly cheaper than Indian players, especially in large volume and fermentation-based products," says Sanjay Singh, Partner, Deal Advisory and Head, Life Sciences, KPMG in India. "So, Indian companies started moving away from APIs and instead focussed on the finished formulations." Indian API manufacturers today include Dr Reddy's, Aurobindo Pharma, Cipla, Sun Pharma, Lupin and Ranbaxy, in a sector that is highly fragmented.

The ongoing pandemic has now triggered a rethink of the Pharma industry's reliance on Chinese imports. "The entire world is revisiting its dependence on a single source of imports," says Sudarshan Jain, Secretary-General of IPA. "But the Indian Pharma industry has also wanted to revive the bulk drugs industry over the last few years. Covid-19 has accelerated the need and has provided the impetus to formulate new APIs or KSM (Key Starting Material) policy."

Prime Minister Narendra Modi announced on March 21 a Rs.6,940-crore scheme to reduce dependency on China and boost domestic manufacturing of APIs over the next eight years. The scheme will cover 53 crucial APIs and KSMs for which India is now critically dependent on imports. Another Rs.3,000 crore was allocated to set up three bulk drug parks over the next five years.

*Samina Hamied, executive vice chairperson, Cipla*

The Pharma industry, however, will need more than that to become self-reliant in APIs. "Producing lower cost bulk drugs in India requires strategic initiatives and can only be possible through supportive policies that will make API manufacturing in India a viable option," says Samina Hamied, Executive Vice Chairperson, Cipla. "Sustainable Production Linked Incentives (PLIs) must be provided at a much larger scale; there should be focus on ease of doing business, incentives and subsidies, infrastructure development and technical capabilities."

Hamied's views echo an April 2020 report titled 'Indian API industry—Reaching the full potential' by KPMG and the Confederation of Indian Industry (CII). It says while India's strengths lie in world-class technological capabilities, strong chemical industry, skilled workforce and high quality and manufacturing standards, its challenges include inadequate infrastructure, utilities and Research and Development support, low Government support and

multiple regulatory bodies, high cost of finance, and delays in land acquisition and environmental clearances.

"The Government's moves to promote domestic manufacturing of critical bulk drugs are certainly a step in the right direction. However, much more can be done, especially regarding the provision of tax sops and expanding the list of molecules under the PLI scheme," adds Hamied.

To these requirements, Reddy adds the need for uninterrupted and low-price supply of utilities, and policy support in the form of favourable licence renewals and capital subsidies. "For the Pharma industry, loans are typically available at higher interest rates and over short tenures. The Government must make provisions like those in the infrastructure sector. First, to borrow money from insurance companies (and other funds) for longer tenures at attractive interest rates; second, to gain access to foreign currency funding through the external commercial borrowing route."

Jain also believes that giving the Pharma industry an infrastructure industry status will help in providing credit at competitive rates on a long term basis with enhanced limits. "India needs to build an ecosystem to support the growth of domestic bulk drug industry," he says.

**"The entire world is revisiting its dependence on a single source of imports."**

**SUDARSHAN JAIN**
SECRETARY-GENERAL, INDIAN PHARMACEUTICAL ALLIANCE

It is this ecosystem that China has developed through subsidies, loans at lower interest rates and tax holidays. The borrowing cost in China is at 4 to 5 percent, whereas in India it is close to 12 to 14 percent. China is also positioned higher on the World Bank's Ease of Doing Business Rankings: It jumped from rank 46 in 2018 to 31 in 2019, whereas India moved from rank 77 to 63. The KPMG-CII report says, "In China, it takes around one year to set up a factory, while in India it takes around three years or more to establish a factory for manufacturing APIs."

The report adds: "China has added modern medical and pharmaceutical industries (including industries supplying raw materials used for production of cell therapy drugs and large-scale cell culture products) to its list of encouraged industries.

These industries are taxed at a lower rate of 15 percent compared to 22 percent in India." Many Chinese Pharma plants are state-owned enterprises, which gives them various advantages with some degree of Government control.

Competing in the global API market, however, is a different ball game when compared to bulk-producing APIs for the domestic market. Pharma giants in the US and in Europe too are eyeing this segment.

New entrants too are taking advantage of the situation, with Eastman Kodak Co, a longtime American maker of photography-related chemicals and inks, securing a $765 million loan to manufacture generic drug APIs. The first-of-its-kind loan, to be repaid over 25 years, was granted under the Defense Production Act and is aimed at lowering America's reliance on API imports from countries such as India and China.

According to the *South China Morning Post*, China manufactures 40 percent of global APIs, supplying $54 billion worth of basic chemicals worldwide.

One of the factors that adds to this nature of Indian APIs is the highly fragmented nature of the country's Pharma industry. According to the report by KPMG and CII, in India there are around 1,500 plants that manufacture APIs. "In FY18, the top 14 to 16 players (including large

formulation companies) comprised just 16 to 17 percent of the total market share. Most large-and mid-sized players export to large and lucrative regulated markets in addition to serving the semi-regulated and domestic market. Other mid-to-small players mostly export to semi-regulated markets and operate in the price competitive domestic markets."

"While countries like India and China manufacture low-cost, high volume APIs, Europe and the US manufacture highly potent and specialised APIs," says Jain. "The pandemic has certainly revealed the need for self-sufficiency, but a collaborative approach is equally crucial.

Through strategic partnerships and collaborations, India can emerge a world leader in the API segment—manufacturing both critical as well as specialised APIs." Singh of KPMG says there is no quick solution to make India regain its position as an API manufacturer: "Regaining its position in the API industry and becoming resilient to China or any other country in the future requires consistent effort.

There should be a concerted and joint effort among the players of the pharmaceutical industry and the Government." Reddy too believes that the industry needs to come together to fulfil a common vision. "All stakeholders in the value chain (government, companies and ancillary industries) need to work cohesively to boost the sector and ensure that it is cost-competitive.

Only then can we become a globally dominant player in the API space," he says. Current anti-China sentiments around the world—in the wake of the Coronavirus pandemic, the implementation of new laws in Hong Kong, and long-lasting disputes over territories with neighbouring countries—might just work in favour of India's API industry, with other countries choosing it as an alternative source of importing low-cost APIs.

"The need to reignite the Indian API industry is of paramount importance, and the time is ripe for us to shift towards self-reliance. Having said that, the primary competitive advantage in the API space lies in cost leadership," says Reddy.

For India to gain this dominant position, several factors need to work in the country's favour over the next decade or so. Some of these factors include governmental and regulatory support, scaling up production to benefit from economies of scale, technological requirements, and tapping various cost advantages.

"Over the next decade, we must work with the government to enhance our production capabilities, invest in new technologies, increase automation, and leverage digital abilities to become more efficient. Only then can we continue to produce large volumes of APIs in a cost-effective manner to build and maintain a leadership position," says Reddy.

He adds that the country needs strong capabilities in biosimilar developments, proprietary products and novel technologies over the next 10 to 15 years. "We must create a vibrant innovation ecosystem, ensure availability of funding through government grants and venture capital to foster innovation, and facilitate collaboration or idea sharing between startups, universities and companies," he says.

*Source: www.forbesindia.com, 11.09.2020 (Excerpts)*

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