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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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Signet

The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 Issue No. 41 01 to 07 November 2022

IDMA ACTIVITIES:

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NDPS MATTERS:

MoEFCC MATTERS:

NATIONAL NEWS:

IDMA – GSB jointly with BCIL and SNL, USA Organizing Two day training programme on "Know-Your-Customer (KYC) best practices" for Indian Pharmaceutical industry at Hotel Courtyard by Marriott, Ahmedabad on November 14-15, 2022

Dear Member,

Greetings of the day!!!!!

We are pleased to inform you that Indian Drug Manufacturers' Association – Gujarat State Board (IDMA – GSB), jointly with Biotech Consortium India Limited (BCIL), New Delhi and Sandia National Laboratories (SNL), USA is organizing a 02 -day training programme on "**Know-Your-Customer (KYC) best practices**" for Indian Pharmaceutical industry at **Hotel Courtyard by Marriott, Ramdev Nagar Cross Road, Satellite Road, Ahmedabad on November 14-15, 2022.**

The objective of the training programme is to raise awareness of chemical weapons proliferation potential and to provide Know-your-customer best practices in the pharmaceutical industry. Details are in attached pamphlet. This training is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines). It is designed for **pharma industry managers, security officers, regulators, and transportation logistics company managers.** There are a total 20 slots and participants will be selected based on the activities undertaken by their organization in reference to the topic of the programme and the usefulness to the participant's organization thereby achieving the objective of the training.

Kindly note that expenses towards travel by Air (economy) / Train (2nd AC fare) / Taxi and boarding & lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by SNL/BCIL. More details and registration link are given in the attached pamphlet.

We request you to nominate concerned officials from your organization for the training programme.

There is No registration fee, however, the REGISTRATION IS MANDATORY for consideration in the training programme.

With kind regards,

Sumit J. Agrawal
Hon. Secretary
IDMA - GSB

Brief about organizing partners:

a) Biotech Consortium India Limited (BCIL), New Delhi

BCIL is a company set up in 1990 as an initiative of the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and All India Financial Institutions. As part of our activities, we are engaged in capacity building related to biosafety and chemical security issues. Such activities are undertaken in collaboration with national and international agencies.

b) Sandia National Laboratories (SNL), USA

SNL undertakes capacity building programmes, with support from US Department of State's Chemical Security Program (CSP).

Know-Your-Customer (KYC) Workshop for Indian Pharmaceutical Industry

14-15 November 2022, 09:00-17:00 IST

Announcement: Biotech Consortium India Limited (BCIL), Indian Drug Manufacturers' Association (IDMA) and Sandia National Laboratories (SNL) on behalf of the United States Department of State's Chemical Security Program (CSP) are organizing an in-person workshop to raise awareness of the chemical weapons (CW) proliferation potential of key pharmaceuticals and to provide Know-Your-Customer (KYC) best practices for the Indian Pharmaceutical industry. During this workshop participants will learn how to recognize suspicious purchase requests, develop customer vetting strategies, and understand regulations regarding the sale of 'dual use' chemicals that may be misused as chemical weapons. Additional topics will also include chemical security threats and chemicals of concern. The overarching focus of this event is to develop strategies that deny access to weaponizable pharmaceuticals. This workshop is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- Up to 20 Indian Pharma industry managers, security officers, regulators, and transportation logistics company managers.

Goal:

- Provide participants with the awareness of the chemical weapons proliferation potential of key pharmaceuticals, an understanding of KYC, and the knowledge and resources to implement KYC best practices and policies at their institutions to ensure their products are not acquired for illicit purposes.

Agenda:

14 November 2022	15 November 2022
• Welcome, Introduction, Goals • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern with exercise • Illicit Procurement Tactics with Case Studies	• Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Next Steps • Valedictory

Registration Site:
https://gcbs-events.sandia.gov/chemical-security-program/remote-know-your-customer-kyc-training-for-indian-pharmaceutical-industry

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Phone no. 98912 44434

The Impact of Regulations On Research and Development of Novel Nutraceutical Products

Dr R K Sanghavi, *Guest Editor, Indian Drugs*
 # Consultant - NeuroMarketing & Techno Regulatory (Pharma & Nutra)
 # Chairman – Nutraceutical Committee (IDMA)

Dear Reader,

'Colonial mindset' is a deeply embedded mindset that feels like the only norm to the perpetrators! Being victimized by the Food and Safety Standards Association of India (FSSAI) invoked 'Product Approval System' (PAS), albeit – and thankfully temporarily, is an akin example of the same.

Revisiting the history of PAS under the FSSAI will clarify the remnants of grey areas yet persisting in minds of many Food Business Operators (FBOs) in understanding the freedom gained via the final order of the apex court proclaimed on the historic date: 19th August 2015 – ironically the same month India acquired independence 68 years ago!

FSSAI by a mere circular (named as advisory) dated 31st January 2012 prophesied a system of product approval. Curiously the CDSCO also initiated a compulsory central licensing of Fixed Dose Combinations (FDCs) for State Licensing Authority (SLA) approved FDCs vide circular dated 15th January 2013 – after exact one year! In both instances the stakeholders fell prey by –

- Applying for approval of already marketed FSSAI 'Nutraceutical' (general term used for referring to: Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose and Prebiotic And Probiotic Food) products – a demand beyond the scope of Food Safety Standards Act (FSSA), 2006.
- Submitting safety and efficacy data of already marketed FDCs in Form 44 – a format meant for 'New Drug' application.

The healthcare industry paid the price for its folly arising from ignorance of FSSA and relevant sections of Drugs & Cosmetics Rules, 1940 on account of poor regulatory in-house system, or misleading advices by external consultants, or even hurriedly issued unclarified directives by the management themselves!

- PAS: The Nutraceutical Committee of IDMA, chaired by self, struggled over three and half years to squash the PAS imposed unlawfully by the FSSAI.

Dr R K Sanghavi *is Mumbai-based privately Consulting Physician since 40 years, who served in Ramakrishna Mission Hospital and many other charitable institutions. He has consulted Ethical & OTC verticals of Healthcare Industry in domains of Medico-Marketing, Training & Dr-lecturing, Techno-Legal & Regulatory, and is a member of the Subject Review Committee of NFI. Dr Sanghavi has near 200 company-years of exposure, experience and expertise by virtue of advising over 80 small, medium and large Pharma companies, including MNCs. He takes credit in pioneering the Nutraceutical vertical of Healthcare in India and was associated since early 1990s with first launch of most nutraceutical ingredients (antioxidants, glucosamine-chondroitin, omega-3 fatty acids, evening primrose oil, CoQ10, phytoestrogens, phospholipids, soluble fiber, St John's Wort, etc.) which have wide acceptance - having delivered near 300 lectures in India including overseas for specialist Drs. As Chairman of IDMA's Medical Committee for 15 years Dr Sanghavi had organized 20 conferences; he is currently chairing the Nutraceutical Committee since last one decade. Dr Sanghavi has successfully represented IDMA on all six occasions in various High Courts, and in Supreme Court, pertaining to banning of irrational FDCs (CDSCO) and implementation of an unjustifiable system of Product Approval for nutraceuticals (FSSAI).*

- SLA FDCs: The axe fell on close to 400 otherwise safely marketed FDCs over decades, including (and surprisingly) those even approved by the Drug Controller General of India (DCGI).

Even after all the bitter experiences, the FBOs are not all yet any wiser. In many interactions and meetings, it is surprising that the 'colonial mindset' stakeholders yet keep on enquiring on how to get their products approved and, also the marketing Companies insist from their manufacturing partners to get the 'Nutraceutical' product endorsed by FSSAI as a pre-condition to acceptance!!

In spite of painstaking explaining that the PAS is redundant and is castigated to the annals of history, the regulatory department personnel, even of multinational companies (MNCs), many a times continues debating on the same. This frustrating scenario defies logic and explanation and many of the FBOs are seemingly a decade behind in their thought process, and possibly even in their functioning.

What is PAS? What does it entail? Is it gainful?

When it pertains to drugs, an approval is a must - whether for single ingredient product or FDCs. Drugs are chemicals or biologics which are intended to treat disease and have been scientifically researched and lab-developed. This is not the case with Nutraceuticals.

The FSSAI primarily regulates food and even Nutraceuticals can be similarly considered since both (food as well as Nutraceuticals) are required on a daily basis to ensure well-being by fostering positive health. Does one require to have an approval for mixing milk and sugar with coffee powder? Does one require to take permission to admix onions, chillies with eggs and make an omelette? Is it mandatory to seek approval for sprinkling salt and pepper on the omelette? Similar to the obvious answers, the Nutraceutical ingredients are approved as listed in the FSSAI (Nutra) Regulations, 2022; even their safe / required amounts have been specified. Like in the specified case of coffee and egg omelette, the FBOs just need to suitably blend the right ingredients for delivering a particular targeted benefit and make the qualitatively formulated product available to the consumer.

It must be emphasized here that getting the product approved by FSSAI does not translate to success of a brand. Instead the FBOs must devote time and energy in deciding the right blend and optimal quantities of ingredients per serving size. There are dime-a-dozen Nutraceutical companies with each having 20 to over 200 products in their portfolio. If one is to truthfully assess the success of one's Nutraceutical basket it would not be surprising that the Company is to a large extent riding on the success of one or a mere couple of brands. The reasons for the same are –

- Poor composition – there are brands targeted for diabetes support but are devoid of critical ingredient for the same - chromium!!
- Miniscule amount of ingredients – 20 mg of curcuminoids per serving content is being trumpeted for the immune- boosting property of traditional 'haldi'!!
- Ineffective communication of merits – even doctors and Dieticians have not been exposed to Nutraceuticals in their degree / diploma curricula; hence, the ingredients' benefits certainly need to be nailed in hard in the minds of the consumer, who is but just a layman.

The need of the hour is to formulate worthwhile products and simultaneously once and for all bury the thought of product approval. Also FBOs need to take a wow to oppose any such possible system in guise if ever imposed by the FSSAI in future.

Courtesy: Indian Drugs, Editorial, 59 (09), September 2022

Disclaimer : The Guest Editorial above expresses the views of the individual expert. The opinions in this Guest Editorial does not reflect the views of IDMA, the Office Bearers or the Editorial Board of Indian Drugs. If you would like to comment on the Guest Editorial, please write to us at: publications@idmaindia.com

TDB invites proposals from Indian Companies ready for commercialization of Innovative Indigenous Technologies in 'Pharmaceuticals and Medical Devices'

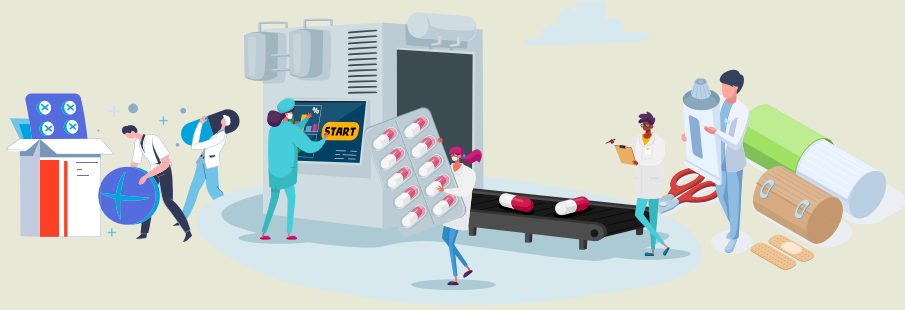
सत्यमेव जयते

Technology Development Board
Department of Science & Technology
Government of India

"Our objectives related to healthcare cannot be achieved without self-reliance in research, medicines and medical equipment related to biotechnology."

Enabling Commercialization in

'Pharmaceutical Innovations'



TDB invites proposals from Indian Companies ready for commercialization of Innovative Indigenous Technologies in 'Pharmacueticals and Medical Devices'

Key Features

- Financial Assistance to Indian Companies for Technology Commercialization
- Evaluation on the basis of Scientific, Technological, Financial and Commercial Merit
- Funding shall be in the form of Loan, Equity and/or Grants.

For more Details, Funding Guidelines & Proposal Submission, Visit - www.tdb.gov.in or scan given QR Code

Who are Eligible?

(a) Indian companies (as per Companies Act,1956 /2013)
(b) Start-ups with Recognition Certificate from DPIIT

For additional info, please contact: projectcoordinator2@tdb.gov.in

TDB is inviting application from industries in the pharmaceutical sector under the major thrust areas:

- **Novel Drugs, biosimilars, vaccines, APIs**
- ***Technological innovation in process and/or efficient manufacturing practices of pharmaceutical w**ith special emphasis on green technologies and technological platforms not available in India.
- **Import Substitution:** Domestic Manufacturing of critical Key Starting Materials (KSMs), Drug Intermediates, Active Pharmaceuticals Ingredients (APIs) etc that are heavily imported
- **Innovative Medical Devices**

*1. Under Green Technologies, emphasis is on at least 50% reduction in solvent consumption and zero discharge processes (including gases and solids), etc.

2. Under Process Innovation, continuous manufacturing, integrated processes, solvent free synthesis, use of membrane technologies for separation, complete backward integration, etc. will be given priority.

3. Under Technological Platforms not available in India, to cover manufacturing based on electrochemical routes, photochemical routes, enzymatic reactions, continuous crystallization, in-line sensing of polymorphs, in-situ generation and consumption of toxic intermediates etc.

However, the call is not limited to these areas only.

Last Date for application submission: 17th December 2022

● ● ●

End of National State of Emergency and Health Emergency in Peru

PXL/HO/Cir-057/2022-23, dated 28th October 2022

IDMA have received communication from Mr Udaya Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 28th October 2022 as reproduced below on the above subject.

Pharmexcil is in receipt of communication from Embassy of India in Lima, Peru regarding **Supreme Decree No. 130-2022-PCM** (copy of unofficial translation attached) as published on 27th October, 2022.

The Peruvian government vide its **Supreme Decree No. 130-2022-PCM** decided to put an end to the Health Emergency and National State of Emergency that started on 15th March, 2020 with **Supreme Decree 008-2020-SA. Supreme Decree No. 051-2020-EF** was published two days after **Supreme Decree 008-2020-SA** (copy of unofficial translation attached) which established a reduction on tariffs to zero on certain products ranging from chemicals, pharmaceuticals and medical devices to help during the health emergency.

The list included 65 items which further grew to 77 items vide **Supreme Decree No. 059-2020-EF dated 28 March, 2022.** This reduction on tariff duties were extended automatically until 24th February, 2023 with the extension of the Health emergency on 16 August, 2022 vide **Supreme Decree 015-2022-SA.**

As on 27th October 2022, the Peruvian government vide **Supreme Decree No. 130-2022-PCM** decided to finalize the health emergency and the national state of emergency, derogating **Supreme Decree No. 015-2022-SA** (copy of unofficial translation attached) and automatically **S.D. 059-2020-EF** (copy of unofficial translation attached along with Annexure), hence restoring the tariff duties on the 77 items with the benefit. The original tariff duties in some of the products are 0%, 6% or 11%.

Member companies having business operations in Peru are requested to take note of this important information and refer the enclosed list of products/decrees for detailed information on the subject.

• • •

Circular on Public Notice for export/import certificates - CBN

Dear Member,

IDMA would once again like to inform its members that pursuant to IDMA's representation on Digitalisation of Import / Export Permits, Central Bureau of Narcotics (CBN), Gwalior had issued a Public Notice, dated February 8th, 2022 requiring all Companies and Traders engaged in the export and import of Narcotic, Psychotropic and Controlled substances to register on the ICEGATE portal, to avail the benefits of e-Sanchit services of the Customs Department. It has been observed that only a few companies have registered on the e-Sanchit portal.

Going forward, CBN will upload the export and import certificates ONLY onto e-Sanchit and physical couriering of such permits would be discontinued. Hence, all Companies are requested to **immediately register** on ICEGATE and share the beneficiary code, as instructed in the Public notice attached, herewith.

However, application for export/import authorisations would continue as per January 13th Public Notice and complete digitalisation would only be achieved, after amendment of NDPS Rules and RCS Order.

Members who are engaged in the export and import of Narcotic, Psychotropic and Controlled substances are requested to register on the e-Sanchit portal.

Thanks & regards,

Daara B Patel
Secretary – General

भारत सरकार
वित्त मंत्रालय
केंद्रीय नारकोटिक्स ब्यूरो
19, माल रोड, मोरार, ग्वालियर- 474006

Government of India
Ministry of Finance
Central Bureau of Narcotics
19,The Mall, Morar, Gwalior – 474006

☎(PBX) : (91) 751-2368996/ 2368997; **E-MAIL: narcommr@cbn.nic.in, supdt-online@cbn.nic.in**

F. No. XVI/13/20/PC/Online/2018- **Dated, the 08th February 2022**

PUBLIC NOTICE

Reference is invited to Public Notice No. 11/2019 dated 12th July 2019 wherein all the beneficiaries who require to obtain export authorizations, import certificates for import/export of narcotic drugs, psychotropic substances and NOCs for import/ export of precursor chemicals (controlled substances) are requested to get themselves registered at ICEGATE portal to avail the benefits of hassle free services of eSANCHIT. This will enable to speed up the process of clearance of export/ import goods from the Customs.

Once they get registered with the ICEATE portal they are requested to share the beneficiary code with this office via e-mail to the following e-mail IDs-

narcommr@cbn.nic.in; supdt-tech@cbn.nic.in; supdt-precursor@cbn.nic.in; suptd-narco@cbn.nic.in

So that the export authorizations, import certificates and NOCs for export/ import of narcotic drugs, psychotropic substances and controlled substances can be uploaded on eSANCHIT portal for faster processing at Customs.

BY ORDER
NARCOTICS COMMISSIONER

Environment Notification on E-Waste (Management) Rules, 2022 – reg.

Environment Notification G.S.R.801(E) dated 02nd November 2022

Whereas the draft rules, namely the E-Waste (Management) Rules, 2022 were published by the Government of India in the Ministry of Environment, Forest and Climate Change, *vide* notification number S.O.360(E), dated the 19th May, 2022 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

AND WHEREAS, the copies of the Gazette containing the said notification were made available to the public on the 19th day of May, 2022;

AND WHEREAS, the objections and suggestions received from the public in respect of the said draft notification within the said period have been duly considered by the Central Government;

NOW, THEREFORE, in exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, and in supersession of the E-waste (Management) Rules, 2016, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely:-

CHAPTER I
PRELIMINARY

1. **Short title and commencement.-** (1) These rules may be called **the E-Waste (Management) Rules, 2022.**

   (2) They shall come into force from the **1st day of April, 2023.**

2. **Application.-** These rules shall apply to every manufacturer, producer refurbisher, dismantler and recycler involved in manufacture, sale, transfer, purchase, refurbishing, dismantling, recycling and processing of e-waste or electrical and electronic equipment listed in Schedule I, including their components, consumables, parts and spares which make the product operational but shall not apply to-

   (a) waste batteries as covered under the Battery Waste Management Rules, 2022;

   (b) packaging plastics as covered under the Plastic Waste Management Rules, 2016;

   (c) micro enterprise as defined in the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006); and

   (d) radio-active wastes as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and rules made there under.

3. **Definitions.** (1) In these rules, unless the context otherwise requires, -

   (a) 'Act' means the Environment (Protection) Act, 1986 (29 of 1986);

   (b) 'bulk consumer' means any entity which has used at least one thousand units of electrical and electronic equipment listed in Schedule I, at any point of time in the particular Financial Year and includes e-retailer;

   (c) 'business' means manufacturing, production, assembling and import of electrical and electronic equipment as listed in Schedule I and refurbishing, recycling, disposal and treatment of e-waste;

   (d) 'component' means one of the parts of a sub-assembly or assembly of which a manufactured product is made up of and into which it may be resolved and includes an accessory or attachment to another component;

   (e) 'consumables' means an item, which participates in or is required for a manufacturing process or for functioning of the electrical and electronic equipment and may or may not form part of

end-product and Items which are substantially or totally consumed during a manufacturing process shall bedeemed to be consumables;

(f) 'dismantler' means any person or entity engaged in dismantling of used electrical and electronic equipment into their components and having authorisation from concerned State Pollution Control Board or Pollution Control Committee as per the guidelines of the Central Pollution Control Board;

(g) 'disposal and treatment' means any operation which does not lead to recycling, recovery or reuse and includes physicochemical or biological treatment, incineration and deposition in secured landfill;

(h) 'end-of-life' of the product means the time when the product is intended to be discarded by the user;

(i) 'environmentally sound management of e-waste' means taking all steps required to ensure that e-waste is managed in a manner which shall protect health and environment against any adverse effects, which may result from such e-waste;

(j) 'electrical and electronic equipment' means equipment which are dependent on electric current or electro-magnetic field in order to become functional and also the equipment for the generation, transfer and measurements of the electricity;

(k) 'e-retailer' means an individual or company or business entity that uses an electronic network such as internet, social media, telephone or any other media, to sell its goods;

(l) 'e-waste' means electrical and electronic equipment**,** including solar photo-voltaic modules or panels or cells, whole or in part discarded as waste, as well as rejects from manufacturing, refurbishment and repair processes;

(m) 'extended producer responsibility' means responsibility of any producer of electrical or electronic equipment as given in Schedule-I for meeting recycling targets as per Schedule-III and Schedule-IV, only through registered recyclers of e-waste to ensure environmentally sound management of such waste;

(n) 'facility' means any location wherein the process incidental to the collection, reception, storage, segregation, refurbishing, recycling, disposal and treatment of e-waste are carried out;

(o) 'historical e-waste' means e-waste generated from electrical and electronic equipment as specified in Schedule-I which was available on the date from which these rules come into force;

(p) 'manufacturer' means a person or an entity or a company as defined in the Companies Act, 2013 (18 of 2013) or a factory as defined in the Factories Act, 1948 (63 of 1948) or Small and Medium Enterprises as defined in the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006), which has facilities for manufacture of electrical and electronic equipment as specified in Schedule-I;

(q) 'orphaned products' means non-branded or assembled electrical and electronic equipment as specified in Schedule-I or those produced by a company which has closed its operations;

(r) 'part' means an element of a sub-assembly or assembly including its component, spares or accessory not normally useful by itself and not amenable to further disassembly for maintenance purposes;

(s) 'portal' means the online system developed by the Central Pollution Control Board for the purposes of these rules;

(t) 'producer' means any person or entity who, -

(i) manufactures and offers to sell electrical and electronic equipment and their components or consumables or parts or spares under its own brand; or

(ii) offers to sell under its own brand, assembled electrical and electronic equipment and their components or consumables or parts or spares produced by other manufacturers or suppliers; or

(iii) offers to sell imported electrical and electronic equipment and their components or consumables or parts or spares; or

(iv) who imports used electrical and electronic equipment;

irrespective of the selling technique used such as dealer, retailer, e-retailer, etc.;

(u) 'recycler' means any person or entity who is engaged in recycling and reprocessing of waste electrical and electronic equipment or assemblies or their components or their parts for recovery of precious, semi-precious metals including rare earth elements and other useful recoverable materials to strengthened the secondary sourced materials and having facilities as elaborated in the guidelines of the Central Pollution Control Board made in this regard;

(v) 'refurbisher' means any person or entity repairing or assembling used electrical and electronic equipment as listed in Schedule-I for extending its working life over its originally intended life and for same use as originally intended, and selling the same in the market;

(w) 'Schedule' means the Schedule appended to these rules;

(x) 'spares' means a part or a sub-assembly or assembly for substitution which is ready to replace an identical or similar part or sub-assembly or assemblyincluding a component or an accessory; and

(y) 'target' means the quantity of e-waste to be recycled through registered recycler by the producer in fulfilment of extended producer responsibility.

(2) Words and expressions used in these rules and not defined but defined in the Act shall have the same meanings as respectively, as assigned to them in the Act.

CHAPTER II

Extended Producer Responsibility Framework

4. Registration. - (1) The entities shall register on the portal in any of the following category, namely: -

(a) manufacturer;

(b) producer;

(c) refurbisher; or

(d) recycler.

(2) In case any entity falls in more than one categories under sub-rule (1), then the entity shall register under those categories separately.

(3) No entity referred in sub-rule (1) shall carry out any business without registration.

(4) The entities registered under sub-rule (1) shall not deal with any unregistered manufacturer, producer, recycler and refurbisher.

(5) Where any registered entity furnishes false information or willfully conceals information for getting registration or return or report or information required to be provided or furnished under these rules or in case of any irregularity, the registration of such entity may be revoked by the Central Pollution Control Board for a period up to three-years after giving an opportunity to be heard and in addition, environmental compensation charges may also be levied as per rule 22 in such cases.

(6) The Central Pollution Control Board may charge such registration fee and annual maintenance charges from the entities seeking registration under these rules based on capacity of e-waste generated or recycled or handled by them as laid down by the Central Pollution Control Board with the approval of the Steering Committee.

CHAPTER III

RESPONSIBILITIES

5. Responsibilities of the manufacturer. – All manufacturer shall have to, -

(1) register on the portal;

(2) collect e-waste generated during the manufacture of any electrical and electronic equipment and ensure its recycling or disposal;

(3) file annual and quarterly returns in the laid down form on the portal on or before end of the month succeeding the quarter or year, as the case may be, to which the return relates.

6. Responsibilities of the producer. - The producer of electrical and electronic equipment listed in Schedule I shall be responsible for -

(1) registration on the portal;

(2) obtaining and implementing extended producer responsibility targets as per Schedule-III and Schedule-IV through the portal:

Provided that the producer having extended producer responsibility plan under the provisions of the erstwhile E-Waste (Management) Rules, 2016 shall migrate under these rules as per the procedure laid down by the Central Pollution Control Board with approval of Steering Committee;

(3) creating awareness through media, publications, advertisements, posters or by any other means of communication;

(4) file annual and quarterly returns in the laid down form on the portal on or before the end of the month succeeding the quarter or year, as the case may be, to which the return relates.

7. Responsibilities of the refurbisher. – All refurbisher shall have to, -

(1) register on the portal;

(2) collect e-waste generated during the process of refurbishing and hand over the waste to registered recycler and upload information on the portal;

(3) ensure that the refurbished equipment shall be as per Compulsory Registration Scheme of the Ministry of Electronics and Information Technology and Standards of Bureau of Indian Standards framed for this purpose;

(4) file annual and quarterly returns in the laid down form on the portal on or before the end of the month succeeding the quarter or year, as the case may be, to which the return relates.

8. Responsibilities of bulk consumer. - Bulk consumers of electrical and electronic equipment listed in Schedule I shall ensure that e-waste generated by them shall be handed over only to the registered producer, refurbisher or recycler.

9. Responsibilities of the recycler. - All recycler shall have to, -

(1) register on the portal;

(2) ensure that the facility and recycling processes are in accordance with the standards or guidelines laid down by the Central Pollution Control Board in this regard from time to time;

(3) ensure that the fractions or material not recycled in its facility is sent to the respective registered recyclers;

(4) ensure that residue generated during recycling process is disposed of in anauthorised treatment storage disposal facility;

(5) maintain record of e-waste collected, dismantled, recycled and sent to registered recycler on the portal and make available all records for verification or audit as and when required;

(6) file annual and quarterly returns in the laid down form on the portal on or before the end of the month succeeding the quarter or year, as the case may be, to which the return relates;

(7) accept waste electrical and electronic equipment or components not listed in Schedule-I for recycling provided that they do not contain any radioactive material and same shall be uploaded on the portal;

(8) create awareness through media, publications, advertisements, posters or by such other means of communication;

(9) account for and upload information about any non-recyclable e-waste or any quantity which is not recycled and disposed of;

(10) take help of dismantlers for recycling purposes:

Provided that it shall be the responsibility of recycler to ensure proper material flow to and from those dismantlers and the dismantler shall give dismantled material to registered recycler only and maintain record of the same.

10. Responsibilities of State Government or Union territories. - (1) The Department of Industry in the State and Union territory or any other government agency authorised in this regard by the State Government or the Union territory, as the case may be, shall ensure earmarking or allocation of industrial space or shed for e-waste dismantling andrecycling in the existing and upcoming industrial park, estate and industrial clusters.

(2) Department of Labor in the State and Union territory or any other government agency authorised in this regard by the State Government or the Union territory, as the case may be, shall, -

(a) ensure recognition and registration of workers involved in dismantlingand recycling;

(b) assist formation of groups of such workers to facilitate setting up of dismantling facilities;

(c) undertake industrial skill development activities for the workers involved in dismantling and recycling;

(d) undertake annual monitoring and to ensure safety and health of workers involved in dismantling and recycling.

CHAPTER IV

11. Procedure for storage of e-waste. - Every manufacturer, producer, refurbisher and recycler may store the e-waste for a period not exceeding one hundred and eighty days and shall maintain a record of sale, transfer and storage of e-wastes and make these records available for inspection and the storage of the e-waste shall be done as per the applicable rules or guidelines for the time being in force:

Provided that the Central Pollution Control Board may extend the said period up to three hundred and sixty-five days in case the e-waste needs to be specifically stored for development of a process for its recycling or reuse.

CHAPTER V

12. Management of solar photo-voltaic modules or panels or cells. – (1) These rules shall be applicable to solar photo-voltaic modules or panels or cells, subject to provisions of this chapter.

(2) Every manufacturer and producer of solar photo-voltaic modules or panels or cells shall, -

(i) ensure registration on the portal;

(ii) store solar photo-voltaic modules or panels or cells waste generated up to the year 2034-2035 as per the guidelines laid down by the Central Pollution Control Board in this regard;

(iii) file annual returns in the laid down form on the portal on or before the end of the year to which the return relates up to year 2034-2035;

(iv) ensure that the processing of the waste other than solar photo-voltaic modules or panels or cells shall be done as per the applicable rules or guidelines for the time being in force;

(v) ensure that the inventory of solar photo-voltaic modules or panels or cells shall be put in place distinctly on portal;

(vi) comply with standard operating procedure and guidelines laid down by the Central Pollution Control Board in this regard.

(3) Recycler of solar photo-voltaic modules or panels or cells shall be mandated for recovery of material as laid down by the Central Pollution Control Board in this regard.

CHAPTER VI

13. Modalities of the extended producer responsibility Regime. – (1) All producers shall fulfil their extended producer responsibility obligation as per Schedule-III and Schedule-IV, in doing so they may also take help of third party organisations such as producer responsibility organisations, collection centres, dealers etc.:

Provided that the extended producer responsibility shall lie entirely on the producer only.

(2) The extended producer responsibility for each product shall be decided on the basis of the information provided by the producers on the portal and the individual product's life period as laid down by the Central Pollution Control Board in this regard and the targets specified in Schedule-III and Schedule-IV.

(3) (i) The producer shall fulfill their extended producer responsibility through online purchase of extended producer responsibility certificate from registered recyclers only and submit it online by filing quarterly return.

(ii) The details provided by producer and registered recycler shall be cross-checked on the portal.

(iii) In case of any difference, the lower figure shall be considered towards fulfilment of extended producer responsibility obligation of the producer.

(iv) The certificates shall be subject to environmental audit by the Central Pollution Control Board or any other agencies authorized by the Central Pollution Control Board in this regard.

14. Extended producer responsibility Certificate Generation. – (1) Recycling. - (i) The Central Pollution Control Board shall generate extended producer responsibility certificate through the portal in favour of a registered recycler in the format laid down by it in this regard.

(ii) (a) The quantity eligible for generation of extended producer responsibility certificate shall be calculated by the following formula namely:

$$*Q_{EPR} = Q_p \times C_f$$

**the Q_{EPR} is the quantity eligible for generation of the certificate, Q_p is the quantity of the end product and C_f is the conversion factor (quantity of inputs required for production of one unit of output)*

(b) Conversion factor C_f for each end product shall be determined by Central Pollution Control Board with the approval of the steering committee.

(iii) The validity of the extended producer responsibility certificate shall be two years from the end of the financial year in which it was generated and the expired certificate automatically extinguished after the period unless extinguished earlier as per the provisions of these rules.

(iv) Each extended producer responsibility certificate shall have a unique number containing year of generation, code of end product, recycler code and a unique code and the extended producer responsibility certificates shall be in the denominations of 100, 200, 500 and 1000 kg or such other denominations as may be laid down by the Central Pollution Control Board with the approval of the Steering Committee.

(2) Refurbishing. – (i) The e-waste shall also be allowed for refurbishing and refurbisher shall have to get registered on the portal and based on the data provided, refurbishing certificate shall be generated in favour of a registered refurbisher in the format laid down by it in this regard.

(ii) On production of the refurbishing certificates purchased from the registered refurbishers, the extended producer responsibility of the producers shall be deferred by the duration as laid down by the Central Pollution Control Board for the corresponding quantity of e-waste and shall be added to the extended producer responsibility of the producer upon expiry of the extended life of the refurbished product.

(iii) To incentivise refurbishing, only 75 per cent of the deferred quantity shall be added to the extended producer responsibility of the producer for recycling upon expiry of the extended life of the refurbished product.

***Example:* -** If a producer has extended producer responsibility obligation of 100 tonnes in the year 2023-2024 and he purchases recycling certificate of 60 tonnes and refurbishing certificate of 40 tonnes and the concerned item has extended life of five years due to refurbishing.

In this case 60 tonnes of the extended producer responsibility of the producer shall be achieved in the year 2023-2024 itself and 75 per cent of the reaming 40 tonne i.e. 30 tonnes shall be carried over and added to the extended producer responsibility of that producer for the year 2028-2029 for that item.

(iv) The extended producer responsibility obligation shall be extinguished only after end of life disposal through a registered recycler and producing extended producer responsibility certificate and not by refurbishing certificate.

15. Transaction of extended producer responsibility certificates. - (1) A producer may purchase extended producer responsibility certificates limited to its extended producer responsibility liability of current year (Year Y) plus any leftover liability of preceding years plus 5 per cent of the current year liability.

(2) The extended producer responsibility obligation shall have to be fulfilled by the producers by proportionately purchasing extended producer responsibility certificate on quarterly basis.

(3) As soon as the producer purchases extended producer responsibility certificate, it shall be automatically adjusted against its liability and priority in adjustment shall be given to earlier liability and the extended producer responsibility certificate so adjusted shall be automatically extinguished and cancelled.

(4) As soon as producer purchases refurbishing certificates its extended producer responsibility liability shall be deferred automatically for the relevant quantity of the product, for the duration as laid down by the Central Pollution Control Board.

(5) The availability, requirement and other details of the extended producer responsibility certificate and refurbishing certificates for every producer or recycler or refurbisher shall be made available on the portal.

(6) All the transactions under these rules shall be recorded and submitted by the producers or recyclers on the portal at the time of filing of quarterly returns.

CHAPTER VII

REDUCTION IN THE USE OF HAZARDOUS SUBSTANCES IN THE MANUFACTURE OF ELECTRICAL AND ELECTRONIC EQUIPMENT AND THEIR COMPONENTS OR CONSUMABLES OR PARTS OR SPARES

16. Reduction in the use of hazardous substances in the manufacture of electrical and electronic equipment and their components or consumables or parts or spares. – (1) Every producer of electrical and electronic equipment and their components or consumables or parts or spares listed in Schedule I shall ensure that, new electrical and electronic equipment and their components or consumables or parts or spares do not contain Lead, Mercury, Cadmium, Hexavalent Chromium, polybrominated biphenyls and polybrominated diphenyl ethers beyond a maximum concentration value of 0.1 per cent by weight in homogenous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers and of 0.01 per cent by weight in homogenous materials for cadmium.

(2) Components or consumables or parts or spares required for the electrical and electronic equipment placed in the market prior to the 1st May, 2014 may be exempted from the provisions

of sub-rule (1) provided reduction of hazardous substances compliant parts and spares are not available.

(3) The applications listed in Schedule-II shall be exempted from provisions of sub- rule (1).

(4) Every producer of applications listed in Schedule-II shall ensure that the limits of hazardous substances as given in Schedule-II are to be complied.

(5) Every producer shall provide the detailed information on the constituents of the equipment and their components or consumables or parts or spares along with a declaration of conformance to the reduction of hazardous substances provisions in the product user documentation.

(6) Imports or placement in the market for new electrical and electronic equipment shall be permitted only for those which are compliant to provisions of sub-rules (1) and (4).

(7) Manufacture and supply of electrical and electronic equipment used for defence and other similar strategic applications shall be excluded from provisions of sub- rule (1).

(8) Every producer shall provide information on the compliance of the provisions of sub-rule (1) and this information shall be in terms of self-declaration.

(9) Manufacturer shall use the technology or methods so as to make the end product recyclable;

(10) Manufacturer shall ensure that component or part made by different manufacturer are compatible with each other so as to reduce the quantity of e-waste.

(11) The Central Pollution Control Board shall conduct random sampling of electrical and electronic equipment placed on the market to monitor and verify the compliance of reduction of hazardous substances provisions and the cost for sample and testing shall be borne by the producer and the random sampling shall be as per the guidelines laid down by the Central Pollution Control Board in this regard.

(12) If the product does not comply with reduction of hazardous substances provisions, the producer shall take corrective measures to bring the product into compliance and withdraw or recall the product from the market, within a reasonable period as per the guidelines laid down by the Central Pollution Control Board in this regard.

(13) The Central Pollution Control Board shall lay down the methods for sampling and analysis of hazardous substances as listed in sub-rule (1) with respect to the items listed in Schedule-I and Schedule-II and also enlist the labs for the said purpose.

CHAPTER VIII

MISCELLANEOUS

17. Duties of Authorities. - Subject to the other provisions of these rules, the authorities shall perform duties as specified in Schedule-V.

18. Annual Report. - The Central Pollution Control Board shall submit an annual report to the Ministry of Environment, Forest and Climate Change regarding status of implementation of the e-waste management rules with quantitative and qualitative analysis along with its recommendations, within one month of the end of the financial year.

19. Transportation of e-waste. - Transportation of waste generated from manufacturing or recycling destined for final disposal to a treatment, storage and disposal facility shall follow the provisions under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

20. Accident reporting. - Where an accident occurs at the facility processing e-waste or during transportation of e-waste, the producer, refurbisher, transporter, dismantler, or recycler, as the case may be, shall report immediately to the concerned State Pollution Control Board about the accident through telephone and e-mail.

21. Appeal. - (1) Any person aggrieved by an order of suspension or cancellation or refusal of registration or its renewal passed by the Central Pollution Control Board, within a period of thirty days

from the date on which the order is communicated to him, prefer an appeal to the Additional Secretary or Joint Secretary, Ministry of Environment, Forest and Climate Change duly nominated by the Central Government in this regard.

(2) The Appellate Authority may entertain the appeal after expiry of the said period of thirty days if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

22. Environmental Compensation. - (1) The Central Pollution Control Board shall lay down guidelines for imposition and collection of environmental compensation on any entity in case of violation of any of the provision of these rules and guidelines issued hereunder and the said guidelines shall be in accordance with these rules and shall be approved by the Ministry of Environment, Forest and Climate Change.

(2) The Central Pollution Control Board shall also lay down guidelines for imposition and collection of environmental compensation on the producer in case of non-fulfilment of obligations set out in these rules and transaction or use of false extended producer responsibility certificate and the said guidelines shall be in accordance with these rules and shall be approved by the Ministry of Environment, Forest and Climate Change.

(3) The environmental compensation shall also be levied on unregistered producers, manufacturer, refurbisher, recyclers and any entity which aids or abets the violation of these rules.

(4) (i) Payment of environmental compensation shall not absolve the producer from the extended producer responsibility as specified in these rules and the unfulfilled extended producer responsibility for a particular year shall be carried forward to the next year and so on and up to three years.

(ii) In case, the shortfall of extended producer responsibility obligation is addressed after one year, 85 per cent of the environmental compensation levied shall be returned to the producer.

(iii) In case, the shortfall of extended producer responsibility obligation is addressed after two year, 60 per cent of the environmental compensation levied shall be returned to the producer, and in case, the shortfall of extended producer responsibility obligation is addressed after three year, 30 per cent of the environmental compensation levied shall be returned to the producer, thereafter no environmental compensation shall be returned to the producer.

(5) False information resulting in over generation of extended producer responsibility certificates by recycler shall result in revocation of registration and imposition of environmental compensation which shall not be returnable and repeat offence, violation of these rules for three times or more shall also result in permanent revocation of registration over and above the environmental compensation charges.

(6) (i) The funds collected under environmental compensation shall be kept in a separate Escrow account by the Central Pollution Control Board and the funds collected shall be utilizsed in collection and recycling or end of life disposal of uncollected, historical, orphaned e-waste and non-recycled or non-end of life disposal of e-waste on which the environment compensation is levied, research and development, incentivising recyclers, financial assistance to local bodies for managing waste management projects and on other heads as decided by the committee.

(ii) The modalities and heads for utilisation of the funds shall be decided by the Steering Committee with the approval of the Ministry of Environment, Forest and Climate Change.

23. Prosecution. - Any person, who provides incorrect information required under these rules for obtaining extended producer responsibility certificates, uses or causes to be used false or forged extended producer responsibility certificates in any manner, willfully violates the directions given under these rules or fails to cooperate in the verification and audit proceedings, may be prosecuted under section 15 of the Act, 1986 and this prosecution shall be in addition to the environmental compensation levied under rule 22.

24. Verification and Audit. – The Central Pollution Control Board by itself or through a designated agency shall verify compliance of these rules by producers, manufacturer, refurbisher, dismantlers and

recyclers through random inspection and periodic audit, as deemed appropriate so as to take action against violations of the provisions of these rules as per rule 22.

25. Steering Committee. - (1) There shall be a Steering Committee under the Chairmanship of Chairman, Central Pollution Control Board to oversee the overall implementation of these rules and the Steering Committee shall comprise of following other members in addition to the chair, namely: -

(a) one representative of the Ministry of Environment, Forest and Climate Change;

(b) one representative of the Ministry of Electronics and Information Technology;

(c) one representative of the Ministry of New and Renewable Energy;

(d) one representative of the Ministry of Housing and urban Affairs;

(e) a maximum of two representatives of electrical and electronic equipment Producer and Manufacturer Association;

(f) a maximum of two representatives of E-Waste Recycler Associations;

(g) one representative of State Pollution Control Board or Pollution Control Committee as co-opted by the Chairman of the Steering Committee;

(h) Head of the Concerned Division of the Central Pollution Control Board – Member- Convener.

(2) The steering committee shall be responsible for overall implementation, monitoring and supervision of these rules and it shall also decide upon the disputes arisen from time to time and on representations received in this regard, and shall refer to the Ministry of Environment, Forest and Climate Change any substantial issue arisen or pertaining to these rules.

(3) The steering committee shall review and revise the guidelines or extended producer responsibility target or addition of new Electrical and Electronic Equipment in Schedule I, in view of the technological advancements and other factors with the approval of the Central Government.

(4) The Steering Committee shall take all such measures as it deems necessary for proper implementation of provisions of these rules.

SCHEDULE - I

[See rules 2, 3 (b), 3 (c), 3 (m), 3 (o), 3 (p), 3 (q), 3 (v), 6, 8, 10 (7), 16 (13)]

Categories of electrical and electronic equipment including their components,consumables, parts and spares covered under the rules

Sl. No.	Categories of electrical and electronic equipment	Electrical and electronic equipment code
(i)	**Information technology and telecommunication equipment**:	
	Centralized data processing: Mainframes, Minicomputers	ITEW1
	Personal Computing: Personal Computers (Central Processing unit with input and output devices)	ITEW2
	Personal Computing: Laptop Computers (Central Processing unit with input and output devices)	ITEW3
	Personal Computing: Notebook Computers	ITEW4
	Personal Computing: Notepad Computers	ITEW5
	Printers including cartridges	ITEW6
	Copying Equipment	ITEW7
	Electrical and Electronic Typewriters	ITEW8
	User terminal and Systems	ITEW9
	Facsimile	ITEW10
	Telex	ITEW11

	Telephones	ITEW12
	Pay telephones	ITEW13
	Cordless telephones	ITEW14
	Cellular telephones	ITEW15
	Answering System	ITEW16
	Products or equipment of transmitting sound, images or other information by telecommunications	ITEW17
	BTS (all components excluding structure of tower)	ITEW18
	Tablets, I-PAD	ITEW19
	Phablets	ITEW20
	Scanners	ITEW21
	Routers	ITEW22
	GPS	ITEW23
	UPS	ITEW24
	Inverter	ITEW25
	Modems	ITEW26
	Electronic data storage devices	ITEW27
(ii)	**Consumer Electrical and Electronics and Photovoltaic Panels:**	
	Television sets (including sets based on Liquid Crystal Display and light Emitting Diode Technology)	CEEW1
	Refrigerator	CEEW2
	Washing Machine	CEEW3
	Air- Conditioners excluding centralised air conditioning plants	CEEW4
	Fluorescent and other Mercury containing lamps	CEEW5
	Screen, Electronic Photo frames, Electronic Display Panel, Monitors	CEEW6
	Radio sets	CEEW7
	Set top Boxes	CEEW8
	Video Cameras	CEEW9
	Video Recorders	CEEW10
	Hi-Fi Recorders	CEEW11
	Audio Amplifiers	CEEW12
	Other products or equipment for the purpose of recording or reproducing sound or images including signals and other technologies for the distribution of sound and image by telecommunications	CEEW13
	Solar panels/cells, solar Photovoltaic panels/cells/modules.	CEEW14
	Luminaires for fluorescent lamps with the exception of luminaires in households	CEEW15
	High intensity discharge lamps, including pressure sodium lamps and metal halide lamps	CEEW16
	Low pressure sodium lamps	CEEW17
	Other lighting or equipment for the purpose of spreading or controlling light excluding filament bulbs	CEEW18
	Digital camera	CEEW19
(iii)	**Large and Small Electrical and Electronic Equipment**	
	Large cooling appliances	LSEEW1
	Freezers	LSEEW2
	Other large appliances used for refrigeration, conservation and storage of food	LSEEW3

	Clothes dryers	LSEEW4
	Dish Washing Machines	LSEEW5
	Electric cookers	LSEEW6
	Electric stoves	LSEEW7
	Electric hot plates	LSEEW8
	Microwaves, Microwave Oven	LSEEW9
	Other large appliances used for cooking and other processing of food	LSEEW10
	Electric heating appliances	LSEEW11
	Electric radiators	LSEEW12
	Other large appliances for heating rooms, beds, seating furniture	LSEEW13
	Electric fans	LSEEW14
	Other fanning, exhaust ventilation and conditioning equipment	LSEEW15
	Vacuum cleaners	LSEEW16
	Carpet sweepers	LSEEW17
	Other appliances for cleaning	LSEEW18
	Appliances used for sewing, knitting, weaving and other processing for textiles	LSEEW19
	Iron and other appliances for ironing, mangling and other care of clothing	LSEEW20
	Grinders, coffee machines and equipment for opening or sealing containers or packages	LSEEW21
	Smoke detector	LSEEW22
	Heating Regulators	LSEEW23
	Thermostats	LSEEW24
	Automatic dispensers for hot drinks	LSEEW25
	Automatic dispensers for hot or cold bottles or cans	LSEEW26
	Automatic dispensers for solid products	LSEEW27
	Automatic dispensers for money	LSEEW28
	All appliances which deliver automatically all kinds of products	LSEEW29
	Indoor air purifier	LSEEW30
	Hair dryer	LSEEW31
	Electric shaver	LSEEW32
	Electric kettle	LSEEW33
	Electronic display panels/board/visual display unit	LSEEW34
(iv)	**Electrical and Electronic Tools (With the exception of large- Scale Stationary Industrial Tools)**	
	Drills	EETW1
	Saws	EETW2
	Sewing Machines	EETW3
	Equipment for turning, milling, sanding, grinding, sawing, cutting, shearing, drilling, making holes, punching, folding, bending or similar processing of wood, metal and other materials	EETW4
	Tools for riveting, nailing or screwing or removing rivets, nails, screws or similar uses	EETW5
	Tools for welding, soldering, or similar use	EETW6
	Equipment for spraying, spreading, dispersing or other treatment of liquid or gaseous substance by other means	EETW7
	Tools for mowing or other gardening activities	EETW8

(v)	**Toys, Leisure and Sports Equipment**	
	Electrical trains or car racing sets	TLSEW1
	Hand-held video games consoles	TLSEW2
	Video games	TLSEW3
	Computers for biking, diving, running, rowing, etc.	TLSEW4
	Sports equipment with electric or electronic components	TLSEW5
	Coin slot machines	TLSEW6
(vi)	**Medical Devices (With the Exception of All Implanted and Infected Products)**	
	Radiotherapy equipment and accessories	MDW1
	Cardiology equipment and accessories	MDW2
	Dialysis equipment and accessories	MDW3
	Pulmonary ventilators and accessories	MDW4
	Nuclear Medicine Equipment and accessories	MDW5
	Laboratory equipment for in vitro diagnosis and accessories	MDW6
	Analysers and accessories	MDW7
	Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) Scanner, Computed Tomography (CT) Scanner, & Ultrasound Equipment along with accessories	MDW8
	Fertilization tests equipment and accessories	MDW9
	Other electric appliances/equipment/kits used for preventing, screening, detecting, monitoring, evaluating, reviewing, examining, investigating, probing, treating illness sickness, disease, disorder, affliction, infection, injury, trauma, abuse or disability including the Mobiles, Tablets or any other device with the features having the potential of sex selection and their accessories	MDW10
(vii)	**Laboratory Instruments**	
	Gas analyser	LIW1
	Equipment having electrical and electronic components	LIW2

SCHEDULE - II

[See rules 16(3), 16(4), 16(13)]

Applications, which are exempted from the requirements of sub-rule (1) of rule 16	
Sl. No.	**Substance**
1.	Mercury in single capped (compact) fluorescent lamps not exceeding (perburner):
(a)	for general lighting purposes <30 W : 2.5 mg
(b)	for general lighting purposes ≥ 30 W and <50 W : 3.5mg
(c)	for general lighting purposes ≥ 50 W and <150 W : 5mg
(d)	for general lighting purposes ≥150 W : 15 mg
(e)	for general lighting purposes with circular or square structural shape and tubediameter ≤17 mm : 7mg
(f)	for special purposes:5 mg
2.(a)	Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):
(1)	Tri-band phosphor with normal life time and a tube diameter < 9mm (e.g.T2): 4mg
(2)	Tri-band phosphor with normal life time and a tube diameter ≥ 9 mm and ≤ 17 mm (e.g. T5): 3 mg

(3)	Tri- band phosphor with normal life time and a tube diameter >17 mm and ≤ 28 mm(e.g. T8): 3.5 mg
(4)	Tri-band phosphor with normal life time and a tube diameter >28 mm (e.g. T12):3.5 mg
(5)	Tri-band phosphor with long life time (≥25000 h):5mg
2.(b)	Mercury in other fluorescent lamps not exceeding(per lamp):
(1)	Linear halophosphate lamps with tube >28 mm (e.g. T 10 and T12):10 mg
(2)	Non-linear halophosphate lamps(all diameters):15mg
(3)	Non-linear tri-band phosphor lamps with tube diameter >17 mm(e.g.T9):15 mg
(4)	Lamps for other general lighting and special purposes (e.g. inductionlamps):15mg
3.	Mercury in cold cathode fluorescent lamps and external electrode fluorescentlamps (CCFL and EEFL)for special purposes not exceeding (per lamp):
(a)	Short length(≤ 500 mm):3.5mg
(b)	Medium length(>500 mm and≤1500 mm): 5mg
(c)	Long length(>1500 mm): 13mg
4.(a)	Mercury in other low pressure discharge lamps (per lamp): 15mg
(b)	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner)in lamps with improved colour renderingindex Ra>60:
(b)-I	P ≤155 W : 30 mg
(b)-II	155 W < P ≤405 W : 40 mg
(b)-III	P >405 W: 40 mg
(c)	Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner):
(c)-I	P≤155 W:25mg
(c)-II	155 W < P ≤ 405 W:30 mg
(c)-III	P >405 W:40 mg
(d)	Mercury in High Pressure Mercury (vapour) lamps (HPMV)
(e)	Mercury in metal halide lamps (MH)
(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Schedule
5.(a)	Lead in glass of cathode ray tubes
(b)	Lead in glass of fluorescent tubes not exceeding 0.2% by weight
6.(a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35% lead by weight
(b)	Lead as an alloying element in aluminium containing up to 0.4% lead byweight
(c)	Copper alloy containing up to 4% lead by weight
7.(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)
(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications
(c)	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in aglass or ceramic matrix compound.
(d)	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or250 V DC or higher

(e)	Lead in dielectric ceramic in capacitors for a rated voltage of less than 125V AC or 250 V DC
8.(a)	Cadmium and its compounds in one shot pellet type thermal cut-offs
(b)	Cadmium and its compounds in electrical contracts
9.	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight in the cooling solution
(a)	Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) application.
10.(a)	Lead used in C-press compliant pin connector systems
(b)	Lead used in other than C-press compliant pin connector systems
11.	Lead as a coating material for the thermal conduction module C- ring
12.(a)	Lead in white glasses used for optical applications
(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards.
13.	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight
14.	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages.
15.	Lead in linear incandescent lamps with silicate coated tubes
16.	Lead halide as radiant agent in high intensity discharge (HID) lamps used forprofessional reprography applications.
17.(a)	Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as specialty lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ($(Sr, Ba)_2Mg Si_2O_7$:Pb)
(b)	Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors suchas BSP ($Ba Si_2O_5$:Pb)
18.	Lead with PbBiSn-Hg and PblnSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL)
19.	Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCDs)
20.	Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses
21.	Lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm and less
22.	Lead in solders for the soldering to machine through hole discoidal and planar array ceramic multilayer capacitors
23.	Lead oxide in surface conduction electron emitter displays (SED) used instructural elements, notably in the seal frit and frit ring.
24.	Lead oxide in the glass envelope of black light blue lamps
25.	Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers
26.	Lead bound in crystal glass
27.	Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB(A) and more

28.	Lead in soldering materials in mercury free flat fluorescent lamps (which e.g. are used for liquid crystal displays, design or industrial lighting)
29.	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes
30.	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers
31.	Lead in cermet-based trimmer potentiometer elements
32.	Mercury used as a cathode sputtering inhibitor in DC plasma displays with acontent up to 30 mg per display
33.	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body
34.	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide
35.	Cadmium in color converting II-VI LEDs (<10 µg Cd per mm^2 of light-emitting area) for use in solid state illumination or display systems.

SCHEDULE - III

[See rules 3(m), 6(2), 13(1), 13(2)]

Sl. No.	Year (Y)	E-Waste Recycling Target (by weight)
1.	2023 -2024	60% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product
2.	2024 -2025	60% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product
3.	2025 -2026	70% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product
4.	2026-2027	70% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product
5.	2027-2028	80% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product
6.	2028-2029 onwards	80% of the quantity of an EEE placed in the market in year Y-X, where 'X' is the average life of that product

Note: ***(1) E-waste recycling target shall be reviewed and may be increased after the end of year 2028-2029.***

(2) The importers of used electrical and electronic equipment shall have 100% extended producer responsibility obligation for the imported material after end of life, if not re-exported.

(3) E-Waste recycling targets shall not be applicable for waste generated from solar photo-voltaic modules or panels or cells.

SCHEDULE - IV

[See rules 3(m), 6(2), 13(1), 13(2)]

Extended Producer Responsibility targets for producers, who have started sales operations recently, i.e. number of years of sales operations is less than average life of their products mentioned in the guidelines issued by the Central Pollution Control Board from time to time.

Sl. No.	Year	E-Waste Recycling Target (by weight)
1.	2023-2024	15% of the sales figure of financial year 2021-22
2.	2024-2025	20% of the sales figure of financial year 2022-23
3.	2025-2026 onwards	20% of the sales figure of the financial year two years back

Note: (1) Once the number of years of sales operation equals the average life of their product mentioned in the guidelines issued by Central Pollution Control Board, their extended producer responsibility obligation shall be as per Schedule-III.

(2) E-Waste recycling targets shall not be applicable for waste generated from solar photo-voltaic modules or panels or cells.

SCHEDULE - V

[See rule (17)]

LIST OF AUTHORITIES AND COPRRERSPONDING DUTIES

Sl. No.	AUTHORITY	COPRRERSPONDING DUTIES
1.	Central Pollution Control Board	(1) Operation and maintenance of Extended Producer Responsibility Portal and monitoring of Extended Producer Responsibility compliance. (2) Coordination with State Pollution Control Boards (3) Prepare and issue guidelines and Standard Operating procedures for collection, storage, transportation, segregation, refurbishment, dismantling, recycling and disposal of e-waste under these rules from time to time, and also issue necessary Forms/ Returns for implementation of these rules. (4) Conduct random check for ascertaining compliance of the e-waste rules and may take help of Customs/State Government or any other agency (ies). (5) Documentation, compilation of data on e-waste and uploading on websites of Central Pollution Control Board. (6) Actions against violation of these rules. (7) Conducting training programmes to develop capacity including State Pollution Control Boards and Urban Local Bodies officials. (8) Conducting awareness programmes on e-waste management, RE/CE label, legislation to make consumers responsible towards product usage and safe disposal. (9) Integrate all stakeholders with the centralized digital system. (10) Submit Annual Report to the Ministry. (11) Enforcement of provisions regarding reduction in use of hazardous substances in manufacture of electrical and electronic equipment. (12) Interaction with IT industry for reducing hazardous substances. (13) Set and revise targets for compliance to the reduction in use of hazardous substance in manufacture of electrical and electronic equipment from time to time. (14) Ensure RoHS compliance and its certifications through a recognized lab and its mandatory checks. (15) Any other function delegated by the Ministry under these rules from time to time.
2.	State Pollution Control Boards or Pollution Control Committees of Union territories	(1) Inventorisation of e-waste. (2) Monitoring and compliance of Extended Producer Responsibility as directed by Central Pollution Control Board. (3) Conduct random inspection of recycler and refurbisher and monitoring recycling capacity utilization.

		(4)	Implementation of programmes to encourage environmentally sound recycling.
		(5)	Any other function delegated by the Ministry/ Central Pollution Control Board under these rules.
3.	Responsibilities of Local Bodies (Urban and Rural).	(1)	To ensure that e-waste if found to be mixed with Municipal Solid Waste is properly segregated, collected and is channelised to registered recycler or refurbisher.
		(2)	To ensure that e-waste pertaining to orphan products is collected and channelized to registered recycler or refurbisher.
		(3)	To facilitate setting up e-waste collection, segregation and disposal systems.
		(4)	Conducting training sessions to develop capacities of the urban and rural local bodies.
4.	Responsibilities of Port authority under Indian Ports Act, 1908 (15 of 1908) and Customs Authority under the Customs Act, 1962 (52 of 1962).	(1)	Verify the import or export with respect to Extended Producer Responsibility under these rules.
		(2)	Inform Central Pollution Control Board of any illegal traffic for necessary action.
		(3)	Take action against importer for violations under theIndian Ports Act, 1908 or the Customs Act, 1962.
5.	Responsibilities of Bureau of Indian Standards/ Ministry of Electronics and Information Technology	To issue standards for refurbished products. Bureau of Indian Standards/ Ministry of Electronics and Information Technology shall also develop guidelines for refurbishers with respect to Compulsory Registration Scheme.	

F. No.12/136/2021-HSMD

Naresh Pal Gangwar, Addl. Secy., Ministry of Environment, Forest and Climate Change, New Delhi.

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Karnataka govt scouts for anchor investors for pharma sector

The Karnataka government is scouting for anchor investors in the pharma sector. This has been the key reason for pharma industry not finding any mention at the ongoing Global Investors Meet where the focus is on new-age industries like green hydrogen, electronics manufacturing, renewables, aerospace and defence, e-mobility, and infrastructure. The state government has set a target of attracting Rs. 5 lakh crore of investments and to generate 5 lakh jobs across sectors including pharmaceuticals.

The 3-day Global Investors Meet, titled 'Invest in Karnataka' held from November 2 to 4 in Bengaluru was inaugurated virtually by Prime Minister Narendra Modi and is positioned as the platform to woo international investors. The state had been a key player in attracting outsourcing in production and is known to produce 7 of the 10 products for global pharma majors.

Its Kadechur-Badiyal Bulk Drug Park in Yadgir district, set up with the Department of Pharmaceuticals (DoP)'s assistance of around Rs. 100 crore, is yet to garner investment interest. Early this year the Karnataka government indicated that Global Investor Meet 2022 will aim to attract investments from across the world even into pharmaceuticals.

In Karnataka, pharmaceuticals has been exporting substantially by its proving capacity, capability and time-line delivery schedules that paved the way for its reliability in the global market. In fact, for Karnataka its last investment from GlaxoSmithKline was in 2014 where it invested Rs. 994 crore to set up its advanced tablet facility at the Vemagal Industrial Area in Kolar district as a Greenfield project.

Minister for large & medium industries, Dr Murugesh R Nirani said, "Karnataka is the preferred destination for investments in the manufacturing. We are looking at forging partnerships. With the key themes of resilience, innovation, sustainability, and equity, we are committed to setting Karnataka's development agenda in line with global best practices and showcasing our strong ability to 'Build for the World. In fact Karnataka is at the top in attracting FDIs in April 2021 to March 2022 to the tune of Rs. 1.76 lakh crore which is a share of 38 percent of the total foreign direct investments into India."

The absence of pharmaceuticals is conspicuous. Pharma has been recognised for its qualified workforce and companies that have shot into international fame, noted industry observers.

According to Harish K Jain, president, Karnataka Drugs and Pharmaceutical Manufacturers Association and director, Embiotic Labs, the last Global Investors Meet held in 2021 had the government focus on pharma industry. This year even in the international road shows there was no interest evinced. The government gathered that there were no big ticket investments which made it to overlook pharma. Moreover, global pharma investors are closely looking at locations like Gujarat, Himachal Pradesh, Uttaranchal and Uttar Pradesh.

The Union government's production linked incentive (PLI) scheme, Make in India for the world initiative allows pharma sector to invest anywhere in the country. The Karnataka Industrial Policy too favours investors to consider the state which is a knowledge based location. It is the headwinds that deter promising investments. Even in the case of Yadgir Pharma Park, it is work in progress for investors to pump in funds. By mid-next year, much of the commercial production will commence which could help companies look at slating investments, added Jain.

Source: Pharmabiz, Nandita Vijay, Bengaluru, 3.11.2022

● ● ●

Health and Tech: Orphan Diseases not 'orphan' anymore

(Representational image). Thanks to DNA sequencing technology, Indian scientists are exploring the possibility of understanding the causes of rare diseases and eventually develop cheaper diagnostics and therapies that can either treat or manage the existing conditions among patients.

Hyderabad: There are a group of ailments that fall under the category of 'Orphan Diseases' and the drugs that are

needed to treat them are often called 'Orphan Drugs'. Since these diseases are rare, pharmaceutical companies tend to avoid rolling out financial resources to conduct expensive research and develop drugs for them. As a result, they have earned the sobriquet of Orphan Diseases.

With the development of technology and a better understanding of the role of genetic mutations in causing these rare diseases, researchers and clinicians now believe that such ailments are preventable and in the near future, novel therapeutics can be developed to treat a few of such diseases.

Such findings are a ray of hope for patients, who struggle with unmet healthcare needs due to lack of drug availability and for Indian couples who are planning to start a family. Thanks to DNA sequencing technology, Indian scientists are exploring the possibility of understanding the causes of rare diseases and eventually develop cheaper diagnostics and therapies that can either treat or manage the existing conditions among patients.

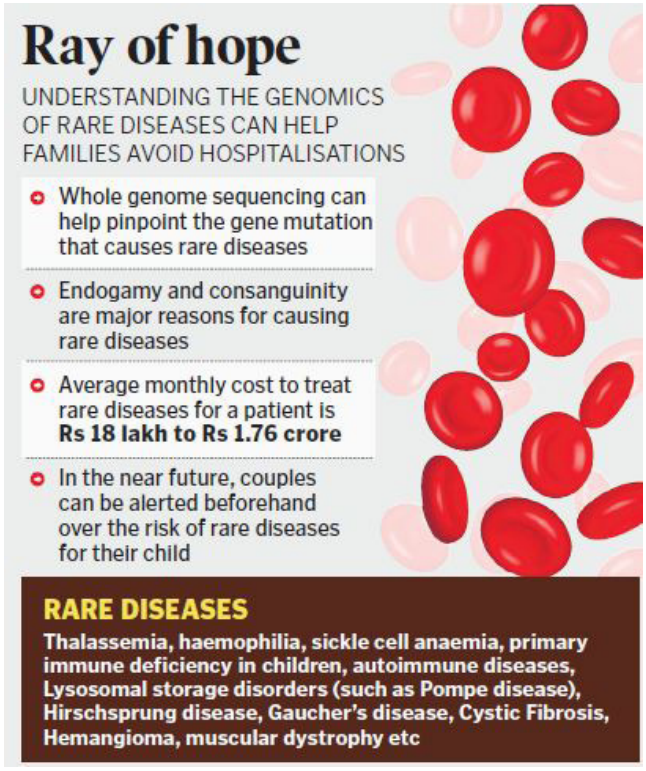
Of all the rare diseases in the world, one-third i.e. 33 per cent, are from India. "Rare diseases are very common in South Asian countries, particularly in India. If you see in general across India, such diseases are rare but at the same time, you will find such ailments in large numbers in one particular region, among a particular community, in India. If you look at rare diseases as a whole, about 70 million people are suffering from rare diseases in India and there is a definite need to find solutions," Director, Centre for DNA Fingerprinting and Diagnostics (CDFD), Dr K Thangaraj, during a meet on rare genetic disorders, said.

Nearly 90 per cent and some even argue that almost all rare diseases are caused by genetic mutations and a majority of them are monogenic, which means that the ailment is caused by one single gene mutation. Usually, these rare diseases are aggressive in nature, chronically very debilitating and life-threatening.

Interestingly, due to rapid advancement in genomic technologies, in the last decade, researchers are now able to identify more rare diseases and the associated genes that are causing such rare ailments. According to various study papers, rare diseases also include rare inherited cancers, autoimmune diseases, congenital malformations and infectious diseases amongst others. Interestingly, nearly half of the rare diseases affect children.

Cost Factor

A major difficulty in handling rare diseases is the cost factor involved in treating the ailment or managing the symptoms. According to Dr K Thangaraj, the average annual recurring treatment cost for one patient who is suffering from a rare disease is Rs 18 lakh to Rs 1.7 crore, which makes it near impossible to afford for patients from economically weaker sections.



"For instance, the monthly cost for treatment of patients with Cystic Fibrosis will cost anywhere between 12,000 and 15,000 UK Pounds. Obviously, this will cost more in India. There are a total of 7,000 rare diseases but less than 300 have some therapies for treatment. However, about 95 per cent of rare diseases have no approved treatment. In this scenario, it is always better to avoid such rare diseases, instead of treating them," Dr Thangaraj, said.

Why rare diseases common in India?

"The primary factor for rare diseases is arranged marriage that is practiced in India for at least 2,000 to 3,000 years. Consanguineous marriages and extended consanguinity like endogamy are major factors for the prevalence of rare diseases in India," says Dr Thangaraj. More or less, there is a general acceptance that endogamy, which is a practice of marrying within a community or caste, prevalent in northern parts of the country and consanguinity in South India are responsible for many of the rare diseases.

Source: M. Sai Gopal, Telangana Today, 03.11.2022

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