ISSUE No. 55

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. - Aug. - Sep. 2022

Delvin Formulations

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MOVING GLOBALLY

R & D and Manufacturing of API

R & D and Manufacturing of Formulations

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Medical Devices

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 55 Jul. - Aug. - Sep. 2022

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 55th issue of Pharma Web Newsletter for Jul – Sep 2022.

This 55th issue contains the program highlights as well as the following article published by eminent person in Pharma industry.

- **Hyaluronic Acid: A wonder molecule for the cosmetic and pharma industries by Dr. Dr. Rudhramyna Gnaneshwar**, Group Leader-Performance and Specialty Materials (PSM), International Ltd, Bengaluru

We have also published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules, important circulars issued by DCGI pertaining to Drugs & Pharmaceuticals.

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

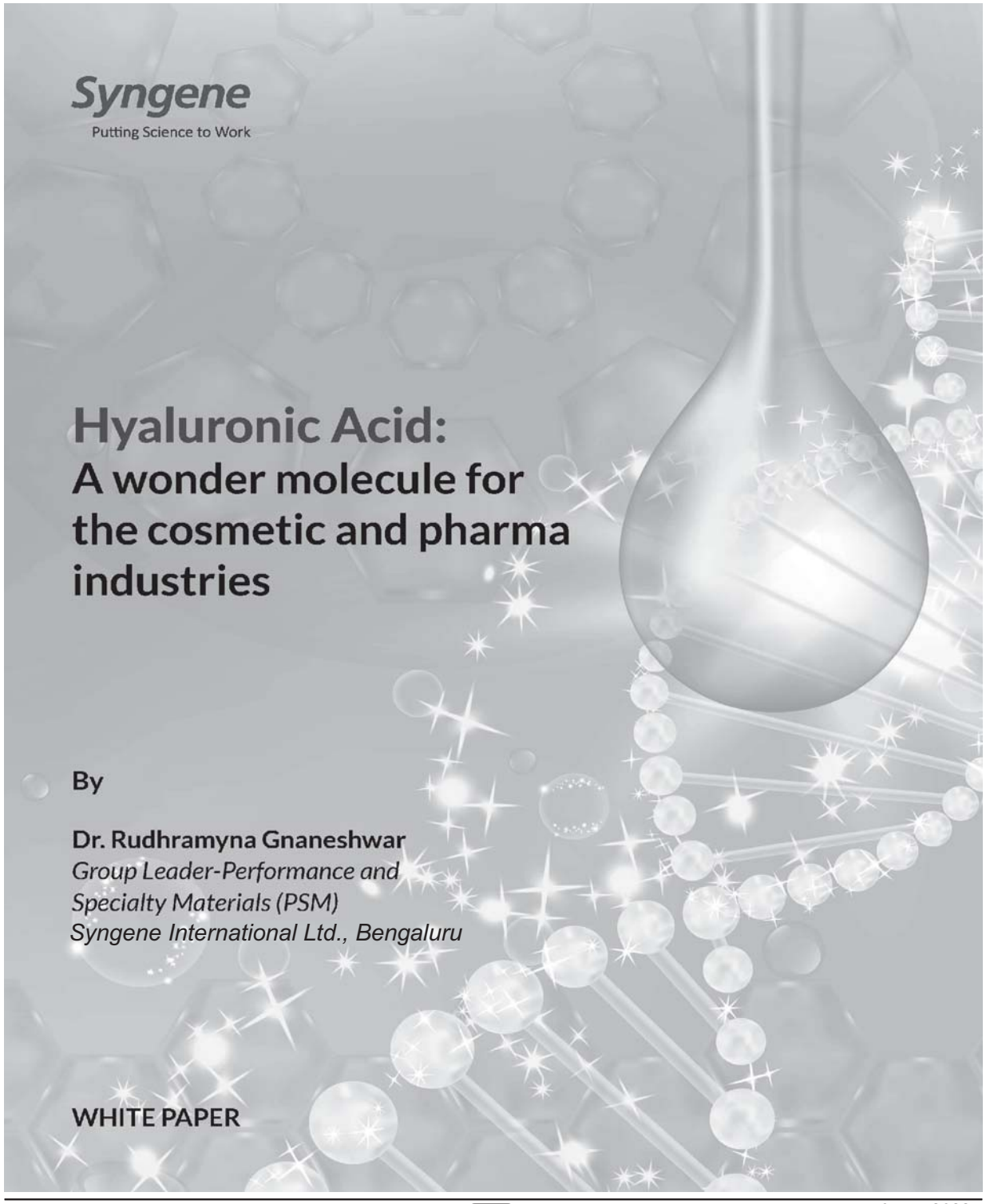
Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,

R. NARAYANASWAMY

Chief Editor


Syngene
Putting Science to Work
Hyaluronic Acid:
A wonder molecule for the cosmetic and pharma industries
By
Dr. Rudhramyna Gnaneshwar
Group Leader-Performance and Specialty Materials (PSM)
Syngene International Ltd., Bengaluru
WHITE PAPER


Overview
Hyaluronic acid (HA) biopolymer is a naturally occurring material that helps retain moisture in the skin, eyes and lubricates the joints. However, with age, the body starts producing less and less of this material, resulting in conditions such as dry eyes, osteoarthritis, aging skin, and so on.
Pharma and cosmetic industries realized that this molecule produced by the body could be supplemented with material made in a factory to treat these conditions. Since then, due to the molecule's valuable physicochemical properties, it is being used in the treatment of various medical conditions. These include arthritis treatment (osteoarthritis), in contact lenses for dry eye syndrome, ocular surgery (ophthalmology), cosmetic space (skincare, plastic surgery), drug delivery, and more.
Ha's crucial role in the wound-healing process presents a massive opportunity in regenerative medicine. Similarly, the chemical modification of HA could enable its application in new areas of medicine. Further, HA being a biodegradable material, it can be used without increasing carbon footprint or causing any environmental damage.
Read on to understand the many applications of HA and possibilities for the future.
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Syngene
Putting Science to Work

About hyaluronic acid

Hyaluronic acid (HA) is a linear biodegradable polymer composed of repeating disaccharide units of b-1,3-N-acetyl glucosamine and b-1,4- glucuronic acid with a molecular weight of up to 6 million Daltons. HA is a highly hydrophilic polymer due to the presence of hydrophilic groups such as hydroxyl, carboxyl, and amide groups in it [1].

Currently, commercially available HA is polydisperse and is either isolated from rooster combs or produced through microbial fermentation [2].

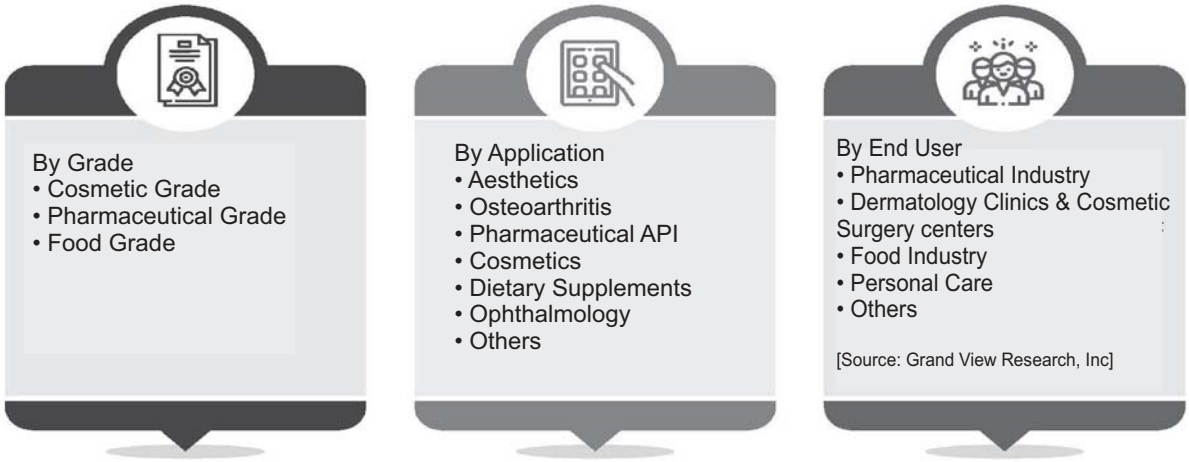
The physiological and pharmacological functions of HA vary with their molecular weight. For example, inhaling high molecular weight HA has been applied to treat inflammation clinically, while low molecular weight HA exhibits proinflammatory characteristics [3]. Most commercial products top out around 4,000 kDa [4].

Additionally, absorption characteristics of intestinal epithelial cells are different for HA having different molecular weights. Certain diseases require optimal absorption of oral HA. Thus, the preparation of low polydispersity/or well-defined/monodisperse HA of appropriate molecular weight is highly desirable [2]

HA market analysis

HA, a natural component with therapeutic properties, commands a higher price than substitute products like collagen, omega-3, chondroitin sulfate, glucosamine, etc., that provide similar benefits.

Companies are marketing a wide range of products containing this molecule. This includes HA drugs for treating osteoarthritis and mouth ulcers, eye surgeries, lip filler, moisturizer and anti-aging products, skin serum, dry eye syndrome etc.

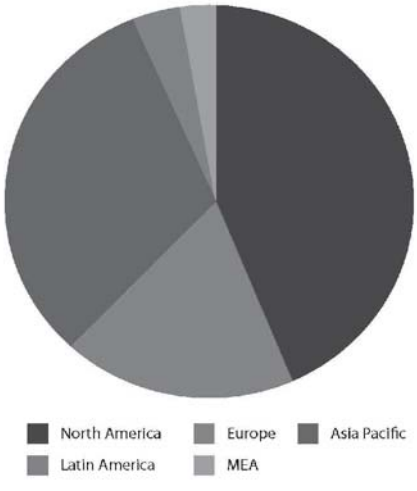


Global HA market

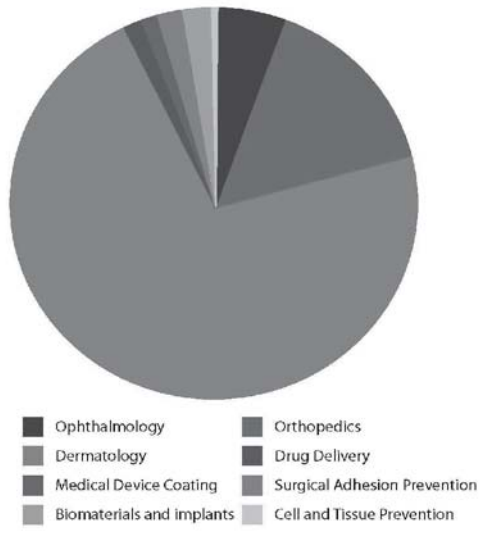
The HA market is projected to grow at 7.2% in terms of value to reach USD 15.48 billion by 2027 [5].

As per the pie chart below, North America accounted for the leading share in the global market for HA in 2019. The dermatology segment held the largest revenue share in 2015 due to various chronic wound cases in diabetic patients and the surge in demand for plastic surgeries requiring HA-based agents. Asia Pacific is anticipated to emerge as the fastest growing regional market in the forecast period due to growing elderly population in China and Japan – which provides a large customer base for anti-aging products and services.

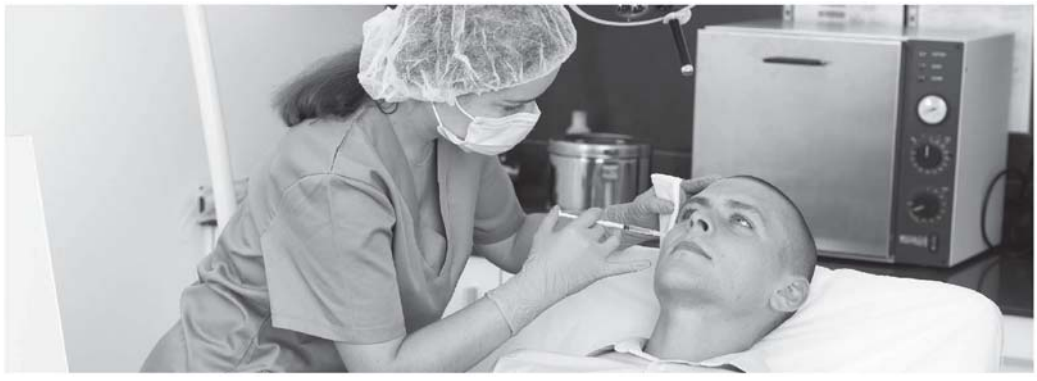
Meanwhile, new HA products are continuing to emerge, with developers creating new applications based on functionality.



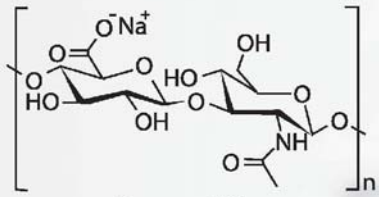
Global HA market share
by region, 2019 (%)
Source: Grand View Research, Inc.



Global HA raw material market volume
by application, 2015
(Thousand kgs)



HA as a component of the human body



Structure of HA

In the human body, HA biopolymer occurs in the Sodium Hyaluronate form and is found in high concentrations in the umbilical cord, skin and vitreous humor of the eye.

HA is engaged in soft tissue hydration and structural scaffolding and provides viscoelasticity, which results in lubrication and shock absorbing functionalities.

HA contributes to variation of many biochemical processes such as cell proliferation and differentiation, cell adhesion and inflammation, wound healing and tissue repair etc.

- The molecular weights of HA from different sources are highly variable, ranging from 104 to108 Da
- Due to a variation in its molecular weight, its physical, chemical and biological properties are also different. As a result, HA derivatives can be utilized to make different formulations like fillers, creams, gels, and drops
- The average human body contains about 15 g of this disaccharide polymer
- Kinetics: The human body replaces about 30% of its HA every day (i.e., degraded and synthesized)

Source: Grand View Research, Mintel, companies

HA as a component of medical products

In Eye Drops and Contact lenses

Contact lenses have become an extensively used medical device, with HA commonly used as an additive for their surface coating, production material, and multipurpose solution [3]. The add-on of HA to specific contact lens solutions could be part of the reason why they work well for particular patients.

HA can also lower protein adhesion to contact lenses and improve hydrophilicity [6]. HA molecules in contact lenses will retain moisture to enhance the wearer's comfort. HA absorbed by contact lenses can also gradually release to the front of the eyes to heal dry eyes.

In the USA, as of 2015, more than 50 million people were suffering from dry eye syndrome [7]. Also, in more than 50% of the cases, people discontinued the use of contact lens due to dry eye and discomfort associated with it, particularly at the end of the day. A cure included the use of rewetting solutions, lubricants, comfort agents, or artificial tears via eye drops to stabilize the tear film. However, the main disadvantage of eye drops is their low residence time (less than 5 minutes) [8].

Extended-release of HA from hydrogel contact lenses to treat dry eye syndrome

A HA-loaded hydrogel contact lens has been successfully developed to treat dry eye syndrome.This form of contact lens can deliver HA within a therapeutic level for 10 days without affecting the optical and physical properties of the contact lens [9]. The HA-CD44 interaction allows retention of water in the ocular space due to its high-water binding capacity.

The HA entrapped in hydrogel sheets has shown sustained release probably due to crosslinked structure of lens matrix and high molecular weight of the long chain-like structure of HA. This compound resists degradation and adheres to the ocular surface for prolonged periods. Contact lenses as a drug delivery device have the potential to overcome the drawbacks of eye drops by providing extended delivery without blurring. The hydrogels appeared safe in a cytotoxicity study [10].

In Osteoarthritis

HA is approved for treating degenerative knee arthritis via intra-articular injections directly into the knee joint. It has resulted in the repair of the damaged tissue, thereby lessening pain and inflammation [11]. HA injections into joints can provide months-long relief from osteoarthritis.

In Cosmetics

HA is a key molecule in skin aging, providing skin moisture by retaining water [12]. While the human body naturally produces HA and acts as 'nature's moisturizer,' cosmetology specialists say an extra drop a day can do wonders for skin tone, texture, and firmness.

HA is used as a dermal filler in cosmetic surgery. Many HA products mainly consist of beauty products, which provide essential moisture to maintain the skin's elasticity and smoothness. These include hyaluronic moisturizers, shampoos, creams, conditioners, and bath oils. A recently approved HA skin filler by the FDA binds to water when injected into the skin, providing volume to easily fill in the larger folds of the skin around the cheeks and mouth.

Today, HA is a workhorse of cosmetics that moisturize skin and reduces the prominence of wrinkles [13]. In medicine, plastic surgeons inject HA as a dermal filler to lift sunken areas in the face. It holds 1000 times its own weight in water. This property is being used in many cosmetic products that come with anti-aging and moisturizing benefits. HA can be used in skincare products or added to health food to reduce dry skin. Due to its high biocompatibility, HA can improve tissue growth to heal wounds when combined with receptors on the cell surface.

HA helps in the reduction of damage caused by scars, wounds, or lines. It is also used to improve the shape of the skin. Hence, it is used as a dermal filler, a major non-surgical procedure. Other key benefits include healing wounds and aiding in UV-damage repair. These special properties are driving sales of products with HA.

In biomedical application

HA is a versatile biomaterial that binds to specific cell receptor CD44 (frequently overexpressed on the tumor cell surface) and is useful in skin rejuvenation, drug delivery, tissue engineering, and molecular imaging. This is due to its biodegradable, non-toxic, biocompatible, non-immunogenic, and noninflammatory characteristics. HA can be chemically modified by crosslinking, grafting, linking with hydrophobic substances and drugs, or through polyion complex formation with oppositely charged polysaccharides, proteins, or surfactants. Its interpenetrating network produces self-assembled aggregates, nanoparticles and gels etc. [14].

- Drug-HA conjugation enables cancer cell-specific targetting and onsite drug release
- Cleavable HA-drug conjugates have shown dramatic improvement in the absorption and efficacy of drugs [15]
- HA-based products are currently undergoing clinical trials catering to the treatment of various diseases. The use of implant technology can be viewed as a worthy prospect in the future. In situ gelling features of crosslinked HA have been tested for implantable and depot drug formulations [14]
- Sustained-release human growth hormone is yet another functional area using HA (Approval is still pending for this application [16]

HA is still one of the most impressive nanomaterials for constructing various drug delivery systems/ biomedical applications. HA-based nanomaterials show great promise for future biomedical applications in cancer therapy.

Challenges

- High hydrophilicity and enzymatic vulnerability of a native HA make it inferior, relative to commercially available synthetic polymers. This can be overcome through its mechanical enforcement, employing covalent and non-covalent approaches. In addition to improved stability and intrinsic properties, chemical modifications have been shown to dictate the biological fate of HA

- Many experiments show that HA-based nanomaterials can serve as a platform for targeted chemotherapy, gene therapy, immunotherapy, and combination therapy with good potential for future biomedical applications in cancer treatment

- The design and synthesis of structurally defined HA are vital to developing safer and more reliable drugs for a better understanding of structure-activity relationships. Although there is just one commercially available drug delivery product using HA, the molecule has been considered to have great potential as a novel drug carrier in the forms of conjugate and physically and chemically crosslinked hydrogel depot systems etc.

- It is necessary to obtain specially designated molecular weight or uniform size-defined HA to extend the applications of HA and make better HA-containing biomedical products. To achieve low polydispersity, we must know the regulatory mechanisms of initiation and elongation during the synthesis process of HA. The key mechanisms which control molecular weight during HA biotechnological synthesis should be clarified to develop methods to produce more uniform-size defined HA

- Additionally, progresses in metabolic engineering is necessary to improve HA yield and find biosynthetic strategies with good sustainability and acceptable production cost

- While various biological fields are developing, HA in the form of a useful formulation with desired properties such as robust stability, reduced dosage frequency, wide options for its delivery can be envisioned, which can improve its market in a broad sense

- Researchers have found that eating hyaluronic acid has several efficacies, including replenishing skin moisture, relieving osteoporosis, and restoring injured gastric mucosa. China granted hyaluronic acid as an ingredient for health food in 2008

- Rooster-comb HA is losing ground in the medical market. Despite the historical association with rooster combs today, only half of the major brands for knee injection products come from rooster comb. There is a need to find other ways of producing medical-grade HA

Syngene's capability in chemical modification of HA

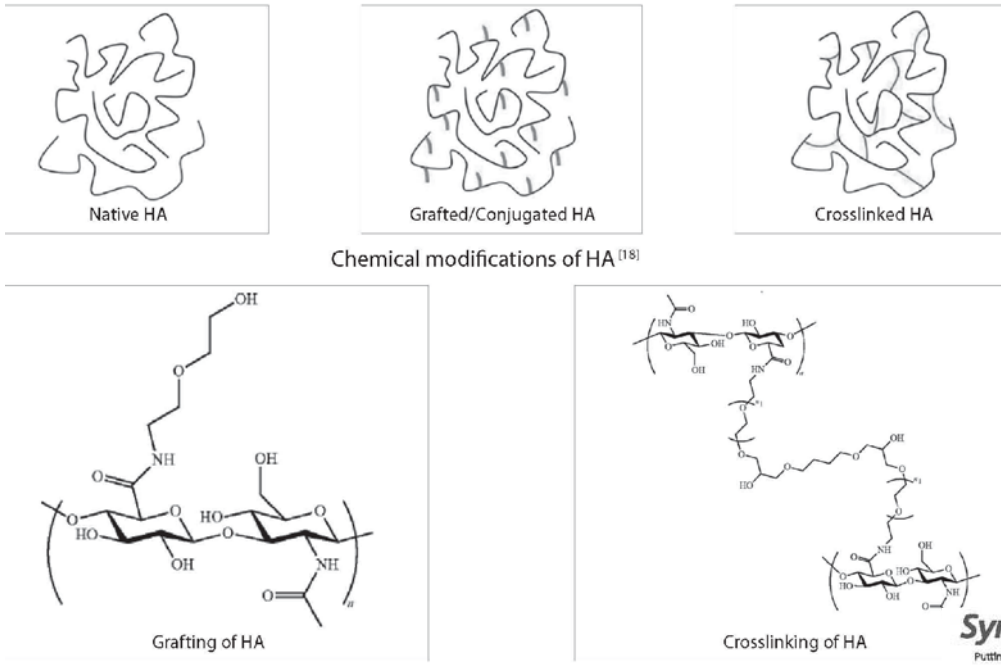
For over 15 years, Syngene's Performance and Specialty Materials (PSM) group has been developing unique value-driven solutions to meet the innovation needs of its clients. Our capabilities include:

- Expertise in chemical modification of HA such as methacrylation, grafting, and crosslinking for various applications by improving and customizing its properties [15, 17, 18]. We have also developed a commercially viable downstream isolation process to produce high purity/ quality modified HA

- HA-based drug research has seen a recent surge mainly due to some properties like mucoadhesion, biocompatibility, and ease of chemical modification.

- Researchers have also been working on hydrogel contact lenses that can release HA at a controlled rate. Finally, exciting technologies on the horizon for eye care include crosslinked HA

Synthesis of a PEGylated HA (1.2 MDa HA) using 2-(2 - aminoethoxy) ethanol, and a covalently crosslinked network of PEG - functionalized HA using BDDE was reported recently [18]. With the suitable chemical modification of HA (as an additive), Syngene's PSM can contribute to a biomedical device such as a contact lens that is highly comfortable for the wearer by improving wettability, lubriciousness etc. It is believed that the functionalized material has higher stability, longer shelf life due to less enzymatic, thermal, and oxidative degradation. It is also believed that these materials exhibit anti-biofouling, antimicrobial properties for prolonged contact with the body.



Future roadmap for HA

- Use of strategies like one-pot synthesis, chemo-selective synthesis, solvent-free methods, and 'click chemistry' approaches need to be employed for optimizing the synthesis of HA derivatives
- New chemical modifications of HA to make the cosmetic and medical ingredient even more common than it already is
- Functionalizing the amide and alcohol groups and studying how the modified HA behaves on the skin and in other biochemical environments
- Improving reproducibility of HA-derivatives during scale-up, their pharmacokinetic and pharmacodynamic properties to allow them to be successfully commercialized
- Developing HA-based next-generation products such as innovative crosslinked derivatives, polymer-drug conjugates, and delivery systems to enable high biocompatibility, prolonged half-life, and improved in situ permanence
- Developing economical approaches to make HA more feasible as a drug delivery agent or product. This is because lab synthesis of HA can be a laborious and time-consuming process. As a result, the final product can become very expensive when other costs such as the inclusion of nanocarriers, chemical conjugates, or any other biological agents are involved

Conclusion

HA has immense possibilities for application in the cosmetic and pharma industries. Apart from the chemical modification of HA by grafting and crosslinking, Syngene's performance and specialty materials (PSM) could contribute to creating new applications using 'click chemistry,' functionalization of the amide, and alcohol groups for preparation of HA derivatives, polymer-drug conjugate, delivery systems and so on.

Syngene's PSM unit has a strong legacy in this space, evidenced by robust and sustained growth from the last 15 years. We have clients across discovery, process development, and supply chain for various polymers of commercial importance. This includes polymers for the consumer industry for use in drug delivery (i.e., injectable, hydrogel), in personal care products (i.e., cosmetics, oral care, hair care), and so on.

By partnering with Syngene, you can accelerate your R&D programs in PSM to achieve faster go-to-market with high-quality products which are in tune with regulatory standards.

Syngene
Putting Science to Work

About the author

Dr. Rudhramyna Gnaneshwar
Group Leader-Performance and Specialty Materials (PSM), Syngene

Dr. Rudhramyna Gnaneshwar is a Group Leader-Performance and Specialty Materials (PSM) at Syngene International Ltd, Bengaluru. He has over 15 years of post-doctoral and industrial experience in synthetic polymer chemistry (Anionic/Cationic polymerization, controlled radical polymerization (ATRP, RAFT) for making various homo, random, block, star and comb polymers, ring-opening polymerization (ROP), functionalization of polymers, grafting of polymers, hydrogenation of polymers and so on).

Dr. Gnaneshwar has a M.Sc in Organic Chemistry and a M.Tech in Material Science. He earned a Ph.D. in polymer chemistry from National Chemical Laboratory, Pune. After 2.5 years of post-doctorate studies in New Synthesis Techniques and Application (NSTA) at the Institute of Chemical and Engineering Sciences (ICES), Singapore, and 1.5 years in Mitsui Chemicals Inc. at Sodegaura center, Chiba, Tokyo, Japan, he returned to India. He is currently working in Syngene for the last 11 years.

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PHARMACY - PHARMACISTS: ALWAYS TRUSTED FOR YOUR HEALTH

by

Ms. Zaiba Fathima. F
P.S.V. College of Pharmaceutical Science & Research, Krishnagiri

Note: This article was awarded 3rd prize in the Essay Competition conducted by our Trust

INTRODUCTION:

Pharmacy and the pharmacist are the basic connection between the public and the Doctor. Pharmacy is the place where the prescribed and non-prescribed (OTC) drugs are sold, provision of drug information, interpretation of prescribed drugs and giving counselling to the patients. Pharmacists are the health professional who specialized in the right way for handling the drugs. That's why pharmacists are also called as a 'chemist' or a 'druggist'. Pharmacists are the only professional, who knows how the drug is going to act on a patient, what are the contraindications and so on. The deference between the pharmacist and a Doctor is pharmacist knows which drug should be used against a specific disease and how the drug will be reacting in patient's body and every other information about a drugs, Doctor knows which drug will be effective against a disease only after a pharmacist providing information about the drug. The Doctor can only prescribe but pharmacist ensuring the prescribed medicine and advising patients about medicine, how to take them, and what reactions may occur, answering patient's question. So the pharmacy and the pharmacist are always trusted for your health.

PHARMACIST:

Pharmacy is profession were they are many areas where we can work, such as community pharmacy, nuclear pharmacy, health-system pharmacy, drug and control administration, pharmaceutical education, wholesales pharmacy, organization management. What does pharmacist do in pharmacy? Just provide the medicine which has prescribed by a doctor. What is the pharmacist work, why pharmacy is one of the top career option, what does it mean to be a pharmacist.

ROLE AND RESPONSIBILITY:

The role of a pharmacist is drug preparation, research and development, quality assurance, and confirming that prescribed calculation of doses are correct. The main responsibility of pharmacy-pharmacists is the quality medicines are supplied to patients, ensuring the supply of medicine is within the law; the prescribed medicine to the patient is suitable, advising patients, explaining the prescription and medicine.

CHALLENGES:

Pharmacist are facing many difficulties on a daily basis, being a pharmacist is not easy by knowledge and by other perspectives. Pharmacist should update their knowledge as well as their skills do deal with patients. Being a pharmacist is dealing with lots of different people like patients and Doctors, so we have to be the best in interpersonal skills. When the scheduled time is less we have to be quick and perfect in every aspects with our work, doing a small mistake may cause a loss of life that's the type pressure a pharmacist handles. Such challenges can be

handled when a person fully devoted to his profession and knows a value of life; this is a reason why pharmacist is always trusted for your health.

CONTRIBUTION:

As we all know the world has faced a hard time due to the pandemic, this is the first time to face such a huge problem without knowing what it is. CONID-19 has taught us many things in personal life, professional life and mainly the value of life. No one had any idea what it was and how it is spreading, that's the point where Doctors and pharmacist teamed up. Without Doctors it was not possible to treat patients but without a pharmacist the Doctors were not able to figure out what to do. The world turned towards the pharmacist, this was the first time were the world found pharmacist as an individual, who is going to save the life of their relative, daughter, mother, son, father, and their families.

The first drug recommended, results were not so good. The second drug, third drug it went off the results started to improve but the loss of life was still a threat. Then the search for vaccine got a success everyone got relieved but the main problem was about to start.

The population of the world is 7.9 Billion, after the news the pressure has gone out of range people are getting restless for the vaccine still the cases were increasing, the world eyes were stuck on pharmacist.

SERVICES AND DISTRIBUTION:

During the COVID-19 everyone was looking forward to the pharmacist. The services provided by the pharmacist, the suggestion on drugs to be used and the combinatory drugs. Suggesting the drugs was a part, now pharmacist has to look up for their side effects, contraindication, doses etc. Then drug which has been suggested has to reach every hospital and nursery homes though out the world. We have to suggest the drugs according to the countries and there conditions that is challenging. Day by day it was getting difficult to handle, the solution has to be given soon. The pharmacist used every probable equation to solve the problem, the result was found as a vaccine. The main problem was supplying, it became easy due to the contribution of all the health care professional and suppliers. The problem has not fully finished but it is under control.

The pharmacy was the only lifeline for every other problem like allergy, stomach pain, ulcer, heart diseases, and every other problem associated with human and animal body. Due to lockdown everyone was stuck not able to go to hospital so everyone had to rely on pharmacy.

CONCLUTION:

Ever profession is special in its own ways; pharmacist is one of the professional which involves the life and health of a patient. Pharmacist is known as a 'Doctor of medicine' who can change poison into a medicine which can cure a disease. Somehow this was forgotten by the people that pharmacist also play a very important role in taking care of their health especial in India. I hope this pandemic was a reminder that every pharmacy-pharmacist always trusted for your health.

INFORMATION

M.PHARM & PHARM D SCHOLARSHIPS 2021-22 AWARDED BY TNPSW TRUST

Profile of 3rd Rank

PHARMACEUTICS

Name: Ms. Archana Ramakrishnan
Project Title: Drug loaded magnetic Nanoparticles Targeting Tumor Microenvironment with Hypoxic and ABCB1 resistant cancer
College: JSS College of Pharmacy, Ooty
Guide's Name: Mr. R. Arun

Name: Ms. K. Chandraleka
Project Title: Formulation and Evaluation of Phytosome of Terminalia chebula for Antihyperlipidmic Activity
College: RVS College of Pharmaceutical Sciences, Coimbatore
Guide's Name: Mrs. B. Kamaleshwari

PHARMACEUTICAL CHEMISTRY

Name: Mr. Navinkumar. M
Project Title: "Synthesis and in-vitro assay of (E)-1-phenyl-N-(2-phenyl-1,3-benzoxazol-6-yl) methanimine derivatives for inhibition of SIRT2 enzyme against Parkinson's disease"
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. Gomathy Swaminathan

PHARMACEUTICAL ANALYSIS

Name: Mr. M. Sivaganesh
Project Title: Analytical method development and validation of Capmatinib in bulk and tablet dosage form by UV and HPLC method.
College: Periyar College of Pharmaceutical Sciences, Tiruchirappalli
Guide's Name: Mr. M.K.M. Abdhul Lathiff

Name: Ms. Geetha. M
Project Title: Validated Bio-analytical method for DDI of Rosuvastatin calcium with caffeine in human plasma using solid phase extraction by RP-HPLC technique and its degradation studies by Spectrofluorimetric method
College: College of Pharmcy, SRIPMS, Coimbatore
Guide's Name: Dr. Sangeetha. R. K.

PHARMACOLOGY

Name: Ms. Akhina Tom

Project Title: Evaluation of PKN antagonist as therapeutic strategy for Alzheimer's disease

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Praveen. TK

PHARMACOGNOSY

Name: Ms. N. Sandhiya

Project Title: Formulation and evaluation of transdermal patch of Cardiospermum halicacabum linn and Cissus quadrangularis for anti-rheumatic activity.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. R. Vijaya Bharathi

PHARMACY PRACTICE

Name: Mr. Gunasekar. M

Project Title: Knowledge, Attitude and Perception towards acceptance of covid-19 vaccination among general population

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Dr. P. Rama

Name: Mrs. Janusha. J

Project Title: Awareness towards HPV infection and vaccination among Pharmacy students and their parents

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Dr. Shalini. S

PHARM D

Name: Ms. Priyanka. R, Ms. Reethika. A, Ms. Rinta Sara Dency Johnson, Mr. Saravanan. K. S.

Project Title: Development and validation of an instrument for the evaluation of discharge medication Counseling by Pharm D students and its comparison with standard guidance documents

College: College of Pharmacy, SRIPMS, Coimbatore

Guide's Name: Ms. A.S. Manjuladevi

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th October, 2022

G.S.R. 778(E).—Whereas a draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019 was published, as required under sub-section(1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 32(E), dated the 21st January, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of fifteen days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 21st January, 2022;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the New Drugs and Clinical Trials Rules, 2019, namely: —

1. (1) These rules may be called the New Drugs and Clinical Trials (Third Amendment) Rules, 2022.

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

2. In the New Drugs and Clinical Trials Rules, 2019 (hereinafter referred to as the principal rules), in rule 8, in sub-rule(3), after clause(ii), the following proviso shall be inserted, namely:—

   "Provided that, where no communication has been received from the Central Licensing Authority within the said period of forty-five working days, the registration of Ethics Committee shall be deemed to have been granted by the Central Licensing Authority and such registration shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules."

3. In the principal rules, in rule 8, after sub-rule(3), the following sub-rule shall be inserted, namely:—

   "(3A) The applicant who has got deemed approval under the proviso to clause(ii) of sub-rule(3) shall, before initiating the functions of the Ethics Committee, inform the Central Licensing Authority in Form CT-02A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-02A which shall become part of the official record and shall be called deemed registration of the Central Licensing Authority."

4. In the principal rules, in rule 22, in sub-rule(2), the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, the permission to conduct all clinical trial shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules."

5. In the principal rules, in rule 22, after sub-rule(2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has got deemed approval under the proviso to sub-rule(2) shall, before initiating the clinical trial, inform the Central Licensing Authority in Form CT-06A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-06A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

6. In the principal rules, in rule 24, the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, the permission to conduct clinical trial shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules:

Provided further that the applicant who has got deemed approval under this rule shall before initiating the clinical trial, inform the Central Licensing Authority in Form CT-06A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-06A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

7. In the principal rules, in rule 34, in sub-rule(2), the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, the permission to conduct bioavailability or bioequivalence study of the new drug or investigational new drug shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate such study in accordance with these rules."

8. In the principal rules, in rule 34, after sub-rule(2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has got deemed approval under the proviso to sub-rule(2) shall, before initiating bioavailability or bioequivalence study of the new drug or investigational new drug, inform the Central Licensing Authority in Form CT-07A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-07A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

9. In the principal rules, in rule 53,—

(a) in sub-rule(1), the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, the permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or test and analysis shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to manufacture the new drug or investigational new drug for said purposes in accordance with these rules." ;

(b) in sub-rule(2), the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, the permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or test and analysis shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to manufacture the new drug or investigational new drug for said purposes in accordance with these rules.".

10. In the principal rules, in rule 53, after sub-rule(2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has got deemed approval under the proviso to sub-rule(1) and subrule (2) shall, before manufacturing the new drug or investigational new drugs for the said purposes inform the Central Licensing Authority in Form CT-11A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-11A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority.".

11. In the principal rules, in rule 60,—

(a) in sub-rule (1), the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, to manufacture unapproved active pharmaceutical ingredient or to manufacture the pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to manufacture the unapproved new drug or its pharmaceutical formulation for said purposes in accordance with these rules." ;

(b) in clause(ii) of sub-rule(2), for the existing proviso, the following provisos shall be substituted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority within the said period of ninety working days, to manufacture unapproved active

pharmaceutical ingredient or to manufacture pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to manufacture the unapproved new drug or its pharmaceutical formulation for said purposes in accordance with these rules:

Provided further that in case of rejection, the applicant may request the Central Licencing Authority to consider the application within a period of sixty days from the date of such rejection on payment of fee as specified in the Sixth Schedule and submission of required information and documents." ;

(c) after sub-rule(2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has got deemed approval under the proviso to sub-rule(1) shall, before manufacturing unapproved active pharmaceutical ingredient or its pharmaceutical formulation for the said purposes inform the Central Licensing Authority in Form CT-15A and CT-14A respectively and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-15A and CT-14A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority.".

12. In the principal rules, in the Eighth Schedule, —

(I) after Form CT-02, the following Form shall be inserted, namely:—

"FORM CT-02A

(See rules 8, 9, 10 and 14)

INFORMATION TO INITIATE THE FUNCTIONING OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

I……. (Name and full address with contact details) hereby inform the Central Licensing Authority to initiate functioning of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place: ……. Signature

Date: ……..... (Name and designation) " ;

(ii) after Form CT-06, the following Form shall be inserted, namely: —

"FORM CT-06A

(See rule 22)

INFORMATION TO INITIATE CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to initiate the conduct clinical trial on new drug or investigational new drug.

The details of the application areas under:

1.Name of Applicant:	
2. Nature and constitution: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id: (ii) Clinical trials site address, telephone number, mobile number, fax number and e-mail id: (iii) Name and address of person responsible for payment of compensation, if any: (iv) Address for correspondence: [corporate or registered office or clinical trial site]	
4. Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].	
5. Phase of the Clinical Trial	
6. Clinical trial protocol number with date:	
8. I hereby declare that I have already submitted the application under rule 21 of these rules and have been granted deemed approval under rule 22(2) and enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials rules, 2019.	
9. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place: …….
Date: ……..... Signature
(Name and designation)

Annexure:

I. Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

II. Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

(iii) after Form CT-07, the following Form shall be inserted, namely: —

"FORM CT-07A

(See rules 34, 35, 36, 37 and 38)

INFORMATION TO INITIATE BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to initiate to conduct bioavailability or bioequivalence study (strike off whichever is not applicable) of the new drug or investigational new drug as per protocol number_____ dated_____ in the below mentioned study centre.

2. Details of new drug or investigational new drug and study centre [As per Annexure].

3. This deemed approval is subject to the conditions prescribed in part B of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: ……. Signature

Date: ……..... (Name and designation)

Annexure:

I. Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

II. Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

(iv) after Form CT-11, the following Form shall be inserted, namely:—

"FORM CT-11A

(See rules 53, 54, 55, 56, 57 and 58)

INFORMATION TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR CLINICAL TRIAL, BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to initiate the manufacturing of the new drug or investigational new drug for conduct of clinical trial or bioavailability or bioequivalence study as per protocol number_____ dated_____ in the below mentioned clinical trial sites or bioavailability and bioequivalence study centre [As per Annexure] or for examination, test and analysis.

Serial Number	Name of the new drug or investigational new drug to be manufactured.	Class of new drug or investigational new drug.	Quantity to be manufactured.

2. This deemed approval is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act, 1940.

3. Details of manufacturer and manufacturing site under this licence.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of manufacturing site (full address with telephone, fax and email address of the manufacturing site).

Place: …….

Date: …….....

Signature

(Name and designation)

Annexure:

Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

(v) after Form CT-14, the following Form shall be inserted, namely: —

"FORM CT-14A

(See rules 60, 61, 62, 63 and 64)

INFORMATION TO MANUFACTURE FORMULATION OF UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR TEST OR ANALYSIS OR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to manufacture the formulation of the unapproved active pharmaceutical ingredient specified below for test or analysis or for conduct of clinical trials or bioavailability or bioequivalence study.

Name of the unapproved active pharmaceutical ingredient (API) to be manufactured	Quantity

2. Details of Manufacturer, Manufacturing site of formulation.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of manufacturing site (full address with telephone, fax and email address of the manufacturing site).

3. Details of Manufacturer and Manufacturing site of active pharmaceutical ingredient to be supplied.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of site where the manufactured unapproved active pharmaceutical ingredient to be used (full address with telephone, fax and e-mail address of the manufacturing site)

4. This deemed approval is subject to the conditions specified in Chapter VIII of the New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act, 1940.

Place: …….

Signature

Date: …….....

(Name and designation) " ;

(vi) after Form CT-15, the following Form shall be inserted, namely: —

"FORM CT-15A

(See rules 60, 61, 62, 63 and 64)

INFORMATION TO MANUFACTURE UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR THE DEVELOPEMNT OF FORMULATION FOR TEST OR ANALYSIS OR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to manufacture the unapproved active pharmaceutical ingredient specified below to manufacture its formulation for test or analysis or for conduct of clinical trials or bioavailability or bioequivalence study.

Name of the unapproved active pharmaceutical ingredient (API) to be manufactured	Quantity

2. Details of Manufacturer, Manufacturing site of active pharmaceutical ingredient.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of manufacturing site (full address with telephone, fax and email address of the manufacturing site).

3. Details of Manufacturer, Manufacturing site of formulation manufacturer to be supplied.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of site where the manufactured unapproved active pharmaceutical ingredient to be used (full address with telephone, fax and e-mail address of the manufacturing site)

4. This deemed approval is subject to the conditions specified in Chapter VIII of the New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act, 1940.

Place: ……. Signature

Date: ……..... (Name and designation) " ;

Annexure

I. Details of record of unapproved active pharmaceutical ingredient manufactured:

Serial number	Date of manufacture	Licence number	Name of the unapproved active pharmaceutical ingredient	Quantity manufactured	Manufactured for

II. Details of reconciliation of unapproved active pharmaceutical ingredient manufactured:

Date	Name of the unapproved active pharmaceutical ingredient	Licence number	Quantity manufactured	Quantity supplied	Quantity remained	Supplied to	Quantity – left over or remain unused or got damaged or expired or found of substandard quality	Action taken

* Write NA where not applicable." .

[F. No. X.11014/29/2021-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification number G.S.R. 227(E), dated the 19th March, 2019 and last amended vide notification number G.S.R. 21(E), dated the 18th January, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th October, 2022

G.S.R. 777(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017 was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 710(E), dated the 20th September, 2022 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (I), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 20th September, 2022;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and subject to ex post consultation with the Drugs Technical Advisory Board and consideration of suggestions of the Board in accordance with the provisions of the said sections, the Central Government hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (1) These rules may be called the Medical Devices (Sixth Amendment) Rules, 2022.

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

2. In the Medical Devices Rules, 2017 (hereinafter referred to as the said rules), in rule 13,—

(a) in sub-rule (2), after the word and letter “Class A”, the brackets and words “(other than nonsterile and non-measuring)” shall be inserted;

(b) in sub-rule (3), after the word and letter “Class A”, the brackets and words “(other than nonsterile and non-measuring)” shall be inserted.

3. In the said rules, in rule 14, after the word and letter “Class A”, the brackets and words “(other than non-sterile and non-measuring)” shall be inserted.

4. In the said rules, after rule 19F, the following shall be inserted, namely:—

"CHAPTER IIIB

REGISTRATION OF CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICES

19G. Application of this Chapter.— (1) This Chapter shall be applicable to all non-sterile and non-measuring devices classified as Class A medical devices as per the First Schedule (herein in this chapter referred to as Class A non-sterile and non-measuring medical device).

(2) The medical devices referred to in sub-rule (1) shall be registered through an identified online portal established for the purpose.

19H. Uploading of information for registration.— (1) The manufacturer of a Class A non-sterile and non-measuring medical device shall upload the information specified in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The manufacturer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the manufacturer stating that the proposed device is a Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the manufacturer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the manufacturer shall self-certify to comply with the standards specified in these rules; and

(vi) an undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.

19-I. Registration number.— The registration number for a Class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19H on the Online System for Medical Devices established for this purpose.

19J. Import of Class A non-sterile and non-measuring medical device.— (1) Any person who intends to import any Class A non-sterile and non-measuring medical device shall upload the information in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The importer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of importer and the name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the importer stating that the proposed device is Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the importer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the importer shall self-certify to comply with the standards specified in these rules;

(vi) self-attested copy of the overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority or Free Sale Certificate issued by the National Regulatory Authority; and

(vii) an undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

19K. Registration number for import.— The registration number for import of a class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19J on the Online System for Medical Devices established for this purpose.

19L. Maintainance of records.— (1) The manufacturer or, as the case may be, importer shall maintain the records relating to manufacturing or importing along with its sales or distribution.

(2) The manufacturer or, as the case may be, importer shall produce the records, labels, instructions for use, on request by Licensing Authorities.

(3) The Licensing Authorities may verify the records and documents referred to in sub-rule (2) at any point of time and investigate quality or safety related failures or complaints.

19M. Cancellation or suspension of registration.— (1) The State Licensing Authority or the Central Licensing Authority, as the case may be, may, after giving the registrant an opportunity to show cause as to why such an order should not be passed, by an order in writing stating the reasons thereof, cancel the registration number generated under the provisions of rule 19-I or rule 19K, or suspend it for such period as the Licensing Authority thinks fit, either wholly or in respect of any of the medical devices to which it relates, if in its opinion, the registrant has failed to comply with any of the provisions of the rules under this Chapter;

(2) Any person who is aggrieved by an order passed by the State Licensing Authority or the Central Licensing Authority, as the case may be, may, within forty-five days of the receipt of a copy of such order, prefer an appeal to the State Government or the Central Government, as the case may be, and the State Government or the Central Government, shall after giving the said appellant an opportunity of being heard, confirm, reverse or modify such order.".

5. In the said rules, in rule 20,—

(a) in the marginal heading, after the word and letter "Class A", the brackets and words "**(other than non-sterile and non-measuring)**" shall be inserted;

(b) after the word and letter "Class A", wherever they occur, the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

6. In the said rules, in rule 31, in sub-rule (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

7. In the said rules, in rule 36, in sub-rule (5), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

8. In the said rules, in the Second Schedule, in the table, for the word and letter "Class A", wherever they occur, the words and brackets "Class A (other than non-sterile and non-measuring)" shall be substituted.

9. In the said rules, in the Third Schedule, in Part II, in paragraph 1, in clause (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

10. In the said rules, in the Fourth Schedule, in Part II, in paragraph (i), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

11. In the said rules, in the Eighth Schedule, in the table, after serial number 7 and the entries relating thereto, the following shall be inserted, namely:—

S.No	Class of medical devices	Extent and conditions of exemptions
"8.	Manufacturing of Class A non-sterile and non-measuring medical devices	All provisions of Chapter IV, VII, VIII and XI of these rules, subject to the condition that the manufacturer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.
9.	Import of Class A non-sterile and non-measuring medical devices	All provisions of Chapter V, VII, VIII and XI of these rules, subject to the condition that the importer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.".

12. In the said rules, in the Appendix,—

(a) in Form MD-2, after the word and letter "Class A", the brackets and words "(other than nonsterile and non-measuring)" shall be inserted;

(b) in Form MD-3, after the word and letter "Class A", the brackets and words "(other than nonsterile and non-measuring)" shall be inserted;

(c) in Form MD-4, after the word and letter "Class A", the brackets and words "(other than nonsterile and non-measuring)" shall be inserted;

(d) in Form MD-5, after the word and letter "Class A", the brackets and words "(other than nonsterile and non-measuring)" shall be inserted;

(e) in Form MD-6, after the word and letter "Class A", the brackets and words "(other than nonsterile and non-measuring)" shall be inserted.

[F. No. X.11014/10/2022-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 754(E), dated the 30th September, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th September, 2022

G.S.R.754(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 104(E), dated the 9th February, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 10th February, 2022;

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

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (i) These rules may be called the Medical Devices (Fifth Amendment) Rules, 2022.

   (ii) These rules shall come into force on the date of their publication in the Official Gazette.

2. In the Medical Devices Rules, 2017(hereinafter to be referred as the said rules), in rule 34, in sub-rule (1), after the words "wholesale licence for sale or distribution", the words, letters and figure "or registration certificate in Form MD-42" shall be inserted.

3. In the said rules, in rule 87, after sub-rule (1), the following sub-rule shall be inserted, namely:—

   "(1A) Any person not holding licence under sub-rule (1) and intends to sell medical devices exclusively as referred to in clause (zb) of rule 3, shall obtain registration certificate as provided in these rules.".

4. In the said rules, after rule 87, the following rules shall be inserted, namely:—

   "87A. Registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device.— (1) The State Licencing Authority shall appoint Licensing Authorities for the purpose of issuing registration certificate under this Part for such areas as may be specified.

(2) Any person who intends to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device, shall make an application in Form MD-41 to the State Licensing Authority for grant of registration certificate to sell, stock, exhibit or offer for sale or distribution.

(3) The application made under sub-rule (2) shall be accompanied with

(i) a fees specified in Second Schedule;

(ii) self certificate of compliance with respect to Good Distribution Compliance;

(iii) details of the applicant or firm including its constitution, along with identification proof, such as, Aadhar card or PAN card;

(iv) documentary evidence in respect of ownership or occupancy on rental of the premises;

(v) details of competent technical staff, under whose direction and supervision the sales activity of medical device shall be undertaken, who shall possess the following educational qualification and experience, namely:—

(a) hold a degree from a recognized University/Institution; or

(b) is a registered pharmacist; or

(c) has passed intermediate examination or its equivalent examination from a recognised Board with one-year experience in dealing with sale of medical devices;

(vi) brief description on other activities carried out by applicant, namely, storage of drugs, medical items, food products, stationeries, etc., or any other activities carried out by the applicant in the said premises; and

(vii) an undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with.

(4) The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a registration certificate in Form MD- 42, or if not satisfied, reject the application for reasons to be recorded in writing, within ten days from the date the application is made under sub-rule (2).

(5) If the application for grant of registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device is rejected under sub-rule (4), the aggrieved person may prefer an appeal before the State Government within forty-five days from the date of receipt of such rejection, which may, after such enquiry and after giving an opportunity of being heard to the appellant, dispose it within a period of sixty days from the date of receipt of such appeal.

87B. Conditions of registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device.— (1) The registration certificate granted under rule 87A shall be displayed at a prominent place in the premises visible to the public.

(2) The registration certificate holder shall provide adequate space and proper storage condition for storage of the medical devices.

(3) The registration certificate holder shall maintain requisite temperature and lighting as per requirements of such medical devices.

(4) The medical devices shall be purchased only from importer or licensed manufacturer or registered or licensed entity.

(5) Separate records, in the form of invoice or register or electronic details including software of purchases and sales of medical devices showing the names and quantities of such medical devices, names and addresses of the manufacturers or importers, batch number or lot number and expiry date (if applicable) shall be maintained.

(6) The records referred to in sub-rule (5) shall be open to inspection by a Medical Device Officer appointed under the sub-rule (2) of rule 18, who may, if necessary, make enquiries about purchases and sale of the medical devices and may also take samples for testing.

(7) All registers and records mentioned under these rules, shall be preserved for a period of not less than two years from the last entry, therein.

(8) The registration certificate holder shall maintain an inspection book in Form MD-43 to enable the Medical Devices Officer to record his observations and defects noticed.

87C. Validity of registration certificate.— (1) A registration certificate issued in Form MD-42, shall remain valid in perpetuity, subject to payment of registration certificate retention fee as specified in the Second Schedule, before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by State Licensing Authority:

Provided that, if the registration certificate holder fails to pay the required registration certificate retention fee on or before due date, the registration certificate holder shall, in addition to the registration certificate retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the registration certificate retention fee for every month or part thereof within six months:

Provided further that in the event of non-payment of such fee within the period referred to in the first proviso, the registration certificate shall be deemed to have been cancelled.

87D. Suspension and cancellation of Registration Certificate.— (1) Where the registration certificate holder contravenes any provision of the Act or these rules, the State Licensing Authority, shall, after giving the registration certificate holder an opportunity to show cause as to why such an order should not be passed, by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or, as the case may be, cancel the registration certificate.

(2) A registration certificate holder whose registration certificate has been suspended or cancelled by the State Licensing Authority under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the State Government and the State Government, shall after giving the registration holder an opportunity of being heard, confirm, reverse or modify such order, with reasons to be recorded in writing.".

5. In the said rules, in rule 88, in sub-rule (1), after the words "retail or wholesale", the words, letters and figures "or registration certificate in Form MD-42" shall be inserted.

6. In the said rules, in the Second Schedule,—

(a) in the provisions reference portion, after the figures and brackets "64(1), 81(1), 84," and before the figure "91", the following figures, letters and brackets shall be inserted, namely:—

"87A(3), 87C(1) and";

(b) in the table, after serial number 51 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:—

Sr. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
"52.	87A(3)	Registration certificate for sale of medical devices	3000
53.	87C(1)	Retention fee for registration certificate for sale of medical devices	3000"

7. In the said rules, in the Fourth Schedule, in Part I, in the format of application of Power of Attorney for issuance of import licence, in paragraph 1, after the words "or manufacturing licence", the words "or registration certificate" shall be inserted.\

8. In the said rules, in the Appendix,—

(a) after Form MD-40, the following Forms shall be inserted, namely:—

"Form MD-41

[See sub-rule (2) of rule 87A]

APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. Name of applicant:

2. Address of the premises to be registered:

3. Contact details of applicant including telephone number, mobile number, fax number and email id:

4. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

5. Name, qualification and experience of competent person appointed:

6. Fee paid on _____ Rs_____ receipt/challan/transaction Id_____.

7. I have enclosed the documents as specified in the sub-rule (3) of rule 87A of the Medical Devices Rules, 2017.

Place: _____

Date: _____

Name, designation & signature of

Director/Proprietor/Partner

Form MD-42

[See sub-rule(4) of rule 87A and sub-rule (1) of rule 87C]

REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

Registration No.: …….

1. M/s, ……(Name of the firm) situated at ……..……(full address with telephone and e-mail) has been registered to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device under the Medical Devices Rules, 2017.

2. Name and qualification of competent person:

3. This registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____

Date: _____

State Licensing Authority

Form MD-43

[See sub-rule (8) of rule 87B]

Form in which the Inspection Book shall be maintained

(A) The cover of the inspection book shall contain the following particulars, namely:—
1. The name and address of the registration certificate holder _____.

2. Registration certificate number_____.

(B) (i) The pages of the inspection book shall be serially numbered and duly stamped by the State Licensing Authority*. The pages, other than the first and the last pages, shall have the following particulars:—

Name and designation of the Medical Device Officer who inspected the premises:

Date of inspection _____

Observations of the Medical Device Officer _____

Signature of the Medical Device Officer

(ii) The first and last pages of the inspection book shall be endorsed by the State Licensing Authority with the following words, namely:—

Inspection book maintained by M/s _____situated at _____ for Registration number _____ in Form MD-43_____ under the Medical Devices Rules, 2017.

State Licensing Authority

Notes:
(i) Printed copy of the inspection book may be obtained by the licencee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time-to-time.
(ii) The inspection book shall be maintained at the premises of the licencee.
(iii) The original copy of observations made by the Medical Device Officer shall be maintained in the premises of the licencee and duplicate copy shall be sent to the State Licensing Authority. The triplicate copy shall be taken as record by the Medical Device Officer.";

(b) in Form MD-14, in paragraph 3, in sub-para (ii), after the words "manufacturing licence", the words "or registration certificate" shall be inserted;

(c) in Form MD-15, in paragraph 1, after the words "manufacturing licence", the words "or registration certificate" shall be inserted;

(d) in Form MD-26, in paragraph 3, in sub-paragraph (ii), after the words "manufacturing licence", the words "or registration certificate" shall be inserted;

(e) in Form MD-28, in paragraph 3, sub-paragraph (ii), after the words "manufacturing licence", thewords "or registration certificate" shall be inserted.".

[F. No. X.11014/15/2021-DR]
DR. MANDEEP K. BHANDARI, Jt. Secy.

Note: The Medical Devices Rules, 2017 was published in the Gazette of India, Extraordinary, Part II, section 3, subsection (i) vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 450(E), dated the 15th June, 2022.

F. No. 29/Misc/03/2022-DC (269)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the 21st October, 2022

NOTICE

Subject: Implementation of Gazette notification vide G.S.R 754(E) dated 30.09.2022 - Regarding.

The Ministry of Health and Family Welfare, Government of India has published Medical Devices (fifth amendment) Rules, 2022 vide G.S.R 754(E) dated 30.09.2022, wherein provision for Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device, as alternative to Drugs Sale License has been implemented with effect from 30.09.2022.

Various representations have been received from stakeholders, regarding implementation of said rules stating that their application in hard copy is not being accepted. As per the said rules, the applicant may apply for grant of Registration Certificate in Form MD-41 to the concerned State Licensing Authority (SLA) and the SLA after satisfying the requirements shall issue Registration Certificate in Form MD-42 to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device in the country.

Accordingly, all the SLAs are requested to accept the applications in hard copy from such applicants of medical devices and dispose off the application expeditiously on priority and also to ensure uninterrupted access/supply of such medical devices.

VGS

(Dr V. G. Somani)
Drugs Controller General (I)

To

All State/ UTs Drugs Controllers

Copy to:

1. All Stakeholders/Associations of Medical Devices & In vitro Diagnostics.
2. All Zonal/Sub-Zonal offices of CDSCO
3. All Port offices of CDSCO

Copy for information to:

PS to DGHS
PS to JS(R)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 28th September, 2022

S.O. 4574(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with sub-rule (1) of rule 18 of the Medical Devices Rules, 2017, the Central Government hereby makes the following amendments to amend the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 3739(E), dated the 2nd August, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii), namely:—

In the said notification, in the Table, after item number (15) and the entries relating thereto, the following shall be inserted, namely:—

Serial No.	Name of Government Analyst	Name of Laboratory	Medical Device
(1)	(2)	(3)	(4)
"16. 17.	Shri. Hitesh Kumar Khare Dr. Debasis Maiti	the Regional Drugs Testing Laboratory, Chandigarh	Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, Catheters, I.V. Cannulae, Scalp Vein Set, Ligatures, Sutures, Staplers, Surgical Dressing, Umbilical Tapes.".

[F. No. X.11035/22/2018-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii) vide number S.O. 3739(E), dated the 2nd August, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 28th September, 2022

S.O. 4573(E).— In pursuance of the provisions of sub-rule (2) of rule 19 of the Medical Devices Rules, 2017, the Central Government hereby makes the following amendment to amend the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 2237(E), dated 1st June, 2018, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii), namely:—

In the said notification, in the Table, after item number (5) and the entries relating thereto, the following shall be inserted, namely:—

Serial Number	Name of Laboratory	Category of medical device
(1)	(2)	(3)
"6.	The Regional Drugs Testing Laboratory, Chandigarh	Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, Catheters, I.V. Cannulae, Scalp Vein Set, Ligatures, Sutures, Staplers, Surgical Dressing, Umbilical Tapes.".

[F. No. X.11035/22/2018-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii) vide number S.O. 2237(E), dated the 1st June, 2018. Uploaded

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th August, 2022

G.S.R. 654(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 382(E), dated the 23rd May, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 23rd May, 2022;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Seventh Amendment) Rules, 2022.

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

2. In the Drugs Rules 1945, in rule 75,—

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

"(3A) The application referred to in sub-rule (3) of rule 75 of these rules, and the application for grant of permission to manufacture new drug for sale or distribution under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B of these rules, as the case may be, shall be made simultaneously.";

(b) for sub-rule (6), the following sub-rule shall be substituted, namely:—

"Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B, the licence to manufacture for sale or distribution of the drugs shall be granted after approval of the drug as new drug.".

[F. No. X.11014/2/2022-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 623(E), dated the 10th August, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th August, 2022

S.O. 3758(E).—In exercise of the powers conferred by section 6 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with clause (a) of sub-rule (1) of rule 19 of the Medical Devices Rules, 2017, the Central Government hereby authorises Dr. Saroj Kumar Ghosh, Director In-charge of Central Drugs Laboratory, Kolkata, to sign statutory certificate of test or evaluation of samples of medical devices sent by Courts of Law under sub-section (4) of section 25 of the said Act or in Form MD-30 of the Medical Devices Rules, 2017, as the Director In-charge of the said laboratory, for the whole of India with effect from the date of publication of this notification in the Official Gazette till the regularly appointed person takes charge of the post or until further orders, whichever is earlier.

[F. No. X.11014/4/2022-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th August, 2022

G.S.R. 623(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 227(E), dated the 29th March, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 30th March, 2022;

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

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Sixth Amendment) Rules, 2022.

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

2. In the Drugs Rules, 1945, in rule 127, in sub-rule (1), for the proviso, the following proviso shall be substituted, namely:—

"Provided that in case of disinfectants, in addition to the above said colours, the colours referred in IS 4707 (Part I) as amended by Bureau of Indian Standards from time to time or any of the colours listed in the table below, which is non-staining shall be permissible to use.

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
1.	Guinea Green B	42085	Monosodium salt of 4-(N-ethyl-psulfobenzylamino)–diphenyl -methylone-(1-(N-ethyl-N-p-sulfonium -benzyl)Δ2,5-cyclohexadien- imine)

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
2.	Light Green SF Yellowish	42095	Disodium salt of 4-[4-(N-ethyl-psulfobenzylamine)-phenyl)-4-sulphonium- - phenyl)methylene]-2(-(N-ethyl-Nsulfobenzyl) Δ2,5-Cyclohexadienimine
3.	Tartrazine	19140	Trisodium salt of 3-carboxy-5-hydroxy-1-psulfophenyl- 4-p- sulfophenylazo -pyrazole
4.	Sunset yellow FCF	15985	Disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid
5.	Ponceau 3R	16155	Disodium salts of a mixture of 1-alkylphenylazo-2-napthol 3, 6-disulfonic acids
6.	Amarnath	16185	16185 Trisodium salt of 1-(4-sulfo-1- napthyl - -azo) 2-naphthol 3, 6- disulfonic acid
7.	Erythrosine	45430	Disodium salt of 9-0-carboxyphenyl-6- hydroxy 2,4,5, 7- tetraiodo-3- isoxanthone
8.	Ponceau SX	14700	Disodium salt of 2-(5 sulfo-2, 4-xylyl- azo)-1-naphthol-4- sulfonic acid
9.	Brilliant Blue FCF	42090	Disodium salt of 4-(9-4-(N-ethyl-psulfobenzylamino)-phenyl)- 2-sulfonium phenyl)- methylene)-(1-(N-ethyl-N-psulfobenzyl)- Δ2, 5- cyclohexadienimine)
10.	Indigocarmine	73015	Disodium salt of 5,5'-indigotindisulfonic acid
11.	Wool Violet 5 BN (Acidviolet 6B)	42640	Monosodium salt of 4-(N-ethyl-psulfobenzylamino)-phenyl)-(4- (N-ethyl-p- (sulfonium-benzylamine)-phenyl) methylene)- (N, N- dimethyl-Δ2,5-cyclohexadienimine)
12.	Light Green SF Yellowish	42095	Calcium salt of 4-(4-(N-ethyl-p-sulfobenzyl) (minophenyl)(4- sulfonium-phenyl) methylene), (1-(N-ethyl-N-p-sulfobenzyl)-Δ2,5-cyclohexadienimine)
13.	Alizarin Cyanine Green F	61570	Disodium salt of 1,4-bis (O-sulfo-p-toluino) anthraquinone
14.	Quinazarine Green SS	61565	1,4-bis-(p-Toluino)-anthraquinone
15.	Fast Green FCF	42053	Disodium salt of 4-(4-(ethyl-psulfobenzylamino)-phenyl) (4- hydroxy-2sulphoniumphenyl) methylene)-(1-N-ethyl-Np- sulfobenzyl) Δ2, 5, cyclohexa -dienimine)

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
16.	Acid Fast Green	42100	Monosodium salt of 4-(4-N-ethyl-psulfobenzylomino) phenyl)- (o-chlorophenyl)-methylene)- 1-(N-ethyl-N-p-sulfoniumbenzyl- Δ2,5, cyclohexa - -dienimine)
17.	Pyranine Concentrated	59040	Trisodium salt of 10-hydroxy-3,5,8-pyrenetrisulfonic Acid
18.	Quinoline Yellow WS	47005	Disodium indandione
19.	Quinoline Yellow SS	47000	2-(2-quinolyl)-1, 3 indandiene
20.	Poneceau 2 R	16150	Disodium salt of 1-xylylazo-2-naphthol-3, 6-disulfonic acid
21.	Lithol Rubin B	15850	Monosodium salt of 4-(o-sulfo-p-tolylazo) 3 hydroxy-2-naphthoic acid
22.	Lithol Rubin BCA	15850	Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid
23.	Lake Red D	15500	Monosodium salt of 1-0-carboxyphenyl-azo-2-naphthol
24.	Lake Red DBA	15500	Barium salt of 1-o-carboxyphenylazo-2-naphthol
25.	Lake Red DCA	15500	Calcium salt of 1-o-carboxyphenylazo-2-naphthol
26.	Toney Red	26100	I-p-phenylazophenylazo-2-naphthol
27.	Oil Red OS	26125	I-Xylylazoxylylazo-2-napththol
28.	Tetrabromofluorescein	45380	2,4,5,7-Tetrabromo-3, 6-flurandiol
29.	Eosin TS	45380	Disodium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6- hyroxy-3-isoxanthone
30.	Eosin YSK.	45380	Dipotassium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6-hyroxy-3-isoxanthone

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
31.	Tetrachlorofluorescein NA	45366	2,4,5,7- tetrachloro-S, 6-Fluorandiol
32.	Tetrachlorofluorescein K	45366	Disodium salt of 9-0-carboxyphenyl-2,4,5,7-tetrachloro-6- hydroxyl-3-isoxanthone
33.	Tetrachloro Tetrabromo fluorescein	45410	2,4,5,7-Tetrabromo-12,13,14,15-tetrachloro-3, 6-fluorandiol
34.	Phloxine B	45410	Disodium salt of 2,4,5,7-tetrabromo-9 (3,4,5,6- tetra chloro- o-carboxyphenyl)-6-hydroxy-3- isoxanthone
35.	Bluish Orange T.R.	45457	1,4,5,8, 15-Pentabromo-2, 7-dicarboxy-3, 6-fluoran diol
36.	Helindone Pink CN	73360	5, 5-Dichloro-3, 3‘ dimethyl-thioindigo
37.	Deep Maroon (Fanchon Maroon)	15880	Calcium salt of 4-(I-sulfo-2-naphthylazo 3-hydroxy-2- naphthoic acid
38.	Toluidine Red	12120	1-(o-Nitro-p-tolylazo)-2-naphthol
39.	Flaming Red	12085	I- (o-Chloro-p-nitrophenylazo)-2-naphthol
40.	Deep Red (Maroon)	12350	3-Hydroxy-N- (m-nitrophenyl)-4-(o-nitro-ptolylazo)-2- naphthamide
41.	Alba Red	13058	o-(p,β,β-Dihydroxy-diethylamino)-phenylazo)-benzoic acid
42.	Orange G	16230	Disodium salt of 1-phenylazo-2-naphthol-6-8-disulfonic acid
43.	Orange II	15510	Monosodium salt of 1-p-sulfophenylazo-2-naphthol
44.	Dichlorofluorescein	45365	4,5-Dichloro-3, 6-fluorandiol
45.	Dichlorofluorescein NA	45365	Disodium salt of 9-o-carboxyphenyl-1-4,5-dichloro-6- hydroxy-3-isoxanthone
46.	Diiodofluorescein	45425	4,5 –Diiodo-3, 6-fluorandiol

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
47.	Erythrosine Yellowish NA	45425	Disodium salt of 9-o-carboxypheny l-6-hydroxy-4, 5- diiodo-3-isoxanthone
48.	Erythrosine Yellowish K	45425	Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5- diiodo-3-isoxanthone
49.	Erythrosine Yellowish NH	45425	Dipotassium salt of 9-o-carboxyphenyl -6-hydroxy-4, 5- diiodo-3-isoxanthone
50.	Orange TR	45456	4,5, 15-Tribromo 2, 7-dicarboxy-3, 6-fluorandiol
51.	Alizarin	58000	1,2- Anthraquinonediol
52.	Dibromodiiodofluoresc ein	45371	4,5- Dibromo-2, 7-diiodo-3, 6-fluorandiol
53.	Alphazurine FG	42090	Diammonium salt of 4-(N-ethyl-p- sulfobenzyl amino)-phenyl)-(2-sulfoniumphenyl)- Methytlene)-(-(1 (N-ethyl-N-p-sulfobenzyl) Δ 2 ,5-cyclohexadienimine)
54.	Allarin Astrol B	61530	Monosodium salt of 1-methylamino-4-(o-sulfop-toluino)-anthroquinone
55.	Indigo	73000	Indigotin
56.	Patent Blue NA	42052	Monosodium salt of 4-(4- (N-ethyl- benzylamino)-phenyl – (5-hydroxy-4-sulfo-2-sulfoniumphenyl-methylene) (N-ethyl- Benzyl-Δ 2, 5-cyclohexadienimine)
57.	Patent Blue CA	42052	Calcium salt of 4-(4- (N-ethyl- benzyl-amino)-phenyl)-(5 hydroxy-4-sulfo-2-sulfoniumphenyl, methylene)- (N-ethyl-N-benzyl- Δ 2- 5-cyclohexadienimine)
58.	Carbrantherene Blue	69825	3, 3- Dichloroindanthrene
59.	Napthol Blue Black	20470	Disodium salt of 8-amino-7-p- nitrophenyl- azo 3- phenylazo-1- naphthol-3, 6-disulfonic acid
60.	Alizurol purple SS	60725	I-hydroxy-4-p-toluino-anthraquinone
61.	Acid Red 89	23910	----
62.	Acid Red 97	22890	----

Serial Number	Common name of colour	Colour Index Number	Chemical name of colour
(1)	(2)	(3)	(4)
63.	Acid Blue 1	42045	----
64.	Food Blue 3	42045	----
65.	Natural Orange	75480	----
66.	Solvent Blues 4	44045	----
67.	Solvent Yellow 18	12740	----
68.	Food Yellow 12	12740	----
69.	Solvent Yellow 32	48045	----
70.	Fanchon Yellow (Hansa Yellow G)	11680	(α)-(O-Nitro-p-tolylazo) accetoacetanilide.”.

[F. No. X.11014/14/2021-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1), dated 21st the December, 1945 and last amended vide notification number G.S.R. 502(E), dated the 30th June, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 2nd August, 2022

S.O. 3739(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with sub-rule (1) of rule 18 of the Medical Devices Rules, 2017, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 3400(E), dated the 11th July, 2018 published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section(ii), except as respects things done or omitted to be done before such supersession, the Central Government hereby designates the following Government Analysts specified in column (2) of the Table given below as Medical Device Testing Officers in respect of the Medical Devices as specified against their names in column (4) of the said table, namely:—

Serial No.	Name of Government Analyst	Name of Laboratory	Medical Device
(1)	(2)	(3)	(4)
1. 2.	Mrs. C. Vijayalakshmi Dr. J. Uma Maheswari	the Central Drugs Testing Laboratory, Chennai	Condoms
3. 4. 5.	Dr. Saroj Kumar Ghosh Dr. Rakesh Kumar Rishi Dr. Anjan Pal	the Central Drugs Laboratory, Kolkata	Surgical dressing, Surgical cotton, Surgical bandages, Disinfectant, Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion sets and Intravenous Cannulas
6. 7.	Dr. Raman Mohan Singh Mrs. S.U. Warde	the Central Drugs Testing Laboratory, Mumbai	Intra Uterine Device(IUD) and Falope rings
8.	Dr. Rajesh Kumar Sharma	the National Institute of Biologicals, Noida	In vitro diagnostic Kits for HIV, HBsAG, HCV
9.	Ms. Kanchan Ahuja		Blood grouping reagent
10.	Ms. Ajanta Sircar		Glucose test strips and fully automated analyser based glucose reagents
11. 12. 13. 14. 15.	Shri C. Hariharan Shri Amar Jyoti Chamuah Shri Dilip Kr. Sarkar Smt. Rinku Kalita Shri Arun Kumar Das	the Regional Drugs Testing Laboratory, Guwahati, Assam	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets and Intravenous Cannulae.

[F. No. X.11014/1/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Appendix A

File No. 29/Misc/03/2020-DC (153) – Part 1
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA, Bhawan, New Delhi-110002

Notice

Classification of Medical Devices Pertaining to Oncology

S. No.	Medical Device Name	Intended Use	Risk class
1	FerriScan R2-MRI Analysis System	The FerriScan R2-MRI Analysis System is intended to measure liver iron concentration to aid in the identification and monitoring of non-transfusion dependent thalassemia patients receiving therapy with deferasirox.	C
2	Alternating electric field antimitotic cancer treatment system generator	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
3	Alternating electric field antimitotic cancer treatment system transducer array	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
4	Bladder instillation buffer solution	A sterile buffer solution intended to be used exclusively for bladder instillation to help create an optimal environment necessary for the effective treatment of superficial bladder cancer with a chemotherapy agent.	B
5	Breast 3-D infrared imaging/vascular analysis system	An assembly of mains electricity (AC-powered) devices intended for three-dimensional (3-D) breast imaging and breast vascular analysis, typically used with mammography screening to perform a breast cancer risk examination.	C
6	Colonic cytology sampling set	A collection of non-sterile devices intended to collect exfoliated colonic cells (colonocytes) from the surface of human rectal mucosa for colorectal cancer investigation and/or patient screening.	B
7	Cryosurgical set	A sterile collection of disposable devices used in conjunction with a cryosurgical unit as well as monitoring and other devices to perform a surgical technique that involves freezing a targeted area of tissue to damage and destroy cancer cells in the unwanted portions.	C

S. No.	Medical Device Name	Intended Use	Risk class
8	Capsular tension ring	A circular band intended to be used to enhance the mechanical stability of a subluxated crystalline lens capsule in the presence of weak or absent supporting zonules.	C
9	Electro cancer therapy system	An assembly of devices designed for the treatment of tumours and the destruction of their cancerous cells using low-voltage direct current of small intensity delivered via electrodes placed across the affected body area.	C
10	Electronic clinical breast examination system	A portable assembly of devices designed to electronically measure, map, document and store information about breast lesions/masses with regard to shape, size, location, consistency/relative hardness during a clinical breast examination (CBE)	B
11	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	C
12	Alternating electric field antimitotic cancer treatment system	An assembly of portable devices designed to apply low-intensity, intermediate-frequency (100-300 kHz) alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	D
13	Balloon kyphoplasty kit	A collection of sterile surgical instruments and devices used for the reduction of a vertebral compression fractures (VCFs) caused by trauma, cancer, or osteoporosis during a minimally invasive procedure commonly known as balloon kyphoplasty.	C
14	Accelerator system chair	A seat, typically with legs, that is a component of a therapeutic accelerator system, and used to support and position a seated patient during radiation therapy treatments involving the use of either a medical linear accelerator or non-linear accelerator.	C
15	Accelerator system quality assurance device	An instrument specifically designed to be used to check the calibration and performance of linear and non-linear medical accelerator systems used for radiation therapy applications, for quality assurance (QA) purposes	C
16	Acupressure wristband	A device designed to be worn on the wrist(s) for the application of pressure to the Nei-kuan (P6) acupressure point, the area identified to help relieve the sensation of nausea.	B
17	Anorectal brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the rectum and/or anus.	C

S. No.	Medical Device Name	Intended Use	Risk class
18	Anorectal brachytherapy system applicator, remote-afterloading	A remote afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the rectum and/or anus.	C
19	Antimicrobial postsurgical brassiere	A woman's undergarment which includes antimicrobial properties designed to support and/or contour the breast(s) or hold a dressing in place after surgical intervention (e.g. thoracic surgery, mastectomy, lumpectomy)	A
20	Antimicrobial postsurgical female underpants	It is intended for use during medical treatment (e.g., chemotherapy) or be used to protect the skin following treatment with a medication (e.g. ointment, cream). It is specifically designed for patient support/comfort in the home or healthcare facility. This is a reusable device.	A
21	Blood photochemical treatment agent	A sterile photochemical agent (psoralen) intended to be used in conjunction with ultraviolet A (UVA) irradiation to eliminate nucleated cells from blood or blood components (e.g. plasma, leukocyte-enriched blood fraction).	C
22	Brachytherapy radionuclide phantom, test object	A non-tissue configured model designed to mimic the functional/physical characteristics of normal or diseased human organs during performance evaluations of brachytherapy system components or radiation therapy treatment planning devices.	A
23	Brachytherapy source spacer	A sterile, bioabsorbable device designed to separate radioactive sources of the seed type that are permanently implanted in close proximity to a selected localized tumour, to increase the distribution of radioactivity to the tumour.	C
24	Brachytherapy system remote-afterloading operator console	A mains electricity (AC-powered) component of a remote-afterloading brachytherapy system intended to function as the primary control panel for the remote afterloader. It typically includes hardware and software that allows for information display and/or transfer, data processing, analysis, and information archiving functions; it may also be intended to interface with other devices (e.g., radiation therapy treatment planning computer) as part of a picture archiving and communication system (PACS).	C
25	Breast binder	A strip or roll of fabric or plastic material applied to the breast or breasts for soft tissue support. This is a single-use device.	A

S. No.	Medical Device Name	Intended Use	Risk class
26	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast. It is typically designed for temporary implantation within the breast and serves as a guide for computer-controlled placement and removal of single or multiple radioactive sources. Included are various types of applicators such as hollow needles, tubes, or catheters, and their associated components. This is a single-use device.	C
27	Breast transilluminator	A mains electricity (AC-powered) transilluminating device with a built-in light source using low intensity emissions of visible light and near-infrared radiation (700 to 1050 nm) that is transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities. This device may also be known as a diaphanoscope.	A
28-a	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for intracorporeal (endosonography or endoscopic) ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast.	C
28-b	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for extracorporeal ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast	B
29	Cervical cone knife	A surgical, manually-operated, instrument that is inserted into the vagina and designed for excising a sample of abnormal tissue, e.g., indicated by the presence of precancerous changes, from the cervix.	C
30	Cervical cytology scraper, reusable	blunt surgical instrument used to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a reusable device.	A
31	Cervical cytology scraper, single-use	A hand-held, manual, blunt surgical instrument designed to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a single-use device.	B

S. No.	Medical Device Name	Intended Use	Risk class
32	Coronary artery brachytherapy system applicator, manual-afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a manual-afterloading brachytherapy system. It is introduced into the patient and subsequently connected to the brachytherapy system source transfer device; it includes radiopaque markers to monitor the position of the radiation source. Disposable devices associated with the procedure may be included (e.g., syringe, connectors). This is a single-use device.	D
33	Cytotoxic waste receptacle	A device designed as a container to allow the safe deposit, collection and storage of cytotoxic materials (e.g., chemotherapy/antineoplastic drugs).	A
34	Electroporation therapy system	A mobile assembly of devices designed to apply electrical impulses to the tissue to enable electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)] and genetic materials [electrogenetherapy (EGT)], to reach the cytoplasm.	C
35	Electroporation therapy system endoscopic applicator	A sterile, patient-contact component of an electroporation therapy system intended to fit onto the distal tip of an endoscope and connect to an electroporation therapy system generator to deliver electrical impulses to tissues during endoscopy as part of electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)], to reach the cytoplasm.	C
36	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].It is used for the screening of colorectal cancer and the detection of other diseases of the lower GI tract. This is a single-use device.	B
37	Extravascular-circulation hyperthermia system	An assembly of devices designed to produce and control heated fluids circulated within a vessel applied to the body (e.g., vest, mattress, jacket, band, pad, body wrap, catheter, probe) for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions.	B

S. No.	Medical Device Name	Intended Use	Risk class
38	Extravascular-circulation hyperthermia system applicator, extracorporeal	A vessel applied to the outside of the body (e.g., in the form of a jacket, vest, body wrap, cushion, blanket, or mattress) that incorporates tubing through which heated fluids are circulated for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions. he applicator typically includes a thermometry component that monitors the temperature of the applicator during operation. The applicator includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a reusable device.	A
39	Extravascular-circulation hyperthermia system applicator, intracorporeal	A component of a hyperthermia system that typically consists of catheter-enclosed tubing which is introduced into the body either manually or endoscopically. Heated fluid is circulated through the applicator's tubing for localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator (also called an interstitial applicator or probe) typically includes a thermometry component that monitors the temperature of the applicator during operation; it also includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a single-use device.	C
40	Facial prosthesis	An externally-applied device intended to be used as an artificial substitute for parts or sections of the face [e.g., nose, eye(s), eye brows, upper lip] to help restore facial appearance.	B
41	Fixed-aperture therapeutic x-ray system collimator	A non-automated, x-ray beam-limiting device that is a component of a therapeutic x-ray system and whose opening size/length/shutter assembly is fixed. It is used in radiation therapy applications to limit the effects of scattered radiation and to protect the patient by limiting or eliminating exposure to non-target body areas during treatment. This device is specifically designed for use with an x-ray simulation or therapeutic x-ray system.	C
42	Flexible fibre optic bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B

S. No.	Medical Device Name	Intended Use	Risk class
43	Flexible fibre optic mediastinoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the mediastinum (the intrapleural space located behind the sternum). It is inserted into the body through an artificial orifice created by an incision made during mediastinoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to examine structures such as lymph nodes during a staging evaluation of lung cancer, or to establish the diagnosis of a tumour that is localized to the mediastinum. This is a reusable device.	C
44	General-purpose infusion pump, mechanical, single-use	A portable, non-electric, mechanically-powered device designed to be operated by healthcare professionals for dispensing a single dose of fluid medication (e.g., for antibiotic therapy, chemotherapy, analgesia). It consists of an empty reservoir intended to be filled with medication, a flow-rate regulator and a non-sterile (sterilizable) administration line intended to be connected to an infusion catheter (not included) for intravenous (IV), subcutaneous, intramuscular, or epidural administration. It may include flow and fluid level mechanical indicators and may be worn by the patient in and outside of healthcare settings. This is a single-use device.	C
45	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device typically through a fibre optic bundle or a video system, and an ultrasound probe. The probe may be built-in or inserted through a dedicated lumen so that its distal tip is positioned adjacent to that of the endoscope. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
46	General-purpose infusion pump, mechanical, reusable	A non-electric, mechanically-powered (e.g., a spring mechanism) device designed for the continuous or intermittent infusion of medication, typically for antibiotic therapy, chemotherapy, or pain management by intravenous (IV), subcutaneous, intramuscular, or epidural routes. It is primarily designed to be worn by the patient during ambulation in the home. It may be used for patient-controlled analgesia (PCA), and may include mechanical indicators for flow and fluid level status. This is a reusable device.	C

S. No.	Medical Device Name	Intended Use	Risk class
47	Flexible video bronchoscope, reusable	An endoscope with a flexible inserted portion for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by a video system with a charge-coupled device (CCD) chip at the distal end and the images showing on a monitor. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
48	Robotic Guidance system for image Guided procedures	The Medical Device is an accessory to an imaging system (CT, CT-PET) intended for the spatial positioning and orientation of an instrument guide. A surgeon then manually advances one or more instruments for percutaneous image guided interventional procedures through the instrument guide. The device is not intended to make any contact with the patient.	B

Appendix A

File No. 29/Misc./03/2020-DC (140) Part-5 (a)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to Dental

S. No.	Medical Device Name	Intended Use	Risk class
1	Dental impression material	This material is primarily used to take an oral impression.	A
2	Dental collar/crown scissors	Scissors use to cut delicate tissue to removing sutures to performing precision procedures.	A
3	Dental excavator, reusable	It is a device intended to cutting, clean out and shape a carious cavity before filling it.	A
4	Dental excavator, single-use	It is a single use device intended to cutting, clean out and shape a carious cavity before filling it.	A
5	Dappen dish, reusable	It is a small bowls used to mix and hold dental materials. These dishes can be disposable or reusable	A
6	Dappen dish, single-use	A small, shallow concave vessel used to knead and hold dental materials.	A
7	Dental examination kit	Intended as a kits for dental examination.	A
8	Dental crown, polymer	A device made entirely of polymer-based material with or without fibre reinforcement, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
9	Dental crown/bridge resin, temporary	A material used to manufacture crowns and bridges.	B
10	Dental crown/bridge, temporary	Intended to make a temporary crown or bridge prosthesis for use until a permanent restoration is fabricated.	B
11	Dental material mixing surface, reusable	A dental instrument slab or tray used as a surface to mix dental materials.	A

S. No.	Medical Device Name	Intended Use	Risk class
12	Dental material mixing surface, single-use	It has pad or tray used to knead or mix dental material (impression material, cement, etc)	A
13	Dental spatula, reusable	A dental instrument used to mix dental materials. Some are equipped with an injection function.	A
14	Dental spatula, single-use	A spatula-shaped device used to knead or mix dental material (impression material, cement, etc).	A
15	Dental crown, metal/ceramic	A device made of a combination of metal and tooth-coloured ceramic, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
16	Dental crown, metal/polymer	A device made of metal, veneered with a polymer-based, tooth-coloured material, and created for a specific patient, that functions as an artificial covering to replace the major part, or the whole part, of the clinical crown of a tooth.	B
17	Dental impression material kit, reusable	Devices and materials used to take the impression.	A
18	Dental impression material kit, single-use	A collection of non-sterile devices designed to obtain a negative imprint of the teeth. The kit typically includes dental impression materials and a dental impression tray(s); This is a single-use device.	A
19	Dental impression material mixer	An electric device used to mix impression materials immediately before use at the chair side.	A
20	Dental impression material syringe	This dental injection syringe is used to inject the impression material onto the impression tray.	A
21	Dental impression tray material	A material intended to be used to create a custom impression tray intended for filling with dental impression materials; it is not intended for the fabrication of a patient-worn dental appliance. The material is used in cases in which a preformed impression tray is not suitable.	A
22	Dental impression tray, reusable	A impression tray is a metal or plastic device intended to hold impression material, to make an impression of a patient's teeth to reproduce the structure of a patient's teeth.	A
23	Dental polishing brush	A rotary dental brush intended for cleaning and polishing by a dental hygienist or a dentist.	A
24	Dental bone particle collector	A device used to collect bone debris generated by drilling, etc. during oral surgery.	B

S. No.	Medical Device Name	Intended Use	Risk class
25	Dental bone matrix implant, animal-derived	A sterile bio absorbable device made primarily of animal-derived bone or dentin matrix (e.g., bovine, porcine) implanted into the body to provide osteoconductive bone-tissue scaffolds to replace maxillofacial and/or mandibular bone lost through trauma or dental surgery. It is used to fill bone cavities and defects and contains pores that promote the ingrowth of endogenous bone for skeletal reconstruction and/or augmentation.	C
26	Dental suction system	It evacuate solids, liquids, aerosols and gases from the oral cavity and immediate surrounding area for the purpose of improving operating effectiveness and efficiency during oral treatment procedures and limiting the contamination of the immediate environment.	B
27	Dental suction system cannula, reusable	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is reusable after sterilization.	A
28	Dental suction system cannula, single-use	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity.	A
29	Carboxymethylcellulose sodium denture adhesive	An adhesive compound composed of carboxymethylcellulose sodium (usually 40 to 100%) used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B
30	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-free	An adhesive compound intended to be used to stabilize a removable prosthesis in the mouth, particularly a denture, by adhering the prosthesis to the oral mucosa. The compound is typically applied to the base of a denture before it is inserted in the mouth.	B
31	Dental amalgam	A dental restorative material used primarily to fill tooth cavities, prepared by mixing liquid mercury (Hg) with an alloy of fine particles, composed mainly of silver (Ag), tin (Sn) and copper (Cu).	B
32	Dental suction system fluid-separation unit	A separator used in the oral cavity. Used for the separation of fluids (saliva, blood) from gases to avoid liquids from entering the suction pump (i.e., dry suction).	A

S. No.	Medical Device Name	Intended Use	Risk class
33	Dental suction system pump	An electrically-powered dental suction pump used as the suction source of a dental suction system, dental treatment unit, etc.	B
34	Temporary mandibular condyle prosthesis	A sterile implantable device intended for the temporary reconstruction of the mandibular condyle of the temporomandibular joint (TMJ) typically in a patient undergoing ablative surgery requiring the removal of the mandibular condyle.	C
35	Temporomandibular joint disc	A sterile interpositional implant or interarticular disc, intended to permanently interface between the natural mandibular condyle and natural glenoid fossa (mandibular fossa) in the temporomandibular joint (TMJ).	C
36	Bar dental precision attachment	It connect removable partial dentures to fixed bridgework under a male/female locking mechanism.	A
37	Dental suction system disinfection control unit	An electrically-powered device intended to control the regular (typically daily) automated/semi-automated disinfection of a dental suction system tubing line.	B
38	Transgingival implant	A sterile device intended to be surgically implanted through the oral mucosa and gingiva to provide support and a means of retention for a dental prosthesis.	C
39	Zinc polycarboxylate dental cement	A non-sterile substance intended for professional use as a dental cement (e.g., luting agent, liner, base) and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between zinc oxide (ZnO) and aqueous solutions of polycarboxylic acid (e.g., polyacrylic acid).	B
40	Transmandibular implant	A sterile transosteal (transosseous) device [transmandibular implant (TMI)] intended to be surgically implanted through mandibular bone to provide support and a means of retention for a dental prosthesis, especially in a patient with an extremely atrophied/deformed mandible.	C
41	Pliable-polymer dental regeneration membrane, bio absorbable, ligated	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C

S. No.	Medical Device Name	Intended Use	Risk class
42	Pliable-polymer dental regeneration membrane, bio absorbable, tacked	A sterile bio absorbable material intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, by acting as a barrier to prevent the down-growth of soft tissue (connective tissue and epithelial cells) into the underlying bone during the healing period.	C
43	Dental surgical procedure kit, medicated, reusable	A collection of various dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
44	Dental surgical procedure kit, medicated, single-use	A collection of various sterile dental instruments, dressings, pharmaceuticals and the necessary materials used to perform a dental surgical procedure.	C
45	Membrane fixation tack, bio absorbable	A sterile bio absorbable tack intended to be used to fix a pliable-polymer dental regeneration membrane in situ to aid in the regeneration of tooth support that has been lost due to periodontal disease or trauma.	C
46	Periodontal root surface regeneration material	A bio absorbable material intended to be used alone or in combination with bone graft materials for the regeneration of tooth support that has been lost due to periodontal disease or trauma. It is applied during periodontal flap surgery to the scaled and preconditioned root surface and forms an insoluble matrix that creates a suitable root surface for selective periodontal cell migration and cell attachment, which re-establishes the lost tooth support.	C
47	Periodontal tissue reconstructive material	A sterile viscous material intended to be injected into the buccal mucosa to treat deficiencies of the gingiva (e.g., interdental papillae), through augmentation, during the treatment of intermediate stage periodontal disease.	C
48	Bone matrix implant, human-derived	A sterile implantable device made primarily of human demineralized bone matrix (DBM) intended to fill bony voids or gaps caused by trauma or surgery, including use in the maxillofacial and/or mandibular bone.	C
49	Collagen dental regeneration membrane	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of tooth support, lost due to periodontal disease or trauma, and/or to regenerate bone or bone defects around dental implants and at sites intended for implant placement, by acting as a barrier to prevent the down-growth of soft tissue into the underlying bone during the healing period.	C
50	Dental cotton roll	It is intended as an absorbent, hard-packed cylinder (a roll) that is used as a saliva absorber from the oral cavity during dental procedures. It may also be used as a packing between the lip/cheek and the gum to give better examination/operative exposure.	A

S. No.	Medical Device Name	Intended Use	Risk class
51	Dental impression tray, single-use	The device is used mainly to facilitate the manufacturing of custom dental prostheses (e.g., dentures). This is a single-use device.	A
52	Preformed dental crown, permanent	A prefabricated prosthetic device designed to function as a permanent artificial covering to partially or fully replace the damaged crown of a tooth. It is available as a single prosthesis or multiple prostheses of various shapes and sizes, and may include one or more try-in prosthesis replicas and other devices intended to assist the restoration procedure.	B
53	Preformed dental crown, temporary	This device is commonly used during prosthodontic treatment or other restorative work required as a result of traumatic injury.	B
54	Zinc phosphate dental cement	A non-sterile substance intended for professional use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between an oxide powder [the principal constituent of which is zinc oxide (ZnO)] and an aqueous solution of phosphoric acid.	B
55	Dental articulation paper forceps	A hand-held manual dental instrument designed for grasping and holding articulation paper during its application to a patient's oral cavity.	A
56	Dental dressing forceps, reusable	A hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
57	Dental dressing forceps, single-use	A sterile, hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity.	A
58	Rubber dam clamp forceps	A hand-held dental instrument used for the insertion and removal of rubber dam clamps.	A
59	Tooth extraction forceps	A hand-held manual dental surgical instrument shaped like pincers and designed for the extraction of teeth.	A
60	Dental amalgam mercury dispenser	A device with a valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form which is to be used to produce amalgam filling material.	A
61	Dental anaesthesia injection kit	A collection of sterile devices designed to inject dental anaesthetics into gingival tissue or the oral mucosa, while preventing or reducing the risk of accidental needle-stick injury, during restorative or surgical dental procedures.	B

S. No.	Medical Device Name	Intended Use	Risk class
62	Dental anaesthesia syringe cartridge	A plastic or glass container prefilled with a single dose of anaesthetic medication intended to be inserted into a dental anaesthesia syringe and injected into oral tissues for a dental procedure.	C
63	Dental anaesthesia syringe, intraligamentary	A hand-held manual dental instrument intended to be used to inject an anaesthetic agent under pressure via the periodontal ligament or into bone through an attached sterile needle. This is a reusable device.	C
64	Dental anaesthesia syringe, reusable	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle; a needle is not included.	B
65	Dental anaesthesia syringe, single-use	A sterile, hand-held, manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle (needle not included).	B
66	Dental anaesthesia syringe/needle	A hand-held manual dental instrument intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an included sterile needle; the needle may be attached or detached.	B
67	Dental anaesthesia system	An assembly of devices used for the administration of a proportional mixture of oxygen (O2) and nitrous oxide (N2O) or medical air during dental surgical treatment.	C
68	Bite registration rim	A schematic model of the dental arch attached to a temporary or permanent base for recording jaw relationships.	B
69	Bite registration rim wax	A dental material (modelling wax) with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims).This is a single-use device.	A
70	Bite registration rim wax, plate	A dental material (modelling wax) delivered as prefabricated plates of wax with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims).	B
71	Calcium hydroxide dental cement	Use as a dental cement and/or direct dental restorative material whereby the majority of the setting reaction is based on the hardening reaction between calcium hydroxide and salicylic acid.	B
72	Ceramic artificial teeth	Prefabricated teeth made of ceramic (porcelain) for mounting on removable dentures or fixed partial dentures.	B

S. No.	Medical Device Name	Intended Use	Risk class
73	Dental soft-tissue matrix implant, animal-derived	A sterile, bio absorbable, animal-derived collagen (e.g., porcine) intended to be used to aid in the regeneration of oral soft tissue, lost due to periodontal disease or trauma, through promotion of new blood vessels and/or by providing a temporary scaffold for tissue ingrowth; it is indicated for various oral soft tissue augmentation procedures (e.g., alveolar ridge reconstruction, localized gingival augmentation, covering of recession defects and extraction sockets). It is a pliable material which may be fixed to soft tissues with sutures; it is applied to soft tissue during periodontal flap surgery and guided tissue regeneration (GTR) surgical procedures. This is a single-use device.	C
74	Dental Bonding Agents	A dental resin used in the bonding of light cured composites and acid modified composites to tooth structure.	B
75	Dental Etchant	The material is applied for temporary etching of dental hard tissue in order to condition the surface for bonding procedures.	B
76	Dental Prosthesis Priming Agent	A material primarily intended to be applied to a dental prosthesis (i.e., indirect restorative) immediately prior to insertion into a tooth structure to promote bonding to a prosthesis component during a dental procedure in the mouth.	B
77	Restorative Material	A dental luting agent, liner, base, pulp-capping material, pit/fissure sealant, and/or direct dental restorative material for restoration of cavities in teeth	B
78	Orthodontic Adhesive	Used as a combined etchant and primer in orthodontic treatment used with/without light curing direct bonding orthodontic adhesive.	B
79	Dental Varnishes/ Glazing	A dental device intended to be applied to the surface of a restorative dental filling to attain a smooth, glaze-like finish on the surface.	B
80	Dental Cements	Intended for direct/indirect restoration (temporary/permanent) of tooth.	B
81	Dental Root Surface Conditioner	Assists in the debridement and cleaning of root canals (dental) Aids in the chemical breakdown of pulp soft tissue (dental).	B
82	Dental Cleansing Solution	A liquid used to clean cavities or root canals after preparation, and may also be used for disinfecting the cavity or root canal in endodontic procedures.	B
83	Endodontic Sealer	To fill and seal all pathways between the root canal and external surfaces of the tooth i.e., for permanent obturation of the root canal. Intended for use in procedure involving root filling, repair of root perforations, pulp capping and apexification.	B

S. No.	Medical Device Name	Intended Use	Risk class
84	Oral Cavity Abrasive Polishing Agent	An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth.	A
85	Root Canal Filling removal Solution	A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetrachloroethylene, formamide, eucalyptol, excipients).	B
86	Dental Composite Resin Kit	A collection of non-sterile substances intended for professional use during dental restoration and prosthesis installation/repair which includes composite resin material and additional materials to support restoration (e.g., etching solution, bonding agent, primer, prosthesis bonding agents, unfilled resin sealant/coating agents), and may include dedicated disposable devices associated with application; it does not include non-resin based cement nor dental prosthesis.	B
87	Gingival Bleaching Protector	A non-sterile paste or gel-like substance designed to protect a patients gums from the hydrogen peroxide (H2O2) found in teeth whitening agents used during chairside light-curing bleaching of the teeth.	B
88	Dental Caries Removal Solution	A liquid substance used in dentistry to detect and remove caries from an infected tooth.	B
89	Denture Base Resin	A collection of resins and other devices and/or materials intended to be used in the dental laboratory to manufacture a complete or partial denture base (the portion of a denture that rests on the oral mucosa and retains the artificial teeth).	B
90	Polymer Based Prosthodontic Material	Light cured, methacrylate-based resin for creating reservoir space for bleaching trays is useful for laboratory procedures such as model, and die repair. It can be block out defects and under cuts on the stone models quickly and securely for precise abutment preparation.	B
91	Powered Surgical Drill Hand piece for Dental applications	A device that consists of a hand piece to which is connected a variety of attachments in order to achieve a number of cutting/inserting/trimming operations.	B

S. No.	Medical Device Name	Intended Use	Risk class
92	Orthodontic appliance, Band	Device for fixed orthodontic appliances. Device affixed to contour of tooth/teeth and cemented into place to support (pressure can be exerted on the teeth) orthodontic appliances or attachments.	B
93	Orthodontic Elastomeric	A tooth positioner/instrument intended to control settling/position and to minimize or eliminate relapse of the teeth after an orthodontic treatment.	B
94	Orthopaedic dental file	A hand-held dental surgical instrument used to enlarge the root canal, smooth out the root canal wall or shaping canals after they are previously cleaned by scratching/scraping with vertical reciprocating motion or rotary motion or plucking motion.	B
95	Dental endodontic enlarger	A device for enlarging and preparing the root canal, which probes, enlarges, and cleans the root canal by dental file, etc. The motion of the file includes vibrating, rotating, repeating rotation, reciprocating, and a combination of these motions.	B

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PARLIAMENT QUESTION AND ANSWERS

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1778
TO BE ANSWERED ON THE 2nd AUGUST, 2022

Proposal for construction of Bulk Drug Park in Tamil Nadu

1778 Dr. Kanimozhi NVN Somu:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has received any proposal for construction of Bulk Drug Park (Pharmaceutical Park) in Tamil Nadu;

(b) if so, the details thereof;

(c) the funds released for construction of the said park; and

(d) the time by which the construction of the said park is likely to be completed?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (d): The Department of Pharmaceuticals implements the Scheme for Promotion of Bulk Drug Parks to facilitate setting up of Three (3) Bulk Drug Parks in the country with the objective to bring down the cost of manufacturing of bulk drugs by creation of world class common infrastructure facilities.

The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), whichever is less. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25.

Under the scheme, the Department has received proposals from 13 States including Tamil Nadu which are under evaluation.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1779
TO BE ANSWERED ON 2nd August, 2022

Pharma companies manufacturing generic medicine

1779 Shri Anil Desai:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the number of pharma companies in Government and private sector which are manufacturing generic medicine, State-wise;

(b) whether it is a fact that cost of these medicines are comparatively lowest in the market;

(c) whether Government has provided these medicines in all Government hospitals including CGHS Hospitals; and

(d) if so, the details of the medicines prescribed and provided to the patients during the last three years?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): The manufacturing licenses for generic drugs and new drugs are granted by the various State Drug Controllers and the Drug Controller General of India (under Ministry of Health and Family Welfare) respectively. A common list of all such manufacturers of generic drugs in the private sector is not maintained in the Department of Pharmaceuticals. However, three PSUs under Department of Pharmaceuticals viz. Bengal Chemicals and Pharmaceuticals Limited (BCPL) in West Bengal, Hindustan Antibiotics Limited (HAL) in Maharashtra and Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) in Karnataka manufacturers generic medicines.

(b): *The Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department with an objective of making quality generic medicines available at affordable prices to citizens of the country. Under the Scheme, dedicated outlets known as Pradhan Mantri Bhartiyta Janaushadhi Kendras (PMBJPs) are opened to provide quality generic medicines at affordable prices. Under the PMBJP, till 30.06.2022, 8742 PMBJKs have been opened across the country including Government Hospitals and Government premises. The Scheme has a product basket of 1,616 medicines and 250 surgical supplies. Prices of medicines sold through these outlets are 50-90% less than that of branded medicines prices in the open market.

(c) and (d): Public Health and Hospitals, being the State subject, the responsibility of providing medicines lies with the respective State Governments and the details of medicines prescribed and provided to the patients are not available with the Department of Pharmaceuticals. Under National Health Mission (NHM), support is provided for provision of essential generic drugs free of cost in public health facilities. Further, CGHS procures generic medicine through Medical Store Organisation of the Ministry of Health and Family Welfare.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3251
TO BE ANSWERED ON THE 5th AUGUST, 2022

Sale of Drugs

3251. SHRI P.C. MOHAN:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has any proposal for bringing in fresh rules/legislation to check the sale of drugs by e-pharmacies without any proper prescription;

(b) the action/measures have been taken/proposed to be taken against such unlawful sales of medicines online;

(c) whether the Government proposes to revamp the Drugs and Cosmetics Act of 1940 for ensuring the safety of patients; and

(d) if so, the details thereof along with the time by which the final decision is likely to be taken or if already taken, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) &(b): To regulate the online sale of medicines comprehensively, the Department of Health and Family Welfare has published draft rules for inviting comments from public/stakeholders for amendment to the Drugs and Cosmetics Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy.

The draft rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e- pharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.

(c) & (d): On 08.07.2022, the Department of Health and Family Welfare has published the draft of "Drugs, Medical Devices and Cosmetics Bill, 2022" for stakeholder consultation on its website [www.mohfw.gov.in]

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1788
TO BE ANSWERED ON THE 2nd AUGUST, 2022

Import and domestic production of APIs

1788 Shri Ayodhya Rami Reddy Alla:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of Active Pharmaceutical Ingredients (APIs) imported, country-wise, in the last three years and the details of the domestic production of APIs during the last three years;

(b) whether Government has taken any steps to reduce import dependence on APIs, if so, the details thereof and if not, the reasons therefor; and

© whether Government has formulated any comprehensive roadmap to increase API production in the country, if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22. However, the country also imports various Bulk Drugs/APIs for producing medicines from various countries and most of the imports of the Bulk Drugs/APIs being done in the country are because of economic considerations. India imported Rs. 35,249 crore worth APIs and Bulk drugs in 2021-22. Year-wise details of the domestic production of APIs is not maintained by the Department of Pharmaceuticals. The details of Bulk drug and Intermediates imported from top 25 countries in last three years is submitted at **Annexure.**

(b) to (c): Yes, Sir. In order to make the country Atmanirbhar in in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries: -

(i) The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.

(ii) The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs.

(iii) The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks.

Annexure

Import of APIs for the last three years

Country	2019-2020 Value (Rs. in crore)	2020-2021 Value(Rs) (Rs. in crore)	2021-2022 Value(Rs) (Rs. in crore)
CHINA RAP	16443	19403	23273
USA	850	1141	3097
ITALY	727	879	830
SINGAPORE	697	814	964
SPAIN	525	645	618
GERMANY	446	490	550
FRANCE	376	367	351
JAPAN	370	356	555
DENMARK	305	311	345
HONG KONG	303	400	493
KOREA RP	302	379	560
BELGIUM	301	345	266
NETHERLAND	252	254	269
SLOVENIA	251	443	389
MEXICO	233	197	178
INDONESIA	194	149	235

Country	2019-2020 Value (Rs. in crore)	2020-2021 Value(Rs) (Rs. in crore)	2021-2022 Value(Rs) (Rs. in crore)
TAIWAN	189	241	227
SWITZERLAND	179	262	272
HUNGARY	159	162	212
U K	154	197	212
MALAYSIA	121	149	200
AUSTRIA	113	244	374
CZECH REPUBLIC	81	98	120
SLOVAK REP	62	30	10
THAILAND	62	27	40

Source: DGCIS, Ministry of Commerce and Industry.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2298
TO BE ANSWERED ON THE 29th JULY, 2022

Production and Export of Important Medicines

2298. SHRI SUBBARAYAN K.:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether it is a fact that the pharma sector in India is growing well and is a major producer and exporter of important medicines like antibiotics, antimalarial, anti-TB drugs, Paracetmol etc.;

(b) if so, the details thereof along with the present position of India in the production and export of these medicines;

(c) whether it is a fact that India was making 70 per cent of the active pharma ingredients (API) or bulk drugs by 1990, but a major part of these bulk drugs are presently being imported and mostly from China;

(d) if so, the details thereof;

(e) whether the Government has any plan to make inputs and intermediates for chemical and fertilizers based APIs in the country and therefor reduce the critical dependence on imported inputs for making medicines in the country; and

(f) if so, the details thereof and if not, the reasons therefor?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (b): Yes, Sir. The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,75,040 crore in the financial year 2021-22, including Bulk Drugs/ Drug Intermediates. The quantity and the value of the drugs exported during the last five years is as under: -

Export of Drugs and Pharmaceuticals		
	Quantity (MT)	Value (In Rs Cr)
2017-18	665934	1,06,038
2018-19	674084	1,28,028
2019-20	524757	1,40,537
2020-21	642718	1,74,064
2021-22	1075906	1,75,040

Source: DGCIS, Ministry of Commerce and Industry.

(c) to (d): India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/ Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22. However, the country also imports various Bulk Drugs/ APIs for producing medicines from various countries including China. Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations and also, China is one of the largest producers of KSMs and APIs in the world.

The quantity and the value of Bulk Drug and Drug Intermediates exported from India to other countries and imported from other countries including China during the last three years is as under: -

	Export to all countries		Imports from all countries		Imports from China	
Year	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2019-20	271544	27533	364433	24172	220875	16443
2019-20	324331	32857	390476	28529	256609	19403
2020-21	453130	33320	400642	35249	264582	23273

(e) to (f): The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country self-reliant in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes: -

(i) The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.

(ii) The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs.

(iii) The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3365
TO BE ANSWERED ON THE 05th August, 2022

Medical Device Parks

3365. SHRI MAGUNTA SREENIVASULU REDDY:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of the medical devices parks in the country, State/UT-wise;

(b) whether the Government proposes to establish more medical devices parks in the country;

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

(d) whether there is any proposal to establish a medical devices park in Andhra Pradesh;

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

(f) the details of the other initiatives taken by the Government to promote the production of medical devices and reduce dependence on imported drugs from other countries?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (e): The Department implements the scheme "Promotion of Medical Devices Parks", with a total financial outlay of Rs. 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to Rs. 100 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025 and the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA). Under the scheme, Department of Pharmaceuticals has received proposals from 16 States/Union Territories. The proposals were evaluated as per the criteria given in the scheme guidelines and final approval for financial assistance of Rs. 100 crore each has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh. There is no proposal to establish more medical device parks in the Country, under the scheme.

Further, the Department has provided grant-in-aid to the project of the Superconducting Magnet Testing, Validation and Integration Centre at AMTZ, Andhra Pradesh under the scheme *"Assistance to Medical Device Industry for Development of Common Facility Centres".*

(f): The Government of India has taken several measures to encourage domestic manufacturing of Pharmaceutical drugs including bulk drugs and medical devices to reduce import dependence. The Programmatic interventions to support Pharma and Medical Devices Industries are as follows;

I. *The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a* financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.

ii. The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years, including five (5) industry applicants selected for In-vitro diagnostic medical devices.

iii. The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. The proposals received are under evaluation.

iv. The Department has launched the scheme of Strengthening of Pharmaceutical Industry (SPI), with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26 and this scheme has three components, to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs.

v. Under the scheme "Promotion of Medical Devices Parks", final approval for financial assistance of Rs. 100 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks.

vi. Further, under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre", grant-in-aid of ₹ 25 crore was provided to Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh for establishment of Common Facility for Super conducting magnetic coil testing and research facility

vii. The Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, with a financial outlay of Rs.3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, provides for financial incentives to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the four Target segments of the scheme, for a period of five (5) years. A total of 21 Applicants have been selected under the scheme.

The non-schematic interventions are as follows:

i. In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector. Similarly, the Government has allowed 100% FDI in pharma sector for greenfield projects under automatic route. For the brownfield projects, upto 74%, FDI investments are allowed under automatic route and beyond 74% to 100%, FDI investments are allowed under government approval route.

ii. To redress the specific challenges of the MedTech Industry, in view of the diversity and multi-disciplinary nature of the sector, the institutional mechanism of Standing Forum of Medical Devices Associations, has been set up to deliberate on various issues with all the stakeholders including regulators.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3369
TO BE ANSWERED ON THE 05th August, 2022

Export and Import of Medical Devices

3369. SHRI KARTI P. CHIDAMBARAM:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of the country's exports and imports in medical devices in FY 2020-21 and 2021-22;

(b) the details of the medical devices forming top 5 categories of the total import during FY 2020-21 and 2021-22;

(c) whether it is a fact that 21 applicants selected under the "PLI Scheme for Promoting Domestic Manufacturing of Medical Devices" are medium and large manufacturers;

(d) whether the Government intends to propose separate PLI schemes for MSMEs and large manufacturers in medical devices sector, if so, the details thereof and if not, reasons therefor;

(e) whether the Government intends to make affordable credit available for MSME's in medical devices sector, if so, the details thereof and if not, reasons therefor; and

(f) the details of the employment opportunities likely to be generated in the country from 2021-22 to 2027-28 after the implementation of PLI Scheme in medical devices sector?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): The details of the exports and imports in Medical Devices for FY 2020-21 and 2021-22 are as under (Source : EEPC):

Financial Year	Export (in US$ million)	Import (in US$ million)
2020-21	2532.16	6240.55
2021-22	2923.16	8539.5

(b): Segment / category wise Import details of Medical Devices during FY 2020-21 and 2021-22 are as below (source : EEPC):

Category	FY 2020-21 (in US$ million)	FY 2021-22 (in US$ million)
Electronics Equipment (EL/EQ)	3568.64	5441.22
Consumables & Disposables (C/D)	1470.77	1623.55
IVD Reagent (IVD)	871.89	882.65
Implants (I)	225.63	423.06
Surgical Instruments (SI)	103.62	169.02

(c) to (f): The Department of Pharmaceuticals implements the "Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices" with a financial outlay of Rs. 3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28. Under this scheme, financial incentives will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the four Target segments of the scheme, for a period of five (5) years. Under the scheme, under two rounds of inviting applications, a total of 42 applications have been received including MSMEs and large manufacturers.

There is no proposal of separate PLI scheme for MSMEs and large manufacturers in Medical Devices, as the current PLI Scheme does not restrict participation of MSMEs. So far, 21 applicants are selected under the scheme and this includes 10 MSMEs and 11 large manufactures. As per the proposals submitted by these applicants, the projects selected under PLI scheme are expected to generate employment opportunities of around 6,411 persons in the tenure of FY 2021-22 to FY 2027-28.

Ministry of MSME provides credit support to eligible MSME industrial units, including for those in Medical Devices Sector, through schemes such as Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE), Fund of Funds, etc.

NEWS

Pharma Firm Directors in the Net in Fraud Case

A local court has convicted directors of a Chennai-based pharma company in connection with a 1 crore bank fraud case investigated by the CBI.

The CBI nearly 10 years ago had filed a case against Seaglad Pharmaceuticals, a drug manufacturing firm, which availed a loan of 70 lakh from UCO Bank's main branch in Chennai for developing their business. The company had mortgaged a vacant land at First Seaward Road in Valmiki Nagar, Thiruvanmiyur as a collateral.

Since their account was irregular, it was declared as Non-Performing Asset (NPA) and the bank filed a money suit before the Debt Recovery Tribunal (DBT). This is when the bank came to know that they were defrauded by the pharma company as the said mortgaged land was already acquired by TNHB for construction of 27 flats.

The fraudulent activities of the borrowers resulted in a loss of 1.04 cr to the bank, CBI told the court.

The court found the directors guilty and sentenced them to undergo two years rigorous imprisonment with a fine of 40,000 each, apart from a fine of another 40,000 against the company.

Source: *The Times of India,* 3rd August 2022

New Drugs Bill is A Prescription for Disaster

The Union Ministry for Health & Family Welfare published a new Bill to replace the colonial-era Drugs & Cosmetics Act, 1940. This proposed Bill was written by a drafting committee of eight bureaucrats headed by the Drug Controller General of India (DCGI) and included a senior bureaucrat who has since been arrested on suspicion of corruption.

While most of the new Bill is a copy of the old legislation, some of the proposed revisions treat drug quality as a divisible concept, wherein it is presumed that a drug will work even if it fails on certain quality parameters. Either a drug passes all quality standards laid down by a government body called the Indian Pharmacopoeia Commission (IPC), which publishes the standards in a publication called the Indian Pharmacopoeia (IP), or else the drug fails in treating patients.

Historically, since 1940, drugs failing quality testing in accordance with standards published in the IP have been declared Not of Standard Quality (NSQ), making the manufacturer liable for minimum imprisonment of one year and maximum imprisonment of two years and a fine of Rs 20,000 with special exceptions. The rationale for criminal punishment in cases of drug quality is simple: Unlike other products, quality issues in the manufacture of drugs have direct implications on the health of citizens.

The new approach proposed by the government can be described as a chalta hai approach to regulation, aimed at accommodating the pharmaceutical industry's demand to "decriminalise" some of the offences under the existing law. Section 56(e) of the new Bill proposes lowering punishments for drugs that have been declared NSQ due to any of the 43 defects listed in the fourth schedule of the Bill. For such defects, manufacturers are liable for lower imprisonment of one year and a fine of Rs two lakh, while for defects that do not fall within the fourth schedule, the manufacturer is liable for a higher punishment of up to two years imprisonment and a fine of Rs five lakh.

The lower punishments for fourth schedule defects, however, hide the true intent of the law, which can be found in section 71. This provision, which is basically the icing on the cake for the pharmaceutical industry, allows for the compounding of a class of offences including those defects in the fourth schedule. "Compounding" means the prosecuting drug controller has the discretion to waive a trial and prison time as long as the accused pharmaceutical company agrees to pay the fine. In effect, the industry has achieved its goal of "decriminalisation". The cherry on top of the icing is section 58 of the Bill, which gives the government the power to expand the list of exceptions in the fourth schedule. Given the political might of the pharmaceutical industry, it will most definitely succeed in forcing the government to expand beyond the current 43 exceptions. The pharma industry's best lobbyist could not have done better than the drafting committee in delivering to the industry its dream law.

In our opinion, there is no valid science guiding the inclusion of 43 defects in the fourth schedule. Take for example the amount of active ingredient in a drug. The IP allows a drug to be declared of standard quality as long as the amount of active ingredient is between 90 per cent to 110 per cent of that advertised on the label. However, entry 4 of the fourth schedule now states that as long as the drug contains at least 70 per cent of the advertised amount, the manufacturer will be subject to lower punishments. This makes no sense because any drug that has only 70 per cent of the active ingredient can result in adverse treatment outcomes. For example, if in a strip of 10 antibiotic tablets each tablet has only 70 mg of active ingredient instead of the 100 mg of active ingredient as listed on the label, at the end of a 10-day course of treatment, the patient would have received only 700 mg of the antibiotic instead of the 1,000 mg that the doctor prescribed. Not only would the patient not recover completely from the infection, but chances are she is now a carrier of antibiotic-resistant bacteria. The treatment outcomes will be several times worse in the case of drugs like Levothyroxine or Budeprion, which have "narrow therapeutic index" (NTI), where even minor changes in the dosage can lead to a significant difference in treatment outcomes.

Other defects included in the fourth schedule are the presence of "particulate contamination/foreign matter" and "heavy metals". Thus, even if a drug is found to be

contaminated with glass particles, fungus or heavy metals, the manufacturer will get reduced or no prison time.

In our opinion, there is no moral or scientific case to justify treating some manufacturing defects more seriously than others when the standard setting body — the IPC — is very clear on the scientific requirements for a drug to be declared of standard quality.

The larger takeaway from this episode is that much of India's drug regulatory apparatus continues to serve the interests of the pharmaceutical industry, and not public health. In 2012, the Parliamentary Standing Committee on Health had levelled this same charge against the Central Drugs Standard Control Organisation, which is headed by the DCGI. That this romance between the regulator and the industry has crept into the law-making process is cause to junk this version of a Bill.

Source: *The Indian Express,* 9th August 2022

SC Quashes Pharmaceutical Council of India's 5-Year Moratorium on Opening New Colleges

The Supreme Court on Thursday quashed a 2019 decision of Pharmaceutical Council of India to impose a five-year moratorium on opening up of new colleges offering diploma and bachelor's degrees in pharmacy and ruled that the fundamental right to establish educational institutions can't be curtailed through an executive order.

The PCI had on July 17, 2019, had put a moratorium on opening of new pharmacy institutions for a period of five years from the academic year 2020-21, worried by the mushrooming growth of such institutions across the country. Later, it exempted the Northeastern states, government institutions and in states and UTs where DPharm and BPharm institutions were less than 50 in number. This was challenged in various high courts, majority of which had quashed the PCI decision. The PCI had challenged the HC decisions before the SC.

A bench of Justices BR Gavai and PS Narasimha dismissed the PCI's appeal and said its resolution was in the nature of executive instructions and hence it could not curtail the sweep of Article 19(1)(g) of the Constitution, which conferred a fundamental right on a person to establish an educational institution.

Writing the judgment, Justice Gavai said the mushrooming of pharmacy institutions could be a genuine worry for the regulatory body, but the decision to prohibit opening up of pharmacy institutions could not have been announced through an executive order.

"Before parting, we may observe that there could indeed be a necessity to impose certain restrictions so as to prevent mushrooming growth of pharmacy colleges. Such restrictions may be in the larger general public interest. However, if that has to be done,

it has to be done strictly in accordance with law," the bench said.

Suggesting a way out, the SC said applications seeking approval of D.Pharm and B.Pharm courses require a NOC from the state government and consent of the affiliating body. "While scrutinising such applications, the PCI can always take into consideration various factors before deciding to allow or reject such applications. Merely because an institution has a right to establish an educational institution does not mean that such an application has to be allowed," it said.

"In a particular area, if there are more than sufficient number of institutions already existing, the Central Council can always take into consideration as to whether it is necessary or not to increase the number of institutions in such an area. However, a blanket prohibition on establishment of pharmacy colleges cannot be imposed by an executive resolution," the bench said.

Source: *The Times of India,* 16th September 2022

Uttarakhand STF Busts Counterfeit Drugs Manufacturing Racket, Conducts Raids in Haridwar and Saharanpur

The pharmaceutical sector has an unparalleled role in India's journey to becoming a more robust and bigger economy. The only thing standing in its way is the high dependence on China for raw materials.

India — a prominent maker of pharma products — relies heavily on China for active pharmaceutical ingredients (APIs), the material that causes the desired effect of the medicine. It also has an uncomfortably high dependence on China for key starting materials (KSMs), which are the raw materials to make APIs.

New Delhi-based Research and Information System for Developing Countries (RIS) estimates the dependence on Chinese imports for APIs for essential medicines as 80-100%. It is 100% for fermentation-based APIs such as penicillin and erythromycin. A government communique released in July 2020 said the imports from China have been growing and now stand at 68% of the country's pharma imports. Over the last decade or so, this reliance has always been consistent, at 60-100%, industry figures reveal.

“We have a significant reliance on China for imports of key starting materials (KSMs, can be a raw material, intermediate or an API),” says Shekhar Bhirud, CEO, Akums Lifesciences Ltd . “Over 75% of our total KSM requirements are directly or indirectly sourced from there.”

This shows an unhealthy trend for a country with 1.4 billion people that wants to be self-reliant and a manufacturing powerhouse. To be clear, India is the third-largest pharmaceutical industry in the world by volume and the 14th largest pharma industry by value. The segment is growing and has shown great potential with the pharmaceutical

industry in India currently valued at $50 billion. The segment is expected to reach $65 billion by 2024 and $120 billion by 2030, says Invest India.

In November 2021, Prime Minister Narendra Modi said India is being called the "pharmacy of the world" after it made and exported "to 150 countries" essential medicines and medical equipment during the pandemic. The sector contributes about 2% to India's GDP and around 8% to the country's total merchandise exports.

However, it does not bode well for the country that the very survival of the $50-billion pharmaceutical sector hinges on API supplies from China. Self-reliance in APIs is a must, especially as the country is said to have a high share of the world's incidence of infectious diseases.

Climate across the border

The country has a network of 3,000 drug companies and about 10,500 manufacturing units with a domestic turnover of Rs 1.4 lakh crore in 2019; and exports to over 200 countries. Domestic API production is valued at $9 billion, and India's API import is valued at $4 billion, according to the Indian Drug Manufacturers' Association (IDMA). The country also has an API export of $3-4 billion.

A bunch of factors motivate Indian players to import. To begin with, the imported raw materials from China are said to cut costs by 15-20% for Indian drug makers.

Beijing subsidises its pharma industry, resulting in a tremendous cost advantage. For example, China guarantees around 13% tax incentives for the export of APIs, according to the World Health Organization (WHO). Besides, the Chinese have an advantage in built-up capacities, which often get a lot of government aid. The abundance of raw materials is another advantage China has.

Manufacturers in the southeast Asian nation get access to utilities at a cheaper price; their Indian counterparts pay twice the rate on a per kWh basis for electricity and over 40-50% more for steam, according to Department of Commerce estimates. The massive scale of operations also confers competitive advantages to Chinese operations, which also get significant subsidies in terms of export rebates.

"Large-scale manufacturing in China is the key to its cheaper drug manufacturing costs, along with cheap power and fuel. The extensive government subsidies given to companies are the chief reasons that drive China to become a global leader in APIs. This is also a major reason the Indian API industry is comparatively smaller," says Bhirud.

Experts point out that API manufacturing cycles can stretch for months. Then come clinical trials and compliances, which can take between 6 months and 2 years. Scale and efficiency of operation play a big role here, and this dissuades many Indian players from getting into API manufacturing. Instead, they say getting stuff from China is more viable.

Hurt by imports

In fact, we have lost the high ground in some aspects. India used to be a world leader in fermentation technology in the '80s and '90s, according to a research paper by Research and Information System for Developing Countries (RIS). The paper notes that after the late '90s, competition from China and import liberalisation led to the closure of many plants. Besides, Chinese manufacturers have kept raw materials costs lower by consistent thrust on R&D. India, on the other hand, has reduced the tax benefits for in-house R&D.

Vinod Kalani, President, Federation of Pharma Entrepreneurs (FOPE), says: “Earlier, a rebate up to 200% on R&D expenses was given under the income tax Act for pharma makers.” For the last decade or so, several pharma firms, including many MSMEs, used to benefit from the government's rebates for pharma production under the specific segment of formulation and development (F&D). This category falls under the broader R&D domain. Kalani says the government has dealt a big blow to several firms by reducing R&D tax incentives.

These measures historically offered companies a cushion. But not any longer, say pharma manufacturers.

Requesting anonymity, a Solan-based pharma producer says: “Lots of companies active in the F&D segment are finding the going tough due to lack of government support and growing Chinese competition. On one hand, the government talks big about Make in India; on the other, it creates an uneven field for us. We can't think of producing any basic medicine without Chinese ingredients. Many of my peers have switched to less cumbersome trading activity instead of manufacturing.”

In the case of fermentation products, industry observers cite the lack of funding and unconducive policies as the main issues. A fermentation plant requires an investment of Rs 700-1,000 crore, says Kalani. The government's production-linked incentive (PLI) scheme has tried to address this anomaly. But that may not be enough to counter the cheaper supplies from overseas. “Domestic players have shown their intent to counter the competition from China. But they want some specific assurances from the government. In case China further reduces prices, many ventures could lose orders, and might even have to close shop. Thus, these companies want the government's help in the form of anti-dumping duty to restrict the ballooning Chinese imports,” he adds.

Action required

The government should actively engage with industry players and stakeholders, says Sanjeev Jain, Marketing Director, Akums Drugs & Pharmaceuticals Ltd. It should provide better benefits to API players. “For India to be completely autonomous in API production and research, it needs a strong understanding of the innovation landscape, innovation facilitators like human capital investment in R&D and regulatory environment,” he adds.

Experts point out that though the pharma sector is featured among the 25 thrust areas in the government's flagship Make in India plan, these glaring issues remain unaddressed.

Bhirud lists the areas where action has to be taken pronto. “First, India lacks the innovative edge in drug development and discovery because of lack of funding. We also lack sufficient talent. The quality of education available in India does not match the demands of the drug innovation arena. We need qualified trainers, proper research infrastructure and sufficient funding. We also have to take into consideration that backward integration of API is the most viable option in the case of large volumes in API manufacturing. For that, government support is very important, be it in the form of cheap land, lower or subsided costs of power and fuel, centralised utility services, and importantly, the ease of carrying out operations,” adds Bhirud.

R&D pays

India is a leader in one area — generic drugs. Indian generics account for 20% of global exports in terms of volume, claims the government, adding that the domestic pharma players meet over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. Notably, the global generic drugs market size was valued at $439.37 billion in 2022 and is projected to hit around $670.82 billion by 2030, according to Precedence Research.

This leadership position highlights the need to increase the thrust on R&D. Masurkar says by 2030, the domestic pharma industry aspires to grow to $120-130 billion from $44 billion now. “However, the pool of drugs going off-patent has been shrinking at 10-12% since 2012. So, it is clear that the country has to shift from generics manufacturing to investing in R&D to develop new molecules and biosimilars,” he says.

Studies have revealed that a 1% increase in R&D investment can lead to a rise in output by 0.05-0.15%, he adds. The government says it's aiming for a 25% cut in API import reliance by 2024. But is this goal reachable? Yes, says IDMA, especially as the government is taking steps to promote greenfield projects in KSMs and APIs.

Industry observers, while upbeat about the government's target, flag up the need to ramp up manufacturing capacities. “According to the Central Drugs Standard Control Organisation's 2020 estimates, over 70% (by value) of the input materials for formulations were being imported from China. This included 58 APIs where the level of import dependency was high. Subsequently, 53 of these APIs were included in the PLI scheme and production has already started for 35. Given this progress, we can aspire for a 25% reduction in API imports by 2024 provided the production is ramped up to desired levels quickly," says Antony Prashant, Partner, Deloitte India.

That indicates we are on the right path. But it is important for the government and the industry to walk together with a holistic plan so that we can reach the finish line within a reasonable time.

https://economictimes.indiatimes.com/small-biz/trade/exports/insights/why-the-health-of-indias-50-billion-pharma-industry-depends-on-china/articleshow/94694846.cms?from=mdr

Source: *The Economics Time,* 7th October 2022

Delhi Cops Bust International Racket Selling Fake Life-Saving Cancer Drugs, Arrest Doctor

In a two-month-long operation, Delhi Police's crime branch has busted an international racket manufacturing and selling spurious life-saving cancer medicines, thus endangering the health of critical patients.

Seven members of this syndicate, including the alleged kingpin - an MBBS doctor - three pharma company owners and an engineer, have been arrested. Two more doctors are under the scanner, but are absconding.

The racket allegedly invested the proceeds of the crime in real estate across India and Nepal. Special commissioner (crime) Ravindra Singh Yadav said a factory in Sonipat and a packaging and storage unit in Ghaziabad's Tronica City have been unearthed and Rs 8 crore worth fake medicines of 20 reputed international brands seized.

Cops trying to trace patients who were conned by gang

The international fake drugs syndicate that has been busted by Delhi Police used to procure capsules from an associate's firm and then manufacture fake medicines by filling them mostly with starch. It cost them a few rupees in making and packaging these but each capsule fetched them Rs 20,000 at the least, Special commissioner (crime) Ravindra Singh Yadav said. While a strip of original life-saving drugs costs around Rs 2 lakh in the white market, the syndicate promised patients they would help them get a strip for Rs 1.5 lakh.

"The gang was selling false hopes by providing fake drugs with no active ingredients and thus playing with lives of innocent victims," Yadav said. The cops are now tracing the patients who became victim to this con. They have also appealed to the public to buy medicines from trusted and established sources and not fall for crooks.

The accused kingpin has been identified as Dr Pabitra Narayan Pradhan, a resident of sector 45 in Noida. He and six of his associates had come under the scanner after the interstate cell of the crime branch received inputs about a gang selling spurious cancer drugs. A team led by DCP Amit Goel, comprising ACP Ramesh Lamba, inspector Satender Mohan and others, was formed to bust the racket.

Technical surveillance and on-ground verification of inputs led the cops to the godown in Ghaziabad. Some arrests were subsequently made. During verification of recovered medicines, the representative of one of the brands, AstraZeneca, confirmed that recovered medicines were fake.

"Amit Kumar, the manager, regulatory affairs of AstraZeneca, reported that the recovered medicine, Tagrisso 80 MG (Osimertinib Tab), was counterfeit and posed a patient safety risk," special CP Yadav added.

During interrogation, Dr Pradhan revealed the roles of one Dr Rasel from Bangladesh and another, Dr Anil. Cops are looking for them.

The accused revealed that they used to prepare the foil strips and outer packaging by replicating the original design and then got them printed in Dehradun and Noida. Their associate then supplied them with empty capsules and other raw materials, following which spurious medicines were prepared in their factory in Sonipat. The consignment, as per demand, was then sent to the unit in Ghaziabad.

The final packaging and supply were carried out from there. During the raid on the godown, the officials of UP Drug Control Department were also roped in, who have filed a separate FIR.

In addition to fake medicines, a huge quantity of packaging material, boxes and equipment like a batchmark embossing machine, induction sealing machine, tablet counter machines, shrink water dryer, stamps for hologram and hologram strips were also seized.

The cops are now digging deeper into where the suspects used the proceeds of crime. Among the seizures are two plots in Gurgaon on which eight flats are being constructed, Rs 1.3 lakh cash, land parcels in Durgapur and Nepal. Cash worth Rs 14.99 lakh has been frozen in the bank locker of the accused.

Source: *The Times of India,* 16th November 2022

Orchid Pharma to Spend up to Rs 500 Cr to Set Up Unit Under PLI Scheme

Orchid Pharma will shell out Rs 300-500 crore over the next two years to set up a new plant to manufacture critical key starting material or drug intermediaries under the production-linked incentive (PLI) scheme.

The Chennai-based company sees demand in the overseas countries for these fermentation-based intermediaries to be around 2,000 tonne.

Manish Dhanuka, MD, Orchid Pharma, told analysts the government has made provision for two years to set up the plant, and the company expects to set up the facility over that timeline. The capex is expected to be between Rs 300 crore and Rs 500 crore.

"With this PLI approval, we expect to start the plant in FY24-25. The current import price of this product is at $65. We expect to generate an Ebitda of about 10% in this business. The PLI benefits shall be 20% of the sales price for the first four years of the business, then 15% for one year, and for the last six years would be 5% over and above the Ebitda of 10% that I have estimated," he said.

On the product pipeline, he said the development of Ceftaroline is on track for a commercial launch in December. The company will be filing the drug master filer for the US market.

The development of Enmetazobactam, a new

chemical entity developed by Orchid Pharma for the Indian market, is also on track. The clinical research organisation for the clinical trial has been finalised and the clinical data management site for formulation of the product manufacturing was also closed.

"Cefovecin, the third product we talked about launching commercially, will be commercialised before March 2023 and Ceftazidime plus Avibactam will be launched in India in January 2023. So, these four launches we are expecting in this financial year. And hopefully they will augur well for the prospects of the company going forward," he said.

Source: *Financial Express,* 31st August 2022

Small Pharma Units Nudge FDCA on 'Ease of Doing Business

While Gujarat is considered the pharmaceuticals hub of the country, small-scale Pharma units here say they are facing a financial burden owing to the policies of the state Food and Drug Control Administration (FDCA).

The Drug Controller General of India (DCGI) had released a list of products under the Kokate committee, and most states charge a product licence fee of Rs 300 for products on the Kokate list. The Kokate committee was set up by the government to examine the safety and efficacy of unapproved drugs that were licenced by the state licencing authorities without approval from the DCGI.

In Gujarat, for around 15% of these products — which do not have a DCGI no-objection certificates (NOC) dates stipulated on the Kokate committee list — the FDCA charges manufacturers a licence fee of Rs 1 lakh. Owners of Pharma units have to buy these products from the market to prove that they have been on sale for at least four years.

An office-bearer of Small Scale Indian Drug Manufacturers Association (SIDMA), on condition of anonymity, said, "Gujarat FDCA practices are hurting small-scale Pharma units. Licences for products on the Kokate committee list, whose NOC date is not mentioned, still cost Rs 1 lakh. Most other states levy a Rs 300 fee for these products. We are demanding that the Gujarat FDCA bring down the fee to par with other states and thus improve the ease of doing business."

Another SIDMA member said, "Gujarat FDCA demands product licences for all brands. This means if a manufacturer has received a product licence for a Paracetamol brand, he will have to get a new licence to manufacture other brand of the same molecule. Other states' FDCA departments allow manufacturers to have more than one brand of the same molecule with one licence. Small scale Pharma companies in Gujarat are active in contract manufacturing and get orders from multiple companies to manufacture multiple medicines of the same molecules and they have to get product licences for each of them. This leads to unfair practices too."

Gujarat FDCA commissioner H G Koshia was not available for comment despite several attempts.

Source: *The times of India,* 14th October 2022

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