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TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

e-NewsLetter

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Apr. - May. - Jun. 2020

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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ISSUE : 46 Apr. - May. - Jun. 2020

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EDITORIAL

Dear Readers,

We are happy to publish the 46th issue of Pharma Web Newsletter for **Apr – Jun 2020.**

We have published the 45th issue Pharma Web Newsletter as e-newsletter, due to COVID 2019. Since the COVID 2019 issue yet to come for normal life and colleges are not functioning we are decided to publish this issue also as e-newsletter. We are sending this issue through email and What's app, and the same will be uploaded in our website.

This 46th issue contains the following article, which was written by our Trustee, Dr. R. Ilavarasan.

- Enhancing Immunity through home remedies and Ayush System in Day to Day Covid-19 situation – **Dr. R. Ilavarasan**. Assistant Director (Scientist-4), Institute In-charge, Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute Central Council for Research in Ayurvedic Sciences (CCRAS) Ministry of AYUSH, Government of India

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

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., M/s. Acid 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

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This issue of Pharma Web is also available online at the Trust website : www.pictrust.com

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ENHANCING IMMUNITY THROUGH HOME REMEDIES AND AYUSH SYSTEM IN DAY TO DAY COVID-19 SITUATION

by

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COVID-19, the pandemic Novel Corona Virus Disease is the biggest threat today for every individual. The disease is spreading more and becoming severe in our day to day lives. The global death toll from the COVID-19 has already touched more than five lakh individuals and more than one crore individuals have been infected worldwide. In India, the numbers of positive cases of the novel coronavirus are in the upright slope, but we are lucky with the death rates when compared with the other world countries due to our healthy food diet and hygienic life style.

Even though many researchers are fighting globally to develop a medical cure for COVID-19, it is in the hands of the common men to stay safe and to safeguard their families. Instead of panicking and falling for fraud remedies and claims, it is time to focus on building your immunity and boosting your health.While practicing basic hygiene, it is also important to support your immune system to function properly. We list down some of the most potent anti-viral food items that you must include in your diet to boost your immune system and protect your body against infectious disease.

In this article, lots of clear and easy ideas are advised to boost the basic immune strength of the human body. The article has been divided into two segments.

1). Through Simple home remedies (sources from kitchen, garden and market) and

2). Through AYUSH system (Ayurveda, Yoga, Unani, Siddha and Homeopathy)

Developing Immunity against COVID-19 by utilizing simple home remedies

As per the ancient Indian tradition, food and drug are not different. Our ancestors have used day to day food materials to treat various ailments and lived a very healthy life. This section explains simply that how to stay fit and healthy by boosting immunity by utilizing food and food products available in kitchen, house gardens and market.

I. Raising immunity from Kitchen

As every individual knows, kitchen is the biggest source of various household remedies used to treat various diseases and disorders. Human immunity against infections can be developed to a vast extent using various food items which we use in our daily life to cook meals. This part discusses about such food items in a useful manner.

1. Garlic

Loaded with a compound known as allicin, the humble garlic is said to have the potential to ward off infections from within when consumed on a regular basis. For the uninitiated, allicin is a compound which is thought to fight viruses and boost immunity. It is formed when a clove of garlic is chewed, crushed or chopped. Allicin is the same compound which gives garlic its unique odour.

You can take two cloves of garlic and consume them with warm water every day or make it a part of your daily meal by adding it to soups and hot stews for added flavour.

2. Cinammon

Yes, this fragrant spice can do a lot more than just adding exotic flavour to your favourite delicacies. A preliminary study conducted by Touro College in New York found that cinnamon may contain antiviral properties. In addition to its proven ability to regulate blood pressure, as per these findings of the research, cinnamon may also protect the body against viral infections.

You can simply soak a cinnamon stick in water overnight and drink it the next morning. In addition to cinnamon-infused water, you can add a pinch of the aromatic spice to your morning cup of tea or coffee for an enhanced flavour and a host of health benefits.Cinnamon has several health benefits. The spice is rich in antioxidants and has several healing properties. During the winter months, cinnamon can be teamed with ginger to beat common cold. Have it along with honey mixed in warm water every morning for effective results.

3. Turmeric:

Turmeric is a native plant of India which is being used for many centuries for various health benefits. Its most active compound curcumin have many scientifically-proven health benefits, such as the potential to prevent heart disease, Alzheimer's and cancer. It's a potent anti-inflammatory and antioxidant and may also help improve symptoms of depression and arthritis. A glass of turmeric milk gulped down every day during the winter months will boost your immune system and keep you away from infections.

4. Fenugreek:

Fenugreek is an herb that is very popular in all parts of India. The seeds are used in cooking, in medicine, and to hide the taste of other medicine. Fenugreek seeds are packed with antiviral properties and have the ability to kill viruses that cause sniffles and sore throats. You can soak them in water overnight and drink up the next morning. Fenugreek leaves are eaten in India as a vegetable. Fenugreek is taken by mouth for diabetes, menstrual cramps, high cholesterol, and many other conditions, but there is no good scientific evidence to support most of these uses. In foods, fenugreek is included as an ingredient in spice blends. It is also used as a flavoring agent in imitation maple syrup, foods, beverages, and tobacco.

Fenugreek appears to slow absorption of sugars in the stomach and stimulate insulin. Both of these effects lower blood sugar in people with diabetes.

5. Black pepper:

Black pepper is one of the most commonly used spices worldwide. It's made by grinding peppercorns, which are dried berries from the vine Piper nigrum. It has a sharp and mildly spicy flavor that goes well with many dishes. But black pepper is more than just a kitchen staple. It has been deemed the “king of spices” and used in ancient Ayurvedic medicine for thousands of years due to its high concentration of potent, beneficial plant compounds. Along with a distinctive taste and pungent aroma, this spice contains various anti-oxidants that accelerate the body's metabolism.

6. Cloves:

Cloves are a spice used in cooking, rich in antioxidants, vitamins, and minerals. Cloves have been used in traditional Chinese medicine and Ayurvedic medicine to strengthen the immune system, reduce inflammation, and aid in digestion. Containing eugenol, a powerful germicide, as well as caryophyllene, which has antimicrobial properties, clove oil is also used to kill parasites and repel insects. Clove has additional antiseptic and pain-relieving properties.

Add cloves to your salad dressings, meats, soups and desserts and enjoy the intense aroma in your daily life to boost your immunity and to have a great health.

7. Cardamom:

Also known as elaichi, these small green pods are rich sources of minerals and antioxidants that aid in blood detoxification and resolve digestive issues. The aromatic spice also contains vitamin C which boosts your immunity and protects you against common cold. Add some to your morning cup of tea to aid your health in an easy and delicious manner.

These wonderful healing spices can ward off all your winter blues. Keep them handy and make the most of them while the season lasts.

8. Ginger

Ginger is one of the great food items which we use in our day to day life. This miraculous ingredient was the perfect fix for most seasonal ailments like cold, cough, fever and flu. Being a root spice, ginger is loaded with nutrients such as vitamin B6 and dietary minerals like magnesium, manganese. In fact, raw ginger has around 79% water, 18% carbohydrates, 2% protein, and 1% fat. In fact, the best way to use ginger is by adding the raw ginger to your foods and drinks. Since ages, ginger has been used for medicinal purposes, due to its rich nutritional properties.

Even in several Ayurvedic medicines ginger has been used as an active ingredient and this is due to the presence of Gingerol, an active component that makes ginger a perfect immunity booster. Apart from that, Ginger has anti-bacterial and anti-inflammatory properties, which help in keeping several ailments at bay and helps fighting infections.

9. Cumin seeds

Cumin and its contribution to an Indian household are immense. Cumin is rich in anti-inflammatory antioxidants, antibacterial and antiseptic. It can fortify digestive tract, relieve nausea and bloating and constipation. Including cumin in your diet could help boost your blood circulation, helps in detoxifying the blood and improves your skin tone. "Ordinary cumin seeds are brown in colour and contain many beneficial properties. However, black cumin seeds, known as "black seed", have a much higher concentration of these medicinal oils.

The experts say that it is thymol, a compound in cumin that stimulates the enzymes, which enables better secretion of digestive juices. The presence of vitamin C in cumin seeds helps booster the immunity system. Zeera is an excellent source of iron and dietary fibre. It is essential to drink zeera water to maintain the normal functionality of your immunity system. It fights diseases and reduces your chances of falling sick. It can also increase the formation of red blood cells and plays a vital role in anemia.

10. Star Anise:

This star shaped spice is rich in antioxidants and vitamins A and C. It is effective in easing sore throats and colds. Its anti-fungal and anti-bacterial abilities can keep you away from flu and other viral infections that are common during the winter season. Place one piece of star anise in your cup of tea and let it infuse all the flavours. You can also simply add it to boiling water, let it steep for 15 minutes and then drink with honey.

II. Fighting COVID-19 by raising immunity from Garden

Indian house gardens are of greater medicinal values. It is no doubt that the simple gardens available in every house are the hubs of medicinal plants and useful green vegetables. We can able to utilize our gardens and its plant wealth to fight the COVID-19 by raising the immunity. The following herbs and preparations can be utilized from our house gardens in very simple manner.. You can also simply add it to boiling water, let it steep for 15 minutes and then drink with honey.

1. Holy Basil or Tulasi leaves:

In India, *Tulsi* (Holy Basil) is revered as "The Queen of Herbs" and has traditionally been celebrated for its therapeutic effects on the body, mind and spirit. *Tulsi* is shown as an "immunomodulator", which refers to agents that improve the functioning of the immune system. The immunomodulatory effects of *Tulsi* have been demonstrated in controlled trials on human volunteers, resulting in statistically significant increases in the levels of helpful antibodies. *Tulsi* has also been shown to regulate cortisol levels, which directly impact your immune system. Consuming *Tulsi* may help you calm your system and fortify its resilience to deal with the demands of modern life. *Tulsi* helps you to cope with physical, infectious, chemical, metabolic and psychological stress through a unique combination of pharmacological actions.

Tulsi which is a pre-eminent adaptogen, contains unique antioxidants and micronutrients that may provide powerful immune protection from free radical damage and increase the body's capacity to fight against disease and infections.

2. Thoodhuvalai:

Thoothuvalai is a favourite among traditional medicine practitioners in many parts of India for its anti-inflammatory, anti-microbial and anti-oxidant properties. While *Solanum trilobatum* (or just solanum) is its botanical name it's also known as the Purple Fruited Pea Egg plant.

The leaves (the thorns are removed while using this herb) are bitter and they are normally fried in ghee to reduce this bitterness. Thoothuvalai has multiple health benefits but it's ability to fight fever and common cold that make it a popular hack for many home remedies in Tamil Nadu and the rest of South India. It's also a popular ingredient to combat sinusitis and asthma ailments. As thoothuvalai is rich in calcium, it can strength the bones and teeth. The phyto constituents of this medicinal plant can improve the physical strength and maintain good health. Adding a small quantity of the powder to your everyday rasam or food is a simple method to add the goodness of thoothuvalai to your regular diet.

3. Indian Borage or Ajwain (Karpooravalli)

Ajwain leaves are said to have a number of health benefits, including remedying stomach problems and for improving appetite and digestion. Bring these amazing leaves into your daily use to enhance taste and flavour of everyday dishes and for everyday home remedies.

Ajwain leaves can be boiled with water and made into a warm concoction to remedy persistent cold and cough. If you have a pesky cold and cough, take some 10 or 12 ajwain leaves, clean them with water and then add them to a glass of water and put it to boil on a low flame. Allow the decoction to boil, until the water is reduced to about three-fourths of its original quantity. Take it off the heat, allow it to cool down a bit and then drink it for relief from cold and cough. Add a little honey to it, if you like.

4. Neem leaves

Neem is being used in India for many centuries. While neem is known around the world as "The Village Pharmacy," its most important benefit may its immune-boosting properties. It is a most important fact that neem boosts the lymphocytic and cell-mediated immune systems. Led by "Killer T" cells, the cell-mediated immune system is the body's first defense against infection, particularly viruses. It recognizes small parts of a virus and then destroys with toxic chemicals.

Neem as an "immunomodulator," meaning that it supports the innate immune's system ability to self-regulate -either up, in times of defense, or down, to avoid over-activity that can lead to what is known as a "cytokine storm," when the immune system becomes dysregulated. Neem helps boost your immune system while cooling down your body internally. It possesses both anti-bacterial and anti-fungal properties that help keep your skin clean, radiant and healthy. Neem also has blood-purifying properties. It helps clear toxins and impurities from the blood leaving you with a strengthened immune system.

5. Guava leaves

Guava is a much-relished fruit and is known to be a rich source of several nutrients like vitamin C, B, potassium, antioxidants, and soluble fibre. Apart from the fruits, guava leaves are equally beneficial to health with its myriads of nutritional elements and medicinal properties. The guava leaf tea helps boost immunity, and thus it can be used as a guard against cough and cold. The compounds in the guava leaf tea inhibit the absorption of sucrose and maltose - the two types of sugar - and thereby regulate the blood sugar levels. They also inhibit several enzymes that convert carbohydrate into glucose during digestion. It is especially useful for type 2 diabetes mellitus patients.

The leaves can prevents diarrhea by preventing the growth of Staphylococcus aureus bacteria, which causes diarrhoea. The guava leaf tea gives quick relief to diarrhoea patients. The best method is to consume it in empty stomach. Guava leaf tea is good for the health of the heart, and drinking it regularly can improve the circulatory system, decrease the bad cholesterol and provide a good anti-diabetic effect.

6. Pennywort or Bhrami (Vallaarai)

Brahmi or Vallarai is a therapeutic herb commonly used as a memory enhancer.Regular consumption of Brahmi helps in strengthening your immune system. A lot nutrients along with antioxidant compounds help increase the response time of our immune system against various diseases and ailments. Brahmi can be a great remedy that provides relief from arthritis, gout and other inflammatory conditions. It also helps in soothing gastric ulcers and treating an irritable bowel syndrome.

Brahmi reduces stress and anxiety as it decreases the levels of cortisol, which is known as the stress hormone. Brahmi counteracts the effects of stress by regulating hormones involved with the stress response. Brahmi is known for regulating the blood sugar levels in patients with diabetes and may help improve symptoms of hypoglycemia.

7. Ponnaankanni

Ponnangannikeerai is an aquatic plant of Asian origin grown in tropical and subtropical regions. Two varieties of ponnangannikeeraiare known. One is with green leaves called nattuponnanganni and the other is with pink leaves called seemaiponnanganni. The benefits from both the varieties are by and large the same. Ponnangannikeerai is mostly consumed as a leafy vegetable only.

Consuming a mixture of ponnanganni juice with cow's milk enhances the body strength and vitality. Goat milk also can be substituted for cow milk. Consuming every day, in the mornings a teaspoon of the extract of ponnanganni leaves mixed well with coconut oil improves the overall energy level of the body. Consumption of two tablespoons of ponnanganni juice with one or two garlic cloves cures intermittent fever, continuous cough and asthma.

The other health benefits such as it can improve normal eye sight, helps secreting breast milk, helps weight gain, enhances energy levels and cures head ache and piles.

8. Cissus quadrangularis (Pirandai)

Pirandai is a common medicinal plant which is very well available in all parts of Tamil Nadu. This plant has numerous health benefits and can be very well used by all individuals. The high levels of ascorbic acid found in this plant mean that your body gets an extra defensive shield against pathogens and foreign substances in the body, as well as additional antioxidant protection. Ascorbic acid, more commonly known as vitamin C, stimulates the production of white blood cells to fight infections and illness, thereby improving your overall health. Vitamin C is also a crucial component of collagen, the material used by the body to build everything from muscle tissue to blood vessels and arteries. High levels of vitamin C help in growth and repair, meaning that wound healing can be sped up and recovery from injury and illness can be quicker.

The Sanskrit word asthisamharaka literally means that which saves the bones from their destruction. It is surprisingly powerful to prevent the degradation of bone matter in the body and stimulate bone growth.

One of the unique benefits of Cissus quadrangularis is its ability to lower blood sugar levels in the body. This is done by regulating the release of blood sugar from the nutritional intake and ensuring that glucose and insulin levels remain optimal in the blood. It has other benefits such as it can reduce inflammation, strengthens bones, help burn fat, reduce appetite, and increase lean muscle mass.

9. Balloon Vine (Mudakaththaan Keerai)

Ballloon vine is found locally in villages and peripheries of Tamil Nadu, it can be identified as a climber having balloon like fruits. The leaves, roots, seeds and the baby leaves of this plant are all used for kaleidoscopic medicinal purposes. It can be used both internally and externally.

Mudakathan keerai or leaves has strong anti-inflammatory properties. It gives noticeable relief in patients of arthritis, joint pain and even gout patients. The oil made out of this herb can be used externally. The powder obtained from the leaves is mixed in popular south Indian dishes and is used for internal consumption. A combination of the two gives faster results. Its anti-inflammatory properties make it an effective home remedy for rheumatoid arthritis and nervous breakdown.

Based on the traditional use, Mudakathankeerai is often used to improve energy level and reduce general tiredness and sluggishness. According to the Ayurveda and Siddha, Mudakathankeerai is also beneficial for skin problems.

10. Betel leaf (Vetrilai)

Betel leaves form an important part of Indian culture and offering them to guests is a sign of hospitality. In South Indian culture, two betel leaves with some areca nuts and coconut are given to guests during any marriage ceremony.

Betel leaves are known to help with cough and prevent phlegm formation. Your inflammation due to the constant coughing will go down too once you start taking them. If you've got a case of chronic bronchitis on your hands, then chewing on paan leaves will help clear it up. It will ease your inflammation and dilate the phlegm, thus improving your breathing by de-congesting your chest. The high polyphenol content in betel leaves makes it an excellent antiseptic. When you apply it on your wounds or cuts, it kills germs and relieves pain instantly by acting as an anti-inflammatory agent. It treats headaches naturally, and you can even use the oil for massage if you don't prefer rubbing the leaves on your forehead.

Betel leaves have many more health advantages such as relieves constipation, boosts digestion, Improves appetite, relieves muscle tension and boosts recovery time. Eliminates water retention, boosts mental alertness, treats acne naturally, prevents aching ears, well for type-2 diabetics, prevents nose bleeds etc.

11. Keezhanelli

Keezhanelli is an amazing plant with wonderful medicinal uses and health benefits. From treating liver diseases and kidney stones to aiding hair growth, this plant has wide uses. Traditionally, it has been used for treating jaundice, hepatitis, kidney stones, hair problems, asthma and fever. Usually the root of this keelanelli plant is used more than the leaves in home remedies. It has numerous chemical constituents such as glycosides, alkaloids, flavonoids, terpenoids, lignans, polyphenols, tannins, coumarins and saponins. Some of the essential elements found in keelanelli plant are calcium, sodium, potassium, zinc, magnesium, manganese, ferrous and copper.

Keezhanelli has amazing antimicrobial properties and traditionally it has been used for treating various skin problems from small wounds, itching, cracked heels, rashes, etc. Keezhanelli has a protective effect on our liver and greatly protects us from getting non-alcoholic fatty liver disease. Keezhanelli is wonderful for diabetic patients as it reduces serum glucose levels and it improves the lipid profile too.

III. Fighting COVID-19 by raising immunity from Market

Markets are the common places where we can purchase whatever we want for our daily needs. There are so many natural foods and medicinal preparations available in the market which can rise up our immunity to a greater extent in a very great way. The following are such items which can be utilized from the normal markets in order to amplify the human immunity against various external agents.

1.Honey

Raw honey has been used as a folk remedy throughout history and has a variety of health benefits and medical uses. It's even used in some hospitals as a treatment for wounds. Many of these health benefits are specific to raw, or unpasteurized, honey.

Raw honey contains an array of plant chemicals that act as antioxidants. Some types of honey have as many antioxidants as fruits and vegetables. Antioxidants help to protect your body from cell damage due to free radicals and automatically maintain immunity. Free radicals contribute to the aging process and may also contribute to the development of chronic diseases such as cancer and heart disease. Research shows that antioxidant compounds in honey called polyphenols may play a role in preventing heart disease. Research has shown that raw honey can kill unwanted bacteria and fungus. It naturally contains hydrogen peroxide, an antiseptic. Its effectiveness as an antibacterial or antifungal varies depending on the honey, but it's clearly more than a folk remedy for these kinds of infections.

2. Liquorice root (Mulethi)

Also known as Mulethi in Hindi, liquorice root has been used widely in traditional Chinese remedy from time immemorial. The active compounds found in liquorice root possess many pharmacological activities, such as antiviral, antimicrobial, anti-inflammatory, antitumor and other activities. More often than not, liquorice can also be used to soothe sore throat and cough due to its antitussive and expectorant properties.

You can simply boil mulethi in water and sip the concoction. You can also use this mulethi water to make yourself a cup of liquorice tea if you feel that you are coming down with a cold.

3. Nutmeg:

Nutmeg is not a common spice which is being used in daily Indian cooking as other Indian spices. Nutmeg can increase immune system function and found to have many other health benefits, including its ability to relieve pain, soothe indigestion, strengthen cognitive function, detoxify the body, boost skin health, alleviate oral conditions, reduce insomnia and prevent leukemia and

improve blood circulation. Nutmeg is packed with nutrients: minerals such as magnesium, manganese, copper, vitamins such as B1, B6 and many essential volatile oils such as myristicin, elemicin, eugenol, safrole etc.

This warm spice can be added to you baked good, biryanis, soothing soups and rich curries to boost the flavours. It has strong antibacterial properties that help strengthen the immune system. A cup of hot milk with nutmeg powder, a few drops of honey and crushed cardamom is sure to keep your winter blues away.

4. Guava

Guava fruits are amazingly rich in antioxidants, vitamin C, potassium, and fiber. This remarkable nutrient content gives them many health benefits. guava can improve blood sugar control, Many scientists believe that the high levels of antioxidants and vitamins in guava leaves may help protect your heart from damage by free radicals. The higher levels of potassium and soluble fiber in guavas are also thought to contribute to improved heart health. Additionally, guava leaf extract has been linked to lower blood pressure, a decrease in "bad" LDL cholesterol, and a rise in "good" HDL cholesterol.

Low levels of vitamin C are linked to an increased risk of infections and illness. Guavas are a fantastic way to get this nutrient, as they're one of the richest food sources of vitamin C. In fact, one guava provides about double the Reference Daily Intake (RDI) for vitamin C. This is almost twice the amount you would get from eating an orange. Vitamin C plays an important role in maintaining a healthy immune system.

5. Mushrooms

Mushroom to be precise are packed with beta-glucans which are known to be antiviral and antibacterial compounds. They not only help in giving a kickstart to your immunity but also appear to subside inflammation.

6. Green tea

Green tea is a recently growing trend among all class of people and well known for its anti-aging properties. It can be used to boost the immune system and to prevent various ailments. Aside from just warding off illnesses, green tea has also been proven to help with weight loss, skin care, increasing life expectancy and also improving brain function.

The secret to green tea's ability to ward off diseases lies in its antioxidant properties. While the body produces its own antioxidants (endogenous), on their own they are not very effective when dealing with free radicals (waste substances resulting from oxidative stress). Oxidative stress has been linked to various ailments, such as cancer, arthritis, stroke, heart diseases, Parkinson's disease and respiratory diseases. Inability of the body to deal with the free radicals exposes you to these diseases. It is due to this reason that you need external sources of antioxidants (exogenous), which green tea is a good source of.

Compared to other types of tea, green tea is rich in polyphenol compounds also referred to as flavanols or catechins. They include epicatechin, epigallocatechin, epicatechin-3-gallate, and epigallocatechin-3-gallate. Immune boosting properties of green tea are facilitated by these flavanols.Green tea has various other properties such as anti-cancer properties, anti-microbial properties, UV protective properties and it has the ability to prevent coronary heart disease.

6. Amla (Emblica officinalis)

More commonly known as Indian gooseberry, amla plays an important role in Ayurvedic medicine and it can boost the immunity to a great extent. It is one of the oldest edible fruits known to India. Indian gooseberries are the edible fruit of a small to medium-sized tree that grows throughout India. The berries have a sour, sharp taste and a fibrous texture. For this reason, the berries are often pickled, soaked in sugar syrup or cooked into dishes to increase palatability. Indian gooseberry and its extract are used in Ayurvedic medicine to treat symptoms like constipation and also used in cancer prevention.

Indian gooseberries are very nutritious and high in vitamin C, amino acids and minerals. They also contain powerful plant compounds like phenols, tannins, phyllembelic acid, rutin, curcuminoids and emblicol.

Several test-tube studies suggest that Indian gooseberries have potent anti-cancer properties. For example, in test-tube studies, Indian gooseberry extract has been shown to inhibit the growth of cervical and ovarian cancer cells. However, there is no evidence that Indian gooseberries prevent cancer in humans.

SIMPLE HOME REMEDIES FOR COMMON AILMENTS

Common cold

- Juice of Ginger & Tulsi – 5 ml each and mixed with honey- 2-3 times a day
- Small piece of ginger fried in ghee- taken 2 times a day
- 1 tsp of powder/paste of turmeric with a cup of milk- twice a day- easy recovery
- Gargle with warm water mixed with salt & turmeric powder- 2-3 times a day- sore throat
- Decoction- Tulsi leaves, Mustha (Cyperus rotundus), ginger, black pepper- fever
- Steam inhalation- 10-15 leaves of Tulsi, 1 tsp turmeric powder & common salt.

Cough

- Leaf extract of fresh leaves of Vasa (Adathodavasica) -7-15 ml + honey- twice daily
- Tea prepared with Tulsi leaves, ginger & honey.
- Cinnamon powder (1 pinch) in warm water or tea- relieves throat irritability
- Turmeric powder + honey- 3 times
- Crush small piece of sugar candy with 1 tsp pepper,jeera&mulethi or licorice (Glycyrrhizaglabra) root- 3-4 times
- In children – decoction made with onion (Alliumcepa) with jaggery- thrice daily.

Nausea & vomiting

- Chew 2-3 g of cardamom seeds fried in ghee thrice daily.
- Soak mint leaves in water for 5-10 minutes. Take out leaves and drink water
- Ginger juice(1 tsp) + lemon juice (1 tsp) with honey- frequently
- Soak puffed rice in water overnight & eat in morning empty stomach- pregnancy morning sickness.
- Keep few pieces of Clove in mouth & suck them for long.
- Drink water boiled with Fennel seeds.

Headache

- Apply paste of cinnamon/ dried ginger/ betel leaves on forehead for half an hour.
- Headache associated with burning sensation- apply paste of sandalwood
- Steam inhalation with coriander seeds
- Peppermint oil application
- Ginger tea
- Scalp massage

Diabetes mellitus

- Soak 2 tsp of Fenugreek seeds in water overnight & drink water along with seeds- empty stomach in morning
- 2 tsp of Amla juice + ½ tsp turmeric powder – empty stomach in morning
- Include 50 g of fresh Moringa leaves to meal – thrice in a week.
- Infuse Giloy (TinosporaCordifolia) powder(whole plant) in water & drink early in morning
- 1 tsp of dried Jamun seeds powder with 1 glass of water – in empty stomach

Hypertension

- Arjuna (Terminalia arjuna) bark powder 5-10 g with jaggery/honey-twice daily
- Chewing 2 raw cloves of garlic on empty stomach
- Long pepper(Piper longum) powder 2gm + Aswagandha (Withania somnifera) root powder with luke warm water
- Include Asafoetida (Hingu) in diet
- Jackfruit

Depression

- Juice of Brahmi (Bacopa monnieri) 5 ml with cow ghee – taken early in the morning
- Sankhapushpi (Convolvulus pluricaulis)- ¼ to ½ tsp with warm milk-twice daily after food
- Jatamansi (Nardostachys jatamansi)-3g twice daily with water after food
- Aswagandha (Withania somnifera) – 1 tsp with warm milk at bedtime
- Mint tea
- Water boiled with Cardamom seeds- taken as tea with honey

Some simple home preparations to fight pandemic situation

1. Turmeric ginger tea

Turmeric Ginger tea is a simple homemade preparation which can boost the immunity in the body against respiratory disorders. It can be very useful to raise the immune strength against COVID-19.

Requirements

Turmeric	- 1 small piece (Fresh) or 1 tea spoon
Ginger	- 1 small piece
Pepper	- 10 seeds approximately
Lemon	- Half lemon
Honey	- 2 table spoon

Procedure

Take 200 ml of water. Add the turmeric and boil the water well. Once well boiled take the turmeric pieces out of the water and grind it using mixer grinder along with the ginger. Take the ginger turmeric paste and add it back to the previously boiled turmeric water. Powder the pepper seeds and add it to the above preparation and boil till it becomes half. Then squeeze half lemon into it, add honey for the sweet taste. Filter the tea and have it once daily. Turmeric can act as a very good anti-infective agent and its phytoconstitutent can act as anti-inflammatory agent. Ginger and pepper can act as anti-tussive agents and reduce cough as per Indian medicine. Lemon is a good source of Vitamin-C and it can able to develop good immune strength. Natural honey which has lots of enzymes can elevate human health. All together the Turmeric ginger tea can act as a good homemade immunity booster.

2. Herbal soup

Drum stick leaves and flowers	- 1 Hand full
Rice washed Water	- 300-500 ml
Small Onion	- 15 Nos.
Tomato	- 02 Nos.
Cumin seeds, Pepper seeds	- Each 1 table spoon
Garlic pieces	- 06 Nos.
Ginger	- 01 small piece
Turmeric	- ½ tea spoon
Salt	- ¼ tea spoon
Corriander leaves	- 01 Hand full
Lemon	- ½ Piece

Procedure

Cut all the above vegetables and spinach into small pieces. Powder the Cumin seeds and pepper seeds. Crush or paste the garlic and ginger. Add all the ingredients into a rice cooker, pour approximately 300 ml of the Rice washed water. Add salt and turmeric. Close the cooker, allow for 3 whistles and turnoff the flame. Open the lid and filter the soup as well as possible. Add lemon, pepper, coriander leaves and the soup is ready to consume.

DEVELOPING IMMUNITY THROUGH THE AYUSH APPROACH TO MANAGE THE COVID-19 OUTBREAK

The AYUSH approach to manage the outbreak broadly comprise of:

i. Preventive and prophylactic

ii. Symptom management of COVID-19 like illnesses

iii. Add on Interventions to the conventional care

Based on potential & strength of AYUSH systems supported by evidences for promotion of immunity and help in improving the respiratory symptoms in similar diseases and as per the recommendations from the research councils under Ministry of AYUSH following system wise approach is recommended.

i. Preventive and prophylactic:

Ayurveda:

SamshamaniVati 500 mg. twice a day with warm water for 15 days. The medicine contains aqueous extract of Tinosporacordifolia.

Siddha:

NilavembuKudineer decoction 60 ml. twice a day for 14 days. The medicine contains aqueous extract of Andrograhis paniculata& others.

Unani:

Preparation of decoction by boiling Behidana (Cydoniaoblonga) 3 gm, Unnab (Zizyphus jujube) 5 in number.Sapistan (Cordiamyxa) 9 in number in water. (Boil these in 250 ml water- boil it till it remains half- filter it — keep in a glass bottle and use it lukewarm).

The drugs used in the preparation of this decoction have been reported to have Antioxidant activity, Immuno-modulatory, antiallergic, smooth muscle relaxant activity and Anti-influenza activity. This decoction may be taken twice a day for 14 days.

Homoeopathy:

Arsenicum album 30, daily once in empty stomach for three days. The dose should be repeated after one month by following the same schedule till Corona virus infections prevalent in the community. In one of the studies Arsenic album as one of the constituents in a formulation

affected HT29 cells and human macrophages. Also, it showed decreased NF-KB hyperactivity (reduced expression of reporter gene GFP in transfected HT29 cells), decreased TNF-a release in macrophages. More over Arsenic album is a common prescription in the cases of respiratory infections in day to day practice.

ii. Symptom management of COVID-19 like illnesses

Ayurveda

1. AYUSH-64 : 02 tablets twice a day
2. AgasthyaHareetaki : 05 gm twice a day with warm water
3. Anuthaila/Sesame oil 02 drops in each nostril daily in the morning

Siddha

1. NilavembuKudineer/KabaSuraKudineer— decoction 60m1 twice a day
2. AdathodaiManapagu — Syrup 10 ml twice a day

Homoeopathy

Various medicine which found to be effective in treating flu like illness are Arsenicum album, Btyonia alba, Rhustoxicodendron, Belladonna Gelsemium Eupatorium perfolia tum. All these medicines should be taken in consultation with qualified physicians of respective AYUSH systems.

iii. Add on Interventions to the conventional care

Ayurveda

1. AYUSH-64 : 02 tablets twice a day
2. AgastyaHareetaki: 05 gm twice a day with warm water

Siddha

1. VishasuraKudineer: decoction 60m1 twice a day
2. KabaSuraKudineer — decoction 60m1 twice a day

Homoeopathy

Medicine mentioned Symptom management of COVID-19 like illnesses" under subhead Homoeopathy can also be given as add on to the conventional care. All these medicines should be taken in consultation with qualified physicians of respective AYUSH systems.

General preventive measures (already notified):

i. Observe good personal hygiene.
ii. Practice frequent hand washing with soap.
iii. Follow respiratory etiquettes - cover your mouth when coughing or sneezing.
iv. Avoid close contact with people who are unwell or showing symptoms of illness, such as cough, runny nose etc.
v. Avoid contact with live animals and consumption of raw/undercooked meats.
vi. Avoid travel to farms, live animal markets or where animals are slaughtered.
vii. Wear a mask if you have respiratory symptoms such as cough or runny nose.

In addition, the following AYUSH specific measures may be adopted:

The diet should be fresh, warm, easy to digest, containing whole cereals, seasonal vegetables etc. Frequent sipping of water boiled with Tulsi leaves, crushed ginger, and turmeric would be beneficial. Honey with a pinch of pepper powder is also beneficial in case cough. Cold, frozen and heavy foods may be best avoided. It is always beneficial to avoid direct exposure to cold breeze. Appropriate rest and timely sleep are advisable.

The practice of Yogasana and Pranayama under the guidance of qualified Yoga instructor is recommended. Common medicinal plants useful in similar symptoms are Tulsi (Ocimum sanctum), Guduchi (Tinosporacordifolia), Ginger (Zingiberofficinale) and Turmeric (Curcuma longa).

Other advises to develop immunity and physical strength

- Drink warm water throughout the day.
- Daily practice of Yogasana, Pranayama and meditation for at least 30 minutes as advised by Ministry of AYUSH (#YOGAatHome #StayHome #StaySafe)
- Nasal application - Apply sesame oil / coconut oil or Ghee in both the nostrils (Pratimarsh Nasya) in morning and evening.
- Oil pulling therapy- Take 1 table spoon sesame or coconut oil in mouth. Do not drink, Swish in the mouth for 2 to 3 minutes and spit it off followed by warm water rinse. This can be done once or twice a day.

Advises to follow during dry cough / sore throat

- Steam inhalation with fresh Pudina (Mint) leaves or Ajwain (Caraway seeds) can be practiced once in a day.
- Lavang (Clove) powder mixed with natural sugar / honey can be taken 2-3 times a day in case of cough or throat irritation.

These measures generally treat normal dry cough and sore throat. However, it is best to

YOGA ADVICE BY MINISTRY OF AYUSH, GOVERNMENT OF INDIA

Yoga Based life style module to improve immune resilience in healthy population of all age groups.

Common Yoga Protocol

Forty-Five-minute module: The Common Yoga Protocol was developed by a team of leading Yoga experts / Yoga Masters include safe practices to improve physical, mental, emotional and spiritual health of the population. Regular practice on empty stomach is recommended to improve immune resilience.

Twenty and ten minute modules are recommended for children, adults, Youths and the elderly population to be repeated twice a day (morning and evening).

Yogic Diet

Follow the recommendations as per the medical advice on diet for your condition of diabetes, or heart disease etc. and add-on these concepts from yoga that promotes mental health. This includes wholesome nutritious freshly cooked traditional home cooked food with plenty of fresh vegetables and fruits (with restrictions as per your disease condition) with added traditional spices in moderate quantities, consumed at regular timings.

Abstinence should be maintained from substance abuse including tobacco, alcohol and other addictive drugs to reduce disease susceptibility in high risk population.

This guideline recommends evidence based safe and simple yoga practices as mentioned above that promote heath of the respiratory, cardiovascular and the immune systems.

	Practices	Name of the Practice	Duration (Minutes)
A	Starting	Prayer	1
B	Loosening Practices (SukṣmaVyāyāma / CālanaKriyā)	Neck Bending	2
		Shoulder movement	2
		Trunk Movement	1
		Knee Movement	1

	Practices	Name of the Practice	Duration (Minutes)
C	Yoga Practices		
	Āsanas performed in standing posture	Tadāsana (The Palm tree posture)	1
		Vrikshāsana (The Tree posture)	2
		PadaHatasana (The Hands to the feet posture)/ArdhaChakrāsana(The Half wheel posture)	1
		ArdhaChakrāsana (The Half wheel posture)	1
		Trikonāsana (The Triangle posture)	2
	Āsana performed in sitting posture	Bhadrāsana (The Firm/Auspicious posture)	1
		Vajrāsana The Thunderbolt/diamond posture)	1
		ArdhaUshtrāsana (The Half camel posture)	1
		Ushtrāsana (The Camel posture)	1
		Sasakāsana (The Hare posture)	1
		UtthanaMandukāsana (The Stretched up-frog posture)	1
		Vakrāsana (The Seated twist posture)	1
	Āsana performed while lying on the stomach	Makarāsana (The Crocodile posture)	2
		Bhujangāsana (The Cobra posture)	1
		Shalabhāsana (The Locust posture)	1

	Practices	Name of the Practice	Duration (Minutes)
	Āsana performed while lying on the back	Setubandhāsana (The Bridge posture)	1
		Utthanapadāsana (The Raised leg posture)	0.5
		ArdhaHalāsana (The Half plough posture)	0.5
		PawanaMuktāsana (The Wind releasing posture)	2
		Shavāsana (The Corpse posture)	2
D	Kriya	Kaphalabhati (The Shining skull practice) 1 rounds, 30 cycles each	2
E	Pranayama	(AnulomaViloma /Nadiswhodhana Pranayama) The Alternate nostril breathing (5 rounds)	2
		Ujjayee Pranayama (The Hissing breathing) (5 rounds)	2
		Bhramari Pranayama (BhramariRechaka) (The Bee sound breathing) (3 rounds)	2
F	Dhyāna	The Meditation	5
	Closing	Sankalpa / Shanti patha	1
	Total Duration		**45**

Prayer

Neck Bending

Shoulder Stretching

Shoulder Rotation

Trunk Twisting

Knee Movement

Tadasana

Vrikshasana

Pada-
Hastasana

Ardh-
Chakrasana

Trikonasana

Dandasana

Bhadrasana

Vajrasana

Ardh-Ushtrasana

Ushtrasana

Shashankasana

Uttana-manduk-asana

Vakrasana

Makarasana

Bhujangasana

Shalabhasana

Setubandh-asana

Uttana-pada-asana

Ardh-hala-asana

Pavan-mukt-asana

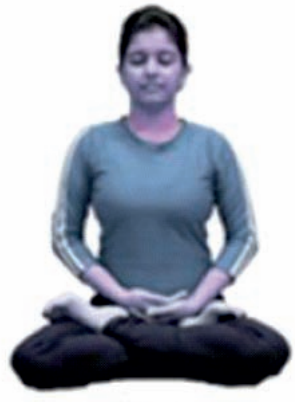
Savasana

Kapalbhati

Nadishodhana

Sitali Pranayama

Bhramri Pranayama



Dhyan

MULTI FACETS OF A COMPETENT PHARMACIST

by

Ms. Caroline. N
College of Pharmacy, Madras Medical College, Chennai

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

I. Synopsis

In the past few decades, the pharmacy profession has evolved from a conventional and traditional focus on just compounding and dispensing to a broader role in the health care team with patient care as the prime focus. The pharmacists of this period need to act as a complete health care provider community rather than just a drug seller. The role of pharmacist has revolutionized from a compounder to a dispenser and lately to a health care professional. The concept of a clinical pharmacist and pharmacist as an industrialist has been a new facet to this ever evolving profession.

II. Content

II.A. Pharmacist – a multifaceted responsibility. The Pharmaceutical Society of Trinidad and Tobago entitle them as "the Seven Star Pharmacist". The "Seven Star" represents the role of the pharmacist as: *Custodian of Services* – to provide services which include clinical, analytical, technological and regulatory. *Administrator* – The pharmacist should be highly qualified and efficient order to take the right decisions concerning resources such as personnel, medicines, chemicals, equipment, procedures, practices etc. *Conversationalists* – Communication is the vital key between a highly skillful pharmacist and the patient or any stakeholder within the discipline. *Leader* – A pharmacist should always be ready to enact his role as a figurehead during times of emergencies and while working as a team. These qualities should involve compassion and empathy. He should also possess the virtue of equanimity. *Manager* – A pharmacist should be equipped to manage and congenial to be managed by others as well. *Bred-in-the-bone learner* – A pharmacist should start learning and foregathering information right from pharmacy school and continuing throughout his/her entire career. *Educator* – A pharmacist is responsible to pass down his/her knowledge and skill to the future generations. This also gives him/her an opportunity to be updated with the latest happenings in the field.

Pharmacist as a prescriber- This current era is a transition and expansion for pharmacy as a profession. Therefore a pharmacist on top of being well equipped to prescribe the right drugs with the right dose should move to expand their boundaries in the profession. In the United Kingdom, supplementary prescribing by pharmacist was approved in 2001. These models require collaborations between physicians and pharmacist. Likewise in Canada, pharmacists in some jurisdictions have been granted the ability to independently prescribe emergency contraception (a schedule 2 product) since early 2000. Therefore a pharmacist must be competent enough to fit the definitions of the new standards for pharmacy practice according to the Pharmacy and Drug Act, 2006.

Pharmacist's role in rational use of drugs- The pharmacist is no longer just a supplier of medicines but a facilitator between the different members of a healthcare team and to physicians and nurses. A proficient pharmacist should educate patients about their drug therapy – namely, potential adverse effects, what signs and symptoms to look for and what action to take if they do experience a problem.

Skills of an adept clinical pharmacist- The skills a competent clinician should possess are patient care, knowledge of drug therapy, knowledge of laboratory, diagnostic skills, communication skills, patient monitoring skills, physical assessment skills, therapeutic planning skills and knowledge of non-drug therapy.

II.B. In the new age, pharmacy has been divided into many intricate types: for each a component pharmacist must possess unique skills. The various fields are:

Community pharmacist- A pharmacist needs to advice the patient on adverse effects, side effects, route of administration, time of administration and rational use of drugs.

Hospital pharmacist-A hospital pharmacist should work in close collaboration with other health professionals for the optimum benefit of a patient. They should be involved in chemical trails and compounding medications for individualized dozing. Teaching, administrative functions in the selection, proper storage, distribution and prescription protocol of drugs, assessing drug levels and drug safety may all be a part of their work.

Clinical pharmacist- A competent clinical pharmacist ensures the optimal use of medication for the best outcomes through the provision of drug information and monitoring for drug safety and efficacy.

Industrial pharmacist- the pharmacist should have thorough knowledge about research, production, packaging, quality control, marketing and sales of pharmaceutical goods.

Compound or formulative pharmacist- In this area, a pharmacist should understand about formulative errors and how to overcome them.

Consulting pharmacist- A pharmacist in this field should have a high theoretical review of medications and visit in-patients to provide them service.

Ambulatory care pharmacist- A proficient pharmacist should help in the management of patients who are at higher risk of drug related problems.

Regulatory pharmacist- He/she should be aware of all the rules and regulations of regulatory health boards such as United States Food and Drug Administration.

Research pharmacist- He/she should be involved in developing new drugs and profiling their actions, effectiveness, side effects and interactions.

III. Conclusion

Overall, a competent pharmacist of this age should possess the skills of accuracy, integrity, interpersonal skills, be highly qualified in his subjects of interest, communication skills, advocacy, management skills, ability to multitask, diplomacy, ability to practice, possess an analytical mind, patient counseling, computer literacy, financial skills, mentoring and belief in ethics; all these to provide a better patient care. Pharmacists of this decade should also thrive to be entrepreneurs of tomorrow through their management skills. A proficient pharmacist should follow his heart and believe in his competence and try to wake the globe a better place to live for himself, his people and communities.

EVENTS

Tamilnadu Pharmaceutical Sciences Welfare Trust Contribution to Govt. Chengalpattu Medical College

The trustees of Tamilnadu Pharmaceutical Sciences Welfare Trust decided trust to contribute TN government towards Covid pandemic relief. The council members had a meeting via Zoom app on 23rd April 2020.

Chairman requested all the members to give their opinion, for the COVID contribution. After due deliberation, it was decided to contribute essential items like Sanitizers, Masks, Personal Protection Equipment (PPE), Gloves, etc. for Rs. 1.5 lakhs. worth of to the needy Govt. Institution.

A 3 member committee was formed under the head of Mr. J. Jayaseelan, to decide the hospital and the kind of items to be procured.

Accordingly the following essential items worth of Rs. 1.5 Lakhs were handed over to the Dean, Chengalpattu Medical college Hospital on 19th May 2020.

- 350 pieces N95 MASK
- 100 Pieces PPE kit
- 1250 nos x 200ml of Hand Sanitizers

IPA – TNSB Activities in COVID TIMES

Distribution of 5Kgs Rice bag for each of the 500 fishermen families at Kovalam

Donated 5000 Surgical Mask, 100 boxes of Gloves & 1000 x 200ml of Hand Sanitizers at Regional Institute of Ophthalmology and Government Ophthalmic Hospital in Chennai for support to fight Covid19. RIOGOH is one of the oldest eye hospitals in the world around 200 years.

Donated the required essentials (N95-300nos, PPE-600nos & Hand Sanitizers-2500x200ml) for the warriors at the Government Stanley Medical College Hospital. We strive to support more Warriors.

The Adyar Cancer Institute (WIA), as you are aware, is a public charitable voluntary institute dedicated to the care of cancer for the last 60 years. During these Covid Times, the institute is badly in need of funds / materials (as covid materials to each health warrior in the hospital is an extra burden to such charitable hospital, but still many patients are dependent on them), as all patients are treated there either free or at a very minimal cost. On the mass request by the Hospital for donors & on a specific request for drugs from the most respected Chairman of the Hospital Padma Vibhushan DR V.SHANTA, IPA Tamilnadu State Branch (TNSB) volunteered to contribute the list of 3 medicines requested by them. Namely Neukine, Pegasta & Peg-Grafeel. IPA TNSB is glad to inform that today, we donated Rs.18.00 Lakhs worth of these 3 medicines. In the presence of President Dr. S. Manivannan, Vice President Mr. J. Jayaseelan, Hony. Secretary Mr. T. Sathish, Joint Secretary, Mr. K. Pandian, Treasurer Mr. Rajesh H. Bhandari. We were fortunate to have Dr. Shanta in Person. She was very thankful to IPA & all its members.

INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2019-20 AWARDED BY TNPSWT

Profile of 2nd Rank

PHARMACEUTICS

Name: Ms. A. J. Mariyambee

Project Title: Design and Charaterisation of Rosuvastatin calcium Nanosponge using a natural polymer at different concentration

College: Kamalakshi Pandurangan College of Pharmacy, Tiruvannamalai

Guide's Name: Mrs. M. Bharathi

PHARMACEUTICAL CHEMISTRY

Name: Mr. Vyshaag. C.M

Project Title: *In Silico* Design and Synthesis of some novel 1,2-disubstituted benzazoles as MurF Inhibitors

College: JSS College of Pharmacy, Ooty

Guide's Name: Prof. Md. Afzal Azam

PHARMACEUTICAL ANALYSIS

Name: Mr. Mohanakishore. G

Project Title: Evaluation of Perampanel, a new Antiepileptic Drug, in the presence of its degradation and process related impurities & its Bioanalysis in human plasma by newly developed methods

College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. Susheel John Varghese

PHARMACOLOGY

Name: Ms. Anitta Augustine

Project Title: Effect of Boswellic acid on Chronic Unpredictable Mild Stress induced HPA axis dysregulation in relation with Glutamate and GABA aberration depressive Rats.

College: KMCM College of Pharmacy, Coimbatore

Guide's Name: Dr. G. Venkatesh

PHARMACOGNOSY

Name: Mr. Sagar. T.R

Project Title: Selective essential fatty acids in ghrita alters aromatase activity in adipose to combat obesity-induced endometrial cancer

College: JSS college of Pharmacy, Ooty

Guide's Name: Dr. Suresh Kumar. M

PHARMACY PRACTICE

Name: Mr. Abdul Gani. S

Project Title: Optimisation of total Parentral Nutrition to prevent extra uterine growth restriction in very low birth weight neonates - A quality improvement initiative by a Clinical Pharmacist

College: Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai

Guide's Name: Dr. N. Vanitha Rani

PHARM D

Name: Ms. Joyita Krishnamurthi

Project Title: Olanzapine versus Aprepitant in the prophylaxis of Chemotherapy Induced Nausea and Vomiting in patient receiving TAC (Taxane/ Adriamycin/ cyclophosphamide) regimen for post mastectomy breast cancer.

College: School of Pharmaceutical Sciences, VISTAS, Chennai

Guide's Name: Dr. M. Vijey Anandhi

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NOTIFICATION

File No. 31 026/54/2020-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Dated: 27th July. 2020

Guidelines of the Scheme "Promotion of Medical Devices Parks"

1. **Background**

1.1 The Medical Device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the hi-tech innovative products originate from a well-developed eco-system and innovation cycle which is yet to be fully developed in India. The industry depends on imports up to an extent of 86%.

1.2 Since the creation of testing and laboratory facilities requires huge investment, a Scheme called 'Promotion of Medical Device Parks" has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities! centre at one place reducing the manufacturing cost significantly and create a robust ecosystem for medical device manufacturing in the country.

1.3 The Scheme has been notified vide Gazette notification no. - 31026/08/2020-MD, dated - 21/07/2020.

2. Objective

2.1. Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.

2.2. Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market.

2.3. Exploit the benefits arising due to optimization of resources and economies of scale.

3. **Definitions**

3.1. Common Infrastructure Facility (CIF): The Common facilities with capacity commensurate with the expected number and type of medical device manufacturing units in the park. Some of the indicative activities under the Common facilities/centres are:

i. Component Testing Centre/ESDM/PCB/Sensors facility

ii. Electra-magnetic interference & Electra Magnetic Compatibility Centre

iii. Biomaterial / Biocompatibility /Accelerated Aging testing centre

iv. Medical grade moulding / milling / injection moulding / machining / tooling centre

v. 3D designing and printing for medical grade products.

vi. Sterilization/ETO/Gamma Centre

vii. Animal Lab and Toxicity testing centre

viii. Radiation testing centre, etc.

ix. Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility

x. Solid waste management/ETP/STP/Electronic Waste management unit

xi. Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation. Customs, Weighbridges, etc.) centre

xii. Emergency Response Centre/Safety/Hazardous Operations audit centre

xiii. Centre of Excellence/Technology Incubator/ ITI/Training Centres

Note: The facilities/centres required are constantly evolving and include laser, tool rooms for mechatronics, etc. The list of common facilities/centre given above is indicative and states are encouraged to plan for facilities, the implementing agency considers useful.

3.2. **Medical Device Park**: For the purpose of this Scheme, a Medical Device Park means a designated contiguous area of land with common infrastructure facilities for the exclusive manufacturing of medical devices.

3.3. **Project cost:** The cost of establishing CIF in the Medical Device Park.

3.4. **Proposer:** The proposer for the purpose of the Scheme shall be a State Government.

3.5. **State:** State or Union Territory of Republic of India.

4. Scope of the Scheme

4.1. This is a Central Sector Scheme.

4.2. Total financial outlay of the Scheme is Rs. 400 Crore.

4.3. Four Medical Device Parks will be supported under the Scheme.

4.4. Maximum grant-in-aid for one Medical Device Park will be limited to Rs 100 crore.

4.5. The duration of the Scheme is from FY 2020-2021 to FY 2024-2025.

4.6. Under the Scheme, a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Medical Device Park proposed by a State

4.7. The Scheme will be implemented through a State Implementing Agency (SIA), a legal entity, set up by the concerned State Government.

4.8. The grant-in-aid will be 70% of the project cost of the common infrastructure facilities. In case of North Eastern States and Hilly States (i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the grant-in-aid will be 90% of the CIF.

5. **Project Management Agency (PMA)**

5.1. A Project Management Agency (PMA) will be nominated by Department of Pharmaceuticals (hereinafter referred as DoP) for providing secretarial, managerial and implementation support to DoP for effective implementation of the Scheme.

5.2. The PMA would be responsible for:

i) Preliminary examination of the proposals received from states and seeking additional information including documents from states, if required for completeness of the proposals.

ii) Appraisal of proposals and making appropriate recommendations to the Scheme Steering Committee (SSC) for approval of proposals under the Scheme.

iii) Appraisal of DPRs including financial viability, commercial sustainability and socio-economic impact of the projects.

iv) Assisting DoP in periodic monitoring of the projects and timely disbursement and utilisation of the funds.

v) Monitoring Medical Device Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (C PM) and Gantt Chart and periodic submission of the report to SSC.

vi) Monitoring event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements

vii) Periodic physical inspection of the Medical Device Parks.

viii) Any other matter pertaining to the Scheme assigned by DoP.

6. **Technical Committee (TC)**

6.1. A Technical Committee, constituted by the DoP will assist SSC in discharging its functions. TC will provide comments on any technical matter referred to by the DoP! SSC.

6.2. Technical committee shall comprise of three experts having knowledge and experience in regulations, manufacturing of medical devices and R&D of medical devices. Out of three, one expert having experience in implementation of infrastructure projects related to development of industrial park! zone.

7. **State Implementing Agency (SIA)**

7.1. State Implementing Agency (SIA) shall be a legal entity (with minimum 51% equity shareholding of State Government in the paid-up capital of SIA) set up by the State Government for the purpose of implementing the Medical Device Park Project.

7.2. SIA shall be responsible for day to day management of Medical Device Park.

7.3. The SIA shall be responsible for:

i) Preparing the Detailed Project Report (DPR) covering the technical, financial, institutional and operational aspects of the CIF project of the Medical Device Park.

ii) Ensuring and making available balance amount of the Project Cost.

iii) Obtaining all statutory approvals / clearances including all environmental clearances.

iv) Providing single window system for various approvals and testing certificates.

v) Recruiting suitable professionals in order to ensure that the project is executed smoothly.

vi) Implementing various interventions as outlined and approved in DPR.

vii) Preparing event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements as specified in DPR.

viii) Furnishing regular progress reports of the project to DoP! PMA.

7.4. SIA shall allot land only on long term lease basis.

7.5. SIA shall keep a provision for cancellation of allotment of the land, if the commercial production is not started by the allottee within a period of two years from the date of allotment order unless it extends the time period by one year on valid reasons.

7.6. SIA shall submit any report sought by DoP, from time to time.

8. **Role of State Government**

8.1. State Government shall be responsible for:

i) Submission of Project Report.

ii) Land: State Government will be responsible for providing encumbrances free land for the development of the Medical Device Park.

iii) Ensuring and making available balance amount of the Project Cost through budgetary and I or other sources.

iv) Obtaining all statutory approvals I clearances including all environmental clearances.

v) Providing single window system for various approvals and testing certificates.

vi) Providing necessary infrastructure such as access road, power, water supply, etc. up to the park.

vii) Providing all project related clearances expeditiously.

viii) Providing all clearances required by individual medical device units expeditiously.

ix) Promoting the Medical Device Park at National & International level.

x) Provide 33KV electricity supply lines and 1500 KLPD water supply lines with the necessary infrastructure up to the project site.

9. **cheme Steering Committee (SSC)**

9.1. The proposals under the Scheme will be approved by the Scheme Steering Committee (SSC) constituted by DoP.

9.2. The composition of the SSC is as follows:

a) Secretary, DoP - Chairperson

b) Financial Adviser, DoP - Member

c) Joint Secretary, Ministry of Environment, Forest and Climate Change - Member

d) Joint Secretary, Department for Promotion of Industry and Internal Trade - Member

e) Joint Secretary, Department of Health and Family Welfare — Member

f) DCGI, Central Drug Standard Control Organisation - Member

g) Joint Secretary(Policy), DoP - Convenor

The SSC may invite representatives of Industry Associations, R&D Institutions and other Government! Private sector expert organizations as special invitees as may be necessary from time to time.

9.3. The SSC shall take all decisions required for successful implementation of the Scheme, including any modifications if required.

9.4. The SSC will be assisted by the Project Management Agency (PMA).

9.5. The SSC will meet as often as necessary to ensure timely consideration of proposals and release of instalments of grant-in-aid and to review progress of the projects under the Scheme. However, it shall hold meeting at least once in 6 months.

10. **Proposer**

10.1. A State Government can make only one proposal of Medical Device Park under this Scheme.

10.2. The proposed park shall not be less than 150 acres in area. For North Eastern States and Hilly States (i.e. Himacha! Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the area of proposed park shall not be less than 100 acres.

10.3. At least 50% of the total area of the Medical Device Park shall be made available for allotment to individual medical device units.

10.4. The proposer shall have to be in full possession of the land free of all encumbrances proposed for establishing the Medical Device Park on the date of submission of proposal.

10.5. The proposer shall submit a Project Report (PR) including the proposed cost of establishing the Medical Device Park including cost of CIF.

10.6. The project report shall cover feasibility study establishing viability of the Medical Device Park at the identified location. The feasibility study shall cover assessment of environmental risk and associated health risk, business risk and management risk.

10.7. Project cost shall not include the following:

I. Cost of Land,

II. Pre-operative expenses like preparation of Project Report,

III. Administrative and management support expenses.

10.8. The proposer shall give full details of the location of the proposed Medical Device Park including land area (in acres), location map and area map.

10.9. The proposer shall provide an undertaking for establishing a single window for all necessary clearances required for the manufacturing units located in the park.

10.10. The proposer shall submit an undertaking to establish a Research and Development facility as a Centre of Excellence in the park. Such facility may be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.

10.11 . The proposer shall submit an undertaking to ensure availability of funds.

10.12. The proposer may be required to make a presentation on the proposal before SSc

11. **Proposal**

11.1. The State Government should identify a suitable location for establishment of Medical Device Park keeping in mind various factors viz., assured availability of power, assured availability of water, transport connectivity with railways, national highway, port, airport, environmental aspects etc. The identified location should be well away from the eco-sensitive zone of protected areas.

11.2. The proposer State shall submit an undertaking that it shall not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

11 .3. The proposal under the Scheme shall be made within 60 days of issuance of these guidelines, in the format provided at Annexure 1.

12. **Selection of Proposal**

12.1. The evaluation criteria provided in Appendix of these guidelines shall be used for selection of States. The States obtaining top four ranks will be considered for selection under the Scheme.

12.2. In case, the selected State fails to submit the DPR in time or fails to implement the project as per the timelines stated in the DPR, the in-principle approval may be cancelled by the SSC. In such case, State in the ranking may be selected for the purpose of the Scheme.

13. **In-Principle approval under the Scheme**

13.1. PMA will evaluate the proposals and give its recommendations to DoP.

13.2. The recommendations of the PMA will be placed before SSC for its consideration.

13.3. After receiving in-principle approval from the SSC, DoP will issue a letter of inprinciple approval to the selected States.

14. **Detailed Project Report (DPR)**

14.1. A Detailed Project Report (DPR) shall be prepared and submitted to DoP along with the details as per the format given in Annexure 2 of these guidelines by the selected State Government within 180 days of date of issuance of in- principle approval letter.

14.2. The DPR shall include, among other things, the following details:

a) Location of the proposed Medical Device Park

b) Total land area of the park

c) Total land area of the park available for the allotment to units

d) Detailed breakup of the utilisation of the remaining land (Green belt, landscape, CIF, etc.)

e) Project cost

f) Number of projected medical device units

g) Proposed time period for obtaining clearances from Central and State Government for establishing the Medical Device Park.

- The time period for completing the CIF
- The date at which the plots will be allocated to the medical device units

h) Details such as brief description of the CIF, estimated capacity of CIF, justification for arriving at the capacity, cost of CIF, technology used, approximate time to establish the CIF, approval required from different agencies, projected time lines for obtaining approval, for each component of CIF based on the projected number of manufacturing facilities.

i) Detailed viability of the project along with the operational cost and proposed user charges.

j) Provide an analysis of occupational hazards in the park

k) Indicative charges (not higher than those committed in the proposal) to be collected from the medical device manufacturing units:

- land lease rate per sq. meter
- Utilities charges:
  - o Power,
  - o Water,
  - o Park maintenance charges
  - o Warehouse charges.
- Quality control testing charges

l) Details of all the business processes of the Medical Device Park to identify impediments and bottlenecks and to draw action plan for enhancing competitiveness of the units to be set up in the Medical Device Park.

m) Mode of funding and phasing of expenditure i.e. contribution of various stakeholders (Gol, State Govt. and others)

n) Financial viability to the extent available i.e. Internal Rate of Return, % occupancy to achieve viability etc.

0) Provide a Medical Device Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt chart.

14.3. **Ceiling on the eligible cost of the project**

i. Assistance for Administrative and other management support of SIA for the project implementation period shall not exceed 5 % of the grant-inaid.

ii. Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5 % of the grant-in-Aid.

iii. No grant shall be given towards construction of roads, compound wall and buildings. However, as far as various scientific facilities! centres are concerned, 30% of the estimated cost of respective facility! centre will be allowed from grant-in-aid towards construction of the building.

15. **Final approval under the Scheme**

15.1. PMA will appraise the DPR and submit its recommendations to the SSC for its consideration.

15.2. After receiving final approval from the SSC, DoP will issue letter of final approval tothe selected State.

16. **Post Approval**

16.1. The project shall be completed within two years from the date of release of the first instalment of the grant-in-aid, unless the period is extended by the SSC

16.2. SIA shall furnish a quarterly progress report on the development of the park

16.3. PMA shall assess the progress of the project from time to time and submit the report to the SSC.

17. **Release of funds**

17.1. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds shall also be necessary before release of Central Government assistance.

17.2. Grant-in-aid will be released in four instalments in the following manner:

Instalment	Percentage of Funds	Remarks! Pre-requisite
1st	30	• On final approval of the project by the SSC and after deposit of 30 percent of SIA's share in the project cost in the Trust and Retention Account (TRA) or Escrow or No Lien Account as the case may be, subject to the condition that all relevant environment clearances are in place.
2nd	30	• 60% utilisation of the 1st instalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR • Against the production of Bills
3rd	30	• 100% utilisation of 1st instalment and at least 60% utilization of 2 instalment and after the proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR • Against the production of Bills
4th	10	• 100% utilisation of 2nd and 31d instalments • SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.

17.3. The SIA shall open a Trust and Retention Account (TRA) or Escrow or No Lien Account as may be decided by the SSC for the purpose of parking the funds received as grant-in-aid from the Central Government under the Scheme and also the State Government share.

17.4. The SIA shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format prescribed in GER.

17.5. Accounts of SIA shall be subject to audit by the Comptroller & Auditor General of India.

18. **Maintenance! Ownership of Assets**

18.1. SIA shall be responsible for Operation and Management of assets created under the Scheme.

18.2. The assets acquired by the SIA out of Central government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

18.3. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Central government should be maintained as per GFR.

18.4. If, for any reasons, SIA is liquidated, Government of India will have the first right to recover the grant-in-aid released for the project in case any surplus is left in the process of liquidation.

18.5. Escalation in the cost of project due to any reason, will be borne by the State government! SIA. The Central government shall not accept any financial liability arising out of operation of any CIF.

18.6. For successful implementation and operation of the Medical Device Park, agreements shall be entered into between Government of India (GoI) and the State Government on one hand and between State Government and SIA on the other hand. The draft agreements will be circulated along with the final approval letter.

18.7. In addition to the CIF, the SIA and the State shall actively facilitate common services!utilities required for smooth running of businesses such as petrol pumps, banks, cafeteria, business centre, parking for trucks, convenience stores, medical service centre etc.

18.8. SIA shall constitute a management committee comprising of the representatives of the State Government, SIA, two representatives nominated from among the manufacturing units situated in the park and State Drugs Controller, for monitoring operation and maintenance of the park after completion of the project.

(Navdeep Rinwa)
Joint Secretary to the Government of India
Tel No. 011-23385131
Email: js.pharma@nic.in

New Delhi, Dated: 27th July, 2020

Appendix

Evaluation Criteria for Selection

S. No.	Marking Criteria	Maximum Marks
1	Utility charges (rates) as per proposal submitted by State Govt. (the State quoting the lowest rate will be awarded full marks and others will be rated pro-rata): I. Power (10) ii. Water (7) iii. Park maintenance charges (5) iv. Warehouse Charges (3)	25
2	Policy incentives of state government applicable for Medical Devices Industry i. Interest Subvention Scheme (6) — (the State quoting highest percentage of interest subvention for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata) ii. GST reimbursement, subsidy, incentive etc. against investment (6) - (the State quoting highest percentage of the reimbursement of investment, for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata).	12
3	Connectivity of the Park i. Air Cargo I Airport within 50 km from site (4) ii. National Highway within 25 km from site (4) iii. Sea Port / In-land waterway! Dry port within 100 km from site (4)	12
4	Lease rate to be offered to individual units of medical device to be set up in the park - the lease rent shall be compared based on the NPV of the upfront lease payment and/or periodic leasel maintenance charges per sq. meter, discounted at SBI 1 Year MCLR applicable on the date of evaluation (the State quoting the lowest lease rent per sq. meter on NPV basis, shall be awarded full marks and others will be rated pro-rata).	10
5	Total area of the proposed park i. The hilly States, as defined in the guidelines, shall get 2.5 marks for every additional 35 acres. over and above 100 acres minimum stipulated land ii. Other States shall get 2.5 marks for every additional 50 acres of land over and above 150 acres minimum stipulated land	10
6	Uninterrupted 24*7 availability, with committed source and necessary infrastructure, of (Yes! No): i. Power (4) ii. Water supply (3)	7
7	Full exemption of Stamp Duty and Registration charges (Yes/No)	5

S. No.	Marking Criteria	Maximum Marks
8	Latest Ease of Doing Business Ranking of the State - The marks shall be awarded based on the slabs of ranking: i. Rank 1 to 5 = 5 Marks ii. Rank 6 to 10 = 4 Marks iii. Rank 11 to 15 = 3 Marks iv. Rank 16 to 20 = 2 Marks v. Rank21 to 25=1 Mark vi. Rank below 25 = 0 Mark	5
9	Availability of Technical Manpower in the State i. No. of Engineering, Medical and Pharmacy colleges $\geq$ 30 (3) ii. No. of specialised research institutes in Medical Device sector $\geq$ 1 (2)	5
10	Presence of Institutes for technology transfer (Yes/No)	5
11	Industrial Network i. Ancillary spare part producers $\geq$ 50 (2) ii. Registered MSMEs $\geq$ 1000 (2)	4
	Total	**100**

Annexure I

Proposal Form

1. **Instructions**

1.1. The proposal shall be duly signed by the authorized signatory.

1.2. Proposers are advised to go through the guidelines carefully before submitting the proposal.

1.3. Proposers shall follow the format provided in this proposal form for submitting the proposals. Proposers shall provide information and enclose all the supporting documents as detailed.

1.4. All proposals will be submitted to the DoP in physical form and soft copy (pen drive/ CD) in a sealed envelope, addressed to Dr. Sumit Garg, Deputy Secretary (Policy), Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, Room No. 228, A-Wing, Shastri Bhawan, New Delhi —110001.

1.5. Proposal has following two sections:

I. Proposer Details

II. Details of the Proposal

2. **Section I — Proposer Details**

2.1 Name of the State

2.2 Authorised Signatory Details — Name, Designation, Contact No. (Mobile and Office Landline No.), Email and complete office address.

3. **Section II - Details of the Proposal**

3.1 **Cost of Development of the Park & tentative source of funds (Rs. in crore):**

I. Cost of Development of the Park (estimated)

ii. Central Government Share (Grant-in-Aid)

iii. State Government /Union Territory share with source of funds for share of State Govt./ Union Territory

3.2 Details of Land: Total land area (in acres) of the proposed park and estimate of area available for allotment to medical device manufacturing units (which shall be not less than 50% of the total land area).

The State is required to furnish the details on the following specific points (in case, any of the following is applicable to the land, including part of the land, proposed for the park):

a) Location of the land on google map, mapping of the land and land survey report

b) Status of ownership, possession and mutation of the land in the revenue records

c) Status of any encroachment, unauthorised possession or habitation on the land (including part of the land) proposed for the park

d) Whether the land (including part of the land) is subject to any rehabilitation requirement etc. The status, procedure and timelines of the same should be clearly mentioned

e) Whether there is any compensation related issue which is pending for the land (including part of the land)

f) Whether there is any legal dispute or claim, pending in any court of law with any party for the land (including part of the land). If yes, detail about nature of dispute, forum where pending and any timelines for closure to be furnished.

g) Any other known encumbrance, restriction or relevant information which may have an impact on timely completion of development of the Park, please furnish the details.

3.3 **Land Lease Rate**

Please specify the land lease rate (annual rent per square meter in Rs.) to be offered to medical device manufacturing units to be set up in the park. The state is required to clearly mention the upfront fee payable by the manufacturing unit and all subsequent payment with the period icity and duration of payment.

The lease rent referred to above shall be a comprehensive levy for allotment of land.

3.4 **Commitment to provide 24*7 availability of power and water supply**

The State is required to give a commitment with broad details for sourcing continuous power and water supply, which shall be considered for the evaluation of the proposal. However, the selected States will be required to provide detailed justification and feasibility for sourcing continuous power and water supply in the Detailed Project Report.

3.5 **Location of the park vis-à-vis connectivity**

The State should specify the distance (in km) of proposed Park from the following:

a) Nearest National Highway

b) Nearest Air Cargo! Airport

C) Nearest Sea Port! In-land waterway! Dry Port

Please specify the location and name the National Highway, Air Cargo and Nearest Sea Port! In-land waterways and Dry Port.

3.6 **Location of the park vis-à-vis eco-sensitive zone of protected area**

Whether the land is in proximity to any of the eco sensitive zone of protected area. The state is required to furnish the detail of distance (in km) of proposed park from nearest such zone.

3.7 **Policy incentives given/proposed by the State government for Medical Device industry**

a) **Interest subvention scheme:** Whether the State has/proposes any interest subvention scheme on the loan availed by the Medical Device manufacturing units. State is required to provide the detail of percentage of interest rate subvention for a period of 10 years from the date of operation of the park.

b) **Incentive in the form of GST reimbursement, subsidy etc. against investment:** The State is required to submit detail of all incentives by way of GST reimbursement! subsidy or any other form of incentive, as a % of the total investment made by Medical Device manufacturing unit. State is also required to submit the calculation of such % of incentive against investment.

c) Whether State commits to exempt the Stamp Duty and Registration Charges for medical device manufacturing units (Yes! No).

Please submit the relevant supporting documents.

3.8 **Utility Charges**

State is required to submit the following utility charges to be charged from Medical Device manufacturing units. The said charges will have to be committed by the State and undertaking in this regard shall be submitted as appended in this Proposal Form.

Utility	Units (for specifying the charges)
Power	kWh
Water	Per kilo litre
Warehouse	Monthly charges per square meter
Park maintenance charges	Annual charges per square meter

3.9 **Availability of technical manpower**

a) Specialised research institutes in Medical device sector- Number, Name, Address and recognition status

b) Engineering, Medical and Pharmacy colleges- Number, Name, Address and recognition status

Institute recognised by concerned State or Central body only shall be considered.

3.10 **Number of Industrial Network in the State**

a) Ancillary spare part producers — Name and location of engineering ancillaries in the State

b) Registered MSMEs — Name and location of engineering MSMEs in the State

3.11 **Institutes for technology transfer**

a) Institute in the State involved in Technology Transfer

Document required: Such Institute's Registration Documents or Letter of Intent to State! SIA to support the Park or MoU with the State.

3.12 **Latest Ease of Doing Business ranking of the State**

Undertaking

In connection with our application for development of a Medical Device Park as notified vide notification no. - 31026/08/2020-MD, dated - 21/07/2020 and guidelines thereunder, the State .....of acting through authorised signatory Sh..... do hereby undertake unconditionally and irrevocably that the State of .....shall ensure to:

i) adhere to the roles and responsibilities of the State as outlined under these guidelines and fulfil all the commitments made in the proposal.

ii) set up a State Implementing Agency (SIA) with the roles and responsibilities, as outlined in the Guidelines of the Scheme "Promotion of Medical Device Parks".

iii) make available balance amount of Project Cost without any delay, as may be required for completion of development of Medical Device Park, through budgetary and/or other sources, as may be necessary.

iv) not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

v) establish a Research and Development facility as a Centre of Excellence in the park to be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.

vi) adhere to the responsibilities as specified in these guidelines and also the SIA, as appointed, and implementing agency, if any, as appointed, shall also adhere to the roles and responsibilities specified in these guidelines.

To be signed by the Authorised Signatory

Mention name and designation

Annexure 2

Detailed Project Report (DPR)

1. The DPR should include the following information among other details.

2. Proposed State Implementing Agency (SIA) - Type of organisation, legal status, shareholding pattern (give detail of any private participation such as PPP agreement, MoU etc. with model terms and structure), functions and responsibilities, budgetary allocation (if any), administrative dept. of the State for SIA.

    a. **Governing Body:** Constitution of governing body of the SIA.

    b. **Key Personnel Details:** Contact details of three senior officials of the proposer. Details would include Name, Designation, Address, phone, email

    c. **Contact Details of Authorized Representative**: Details would include Name, Designation, Address, phone, email

    Documents to be furnished: all applicable documents.

3. **Description of the Park:**

    a. Details of area of land allocated for Park, address and location

    b. Land Acquisition details with Survey nos.

c. Any change in the status of encumbrance, pending legal dispute etc. submitted earlier in the proposal form

d. Connectivity and linkage (distance from the nearest National Highway, Airport, Sea Port, Railway Station, residential area, etc.)

e. Strength of the project location, description of the terrain, natural water resources available, type of land (forest, agriculture, etc.) and other relevant detail, if any.

f Specify the useable land (Industrial Plots and plotting pattern based on number and size of plots), number of projected manufacturing facilities, internal roads, green buffer, open space, social infrastructure, support facilities and CIF.

Document to be furnished: Layout of the proposed Medical Device Park and Geotagging details

4. **Cost estimation & source of funds:**

a. Furnish detailed head-wise cost of:

- Development of the Park: Provide breakup of cost into land development, green belt, internal roads, sewage, culverts, RCC drains, compound wall, street lighting, support facilities & misc. Provide cost of each building proposed in the Park with purpose of such building.
- Development of CIF: Provide break-up of cost of every project! facility covered under common infrastructure facility.

b. Give Source of funds under the following broad heads:

- Share of Central Govt. (grant-in-aid)
- Share of State Govt. (Please specify details of Budgetary Allocation, Equity, Loan or any Other form of funding)
- Other Source of funds — (Please specify the source as bank loans, public bonds, private participation etc.)

c. Specify whether external funds, if any, shall be raised by the State of SIA and proposed model of fund raising.

d. Give phase-wise disbursement schedule of funds from all the sources till completion of the Park.

5. **Source of Revenue**: Furnish the detailed sources of revenue, with estimated annual revenue from each source.

a. Budgetary Allocation from the State
b. Land lease
c. Utility Charges
d. Any other source of revenue envisaged

Revenue Head	Charge per unit	Annual Revenue (Rs. In crore)
Land Lease	per sq. meter	
Power	kWh	
Water	per kilo litre	
Warehouse	Monthly charges per square meter	
Park maintenance	Annual charges per square meter	
Any other	Specify nature and unit Page	

6. **Development of Common Infrastructure Facility (CIF):** The State is required to submit the detail for individual project item! facility under CIF, as defined in the guidelines.

   a. Brief description the project item! facility,

   b. Estimated capacity with detailed justification for arriving at such capacity considering area of the Park, proposed number of manufacturing units etc.

   c. Cost of each project item! facility

   d. Comment on the technology applied with technical feasibility

   e. Timelines for starting the construction and completion of individual project item! facility

   f. Phasing of individual project item! facility, based on the estimated allotment of land to manufacturing facilities

7. **Infrastructure Support by the State:** The DPR should contain the following for support infrastructure to be provided by the State with timelines of completion:

   a. **Power & Water:** Detailed plan for committed source of water and power supply with capacity and adequacy to support the size of park and projected number of manufacturing units. Provide details of any necessary infrastructure to be created by the State like sub-station, transmission line, dedicated water reservoir and pipe-line etc. with timelines.

   b. **Ancillary Infrastructure**: All ancillary infrastructure like road, sewage, sanitation and social infrastructure to be developed by the State. Give size and scale of such ancillary infrastructure and proposed timelines of completion.

8. **Schedule for completion of the Park**

a. Provide the Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart including financial expenditure plan for each activity with proposed starting and completion date.

b. Provide the "Schedule Date of Commercial Operations of the Park".

9. **Single Window Mechanism:**

a. Provide details of single window mechanism proposed to be set-up in the park for giving clearance to the manufacturing units.

b. Mention if any clearance under the proposed single window mechanism is to be given by Central Govt.

c. Provide details, if any clearance is not proposed to be kept under the single window mechanism and the reason for the same.

10. **Financial viability of the Park:**

a. Provide detailed market survey with respect to existing status of pharmaceutical sector in the State, strategic and locational advantage of the Park for new investment, policies of the State Govt. to attract FDII Domestic investment in the Sector, any MoU/ commitment from the interested investors to set-up units in the proposed Park etc.

b. Provide financial projection taking into account projected revenue, budgetary allocation, estimated occupancy, operational expenses, interest expense (if any) and other relevant factors.

c. Provide projected P&L, Balance Sheet, Cash Flow projection with detailed assumption and key ratio such as IRR, NPV, minimum occupancy for Break Even etc.

11. **Regulatory Approvals:**

Provide detail of all regulatory approvals and clearances required from State Govt. and Central Govt. with timelines, procedure and also whether the proposed Park and construction plan as per DPR is in compliance with the applicable regulations and standards.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th June, 2020

G.S.R. 354(E).—The following draft of certain rules to amend the New Drugs and Clinical Trials Rules, 2019 which the Central Government proposes to make, in exercise of the powers conferred by subsection (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of fifteen days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the New Drugs and Clinical Trials (....Amendment) Rules, 2020.
(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the New Drugs and Clinical Trials Rules, 2019,
A. In CHAPTER XI, after rule 96, the following shall be inserted, namely:—
"96A. Application for import of unapproved new drug for Compassionate use for treatment of patients by hospitals or and medical institution

1) Notwithstanding anything contained in these rules, a medical officer of a hospital or medical institution may import new drug for compassionate use for treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, by making an application duly certified by the Medical Superintendent of the hospital or Head of the medical institution, as the case may be, to the Central Licensing Authority in Form CT-28

2) The application under sub-rule (1) shall be accompanied by such other particulars anddocuments as are specified in Form CT- 28.

3) The application under sub-rule (1) shall be accompanied by the following details:

(i) The rationale for the use of the new drug as compassionate use over the available therapeutic options;

(ii) The criteria for patient selection with description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;

(iii) The method of administration of the drug, dose, and duration of therapy;

(iv) A description of the manufacturing facility;

(v) Chemistry, manufacturing, and controls (CMC) information adequate to ensure the proper identification, quality, purity, and strength of the drug;

(vi) Pharmacology and toxicology information adequate to conclude that the new drug is reasonably safe at the dose and duration proposed for compassionate use, and

(vii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

96B. Grant of licence for import of new drug for compassionate use:

The Central Licencing Authority may, after scrutiny of information and documents enclosed with the application and such further enquiry, if any, as considered necessary,-

(i) if satisfied, that the requirements of these rules have been complied with, grant permission to import new drug but under clinical trial for compassionate use in Form CT-29;

(ii) if not satisfied with the requirements as referred to in clause (i), reject the application, for reasons to be recorded in writing, within a period of thirty days, from the date of application made under rule 96A.

1) An applicant who is aggrieved by the decision of the Central Licencing Authority under sub-rule (1), may file an appeal before the Central Government within forty-five days from the date of receipt of such rejection and that Government, may, after such enquiry, and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty working days from the date of filing the appeal.

2) The quantity of any single drug imported on the basis of licence granted under sub-rule (1), shall not exceed one hundred average dosages per patient but in exceptional circumstances and on being satisfied about the necessity and exigency the Central Licencing Authority may allow import of new drugs in larger quantities depending on the condition and requirement of such patient.

96C. Conditions of licence:

1) The import licence granted under rule 96B in Form CT-29 shall be subject to the following conditions, namely:-

(i) The licence shall remain valid for a period of one year from the date it has been issued;

(ii) The licence shall be displayed in the premises of the medical institution including where the new drug is being stocked and used in the office of the Medical Superintendent of the hospital or Head of the medical institution;

(iii) the licencee shall stock the new drug imported under this licence under proper storage conditions;

(iv) the new drug imported under this licence shall be exclusively used for compassionate use;

(v) the registered pharmacist shall maintain a record as specified in Annexure of Form CT-29, countersigned by the Medical Superintendent of the hospital or Head of the medical institution which shall be produced, on demand by the officer authorised by the Central Licencing Authority under these rules;

(vi) the hospital or medical institution referred to in sub-rule (1) of rule 96A, shall submit to the Central Licencing Authority a quarterly report about the status and stock of new drugs imported, utilized and destroyed;

(vii) where the new drugs imported under licence granted under sub-rule (1) of rule 96B, are left over or remain unused or get damaged or its specified shelf life has expired or has been found to be of sub-standard quality, the same shall be destroyed and the action taken in respect thereof be recorded as referred to in clause (iv) by the registered pharmacist.

96CA.Suspension or cancellation of license to import new drug for the purpose of compassionate use:

(1) Where an importer to whom the license is granted under rule 96B fails to comply with any provision of the Act and these rules, the Central Licencing Authority, may, after giving an opportunity of being heard, by an order, in writing, suspend or cancel the license for such period as considered appropriate either wholly or in respect of some of the substances to which the violation relates.

(2) Where the manufacturer whose license is suspended or cancelled under sub-rule (1) is aggrieved by an order of the Central Licencing Authority, he may, within a period of forty-five days from the receipt of the order, make an appeal to the Central Government in respect of suspension or cancellation of the license and that Government, may, after such enquiry, as deemed necessary and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.

96D. Application for the permission to manufacture new drug for Compassionate use:

1) Where any medical officer of a hospital or medical institution prescribes a new drug for compassionate use for treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, then, such new drug may be approved to be manufactured in limited quantity subject to provisions of these rules.

2) Where any manufacturer intends to manufacture new drug referred to in sub-rule (1), he shall obtain the consent in writing from the patient to whom the new drug has been prescribed under sub-rule (1) or his legal heirs and make an application to the Ethics Committee of the hospital or medical institution, as the case may be, for obtaining its specific recommendation for manufacture of such new drug.

3) After obtaining the recommendation of the Ethics Committee under sub-rule (2), the manufacturer shall make an application in Form CT-30 to obtain the permission, to the Central Licencing Authority for manufacturing the new drug for the purpose of compassionate use.

4) The application under sub-rule (3) shall be accompanied by consent in writing from the patient referred to in sub-rule (2) or his legal heirs regarding use of such new drug and such other particulars and documents as are specified in Form CT-30.

5) The application under sub-rule (3) shall be accompanied by the following details:

(i) The rationale for the use of the new drug as compassionate use over the availabletherapeutic options;

(ii) The criteria for patient selection viz. description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;

(iii) The method of administration of the drug, dose, and duration of therapy;

(iv) A description of the manufacturing facility;

(v) Chemistry, manufacturing, and controls (CMC) information adequate to ensure the proper identification, quality, purity, and strength of the drug;

(vi) Pharmacology and toxicology information adequate to conclude that the investigation new drug is reasonably safe at the dose and duration proposed for compassionate use and

(vii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

96E.Grant of the permission to manufacture new drug for Compassionate use:

(1) The Central Licencing Authority may, after scrutiny of information and documents enclosed with the application and such further enquiry, if any, as considered necessary,-

(i) if satisfied, that the requirements of these rules have been complied with, grant permission to manufacture new drug or compassionate use in Form CT-31;

(ii) if not satisfied with the requirements as referred to in clause (i), reject the application, for reasons to be recorded in writing, within a period of thirty days, from the date of application made under rule 96D.

(2) The quantity of any single new drug manufactured on the basis of permission granted under sub-rule (1) shall not exceed one hundred average dosages per patient but in exceptional circumstances on the basis of the prescription of the medical officer referred to in sub-rule (1) and the recommendation of the Ethics Committee, the Central Licencing Authority may allow the manufacture of such new drug in larger quantity.

96F. Condition of permission: The permission granted under rule 96E in Form CT-31, is subject to the following conditions, namely:-

(i) The permission shall remain valid for a period of one year from the date it has been issued;

(ii) the patient(s) to whom the unapproved new drug is prescribed under sub-rule (1) of rule 96E shall use such new drug under the supervision of the medical officer at the place specified in the permission or at such other places, as the Central Licencing Authority may authorise;

(iii) the manufacturer to whom the permission is granted under sub-rule (1) of rule 96E, shall make use of the new drug only for the purposes specified in the permission and no part of it shall be sold in the market or supplied to any other person, agency, institution or place;

(iv) the manufacturer referred to in clause (iii) shall keep record of the new drugs manufactured, stored and supplied by him to the patient in a register in the format as specified in annexure of Form CT-31

(v) the manufacturer referred to in clause (iii), shall submit to the Central Licencing Authority a quarterly report about the status of the new drugs manufactured, supplied to the authorized patient;

(vi) the manufactured new drugs shall be kept and stored in accordance with the storage conditions specified on its label and supplied to the patient under the supervision of the medical officer referred to in sub-rule (1) of rule 96D or a registered pharmacist duly authorised by him;

(vii) the registered pharmacist shall maintain a record of the full name and address of the patients, diagnosis, dosage schedule, total quantity of drugs received and issued, countersigned by the Medical Superintendent of the hospital or Head of the medical institution which shall be produced, on demand by the officer authorised by the Central Licencing Authority under the Act;

(viii) where the new drug manufactured in accordance with the permission issued under sub-rule (1) of rule 96E, is left over or remain unused or get damaged or its specified shelf life has expired or has been found to be of sub-standard quality, the same shall be destroyed by the manufacturer and the action taken in respect thereof shall be recorded;

(ix) the permission holder shall inform the Central Licencing Authority of the occurrence of any serious adverse event and action taken thereon including any recall within fifteen days of occurrence of such event.

96G. Inspection of manufacturing site of new drug for the purpose of compassionate use:

(1) The manufacturer referred to in rule 96E, shall allow persons authorized by the Central Licencing Authority including the person authorised by the State Licencing Authority to enter the premises where the new drug is being manufactured, stored and supplied, with or without prior notice, to inspect such premises and records, investigate the manner in which the new drug is being manufactured, supplied and to take sample thereof.

96H. Suspension or cancellation of permission to manufacture new drug for the purpose of compassionate use:

(1) Where the manufacturer to whom permission is granted under rule 96E fails to comply with any provision of the Act and these rules, the Central Licencing Authority, may, after giving an opportunity of being heard, by an order, in writing, suspend or cancel the permission for such period as considered appropriate either wholly or in respect of some of the substances to which the violation relates.

(2) Where the manufacturer whose permission is suspended or cancelled under subrule (1) is aggrieved by an order of the Central Licencing Authority, he may, within a period of forty-five days from the receipt of the order, make an appeal to the Central Government in respect of suspension or cancellation of the permission and that Government, may, after such enquiry, as deemed necessary and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.

96I. Licence to manufacture new drug for compassionate use under the Drugs and Cosmetics Rules, 1945:

(1) After obtaining permission under rule 96E, the person intending to manufacture a new drug for compassionate use, shall make an application for grant of licence to manufacture the new drug under the provisions of the Act and the Drugs and Cosmetics Rules, 1945.

(2) The application referred in sub-rule (1) shall be accompanied by the permission in Form CT-31 obtained by the applicant from the Central Licencing Authority to manufacture the new drug.

Explanation: For the purpose of these rules, compassionate use means use of new drug, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, for diagnosis, treatment, mitigation or prevention any life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need under a treatment protocol."

B. In the EIGHTH SCHEDULE, after the Form CT-27, following shall be inserted, namely:-

"FORM CT-28

APPLICATION FOR GRANT OF LICENCE TO IMPORT NEW DRUG FOR COMPASSIONATE USE BY HOSPITAL OR MEDICAL INSTITUTION

I/We, ... *(name and address of the applicant)* of M/s ..... hereby apply for grant of licence to import new drug for compassionate use or expanded access in a hospital or medical institution.

The details of the application are as under:

1. Name of Medical officer/Applicant:	
2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified) (Hospital or Medical Institution)	
3. (i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Applicant's address including telephone number, mobile number, fax number and e- mail id: (iii) Address for correspondence:	
4. Details of new drugs to be imported [As per Annexure].	
5. Particulars of overseas Manufacturer, Manufacturing sites [As per Annexure].	
6. Details of the patient and disease [As per Annexure].	
7. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and Chapter IX of the New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be imported from M/s..... shall be used exclusively for the purpose of compassionate use and no part of it shall be diverted to the domestic market. 8. A legal undertaking stating that the unapproved new drug to be imported shall be used for the treatment of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.	

Place: Digital Signature

Date: (Name and designation)

Annexure:

Details of new drug:

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

Details of manufacturer and manufacturing site:

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 e-mail address of the manufacturing site)	

Details of patient:

Name of the patient:	
Disease name:	

Certificate

Certified that the unapproved new drug specified above for import is urgently required for the treatment of patients suffering from ..... and that the said drug is not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

"FORM CT-29

LICENCE TO IMPORT NEW DRUG FOR THE PURPOSE OF COMPASSIONATE USE BY HOSPITAL OR MEDICAL INSTITUTION

Licence Number:_____

The Central Licencing Authority hereby grants licence to_____ (Name and full address with contact details of the applicant) to import new drug as per protocol number dated_____ for compassionate use in the _____ (Name and full address with contact details of the Hospital) .

[As per Annexure].

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of its issuance.

4. Details of overseas 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 e-mail address of the manufacturing site)

5. The licencee shall maintain the record of imported new drugs [As per Annexure].

Place: .....

Central Licencing Authority

Date: .....

Stamp

Annexure:

Details of clinical trial site or bioavailability or bioequivalence study centre:

Names and address:	
Ethics committee details:	
Name of investigator:	

"FORM CT-30

APPLICATION FOR GRANT OF PERMISSION TO MANUFACTURE NEW DRUG FOR COMPASSIONATE USE OR EXPANDED ACCESS

I/We, ...name and full address of the applicant) of M/s ..... hereby apply for grant of permission to manufacture new drug for compassionate use in hospital or medical institution.

The details of the application are as under:

1. Name of Medical officer/Applicant:	
2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified) (Hospital or Medical Institution)	
3. (i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Manufacturer's address including telephone number, mobile number, fax number and e- mail id: (iii) Address for correspondence:	
4. Details of new drugs to be manufactured [As per Annexure].	
5. Particulars of overseas Manufacturer, Manufacturing sites [As per Annexure].	
6. Details of the Medical officer and Government Hospital and Medical Institution.	
7. Copy of recommendation of the ethics committee and consent from the patient in accordance with Rule 81 of the Regulation of New Drugs and Clinical Trials Rules 2019 are hereby enclosed.	
8. A legal undertaking stating that the new drug to be manufactured shall be used for the Purpose of compassionate use of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.	

Place: Digital Signature

Date: (Name and designation)

Annexure:

Details of new drug:

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

Details of manufacturer and manufacturing site:

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 e-mail address of the manufacturing site)	

Details of the government hospital or government medical institution and patient:

Name of the hospital or medical institution:	
Address of the hospital or medical institution:	
Name and address of the patient:	
Disease name:	

Certificate

Certified that the new drug specified above for manufacture is urgently required for the compassionate use in patients suffering from ..... and that the said drug is not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

FORM CT-31

PERMISSION TO IMANUFACTURE NEW DRUG FOR THE PURPOSE OF COMPASSIONATE USE

Licence Number:_____

The Central Licencing Authority hereby grants licence to_____ (Name and full address with contact details of the applicant) to manufacture new drug as per protocol number dated_____ for compassionate use in the _____ (Name and full address with contact details of the Hospital) . [As per Annexure].

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act,1940

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of its issuance.

4. Details of manufacturer and manufacturing site under this permission.

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 e-mail address of the manufacturing site)

5. The licencee shall maintain the record of imported new drugs [As per Annexure].

Place: .....

Central Licencing Authority

Date: .....

Stamp

Annexure:

Details of new drug manufactured:

Names and address:	
Ethics committee details:	
Name of investigator:	

Details of unapproved new drug manufactured:

Serial number	Date of manufacture	Licence number	Name of the new drug	Quantity manufactured

Details of record of patient history:

Licence number	Name of the new drug	Patient name	Diagnosis detail with date	Disease name	Dosage schedule

Details of reconciliation of new drug manufactured:

Date	Name of the new drug	Licence No.	Quantity manufactured	Quantity supplied	Quantity Remained	Quantity – left over or remain unused or got damaged or expired or found of sub standard quality	Action taken

[F. No. X.11035/167/2020-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.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th July, 2020

S.O. 2450(E).---Whereas, an outbreak of COVID -19 pandemic is prevailing throughout India and worldwide;

And whereas, several Registration Certificates in Form-41 are in existence and their validity periods of three years are likely to expire shortly;

And whereas, pharmaceutical companies and their associations have requested for extension of the validity of Registration Certificate (Form-41) for six months in the wake of COVID-19 pandemic;

And whereas, the Central Government is of the considered view that supply of drugs may not get affected and the drugs must remain available to the public;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby directs that notwithstanding anything contained in rule 28A of the Drugs and Cosmetics Rules, 1945, for import of drugs for sale or distribution, if an existing Registration Certificate holder under the said rules, makes an application for a fresh Registration Certificate before the expiry of the existing certificate, the existing Registration Certificate shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes.

2. This order shall come into force on the date of its publication in the Official Gazette and shall remain valid for a period of six months.

[F. No. X.11014/01/2020-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th July, 2020

S.O. 2451(E).---Whereas, there has been an outbreak of COVID-19 pandemic in India and worldwide;

Whereas, several representations requesting to exempt hand sanitizers from the requirement of sale licence under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the provisions of the Drugs and Cosmetics Rules, 1945 for stocking or sale of the drug have been received;

Whereas, the Central Government is satisfied that hand sanitizers are essential to meet the requirements of emergency arising due to COVID-19 pandemic and their easy availability is made in public interest;

Whereas, the Central Government considers it necessary that hand sanitizers are required to be made widely available to the public at large;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby directs that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, subject to the condition that provisions of condition (17) of rule 65 of the said Rules are complied with by the person stocking or selling hand sanitizers.

2. This order shall come into force on the date of its publication in the Official Gazette

[F. No. X.11014/3/2020-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

PARLIAMENT QUESTION ANSWERS

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 266
TO BE ANSWERED ON THE 04th February, 2020

Pharma City

266. SHRI MANNE SRINIVAS REDDY:

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

(a) whether the Government is aware that the State Government of Telangana is taking an initiative to establish a pharma city at Mucherla, Hyderabad;

(b) if so, the details thereof ;

(c) whether the Government is planning to provide any financial support for the infrastructure development for the said pharma city; and

(d) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) to (d): Government of Telangana has informed that State Government has appointed Telangana State Industrial Infrastructure Corporation Limited (TSIIC) for implementation of a project namely Hyderabad Pharma City (HPC)which is an integrated pharmaceutical cluster with best in class infrastructure and common industry amenities. Department of Pharmaceuticals has given „in-principle" approval to the proposal for development of Zero Liquid Discharge based Common Effluent Treatment Plant in HPC under the sub-scheme "Assistance to Bulk Drug Industry for Common Facility Centre". This sub-scheme aims to provide financial assistance of 70% of the project cost or Rs.100 Cr, whichever is less, for establishment of Common Facility Centre in any upcoming Bulk Drug Park promoted by the State Governments/State Corporations.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1506
TO BE ANSWERED ON THE 11th February, 2020

e-Pharmacy

1**506. SHRI S. JAGATHRAKSHAKAN:**

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

(a) whether the Government has any proposal or taken any steps to prevent e-pharmacies from stocking life saving drugs;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) to (c): Ministry of Health & Family Welfare has published a draft gazette notification vide G.S.R. 817 (E) dated 28th Aug 2018 for amendment to the Drugs and Cosmetics Rules, 1945 to regulate the online sale of medicines through e-platform in the country.The draft rules published on 28.08.2018 contains provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, prohibition of sale of certain categories of drugs through e-pharmacy, monitoring of e-pharmacy, etc. After considering the comments received on the draft rules, a draft for the final notification has been forwarded for approval of Hon'ble Health and Family Welfare Minister before its eventual publication. The matter presently stands referred to the Group of Ministers.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3693
TO BE ANSWERED ON THE 17th March, 2020

Medical Device Parks

3693. SHRI KESINENI SRINIVAS:
DR. NISHIKANT DUBEY:

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

(a) whether the Government has received any proposals from the State Governments for establishing Medical Device Parks;

(b) if so, the number of proposals received and the status thereof, State-wise;

(c) whether there is any policy/scheme for assistance to promote/establish Medical Device Parks in the States and if so, the details thereof; (d) whether permission for setting up of a Medical Device Park in Andhra Pradesh has been granted and if so, the details thereof; and (e) the details of the current progress on the project and the goals and objectives of setting up of such a medical device park?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) to (c): Department of Pharmaceuticals has a sub-scheme viz. Assistance to Medical Device Industry for Common Facility Center under the umbrella scheme for Development of Pharmaceuticals Industry. Under this sub-scheme, financial assistance to the tune of Rs.25 Crore or 70% of the project cost, whichever is less is provided for creation of common facilities under any upcoming Medical Device Park promoted by State Governments/State Corporations. Department has received four proposals seeking financial assistance under this sub-scheme from the State Governmets of Andhra Pradesh, Telangana, Kerala and Tamil Nadu. The "in-principle" approval has been given to proposals received from State Governments of Telangana, Kerala and Tamil Nadu while "final approval" has been given to proposal received from Andhra Pradesh.

(d) & (e): Under the above sub-scheme, Department has accorded "final approval" for financial assistance of Rs.25 Crore to the project of State Government of Andhra Pradesh for setting up of Common Facility Centre for Superconducting Magnetic Coil. However, no financial assistance has so far been disbursed. The objective is to incease the competitiveness, easy access to standard testing facilities and value addition in the domestic Medical Device Industry through creation of such common world class facilities in a Medical Device Park.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. †3698
TO BE ANSWERED ON THE 17th March, 2020

Drug Import and Export

†3698. SHRI RAMCHARAN BOHRA:

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

(a) the details regarding the quantity and cost of import and export of medicines/drugs during each of the last three years and the current year, country-wise;

(b) whether the country is dependent on imports particularly from China to meet the heavy demand of essential medicines and Active Pharmaceutical Ingredients;

(c) if so, the details thereof and the reasons therefor; and

(d) the measures taken by the Government to encourage Indian Pharmaceutical companies to increase their production so as to reduce the dependency on imports and also to promote export of medicines/ drugs?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): The details of quantity and cost of import and export of medicines/drugs during each of the last three years and the current year, major country-wise is as following :

DRUG FORMULATIONS, BIOLOGICALS Import data from 2016-2019:

Country	2016-17 Volume (in Kgs)	2016-17 (Value in US $)	2017-18 Volume (in Kgs)	2017-18 (Value in US $)	2018-19 Volume (in Kgs)	2018-19 (Value in US $)	2019-20 Volume (in Kgs) (April 19-Dec 19)	2019-20 (Value in US $) (April 19-Dec 19)
USA	457463	285890072	595831	309482618	683589	270175979	722982	232435316
Germany	553743	232268654	842317	207469300	937470	200861663	750863	149684304
France	224924	141889389	227511	122286786	401566	131668335	525783	110950747
China	800533	135207004	1292226	128771468	1704937	149498662	1495056	147294699
Switzerland	111900	105552151	194362	132665826	521474	302047568	509253	219759657
Total Imports from all countries	4325475	1662175762	9140935	1840778441	19030788	2018563123	17914366	1767129089

DRUG FORMULATIONS, BIOLOGICALS Export data from 2016-2019:

Country	2016-17 Volume (in Kgs)	2016-17 (Value in US $)	2017-18 Volume (in Kgs)	2017-18 (Value in US $)	2018-19 Volume (in Kgs)	2018-19 (Value in US $)	2019-20 Volume (in Kgs) (April 19-Dec 19)	2019-20 (Value in US $) (April 19-Dec 19)
USA	72169919	5057829263	67492681	4601523089	55630576	5327205621	40309985	43736750242
UK	18810063	439431269	13772256	454450341	11325510	524317178	6608351	329074941
South Africa	8613140	389027509	8738119	479530849	8441085	525454816	5170803	392701354
China	392701354	23178436	520470	26769082	667317	33152930	342458	31007724
Total Exports to all countries	352124554	12666440148	320564438	12909093200	307467690	14388794412	188713934	12017224892

(Source: DGCIS Kolkata)

(b) & (c): As per Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata, during the year 2018-19, the share of China in the total bulk drugs/APIs imported into the country was approximately 67 per cent. Some of these bulk drugs/APIs are also used for manufacturing essential medicines. The imports from China are mainly due to economic considerations. The details of India's imports of Bulk Drugs/ Drug Intermediates and Drug Formulations (including from China) are as under:

Import of Pharmaceutical products			
Item	Imports during 2018-19 (In US $ mn)	Imports during 2018-19 (In US $ mn)	Percent of Imports from China
Bulk Drug, Drug Intermediate	3560.3	2405.42	67.56%
Drug Formulations, Biologicals	2018.56	149.49	7.40%

(d): The policies formulated by Government from time to time are designed to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In this direction, with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry the Department of Pharmaceuticals has prepared an umbrella scheme for Development of Pharmaceuticals Industry with the following sub-schemes: (a) Assistance to Bulk Drug Industry for Common Facility Centre; (b) Assistance to Medical Device Industry for Common Facility Centre; (c) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS); (d) Assistance to Pharmaceutical Industry for Common Facilities; and (e) Pharmaceutical Promotion Development Scheme (PPDS).

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. †3844
TO BE ANSWERED ON THE 17th March, 2020

Import of Bulk Drugs/APIs

†3844. SHRI RAVI KISHAN:
SHRI RAVINDRA KUSHWAHA:
SHRI RAJIV RANJAN SINGH ALIAS LALAN SINGH:
SHRI ACHYUTANANDA SAMANTA:
SHRI A. RAJA:

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

(a) whether India imports around 70 per cent of its total bulk drugs or Active Pharmaceutical Ingredients (APIs) from China;

(b) if so, the details thereof along with the percentage of raw material imported for the manufacture of antibiotics;

(c) whether the current coronavirus outbreak has limited such import, if so, the steps being taken by the Government to ensure that stocks last for the foreseeable future;

(d) whether the Government is considering restrictions on export of paracetamols, other key drug ingredients and their formulations and if so, the details thereof; and

(e) whether the Government has any proposal to develop bulk drug parks in the country to reduce dependence on imports, if so, the details thereof and the progress and timeframe for completion of the bulk drug parks?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): The Indian Pharmaceutical industry is 3rd largest in the world in terms of volume and 14th largest in terms of value. India exported medicines worth US $14389 mn in Financial Year 2018-19. India also exported Bulk Drug/Drug Intermediates worth US $ 3911mn in Financial Year 2018-19. However, the country also imports various Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for producing medicines. Two-thirds of the total imports of Bulk Drugs/ Drug Intermediates is from China. The imports from China are mainly due to economic considerations. The details of India's imports of Bulk Drugs/ Drug Intermediates (including from China) are as under:

Year	Total imports (US $ mn)	Imports from China (US$ mn)	Percent of Imports from China
2018-19	3560.35	2405.42	67.56%

As per the information received from the port offices of CDSCO, the quantity of raw materials imported for the formulation of antibiotic medicines in the country during each of the last three years is as follows:

Year	Quantity of raw materials imported for the formulation of antibiotic medicines in the country (in MTs)
2019	11230.50
2018	12006.11
2017	5591.44

© & (d): Department of Pharmaceuticals has constituted a Committee under the chairmanship of Dr. Eshwara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to address the issue of drug security in the country in the context of novel coronavirus outbreak in China. Based on the recommendations of the Committee, the department has issued necessary instructions to National Pharmaceutical Pricing Authority (NPPA), Drugs Controller General of India (DCGI) and State Governments to ensure adequate supply of APIs and formulations at affordable prices in the market and to prevent black-marketing, illegal hoarding, creating artificial shortages in the country. In this regard, Department of Pharmaceuticals has written to DGFT to restrict exports of 13 API and formulations made out of these APIs which includes paracetamol. NPPA has also written to Chief Secretaries of States with copies to Principal Secretaries Health and State Drug Controllers requesting them to closely monitor the production and availability of APIs and formulations to prevent the black marketing and hoarding in their States and UTs as well as to ensure that there is no violation of provisions of Drugs (Prices Control) Order, 2013 with regard to compliance of ceiling prices/ permissible increase in prices of scheduled/ non-scheduled formulations respectively.

(e): The Department of Pharmaceuticals has formulated a Scheme namely 'Assistance to Bulk Drug Industry for Common Facility Centre' for providing assistance of upto Rs. 100 crore for creation of Common Facility Centre (CFC) in any upcoming bulk drug park promoted by State Governments/State Corporations. The department has given 'In-principle' approval to the following proposals under this scheme:

1. Govt. of Andhra Pradesh (AP Economic Cities Promotional Corporation Ltd.)
2. Govt. of Telangana (Telangana State Industrial Infrastructure Corporation Ltd.)
3. Govt. of Himachal Pradesh (HP State Industrial Development Corporation Ltd.)

As per the said scheme the time frame for development of a CFC is 2 years from the date of final approval.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3858
TO BE ANSWERED ON THE 17th March, 2020

Import of Medical Devices

3858. SHRI P. RAVEENDRANATH KUMAR:

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

(a) whether it is a fact that approximately eighty per cent of the medical equipments used for critical care are being imported;

(b) if so, the details thereof and the total import of medical devices along with the implication of foreign exchange during the last three years;

(c) whether the Government has planned to establish multiple medical device parks across several States of the country to support medical technology innovation and manufacturing under Make in India initiative; and

(d) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): The country is dependent on imports of medical devices to an extent of 85%. The total amount of foreign exchange incurred on imports of medical devices during the last three financial years is as under:

Financial Year	Import Value (USD MN)
2016-17	4406.9
2017-18	2017-18
2018-19	6204.0

C & (d): Department of Pharmaceuticals has a sub-scheme viz. Assistance to Medical Device Industry for Common Facility Center under the umbrella scheme for Development of Pharmaceuticals Industry. Under this sub-scheme, financial assistance to the tune of Rs.25 Crore or 70% of the project cost, whichever is less may be provided for creation of common facilities under any upcoming Medical Device Park promoted by State Governments/State Corporations. Department has received four proposals seeking financial assistance under this sub-scheme from the State Governments of Andhra Pradesh, Telangana, Kerala and Tamil Nadu. The "in-principle" approval has been given to proposals received from State Governments of Telangana, Kerala and Tamil Nadu while "final approval" has been given to the proposal received from Andhra Pradesh.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
STARRED QUESTION NO. 386
TO BE ANSWERED ON THE 20TH MARCH, 2020

SINGLE REGULATOR FOR FOOD, DRUGS AND MEDICAL DEVICES

***386. SHRI SYED IMTIAZ JALEEL:**
SHRI ASADUDDIN OWAISI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes a single regulator to oversee the functioning of the three regulators of Food, Drugs and Medical Devices;

(b) if so, the details thereof;

(c) whether industry has welcomed this step of the Government as the single regulator will minimize procedural delays and multi-functional agencies; and

(d) if so, the time by which a final decision in this regard is likely to be taken?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

(a) No Sir. There is no such proposal.

(b to (d) Does not arise.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 4552
TO BE ANSWERED ON 20TH MARCH, 2020

BANNED/UNAPPROVED DRUGS

4552. SHRI K. NAVASKANI:
SHRI BALUBHAU ALIAS SURESH
NARAYAN DHANORKAR:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to put in place a comprehensive mechanism to stop manufacturing and marketing of banned/unapproved drugs across the country;

(b) if so, the details thereof;

(c) whether certain cases of manufacturing and marketing of banned/unapproved drugs have been reported in the country;

(d) if so, the details thereof indicating the number of such cases reported during each of the last three years and the current year, State/UT-wise; and

(e) the action taken against the offenders during the said period, State/UT-wise?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (e): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Under the said Rules, for manufacture of any New Drug, permission is required from Central Drugs Standard Control Organsiation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority.

Under the afore-said Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments in this regard, the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further, the Central Government had also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petition (SLP). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court vide its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Accordingly, a Sub-Committee of DTAB was constituted which after providing hearing toall the petitioners/appellants, submitted its report to DTAB which was accepted by DTAB.

Based on the recommendations of DTAB, the Central Government vide notifications dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writ petitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

Further, based on the recommendations of DTAB, the Central Government vide notifications dated 11.01.2019 prohibited 80 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. These 80 FDCs were part of the list of 294 FDCs identified in year 2007, which were earlier subjudice in Hon'ble High Court of Madras.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 1806
TO BE ANSWERED ON 6th March, 2020

Variation in prices of branded and generic medicines

1806. DR. BANDA PRAKASH:

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

(a) whether it is a fact that the prices of branded and generic medicines vary even upto hundred per cent; and

(b) if so, the reasons for such a big difference between the prices of branded and generic medicines?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b):The prices of generic medicines are generally kept lower than that of corresponding branded medicines as there are no marketing costs involved in case of generic medicines whereas for branded medicines, the companies incur a lot of expenditure in promoting their brands.

Both generic drugs without any brand name and branded drugs are treated alike for fixation of ceiling price under the provisions of the Drugs (Prices Control) Order (DPCO). As per provisions of the DPCO, all manufacturers of Scheduled medicines (branded or generic) have to sell their products within the ceiling price fixed by the Government. As regards non-scheduled formulations, a manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation (branded or generic) launched by it. However, as per the DPCO, the manufacturers are not allowed to increase the price of a non-scheduled formulation by more than 10 % per annum. The prices are both fixed as well as monitored in case of scheduled medicines and monitored only in case of non-scheduled medicines by the National Pharmaceutical Pricing Authority (NPPA). In case a violation of an order issued under DPCO is detected, action for overcharging is taken as per provisions of DPCO.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 2276
TO BE ANSWERED ON THE 13th March, 2020

Domestic production of APIs

2276. DR. AMAR PATNAIK:

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

(a) whether it is a fact that there is a shortage of Active Pharmaceutical Ingredients (APIs) in the country, the details thereof;
(b) whether the domestic capacity for manufacturing of APIs in India is inadequate and if so, the details thereof;
(c) whether the manufacturing capacity of APIs in the country is being fully utilised;
(d) the details of domestic dependence on APIs imported from China; and
(e) the details of measures taken by the Government to increase API production in the country?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): National Pharmaceutical Pricing Authority (NPPA) has informed that they have not received any reference regarding shortage of Active Pharmaceutical Ingredients. The Indian Drugs Manufactures Association (IDMA) has assured that its members have enough stocks of APIs and formulations.

(b) to (d): The Indian Pharmaceutical industry is 3rd largest in the world in terms of volume and 14th largest in terms of value. India exported medicines worth US $14389 mn in Financial Year 2018-19. India also exported Bulk Drug/Drug Intermediates worth US $ 3911mn in Financial Year 2018-19. However, the country also imports various Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for producing medicines. Two-thirds of the total imports of Bulk Drugs/Drug Intermediates is from China. The imports from China are mainly due to economic considerations. The details of India's imports of Bulk Drugs/Drug Intermediates (including from China) are as under:

Year	Total imports (US $ mn)	Imports from China (US$ mn)	Percent of Imports from China
2018-19	3560.35	2405.42	67.56%

(e): The policies formulated by Government from time to time are designed to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In this direction, the Department of Pharmaceuticals has formulated a Scheme namely 'Assistance to Bulk Drug Industry for Common Facility Centre' for providing assistance to Bulk Drug Industry for Common Facility Centre in any upcoming bulk drug park promoted by State Governments/State Corporations.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 3088
TO BE ANSWERED ON THE 20th March, 2020

Dependence of Indian pharma industry on China

3088. SHRI A. K. SELVARAJ:

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

(a) whether it is a fact that many pharmaceutical companies in India are facing shortage of materials due to Coronavirus outbreak in China;

(b) whether it is also a fact that China accounts for around 65-70 per cent of ingredients of drugs manufactured in the country; and

(c) if so, the steps taken by Government in this regard to ensure availability of drugs in the domestic market?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): National Pharmaceutical Pricing Authority (NPPA) has informed that they have not received any reference regarding shortage of Active Pharmaceutical Ingredients. The Indian Drugs Manufactures Association (IDMA) has assured that its members have enough stocks of APIs and formulations.

(b): As per the data from Directorate General of Commercial Intelligence and Statistics (DGCIS), Kolkata, India imported 67.5% of Bulk Drugs/Drug Intermediates from China during the year 2018-19.

C): To address the issue of drug security in the country in the context of novel coronavirus outbreak in China, the department has issued necessary instructions to National Pharmaceutical Pricing Authority (NPPA), Drugs Controller General of India (DCGI) and State Governments to ensure adequate supply of APIs and formulations at affordable prices in the market and to prevent black-marketing, illegal hoarding, creating artificial shortages in the country. In this regard, Department of Pharmaceuticals has written to DGFT to restrict exports of 13 API and formulations made using these APIs. NPPA has also written to Chief Secretaries of States and State Drug Controllers requesting them to closely monitor the production and availability of APIs and formulations to prevent the black marketing and hoarding in their States and UTs as well as to ensure that there is no violation of provisions of Drugs (Prices Control) Order, 2013 with regard to compliance of ceiling prices/ permissible increase in prices of scheduled/ non-scheduled formulations respectively.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.1358
TO BE ANSWERED ON 3RD MARCH, 2020

LIST OF OTC MEDICINES

1358. SHRI KUMAR KETKAR:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the reason for not having the list of Over the Counter (OTC) medicines.

(b) whether Government is planning to prepare the list of OTC medicines;

(c) if so, by when and the criteria of medicines to be included in the list;

(d) whether Government will put this information in public domain;

(e) whether Government will make it mandatory to print these OTC medicine labels with drug information such as Do's and Don'ts since OTCs can be purchased without prescription; and

(f) whether Government will consider the international norms to print the required information on medicines with prescribed fonts and readability and the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (f): Schedule K of the Drugs and Cosmetics Rules, 1945 already provides the list of certain medicines which are exempted from the requirements of obtaining sale license under the Drugs and Cosmetics Act and Rules made thereunder subject to the conditions as mentioned therein.

State Licensing Authorities (SCAs) appointed by respective State governments are empowered to monitor/track the sale of drugs including the drugs allowed to be sold without prescription and take action in case of non-compliance.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.2673
TO BE ANSWERED ON 17TH MARCH, 2020

SELLING OF CARCINOGENIC DRUGS

2673. DR. ASHOK BAJPAI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether some drugs are in use in the country which are known to be carcinogenic elsewhere;

(b) if so, the reasons for such drugs in use in India;

(c) whether Government is contemplating to ban such drugs in India too, in future; and

(d) if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY)

(a) to (d): There were reports in other countries regarding the presence of a nitrosoamine impurity called N-Nitrodimethylamine (NDMA) in certain drugs which is classified as a probable human carcinogen.

Following the reports, Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare asked the State Drug Controllers to instruct the manufacturers of Ranitidine API & formulations to verify/test their products and take appropriate measures to ensure patient safety. CDSCO had also instructed zonal offices for drawing of samples for testing the level of NDMA impurity in ranitidine.

World Health Organisation has also published Information Note dated 20.11.2019 regarding Nitrosamine impurities in certain drugs including ranitidine. In the said 'Information Note' WHO has mentioned the details of nitrosamine impurity, toxicity, test methods, regulatory action taken in various countries etc. w.r.t. Rantidine.

Considering various aspects, WHO has recommended for certain measures to control such impurity.

CDSCO has accordingly forwarded a copy of the WHO Information Note to all the State / UT Drug Controllers.

NEWS

Drug Makers Manage to Up Manufacturing Capacity to 50-60%

A steady supply of medicines, particularly in remote areas, may be impacted as drug companies continue to face challenges in distribution and logistics. Supply disruption and bottlenecks continue to affect the Pharmaceutical industry, with units operating at 50-60% capacity at the end of lockdown 3.0

A major challenge is congestion at ports, which may lead to shortages of key starting materials and active pharmaceutical ingredients (APIs), Pharma companies told TOI. Containers with imported raw materials and APIs remain stuck, as port employees and agents are not reporting to work amid the pandemic. The worst affected is JNPT, one of the busiest and largest ports, while movement of air cargo at Mumbai airport is also hit, industry experts said.

"Not only is the cargo not being cleared, shipment costs have nearly doubled from $750 per container. There is also an increase in air freight costs to about four times. There are containers with medicines/insulins requiring a cool chain, which could be affected. We could face a shortfall in raw materials, and disruption in production as our inventory is also over," an executive at a Mumbai-based company said.

Efficient operations at major ports and airports is crucial for the industry, which is heavily dependent on imports of key raw materials, mainly from China. Also, lower production at manufacturing hubs like Baddi (Himachal Pradesh) and Pithampur (Madhya Pradesh) would hit exports of generic drugs to major developed markets, leading to significant shortages in the US. Domestic companies command around 35% volume share in the highly lucrative US generic market, valued at about $70 billion.

"We continue to operate our Nashik factory at 100% capacity, and our contract manufacturing factories are now operating at 60-65% capacity up from 30-35% a couple of weeks ago. In some states, we face some minor last-mile logistics and distribution challenges on account of interstate transfer of medicines. But overall, the situation has improved significantly," a GSK spokesperson said.

Issues like permission from local authorities, employees and inter-state travel have been largely resolved at Baddi, but Daman continues to be impacted. The movement of medicines and devices from factories to stockist's is affected as some of them are based in red zones or containment areas.

Also, ancillaries including the packaging industry, are facing financial distress, which create bottlenecks for the drug industry. Market research firm IQVIA expects growth to decline to 1-5% in FY21 as the lockdown-driven disruption will impact the pharma market, despite it being classified as essential.

Source: *The Times of India,* 18th May 2020

High-Level Panel Formed to Recommend Reforms in India's Drug Regulatory System

A high-level committee of experts has been formed by the government to recommend reforms in India's drug regulatory system so that approval processes can be fast-tracked.

Faced with the ominous threat of the coronavirus infection, a number of steps such as fast-tracking the approval process for drugs, research and vaccine development were taken. A health ministry oicial said the aim of the panel is to identify and institutionalise these measures.

According to a recent Union Health Ministry order, the committee will study the current drug regulatory system and submit recommendations for reforms, so as to bring the system in line with global standards and make it more efficient.

"The issue of reforms in the Drug Regulatory System has been engaging the attention of the government for quite some time now.

" Although requisite procedural changes have been carried out during the COVID-19 pandemic and have worked quite well, it is felt that comprehensive changes in the drug regulatory regime should be carried out to reect global best practices as well as domestic requirements, and to streamline Central Drugs Standard Control Organization (CDSCO) to make it more effective," the order issued on May 11 stated.

The committee chaired by Rajesh Bhushan, the OSD to the Union health minister, comprises top drug and vaccine entrepreneurs of India along with oicers nominated from the Department of Pharmaceuticals, Department of Biotechnology, Indian Pharmacopoeia Commission, Indian Pharmaceutical Alliance, ICMR along with public health expert from AIIMS.

The order stated, "While nominating a member, the ministries/ departments/ institutions should keep in mind that the oicer being nominated should have a exible approach and willing to consider far-reaching reforms with an open mind."

India's Joint Drug Controller Dr Eswara Reddy will assist the committee in their work on adopting global best practices. The committee, which has met twice till now, will submit its report within one month from the date of its formation.

The committee has been asked by the ministry to also study earlier reports given by the department-related Parliamentary Standing Committee on clinical trials and working of the CDSCO and address the unimplemented recommendations of the previous panels.

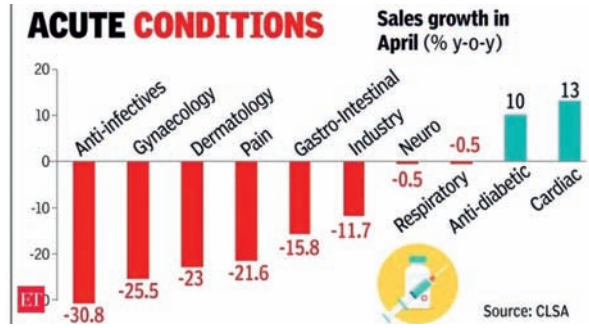
Source: *The Economics Time,* 23rd May 2020

Pharma Shrinks 12% in April, Worst in 3 Years

The national lockdown due to the Covid-19 pandemic has led to one of the sharpest falls in three years in the domestic pharma retail market, with growth declining by 12% in April. This is the first year-on-year (YoY) decline since GST's implementation in July 2017. Production at pharmaceutical units continues to be impacted due to the lockdown driven disruption, with companies facing challenges in distribution, manufacturing and logistics.

The market was pulled down by acute therapies, with demand for these medicines collapsing by nearly 21% in April YoY. With prescriptions for anti-infectives down, sales of pain, gastro and vitamins — usually prescribed together — were also impacted, an industry expert said, adding that these four together comprise around 40% of the overall market (see graphic). Acute therapies were worst hit in April with anti-infectives (-31% YoY), pain (-22% YoY) and gastro (-16% YoY) seeing big declines.

Among the therapies, chronic saw low single-digit growth of around 5%, helped by pre-buying from patients in cardiac and diabetes categories, according to data from market research firm IQVIA. In this chronic therapy category, cardiac (13% YoY) and diabetes (10% YoY) segments managed growth. On a trailing 12-month basis, seasonal segments such as respiratory (13.5% YoY) and anti-infectives (9.8% YoY) were main drivers of the 10.6% YoY growth in the acute segment.



In FY21, IQVIA expects the domestic market to grow at 1-5%, one of the lowest rates in recent years, with a muted 4-8% YoY growth for major companies. Earlier, the pharma market — valued at around Rs 1.49 lakh crore ($20 billion) — typically recorded strong YoY growth of 10-12%.

The decline in pharma growth over March, when the lockdown had just started, stood at 7%, while trailing 12-month growth stood at 8.6% YoY. Pricing has driven nearly 60% of growth for the industry on the trailing 12-month basis, with volume growth attributing an insignificant 0.7 percentage point and contribution from new launches at 2.8 percentage points.

Cadila Health, Cipla and Dr Reddy's — those with a substantial exposure to the acute therapy — underperformed the market during the month. Ipca and Torrent Pharma were the only companies with positive growth in April, according to a note by brokerage firm CLSA. Interestingly, Ipca saw yet another strong month with nine of its top 10 therapies growing in double digits. Its anti-malarial drug Hydroxychloroquine, considered a potential treatment for Covid-19 in certain countries, registered 19% YoY growth.

Overall, other than the two chronic therapies of cardiac and anti-diabetic, all the top 10 therapies, especially acute, saw big declines on a YoY basis. Chronic therapy brands had strong sales growth — Mixtard (under diabetes, 19%), Lantus (diabetes, 30%), Levipil (CNS, 24%), Thyronorm (thyroid, 10%), and Telma (cardiac, 23%).

Source: *The Times of India,* 25th May 2020

5 Firms Await Regulator's Nod to Make Remdesivir

Despite rapidly rising Covid-19 deaths and an approval to use Remdesivir for treatment of severe cases, Indian patients are still waiting for the drug to be available in the country as companies are awaiting marketing approval from the Drugs Controller General of India (DCGI). "It might take some time before the drug (Remdesivir) is available in the Indian market. The regulator has asked companies to submit various sets of data, including stability study, animal toxicity etc. Even if these trials are conducted on a fast-track basis, they will take at least a month's time," an official said.

Five Indian pharma companies have applied to the DCGI seeking permission to manufacture and sell Remdesivir — an experimental drug that has shown promise in treating Covid-19 patients — in India. These companies have signed a licensing agreement with US drug maker Gilead Sciences to manufacture and distribute the drug in around 127 countries. Gilead is the original developer of the re-purposed ebola drug.

While the drug regulator has granted approval to Gilead to import and sell the medicine in India, it was primarily with a purpose to support the licencees or Indian firms with whom Gilead signed non-exclusive agreements to further expand supply of Remdesivir, sources said.

However, despite local companies citing Gilead's data as the reference point, the DCGI has recently written to the five Indian companies to submit data from animal toxicity studies, stability studies and test licences.

"We have asked the companies for this data to ensure quality of these products. Only clinical trials can be waived off based on Gilead's data," a senior official in the Central Drugs Standard Control Organisation (CDSCO) said.

When asked how Maharashtra government was procuring 10,000 vials of Remdesivir from Bangladesh, the official said, "We have given permission to only Gilead. Everything else is now from the grey market and unapproved." Sources said the matter was taken up in a high-level meeting in the government on Sunday.

Local manufacturers said they had everything in place, starting from raw material to capacity, and were only waiting for regulatory approval to start manufacturing the drug.

Source: *The Times of India,* 8th June 2020

CM Invites Pharma Majors to Invest in T.N.

Chief Minister Edappadi K. Palaniswami has written to the heads of eight pharmaceutical majors inviting them to invest in the State.

The Chief Minister has written to President and CEO of Accuray Joshua Levine, Chief Executive Officer of Philips Medical Systems Frans Van Houten, Managing Director and President of Siemens Healthcare Gerd Hofner, CEO of Sirona Dental Systems Donald Casey, President of Copioumed International William Liu, CEO of GE Healthcare Kieran Murphy and Chief Executive Officer of Hurco Companies Inc Michael Doar and Chairman and CEO of Boston Scientific Michael F. Mahoney.

In his letters, the CM outlined the investment attractiveness and inherent advantages of Tamil Nadu and the facilitation support provided for business and industry to further their growth, and promised a customised incentive package as per their requirement, an official release stated.

Source: *The Hindu,* 9th June 2020

Iisc Researchers Find 29 Drugs that Could be Used to Fight Covid-19

Researchers at Indian Institute of Science (IISc) have identified at least 29 drugs that have the potential of being repurposed to treat Covid-19 patients.

"Covid-19 has almost brought normal life to a standstill in most parts of the world. With our research interest on repurposing known drugs/drug candidates targeting various diseases, we decided to analyse the available data on the deadly pathogen," the team said.

The team, comprising Prof Narayanaswamy Srinivasan (leader), Sohini Chakraborti and Sneha Bheemi reddy, has identified 29 potential repurpose-able agents that are either approved and/or investigational drugs.

This was achieved using a simple in silico (performed on computer) approach based on the principle of 'neighbourhood behaviour' in three-dimensional (3D) space and two-dimensional (2D) space of protein and small molecules respectively.

"Using this, we identified potential drugs/drug candidates which can be repurposed against protein targets encoded by the SARS-CoV-2 [the virus that causes Covid-19] genome," the researchers said. "And, based on our preliminary analysis, we have so far prioritized more than 20 known drugs/drug candidates which might elucidate anti-coronavirus properties by binding to the main protease of the pathogen." The team also said they have identified nine other investigational drug molecules.

These drugs belong to diverse therapeutic areas such as antiviral, anticancer, antibacterial agents etc. Their research has been published on ChemRxiv, an open access preprint archive for chemistry, and is yet to be peer reviewed.

"The sole purpose of making these preliminary findings openly available to the community is for experimental biologists and biomedical researchers to investigate our predictions in experimental set ups and for clinicians to evaluate the potential of these findings for anti-Covid-19 treatment," the researchers added.

Notably, apart from many synthetic molecules, their analysis also hints that phytochemicals obtained from vinca plant (vinca alkaloids) and camptotheca tree (camptothecin and its derivatives) have the potential to bind to main protease of SARS-CoV-2

"In-depth investigation on our findings are currently on-going. Our findings should only be used for research purposes and we strongly urge that no individual should interpret these findings for any self-diagnosis or self-medication without the prior approval from competent international health/medical regulatory agencies," the team said.

Source: *The Times of India,* 15th June 2020

Licence for Chinese Kits Issued After Validation, Drug Controller Tells HC

The office of the Drugs Controller General of India (DCGI) told the Madras High Court that it had issued import licences to various importers between March 26 and April 22 for procuring SARS-CoV-2 antibody test kits manufactured by Guangzhou Wondfo Biotech Co. Ltd in China only after obtaining a validation report from the National Institute of Virology (NIV) in Pune.

Justices R. Subbiah and Krishnan Ramasamy were told that all licences were cancelled on April 29 after the performance of the test kits was found to be unsatisfactory by the Indian Council of Medical Research (ICMR).

The submission was made in reply to a public interest litigation petition which claimed that use of defective kits was posing a challenge in controlling COVID-19.

A counter affidavit filed on behalf of DCGI stated that import licences were issued based on submission of a host of documents including power of attorney, free sale certificate issued by the national regulatory authority of country of origin (China), in-house performance evaluation report, stability report and validation/evaluation report from NIV, Pune.

The ICMR, in its counter affidavit, told the court that the kits of Guangzhou Wondfo Biotech and Zuhai Livzon Diagnostics were evaluated in field conditions and the results showed wide variations in their sensitivity. Hence, on April 27, all State governments were advised to stop using the kits procured from the two companies and return them to the suppliers.

The council also stated that it validates new diagnostic kits for COVID-19 if they had not been approved by US-FDA or European CE. "The kits which are found promising, after validation, are referred to the DCGI for approval and marketing permission. The ICMR is not according approval to any kits independently as this does not fall under the purview of ICMR," its counter read.

After taking the counter affidavits on file and hearing preliminary arguments of advocate Kabilan Manoharan, representing the PIL petitioner M.L. Ravi, of Desiya Makkal Sakthi Katchi, who insisted upon the need to use good quality kits to diagnose the disease, the judges adjourned the case to Thursday for hearing Additional Solicitor General G. Rajagopalan.

In his affidavit, the litigant stated that there were two types of test kits: RT-PCR kits and Antibody Rapid Test Kits.

He said nations that had controlled better the spread of COVID-19 were the ones which had done extensive and effective testing using good quality kits and cited South Korea, Taiwan and Hong Kong which achieved success without resorting to measures such as lockdown. He said test kits with even a 3% false result were not interpretable and those with a 13% false result were useless.

Source: *The Hindu,* 15th June 2020

Govt Moves to Fast-track Domestic API Production

With tension brewing between India and China, the Centre is readying guidelines to fast-track launch of the production-linked incentive (PLI) scheme to promote local manufacturing of active pharmaceutical ingredients (API) used in making medicine formulations.

India currently sources 70-80% of APIs and key starting material for drug formulation from China because of cost viability.

"We are ready with the guidelines for API incentive scheme and plan to kick-start it by July 1," a senior official in the department of pharmaceuticals said. "The objective is to boost local manufacturing of critical APIs and in the current situation, it assumes prime importance. We are regularly holding meetings to ensure that the process of implementing the scheme is completed as early as possible," the official added.

Pharmaceutical companies say supplies from China are running smooth so far, but with the evolving situation at the border, they are expecting an increase in API cost and even possible disruptions in supply.

"We are keeping a close watch on the situation. So far, we have not received any reports about any disruption in supplies and there is always inventory for a few weeks but if the situation worsens then there can be a crisis," a senior executive with a pharma industry association said.

The government had in March approved a Rs 10,000 crore PLI scheme to reduce India's dependence on China for raw materials to produce crucial antibiotics, anti-HIV drugs, vitamins and cardio medicines.

The government will provide Rs 10 crore each to domestic companies for setting up plants to produce 41 products covering 53 crucial APIs. The proposal says incentives will be given on condition that products must be manufactured with complete backward integration and supplied to domestic drug-makers only.

Source: *The Times of India,* 19th June 2020

DCGI Nod for India-Made COVID-19 Vaccine 'Covaxin' Human Trials

Bharat Biotech gained an edge in the race among a few entities in the country and several more globally to ready a vaccine for COVID-19 when the Drug Controller General of India (DCGI) cleared its product for human clinical trials.

The collaboration with the Indian Council of Medical Research (ICMR)-National Institute of Virology (NIV) was instrumental in the development of the vaccine, Chairman and Managing Director Krishna Ella said on Monday. The trials of Covaxin, the vaccine, will begin next month.

The proactive support and guidance from the Central Drugs Standard Control Organization (CDSCO) had enabled approvals for the project, Mr. Ella said in a statement.The indigenous, inactivated vaccine has been developed and manufactured in Bharat Biotech's Bio-Safety Level 3 (BSL-3) High Containment facility located in Hyderbad's Genome Valley.

'National importance'

Bharat Biotech is committed to advancing vaccine development as a matter of national importance to demonstrate India's strength in handling future pandemics, Joint Managing Director Suchitra Ella, was quoted as saying in the statement.

Bharat Biotech's track record in developing vero cell culture platform technologies has been proven in several vaccines for Polio, Rabies, Rotavirus, Japanese Encephalitis, Chikungunya and Zika. The company is proficient in conducting extensive multi-centre clinical trials, having completed more than 75 trials in over 300,000 subjects globally, the release said.

The company is also involved in the development of CoroFlu, a nasal vaccine for COVID-19, as part of an international collaboration of virologists at the University of Wisconsin–Madison and vaccine firm FluGen.

Source: *The Hindu,* 30th June 2020

Key Covid-19 Drugs to be Hit by Customs Checks at Ports

Import consignments of crucial raw materials stuck at ports and airports will impact production of key Covid-19 drugs, Remdesivir and Favipiravir, as well as other life-saving medicines, leading to potential shortages across the country.

Besides, shipments of even critical medical devices such as infrared thermometers and pulse oximeters are also affected. The delay in clearance of consignments of key chemicals used to produce advanced pharmaceutical ingredients (APIs) and formulations for lifesaving Covid-19 drugs, will impact the drugs' production schedule, which is critical in the present scenario. Mylan, one of the six manufacturers of Remdesivir, a drug granted “emergency use” approval by US Food and Drug Administration for treatment of severely-ill Covid-19 patients, said the delay and hold up will impact the availability of drugs.

This is even as the health ministry and Pharmexcil have sought early clearance of consignments. The industry body sought an urgent intervention from the government to resolve the "man-made disruption", which started a fortnight back. Faced with an "acute disruption" it has sought instructions to customs authorities for immediate clearance of the supplies at ports and airports, particularly Nhava Sheva port (Maharashtra) and Delhi Airport.

"We have been inundated with distress calls from a lot of our member companies that there has been an acute disruption in manufacturing of pharmaceutical products over the last three days," Pharmexcil said in a letter to various government departments.

The delays at ports and airports due to examination of all imports from China by customs authorities will impact costs for domestic manufacturers, a company official told TOI, as China has issued a directive to tighten credit. Also, several companies enter into annual contracts for their large volume purchases in the past. Due to political uncertainty, Chinese companies now prefer to sell products on a consignment basis which works out to be more expensive for the buyer.

Critical raw material and bulk drugs are imported from China, with the country accounting for nearly 70% of API (active pharmaceutical imports), while in certain cases like antibiotics, the dependence is around 90%.

"The delay in clearance of consignments for manufacturing APIs and formulations for life-saving drugs meant for COVID-19 treatment is going to impact the healthcare delivery in these challenging times," a company manufacturing Covid-19 drugs said.

"APIs import clearances are impacted and will be a concern if it continues for longer period," Ashok Madan of Indian Drug Manufacturers Association (IDMA) said.

Pharmexcil chairman Dinesh Dua said that there will be disruption in supply as there is near-total dependence on China for key raw materials used in making antibiotics, cardiovascular, respiratory and diabetes medicines.

The congestion at ports particularly Nhava Sheva needs to be cleared quickly as rains will further lead to a huge pile up. Also, chemicals and pharma cargo will only be cleared after the perishables have been attended to.

The "scrutiny" is being attributed to the ``intelligence'' received around illegal imports of narcotics at Chennai port a few days back. Officials are seeking stricter compliance and more documentation from importers, which is not a normal routine procedure, a Chennai-based company said. Some cargo was cleared last week after a detailed investigation and scrutiny of documentation at Chennai, while the bigger containers of commodities and goods are still held up.

Customs officials across the country are conducting a detailed examination and rechecking all shipments from China, even though there was no official intimation on the exercise. As against this, earlier only random testing was carried out of the containers.

Source: *The Times of India,* 30th June 2020

Emcure Pharma Launches Generic Drug for Hyperphosphatemia in Chronic Kidney Disease Patients

Pharmaceutical company launched generic version of sucroferric oxyhydroxide tablets, indicated for the control of increased serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis, at a price of Rs 4,200 for 90 tablets. The drug will be sold under the brand name 'Dynulta' and will be manufactured at the company's facility at Jammu, Emcure Pharma said in a statement.

When asked about the cost of the generic drug for the patients here, Emcure Pharma said, "The drug will be sold at Rs 4,200 for 90 tablets".

The innovator company for sucroferric oxyhydroxide is Vifor Fresenius Medical Care Renal Pharma Ltd. It markets the product internationally as 'Velphoro'. The product is not available in India, Emcure Pharma said.

"The incidence of CKD is on the rise in India. Dynulta will provide efficacious and cost-effective remedy for Indian patients," Emcure Pharmaceuticals Executive Director Namita Thapar said.

When asked about the cost of the innovator drug, Emcure Pharma Senior Director Sales and Marketing (Nephrology and Oncology) Manisha Sonavadekar said in a virtual press conference that it costs around USD 1,000 for 90 tablets.

Hyperphosphatemia is a serious and common consequence of advanced CKD. Hyperphosphatemia is associated with increased risk of cardiovascular events and mortality in patients undergoing dialysis, Emcure Pharma said.

Sucroferric oxyhydroxide displays a high phosphate binding capacity, resulting in effective serum phosphorus control.

Source: *ET Healthworld,* 1st July 2020

Drug Makers Get Nod to Raise One-Time Price Increase on Heparin Injections

The National Pharmaceutical Pricing Authority (NPPA) has allowed drug companies to take a one-time price increase on the heparin injections, a blood thinner that is recommended by the health ministry for treatment of severe Covid-19 patients.

The move comes after companies complained about rising prices of the active pharmaceutical ingredient of the drug. The NPPA has allowed for upward revision of heparin injection 1000IU/ ml and heparin injection 5000IU/ ml under para 19 of DPCO 2013 by 50%. The ceiling price of the drug is now fixed at Rs 24 and Rs 60.

The regulator had received applications from companies who had made their case on the grounds that the cost of APIs which constitute a major portion of the input cost and mainly imported from China, has risen to a considerable extent making the companies entirely unviable to continue manufacturing the formulations.

"The companies also contended that over the years the regulated price have decreased whereas there is consistent increase in the price of imported APIs thereby making it commercially unviable for the drug manufacturers to manufacture the said product," said Prasanjit Das, additional director of NPPA.

Reports of shortage India allowed prices of a blood thinner recommended for some Covid patients to be raised by 50% due to higher input costs.

The National Pharmaceutical Pricing Authority permitted a one-time price increase for heparin injections after companies complained about the rising cost of its active pharmaceutical ingredients.

The regulator set the ceiling price for Heparin 1000 IU/ml at Rs 24 and for heparin 5000 IU/ml at Rs 60.

The regulator had received applications from heparin manufacturers that the cost of APIs, which constitute a major portion of input expenses and are mainly imported from China, had risen to a considerable extent, making it unviable for the companies to continue producing the formulations.

Source: *The Economics Time,* 3rd July 2020

Kit Import Licence of 3 Firms Cancelled, 15 Suspended; Order Based on Ban by USFDA

Citing a ban by the US government, the Central Drugs Standard Control Organisation (CDSCO), under the country's apex drugs regulator DCGI, has canceled kit import licences of three firms and suspended those of 15 others.

While most licences were for Chinese rapid antibody test kits that never entered the country, at least two others have been sold in the Indian market.

One is an ELISA antibody test kit (different from rapid antibody test kit) owned by Mumbai-based Transasia, which said they have sold 3 lakh kits since June to different hospitals. Deals for 5 lakh more are currently in the pipeline, the company said.

In addition, 1 lakh supply of a suspended rapid antibody test kit made by South Korean SD Biosensor was sold to Andhra Pradesh in April, a company representative told The Sunday Express.

On July 17, CDSCO sent these 18 companies a showcause notice stating that "as per notification by the US Food and Drug Administration (USFDA) the…product has been removed with direction that it should not be distributed". It gave the firms time until July 20 to respond.

On July 21, CDSCO said their responses to the showcause was not "satisfactory".

The cancelled licences were of MDAAC International, Cadila Healthcare, and N.W. OVERSEAS.

The suspended licences were held by Aracion Technology, DiaSys Diagnostic, Jettalabs, Saffron Naturele Products, Cosmic Scientific Technologies, Inbios India, Vishram Distributors, SD Biosensor, Transasia, Accurex, Biohouse Solutions, V S Yarns, Raymed Trading Group, Sowar, and Trivitron.

Barring Transasia and SD Biosensor, all these firms were approved to import a set of seven Chinese antibody test kits that were banned by US FDA in June. The Sunday Express spoke to seven of these Indian companies, all of whom said they had not imported these kits since rapid antibody test kits fell out of government strategy around May.

Transasia owns California-based Calbiotech, which manufactures the kit called ErbaLisa. As one of the first ELISA antibody test kits to be approved in the country, it remains on the most recent Indian Council of Medical Research (ICMR) validation list of July 22.

Calbiotech's response to CDSCO on July 20, seen by The Sunday Express, included an ICMR-National Institute of Virology validation approval on June 3, US license documents-authorising export, and an Air Force Central Medical Establishment report citing satisfactory results on July 8.

Calbiotech and Transasia stated that the USFDA decision should not stop export of the kit to India, that the US FDA's removal was not due to performance issues but a policy change, that the company's application is awaiting a reply from the US agency, and that it never claimed USFDA approval in their validation process in India.

Transasia's MD Suresh Vazirani said he plans to file a legal complaint in Delhi High Court. “Somehow we don't believe our own testing protocol. We are discarding ICMR approval because USFDA has done something,” he said.

Vazirani said USFDA has not reached out to the company about their removal.

Dr Arvind Lal, chairman and MD of Lal PathLabs, said this test kit failed their internal validation three weeks ago. Thyrocare chairman and MD Arokiaswamy Velumani said they had used 20,000 of these ELISA test kits nationwide up until 10 days ago.

Companies go through three batches of ICMR trials before the agency sends their validation to the Director Controller General of India (DCGI) for final approval. If a test kit already has USFDA approval, it skips ICMR validation for DCGI approval.

ICMR's senior scientist Nivedita Gupta answered queries on July 18 by stating that “pertinent action will be taken by CDSCO/DCGI”.

CDSCO, which sits under DCGI, did not respond to repeated attempts at comment.

When asked what the protocol is when the US bans a kit, an official in charge of kit validation at one of ICMR's institutes said, “If a kit banned by the US comes to us, we do consider if it is banned at that time.”

Another ICMR scientist in the Delhi headquarters said it would be a “red flag” to see the US ban any test kits that ICMR or CDSCO has approved.

In mid-March, the USFDA allowed test kits with external validation to bypass their validation process. After US Congress committee findings criticised their leniency, they began cracking down on "poor performance or misleading statements" and began publishing "removed" manufacturers on May 21.

SD Biosensor's duo rapid antibody test kit was revoked by USFDA on June 24 and was under a list sent to labs and healthcare providers on June 22 of kits that were "less than optimal performance, and should not be used clinically".

Company sales director Attaullah Khan said the test kit was approved by ICMR-NIV, but SD Biosensor transitioned to a new combo rapid antibody test kit in April and, thus, did not reapply for FDA approval for their duo test kit. They still hold an Indian manufacturing licence to make the duo and combo test kit in the country, even though few entities use rapid antibody tests.

When ICMR banned several Chinese antibody kits, the Indian Ambassador to South Korea visited SD Biosensor's facility on April 22 to facilitate a shift to South Korean brands. Biosensor was also the first company to sell the heavily-used antigen test kits in India.

Source: *The Indian Express,* 26th July 2020

New Nano Drug Candidate Kills Aggressive Breast Cancer Cells

Researchers at the University of Arkansas have developed a new nano-drug candidate that kills triple-negative breast cancer cells.

Triple-negative breast cancer is one of the most aggressive and fatal types of breast cancer. The research will help clinicians target breast cancer cells directly while avoiding the adverse and toxic side effects of chemotherapy.

The study was published in the latest issue of the journal -- Advanced Therapeutics.

Researchers led by Hassan Beyzavi, assistant professor in the Department of Chemistry and Biochemistry, linked a new class of nanomaterials, called metal-organic frameworks, with the ligands of an already-developed photodynamic therapy drug to create a nano-porous material that targets and kills tumor cells without creating toxicity for normal cells.

Metal-organic frameworks are an emerging class of nanomaterials designed for targeted drug delivery. Ligands are molecules that bind to other molecules.

"With the exception of skin cancers, breast cancer is the most common form of cancer in American women. As we know, thousands of women die from breast cancer each year. Patients with triple-negative cells are especially vulnerable, because of the toxic side effects of the only approved treatment for this type of cancer," said Beyzavi.

"We've addressed this problem by developing a co-formulation that targets cancer cells and has no effect on healthy cells," Beyzavi added.

Researchers in Beyzavi's laboratory focus on developing new, targeted photodynamic therapy drugs. As an alternative to chemotherapy -- and with significantly fewer side effects -- targeted photodynamic therapy, or PDT, is a non-invasive approach that relies on a photosensitizer that, upon irradiation by light, generates so-called toxic reactive oxygen species, which kill cancer cells.

In recent years, PDT has garnered attention because of its ability to treat tumors without surgery, chemotherapy or radiation.

Beyzavi's laboratory has specialised in integrating nanomaterials, such as metal-organic frameworks, with PDT and other and therapies. Metal-organic frameworks significantly enhance the effectiveness of PDT.

Doctoral student Yoshie Sakamaki from Beyzavi's laboratrory prepared the nanomaterials and then bio-conjugated them with ligands of the PDT drug to create nanoporous materials that specifically targeted and killed tumor cells with no toxicity in normal cells.

In addition to cancer treatment, this novel drug delivery system could also be used with magnetic resonance imaging (MRI) or fluorescence imaging, which can track the drug in the body and monitor the progress of cancer treatment.

This collaborative project also included contributions from U of A research groups through Julie Stenken, professor of analytical chemistry; Yuchun Du, associate professor of biological sciences and Jin-Woo Kim, professor of biological and agricultural engineering.

The American Cancer Society estimated 268,600 new cases of invasive breast cancer in 2019 and 41,760 deaths. Currently, there are more than 3.1 million breast cancer survivors in the United States.

Since 2007, breast cancer death rates have been steady in women younger than 50 but have continued to decrease in older women. This decrease is believed to be the result of earlier detection and better treatments.

Triple-negative breast cancer is aggressive and lacks estrogen receptors, progesterone receptors and human epidermal growth factor receptor 2, which means it cannot be treated with receptor-targeted therapy. It is difficult to treat with existing chemotherapy and often requires surgery because it quickly metastasizes throughout the body.

Cytotoxic chemotherapy is the only approved treatment for this type of breast cancer. More than 80 per cent of women with triple-negative breast cancer are treated with chemotherapy regimens that include anthracyclines, such as doxorubicin, which can cause cardiotoxicity as a serious side effect.

Furthermore, chemotherapy treatment of breast cancer cell lines using either 5-FU, cisplatin, paclitaxel, doxorubicin or etoposide has shown multi-drug resistance.

Source: *ET Healthworld,* 20th July 2020

DCGI Notice to Glenmark over Overpricing of Antiviral Drug Fabiflu

The Drug Controller General of India (DCGI) has, earlier this week, issued notice to Glenmark Pharmaceuticals asking it to respond to allegations of overpricing and claim that its antiviral drug Fabiflu is effective in COVID-19 patients with co-morbidities.

The DCGI has sought a response from the company.

"It has been mentioned in representation that Glenmark has claimed that this drug is effective in co-morbid conditions like hypertension, diabetes whereas in reality, as per protocol summary, this trial was not designed to assess the Fabiflu in co-morbid conditions. No clinically sufficient data specific to these conditions are available," said V.G. Somani, DCGI, in the notice to the company.

'Misleading claims'

The notice adds that Fabiflu was not tested as monotherapy in any of the mild or moderate cases and that claims by the company were misleading.

On pricing of the drug, the drug controller said Glenmark's drug had been priced too high and was not in the interest of the poor and the common man.

Glenmark said in a regulatory filing recently that it has slashed the price of its Favipiravir tablet by 27% to ₹75 MRP. "The price reduction has been made possible through benefits gained from higher yields and better scale, as both the active pharmaceutical ingredient (API) and formulations are made at Glenmark's facilities in India, the benefits of which are being passed on to patients in the country," it had stated in the filing.

Source: *The Hindu,* 19th July 2020

All Pharmaceutical Products Could Come With QR Codes in Bid to Ensure Authenticity

Medicine packs will soon have to bear a unique quick response (QR) code in an attempt to ensure authenticity and enable tracking. A committee has been set up to fine-tune the modalities, people aware of the matter said.

QR codes help in tracking and tracing the origin of drugs and minimise the chances of spurious, sub-standard or counterfeit drugs reaching patients.

Representatives from the Prime Minister's Office, Niti Aayog, commerce ministry, Department of Pharmaceuticals and the health ministry met last week and decided to settle the matter and issue a notification to this effect soon.

"A committee has been set up under the health secretary which will come out with the report in the next 21 days," the people said.

The government has been trying to introduce QR codes since 2011 but it hasn't been implemented. Pharma companies and lobby groups had expressed concern over multiple sets of directions regarding tracing and tracking being issued by various departments and had asked for a single QR code system.

"There was too much confusion regarding this. Finally, the issue will be settled. In the recent meeting it was decided that one QR code should be there," one person said.

Last year, India's drug regulator issued a draft notification mandating the use of the QR code for active pharmaceutical ingredients. It was proposed that every API (bulk drug) manufactured or imported in India should bear a QR code on its label at each level of packaging that stores data or information readable with software applications to facilitate tracking and tracing.

The stored data or information would include the unique product identification code, the name of the API, brand name (if any), name and address of the manufacturer, batch number, batch size, date of manufacture, date of expiry or retesting, serial shipping container code, manufacturing licence number or import licence number and special storage conditions required, among others.

Source: *ET Healthworld,* 16th July 2020

India Needs Holistic Ecosystem to Rebuild API Manufacturing Facilities: PWC India

India needs a holistic and conducive ecosystem to rebuild its active pharmaceutical ingredient (API) manufacturing capabilities, as high dependence on a single source can be a cause of concern in emergency-like situations, PwC India said on Thursday. Dependence on China for APIs has been an ongoing concern for the Indian pharma industry. Around 50 per cent of the critical APIs are being imported and almost all the imports are from China, a study by PwC India noted.

The Chinese API industry has an inherent advantage because of economies of scale and support from the Chinese government in the form of financial incentives, infrastructure and regulatory policies, it added.

High dependence on a single source can have a significant adverse impact in emergency-like situations, the study 'Reviving India's API industry' said.

A favourable financial and regulatory ecosystem and policies are likely to enable the API industry to ensure health security in India by making it self-reliant, it added.

The study recommended that to revive the API industry, in the immediate term there is a need for faster environment clearance, encouraging manufacturing of key APIs/intermediates and fermentation products by providing a fiscal stimulus, accommodative pricing policy under the Drug Price Control Order, 2013 and financial incentives.

For the long term, the government may look at the Chinese model and work on developing clusters for API and fermentation, along with looking at ways to encourage alternative sources, it added.

There is also a need for the industry-academia initiatives to improve process technologies, the study recommended.

"High dependence on a single source can have a significant adverse impact in emergency situations like COVID-19. With recent changes in API's prices rising up to 100 per cent, it is time we revive our domestic API industry," PwC India Partner and Leader Health Industries Sujay Shetty said.

While some policy changes may take time, "we need to collectively evaluate and strategize for ways to encourage alternative sources," he added.

Source: *ET Healthworld,* 16th July 2020

New Antiplatelet Drug Shows Promise for Treating Heart Attack

Researchers have developed a new drug that prevents blood clots without causing an increased risk of bleeding, a common side effect of all antiplatelet medications currently available.

The study, published in the journal Science Translational Medicine, described the drug and its delivery mechanisms and shows that the drug is also an effective treatment for heart attack in animal models.

"Unfortunately, current antiplatelet medications prevent the blood clotting that causes heart attack and stroke but also disrupt platelets' ability to stop bleeding if a blood vessel is torn," said study researcher Xiaoping Du from the University of Illinois in the US.

"The magic of this new drug is it prevents clots but does not make people prone to bleeding, which other drugs have failed to do," Du added.

In a previous study, the research team identified a signalling mechanism that is important in the blood clotting process but not required for platelets' ability to adhere to a wound and prevent bleeding. Based on this finding, the researchers derived a peptide to target the signalling mechanism and designed a nanoparticle that successfully delivered the peptide into platelets.

The peptide-derived nanoparticle drug -- called M3mP6 high-loading peptide nanoparticle, of HLPN -- was then tested in mice as a possible treatment for heart attacks.Du said a heart attack can cause heart failure and death in two different ways. One, from the initial damage caused by the clot, which blocks blood flow and reduces oxygen supply.

This typically is treated by a procedure called angioplasty and a stent to open the artery, combined with antiplatelet drugs to prevent it from clotting again. However, fresh blood flowing into the damaged heart tissue following the reopening of the artery can trigger inflammation, causing leaks and clots in small blood vessels and further damage to the heart, the researchers said.

"This is called reperfusion injury and this is the second way a heart attack can lead to heart failure or death," Du said. In the study, among mice that received the treatment, administered as an injection, there was reduced damage to the heart, reduced clotting and reduced inflammation. There also was improved heart function and improved survival.

"It is very exciting to see such promising results in the lab and we hope to one day test this in humans," Du said. "We were hopeful that this new drug, which does not cause blood vessel leaks, would help limit reperfusion injury and reduce the chance of heart failure and death," the study authors wrote.

Source: *ET Healthworld,* 16th July 2020

India Gets its First Desi Pneumonia Vaccine

India has got its first locally developed pneumonia vaccine, reducing its dependence on imports for immunization against a disease that contributes to most deaths in children under five years of age. The Drugs Controller General of India (DCGI) approved Pneumococcal Polysaccharide Conjugate Vaccine developed by Serum Institute of India. The Pune-based company can now manufacture the vaccine in India for use.

This vaccine is used for active immunization against invasive disease and pneumonia caused by "streptococcus pneumonia" in infants. "Having an indigenous pneumococcal vaccine will be a game-changer in our endeavour to reduce child mortality. Pneumonia is the most important cause of child deaths, and pneomococci are responsible for half of serious pneumonias. India's vaccine is a boon for our country and the world," says Dr V K Paul, member -health at NITI Aayog.

India accounted for the second highest number of deaths in under-five children in 2018 because of pneumonia. According to Unicef, India reported 1,27,000 under five deaths due to pneumonia in 2018. Earlier, the demand of this vaccine was met substantially by licensed importers in the country since the manufacturers were all vaccine companies based outside. The regulatory approval is based on clinical evidence secured by the company after conducting Phase I, Phase II and Phase III clinical trials of the vaccine. Serum Institute has conducted these trials in India as well as in Gambia.

While immunisation against the disease has improved in India led by government initiatives and awareness programmes, many children — mainly female children — are still left out of the coverage. Experts say a locally made vaccine is likely to make the vaccine more accessible and affordable.

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Source: *ET Healthworld,* 16th July 2020

Not the Time to Profiteer, Says National Pharmaceutical Pricing Authority

To ensure sufficient availability of critical medical equipment for clinical management of COVID-19 in the country, the Union Health Ministry said on July 3 that it has identified a list of critical medical equipment and has requested National Pharmaceutical Pricing Authority (NPPA) to ensure its availability at affordable prices to the consumers.

"In order to keep check on the price rise of critical medical equipment, NPPA, in exercise of powers conferred under DPCO, 2013, has called for price-related data from manufacturers/importers of Pulse Oximeter and Oxygen Concentrator to ensure that prices existing as on 1st April, 2020 should not be increased more than 10% in a year," noted a release issued by the Ministry.

All the medical devices have been notified as Drugs and have come under regulatory regime of the Drugs & Cosmetics Act, 1940 and Drugs (Prices Control) Order, 2013 w.e.f. 1st April 2020.

A stakeholders consultation with medical devices industry association and civil society group was held in NPPA on July 1 wherein it was stressed that all the manufacturers/importers of critical medical equipment shall ensure sufficient availability of the same in the country.

"It has been reiterated that all the Medical Devices have come under price regulation accordingly, price increase of medical devices would be monitored," noted the release.

The NPPA also urged the industry that it was not "business as usual" and not the time to profiteer in the public health emergency.

"The Medical Devices Industry Associations have been urged to bring down the retail price of critical medical equipment in larger public interest in the prevailing situation as has been done by the manufacturers / importers of N-95 masks," noted a senior health official.

Source: *The Hindu,* 3rd July 2020

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