

# ADCBP

Ashta

## TECHNICAL MAGAZINE

The doctor of the future will no longer treat the human frame with drugs, but rather will cure and prevent diseases with nutrition.

- Thomas Edsion

# Scienicia

# COVID-19, HUMAN HEALTH & PHARMA INDUSTRY

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# CONTENTS

04  
A Global Crisis- UNDP  
Administrator Message

12  
WHO Talks

15  
News Insights: Covid  
Guidlines

COVID-19 A  
Wakeup Call  
For Humanity -

01  
**Covid-19, Human Health and Pharma  
Industry**

Preface by Dr. Jadhav R. B.

02  
**The Role Pharmaceutical Industry in  
'COVID-19' Pandemic**

By Dr. Jagtap R. S.

05  
**Importance of Diet in COVID-19**

By Dr. Tamboli E. T.

07  
**Role of Chemistry in COVID-19**

By Miss. Momin Y. H.

09  
**Clinical trials and Vaccine  
Development**

By Mr. Sutar G. V.

13  
**Role of Pharmacists in COVID-19  
Pandemic**

By Mr. Suryawanshi Abhinandan S.

14  
**Pharmacovigilance in the age of  
COVID-19**

By Miss. Nalavade Komal G.

## Thank You

To all the healthcare workers and  
public service professionals across  
the nation who are on the frontline  
working to fight against the COVID-19  
Pandemic

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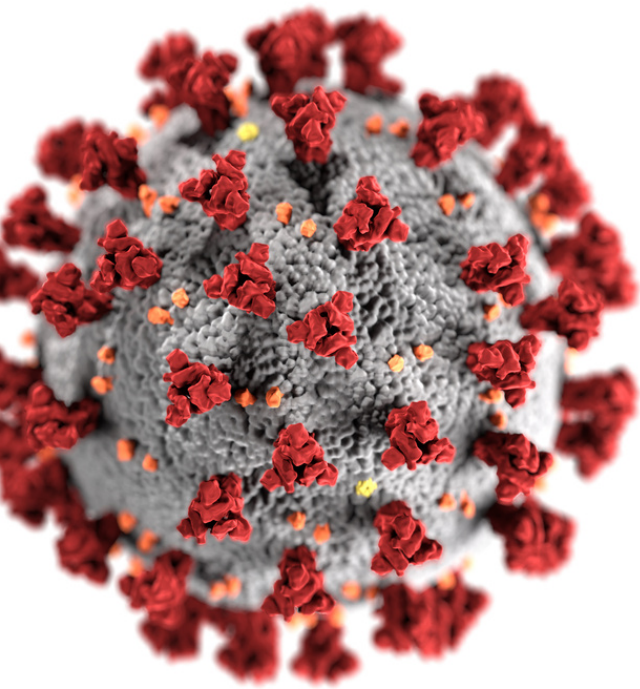
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# COVID-19, HUMAN HEALTH AND PHARMA INDUSTRY



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I congratulate the editorial team for selecting the topic on Covid-19 since it is the devastating threat of viral pandemic revisiting after 100 years. In this digital & technological age, we largely forgot to co-evolve with other organisms & we conducted so-called developments in a unilateral way by forgetting the existence of lively nature. It is, therefore, high time for the human race to think on this issue & accept co-existence.

There are a number of mistakes we have made to prevent the spread of Covid-19 which is largely attributed to overconfidence & arrogance cultivated over the years by many countries including ours. The main threat is not only to prevent spread but viral mutation that will demolish all preventing measures including vaccination programs.

Covid-19 teaches us not only to accept co-existence but also to identify ways to reduce inter-dependence among countries & probably work against globalization. This is a very challenging task since self-reliance cannot be evolved overnight & required constructive work for years by the youth population. Being a growing Pharmacist, you all need to think comprehensively on this challenge & work on short-term as well as long-term solutions including other probable threats hidden in the uncertain & chaotic future.

Take care of yourself & your family members. Follow preventive measures & guidelines issued & be safe.  
Best Wishes





SCIENCIA

# THE ROLE OF PHARMACEUTICAL INDUSTRY IN 'COVID-19' PANDEMIC



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There are significant global efforts underway to diagnose, treat and prevent infections from the virus. Pharmaceutical companies are working globally to combat COVID-19. Pharmaceutical industries play a vital role during COVID-19 crises for providing life saving drugs as well vaccine in order to avoid the infection of coronavirus at the Same time it supports economy of country at higher level as it contribute majorly in GDP as per as industrial sector concern.

The end quarter of year 2019 was started with big challenge to human being 'COVID-19'. The emergence of this new type of coronavirus made significant impact on lifestyle of human being throughout the world. Coronavirus was spread from one city to the country and to almost all countries of the world within few weeks. Spread of coronavirus was too fast, aggressive, and lethal. And world was staring very hopefully towards great samurai 'Pharmaceutical and Health Industry'. In recent years, the world went through SARS, MERS, Ebola and Influenza (H1N1), and pharmaceutical companies were part of the effective solution to these pandemics. That is why governments and people have trusted the industry and are asking it to help end COVID-19. This responsibility resulted to significant pressure on the pharmaceutical industry. Pharmaceutical and health industry started fighting this war on two fronts. First is to figure out existing medicines to treat patients and the second one is to invent new medication or vaccine to stop this spread. As health professionals were figuring out how to treat the virus, pharmaceutical providers set out to investigate what existing drugs might help treat patients with COVID-19, potential new medicines to help mitigate the symptoms and long term effects and the production of a vaccine. Alongside this, they also needed to ensure that regular production of other medicines was able to continue to ensure treatments for other conditions were not impacted.



Aside from responding to the immediate threat, industry had adapted quickly to ensure that they can be resilient to disruption and work in more agile ways, both in a post-COVID environment and in preparation for a possible second wave of the virus. Preparing for multiple possible scenarios is key to ensuring continuity and the management of risk no matter the situation. Possible scenarios are keys to ensuring continuity and the management of risk no matter the situations.

Looking at treatments for individuals infected with COVID-19 has also been a priority activity for pharmaceutical companies since the virus appeared and began to spread internationally in January 2020. The RECOVERY trial was set up in March 2020 to test a range of existing treatments to find ways to treat patients with COVID-19. In mid-June, the trial had a breakthrough with the drug dexamethasone, which is a low-cost, widely available steroid treatment used to treat asthma and other inflammatory conditions. The trial found that dexamethasone helped reduce deaths by one third in hospitalised patients with respiratory complications. Pharmaceutical company Gilead have also produced a drug called Remdesivir which can help patients recover quicker from COVID-19. It was found to have positive results on two older forms of coronavirus, MERS and SARS, which have a similar structure to COVID 19.

Business continuity is essential for the pharmaceutical industry in order to keep operating during the COVID-19 pandemic and prioritise COVID-19 treatments. Thorough risk assessments and reviewing previous procedures are key to building resilience and enabling critical work to continue during the pandemic.

Digital solutions provide the necessary backbone to streamlining these processes. Our software provides quality management and document collaboration solutions for pharmaceutical companies, allowing them to maintain operations and work remotely with colleagues during this unprecedented time. Pharmaceutical companies have deep scientific knowledge gained from decades of experience with similar viruses. Companies

are researching vaccine candidates and undertaking inventories of research portfolio libraries to identify additional potential treatments for R&D. Some have donated compounds with the potential to treat coronavirus for emergency use and clinical trials, including compounds formerly tested on other viral pathogens such as Ebola and HIV. Other are exploring ways to use existing technologies that provide the ability to rapidly upscale production once a potential vaccine candidate is identified.

The impact of the SARS-CoV-2 coronavirus outbreak, COVID-19, has exposed the dependency of the Indian Pharma sector on China for its API procurement. Supply chain disruptions and product exportation restrictions from India resulted from manpower shortages in China's manufacturing plants. This was caused by the quarantine policies adapted and adopted by different provincial governments in China in response to the virus. Supplies were further impacted by the disruption of logistics and transportation systems, restricting access and movement of products to and from ports.

Bottom-line the pharmaceutical industries play a vital role during COVID-19 crises for providing life saving drugs as well vaccine in order to avoid the infection of coronavirus at the Same time it supports economy of country at higher level as it contribute majorly in GDP as per as industrial sector concern.





# A GLOBAL CRISIS

-The coronavirus COVID-19 pandemic is the defining global health crisis of our time and the greatest challenge we have faced since World War Two. Since its emergence in Asia in 2019, the virus has spread to every continent except Antarctica.

We have now reached the tragic milestone of more than two million deaths, and the human family is suffering under an almost intolerable burden of loss.

*"The climbing death toll is staggering, and we must work together to slow the spread of this virus." - UNDP Administrator Achim Steiner.*



# IMPORTANCE OF DIET IN COVID-19



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*For smooth functioning of all these syntheses a raw material in the form of food is necessary, which leads to maintenance of good healthy condition. The strategies to fight against any disease includes its prevention through vaccination, or a medication but looking towards the COVID-19 either prevention or medication were not effective in initial phases. So, ultimate strategy which worked best was developing own immunity by taking balanced diet.*

Since last year the world is suffering from ill effects of COVID-19, even though it is a simple viral disease which only affects humans, it has adversely affected the world economy as well. Day after day technology is reaching to newer peaks where humans have never reached before, but at the same time newer problems like pollution, global warming, lower average life, strange type of infections or diseases and so many are rising. Considering these attributes of development and problems humans must evaluate their need and greed as well. The origin of corona virus is also based on the imbalance of human need and greed. There are several opinions behind this initiation of corona virus, few says it is genetically engineered in laboratory, so the question arises if it is true then what was the need of it. While another theory says it got transferred from bats which brought for eating purpose, so if it is true then greed of eating such animals pushed an entire globe into a darkest zone. This debate can reach to newer fathoms, but eventually what problem lies in front of world is Covid 19, a challenging disease.

Considering the pathophysiology of diseases, they can be classified in lifestyle oriented, old age oriented, and vector-oriented diseases. Further analysis of all three type leads to a common reason for their initiation is diet. Even though people are aware about the role of diet in good health yet they are much passive about it. Human body is also a complex chemical synthesizing biochemical factory. For smooth functioning of all these syntheses a raw material in the form of food is necessary, which leads to maintenance of good healthy condition. The strategies to fight against any disease includes its prevention through vaccination, or a medication, but looking towards the Covid-19 either prevention or medication were not effective in initial phases. So, ultimate strategy which worked best was developing own immunity by taking balanced diet.

Ancient medical science as well as modern medical science have one common belief is immunity. For better health or immunity, nutrition is one of the important facets. Strengthening of immunity is key concept for fighting against any disease whose pathophysiology is unknown or disease for which medicines are not available. Hence, immunity boosting diet became imperative in the management of Covid-19. Immunity of body is much dependent on vitamins, minerals, and antioxidants. The food rich in these found effective in management of infection. Citrus fruits or fruits which are rich in ascorbic acid and other vitamins as well as mineral like amla, kiwi, various types of oranges, lemons acted as prime preventive agents. Vitamin C is believed to increase the production of white blood cells, which are key to fighting infections. Almost all citrus fruits are high in vitamin C.



The fruits which are rich in anthocyanins like grape fruits, blueberries, black berries, strawberries also effective in boosting antioxidant effect which ultimately helps in boosting immunity.

Few of the food items used all over the world can be listed as garlic, ginger, and turmeric. Since ancient time these three magical herbs are moderately effective in management of vector borne diseases. Presence of allyl disulphide derivatives in garlic helps to fight against various infections. Gingerol and shogaol like compounds in ginger helps to relieve cough and cold conditions as well as fight against sore throat. While curcumin derivatives in turmeric have shown antibacterial, antiviral as well as anticancer properties. Constituents in turmeric also rejuvenates entire body reduces inflammation and relives pain. Along with all these mentioned herbs and fruits complete nutrition or diet is irreplaceable base for health. Hence while fighting against Covid-19 one should take proper diet and include fruits rich in antioxidant and mineral for prevention of infection; this could be best strategy because prevention of infection is always better up to finding its cure.

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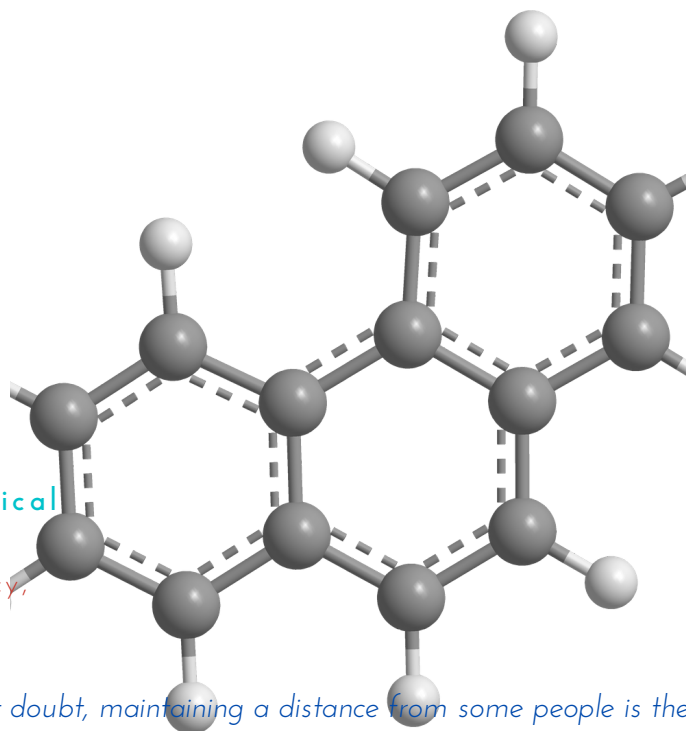
*Nutrition is the only remedy that  
can bring full recovery and can be  
used with any treatment.  
Remember, food is our best  
medicine!  
-Bernard Jensen*



# ROLE OF CHEMISTRY IN COVID-19



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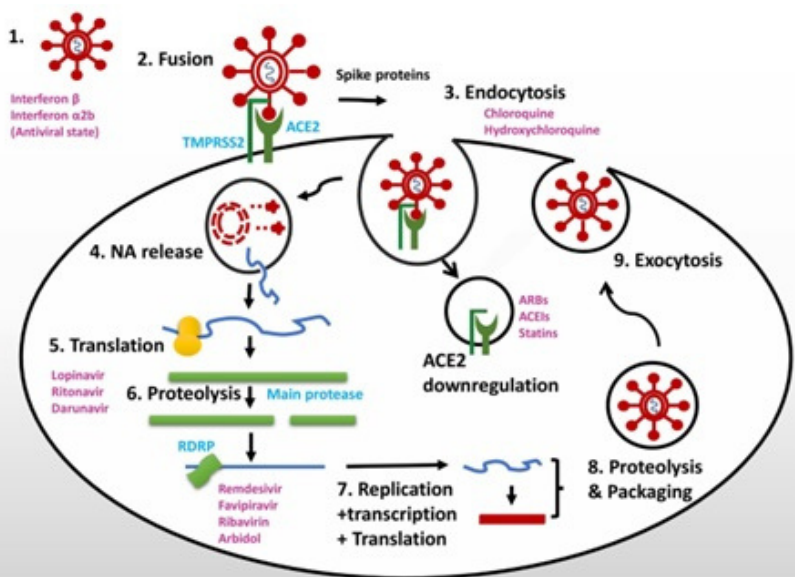
*"Without doubt, maintaining a distance from some people is the only way to maintaining your equanimity – and, of course, to avoid catching COVID-19!"*

The COVID-19 pandemic, which is caused by SARSCoV2 infection, is spreading at an alarming rate and has created a global health crisis. Research and development has play crucial role to fight against the global epidemic situation created by COVID-19. Most of the core chemistry based research organization and pharmaceutical companies are accompanying their efforts towards collecting more and more information about the Corona virus, evolving improved testing tools, and sooner or later creating a vaccine. Saliva-based COVID-19 test was developed by chemistry researcher to enable fast and frequent testing on a large scale. Chemistry is an important aspect at every step at battle against Corona virus pandemic. Beyond research, technicians provide the specialized skills required to run tests, maintain equipment, and manage laboratory supplies, including donations of chemicals for hand sanitization and safety equipment that are delivered directly to doctors and nurses on the front lines.

Angiotensin converting enzyme-2 receptor, corona virus main proteinase (3CLpro) and the papain-like protease [PLpro], RNA-dependent RNA polymerase (RdRp), are potential targets to tackle the SARS -CoV-2.

Drug repurposing is a another method of identifying new uses for approved or investigational drugs and it is considered as a very effective strategy for drug discovery as it involves less time and cost to find a therapeutic agent in comparison to the de novo drug discovery process.

Remdesivir, Favipiravir are the drugs acting on viral replication and Inhibits viral replication. Lopinavir-ritonavir, Darunavir are the drugs acting on viral entry. Auranofin, Doxycycline, Baricitinib are acting on cytokine release. Ivermectin, Statins, Pegylated IFN $\alpha$ -2b, Nitazoxanide are the Miscellaneous drugs which are used as antiviral agents.



Elbasvir, an antiviral drug, (approved for the treatment of hepatitis C) has shown predicted multiple binding sites at RDRP, papain-like proteinase and helicase of SARS-CoV2 using the docking simulations and computational modeling.

Currently, Oxford University-AstraZeneca's Covishield vaccine, manufactured by Serum Institute of India and Bharat Biotech's Covaxin are being used for the vaccination against Covid 19.

A chemotherapeutic fluoroquinolone antibiotic, prulifloxacin, with broad-spectrum activity, and some anti-HIV drugs such as tegobuvir, (a novel non-nucleoside inhibitor of human corona virus RNA replication), nelfinavir (a protease inhibitor which inhibits the cleavage of the polyprotein gag-pol) and bictegravir (HIV-1 integrase inhibitor) have protein binding sites of the proteases which have been shown using the high throughput screening as molecular docking with bioinformatics analysis and would be considered the potential candidates for re-tasking against COVID-19 in future and in-vitro and in-vivo animal models may provide a lead against this disease. According to another recent molecular docking study based on RDRP modeling and multiple sequence alignment (MSA) showed a binding capacity to RDRP against SARS-CoV2 by various antiviral agents such as sofosbuvir (FDA approved against Hepatitis C virus), ribavirin, Remdesivir and IDX-184; (under clinical trial against Hepatitis C virus).



# CLINICAL TRIALS AND VACCINE DEVELOPMENT

*We are facing the SARS-CoV-2/COVID-19 as pandemic disease over all the world. Thus, researchers are trying their best to develop vaccine for prevention from this pandemic so as to receive the benefits of vaccination in the future for the society*



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Vaccination is regarded as one of the biggest triumphs in the history of medicine. The accumulation of multidisciplinary knowledge and the investment of massive funding have enabled the development of vaccines against many infectious diseases as well as other diseases including malignant tumors. The paradigm of clinical vaccine evaluation and licensure has also been modernized based on scientific improvements and historical experience. Infectious diseases caused by viruses have been the most challenging problem in human health.

The diseases with high infectivity and mortality are particularly feared, and in the past, people have regarded such diseases as a disaster or a punishment. Although numerous efforts have focused on producing qualified and effective vaccines, there are insufficient barriers to protect populations from diseases that may cause epidemics or pandemics.

As you know all currently, we are facing the SARS-CoV-2/COVID-19 as pandemic disease over all the world. Thus, researchers are trying their best to develop vaccine for prevention from this pandemic so as to receive the benefits of vaccination in the future for the society.

In addition, vaccine development strategies are being tailored to the particular economic and health requirements of specific countries. This is why physicians and others involved in vaccine development should be alert to the current paradigm.

## Current Clinical Evaluation Vaccines

To meet society's, need for safe and efficacious vaccines, the clinical vaccine development process has been refined for more than a century. Similar to that of chemical drugs, the clinical evaluation of a vaccine typically comprises three phases. A vaccine-specific developmental plan should be clearly established to ensure the efficient and successful development before clinical evaluation.

## Stages of Vaccine Development and Testing

In the United States, vaccine development and testing follow a standard set of steps. The first stages are exploratory in nature. Regulation and oversight increase as the candidate vaccine makes its way through the process.

## First Steps: Laboratory and Animal Studies

### Exploratory Stage

This stage involves basic laboratory research and often lasts 2-4 years. Federally funded academic and governmental scientists identify natural or synthetic antigens that might help prevent or treat a disease. These antigens could include virus-like particles, weakened viruses or bacteria, weakened bacterial toxins, or other substances derived from pathogens.

### Pre-Clinical Stage

Pre-clinical studies use tissue-culture or cell-culture systems and animal testing to assess the safety of the candidate vaccine and its immunogenicity, or ability to provoke an immune response. Animal subjects may include mice and monkeys. These studies give researchers an idea of the cellular responses they might expect in humans. They may also suggest a safe starting dose for the next phase of research as well as a safe method of administering the vaccine.

Researchers may adapt the candidate vaccine during the pre-clinical state to try to make it more effective. They may also do challenge studies with the animals, meaning that they vaccinate the animals and then try to infect them with the target pathogen.

Many candidate vaccines never progress beyond this stage because they fail to produce the desired immune response. The pre-clinical stages often lasts 1-2 years and usually involves researchers in private industry.

### IND Application

A sponsor, usually a private company, submits an application for an Investigational New Drug (IND) to the U.S. Food and Drug Administration. The sponsor describes the manufacturing and testing processes, summarizes the laboratory reports, and describes the proposed study. An institutional review board, representing an institution where the clinical trial will be conducted, must approve the clinical protocol. The FDA has 30 days to approve the application.

Once the IND application has been approved, the vaccine is subject to three phases of testing.

### Next Steps: Clinical Studies with Human Subjects

#### Phase I Vaccine Trials

This first attempt to assess the candidate vaccine in humans involves a small group of adults, usually between 20-80 subjects. If the vaccine is intended for children, researchers will first test adults, and then gradually step down the age of the test subjects until they reach their target.

The goals of Phase I testing are to assess the safety of the candidate vaccine and to determine the type and extent of immune response that the vaccine provokes. In a small minority of Phase I vaccine trials, researchers may use the challenge model, attempting to infect participants with the pathogen after the experimental group has been vaccinated. The participants in these studies are carefully monitored and conditions are carefully controlled.

#### Phase II Vaccine Trials

A larger group of several hundred individuals participates in Phase II testing. Some of the individuals may belong to groups at risk of acquiring the disease. These trials are randomized and well controlled, and include a placebo group.

The goals of Phase II testing are to study the candidate vaccine's safety, immunogenicity, proposed doses, schedule of immunizations, and method of delivery.

#### Phase III Vaccine Trials

Successful Phase II candidate vaccines move on to larger trials, involving thousands to tens of thousands of people. These Phase III tests are randomized and double blind and involve the experimental vaccine being tested against a placebo.

One Phase III goal is to assess vaccine safety in a large group of people. To detect a significant difference for a low-frequency event, the trial would have to include 60,000 subjects, half of them in the control, or no vaccine, group.

Vaccine efficacy is tested as well. These factors might include 1) Does the candidate vaccine prevent disease? 2) Does it prevent infection with the pathogen? 3) Does it lead to production of antibodies or other types of immune responses related to the pathogen?

### Next Steps: Approval and Licensure

After a successful Phase III trial, the vaccine developer will submit a Biologics License Application to the FDA. Then the FDA will inspect the factory where the vaccine will be made and approve the labelling of the vaccine.

After licensure, the FDA will continue to monitor the production of the vaccine, including inspecting facilities and reviewing the manufacturer's tests of lots of vaccines for potency, safety and purity. The FDA has the right to conduct its own testing of manufacturers' vaccines.

### Post-Licensure Monitoring of Vaccines

A variety of systems monitor vaccines after they have been approved. They include Phase IV trials, the Vaccine Adverse Event Reporting System, and the Vaccine Safety Datalink.

### Phase IV Trials

Phase IV trial are optional studies that drug companies may conduct after a vaccine is released. The manufacturer may continue to test the vaccine for safety, efficacy, and other potential uses.

Even though a vaccine may be licensed, the safety information provided for licensure is regarded as insufficient, because at that point, only a few thousand people have likely been exposed to the vaccine. Thus, many vaccines undergo postlicensure ('Phase IV') studies. In the United States, the Vaccine Adverse Event Reporting System (VAERS) was established to detect possible signals of adverse events associated with vaccines.

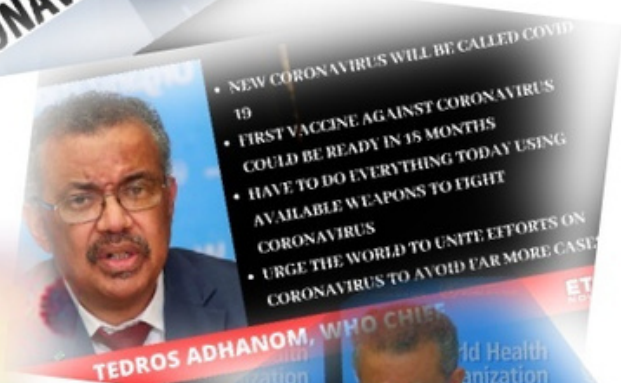
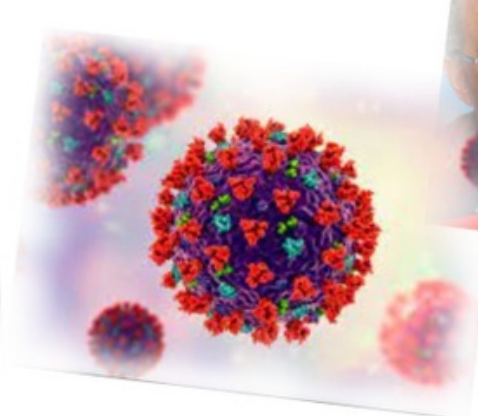
### Conclusion

Vaccines are developed, tested, and regulated in a very similar manner to other drugs. In general, vaccines are even more thoroughly tested than non-vaccine drugs because the number of human subjects in vaccine clinical trials is usually greater. In addition, post-licensure monitoring of vaccines is closely examined by the centers for Disease Control and the FDA.

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# WHO TALKS....!





*Pharmacists along with other health care professionals assist in treatment and involve in prevention and control of COVID-19 infection.*

# ROLE OF PHARMACISTS IN COVID-19 PANDEMIC



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The novel corona virus (nCoV) disease also called as COVID-19 is now a major pandemic-cum-epidemic spreading in several countries throughout the world in which the governments and health care systems are in an emergency having a responsibility to handle this serious situation with the access of health care professionals, sanitation workers, policemen and policewomen throughout their countries in order to control the spread of pandemic COVID-19 among the community.

First of all novel Corona Virus (nCoV) causes respiratory illness, that was identified during its spread among the people of Wuhan city of Hubei province in China as an 'EPIDEMIC' and it has now become a 'PANDEMIC' outbreak in multiple countries throughout the world.

The disease was termed as COVID - 19 (Corona Virus Disease - 19) by the World Health Organisation (WHO) as the disease first occurred during the December month of 2019 in China.

It was first thought as flu fever similar to influenza and manifested pneumonia like symptoms in affected people, until the first death occurred on January 11, 2020 after which it became a serious concern.

Pharmacists are the professionals utmost needed in the situation of global emergency of pandemic outbreak in order to assist the physicians in providing symptomatic treatment and supportive care, create awareness to the public and to the people with co-morbidities who are likely to get infected with COVID-19.

The several roles and responsibilities of pharmacists in the COVID-19 pandemic situation are detailed as follows,

## 1. BE AWARE ABOUT THE WIDESPREAD PANDEMIC OUTBREAK :

A pharmacist should know about the Operational Planning Guidelines by WHO in order to actively involve on having a clear idea about the outbreak.

## 2. TO ASSIST WITH HEALTH CARE PROFESSIONALS TO TREAT COVID-19:

The pharmacist in a hospital setting should provide a supportive care along with physicians and nurses to those patients affected with COVID-19, provide them medication knowledge and monitor patient health outcomes regularly.

**3. PROVISION OF PROPHYLACTIC AGENTS :** like hydroxy-chloroquine to all health care workers, susceptible cohorts, etc.,

**4. PROVIDE SPECIAL CARE FOR VULNERABLE & CO-MORBID COHORTS:** like elderly people with Diabetes, Hypertension, etc., who are more susceptible to get infected.

## 5. CREATING AWARENESS BY PATIENT AND PUBLIC EDUCATION

: It is a responsibility to create awareness among the public about the infection, educate them about the hand hygiene, self-quarantine, appropriate use of masks and other Personal protective equipments, social distancing, etc.,





# Pharmacovigilance in the age of COVID-19



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*The ongoing pandemic is affecting how clinical trials are managed, not just in terms of patient recruitment and immediate patient care but also in terms of data collection, analysis and safety reporting.*

In 2020, the role of pharmacovigilance professionals became more important than ever. The Life Sciences industry is working tirelessly towards finding vaccines and treatments against COVID-19, and the efforts of pharmacovigilance teams across the world are vital for monitoring their safety.

In challenging times like this, we as pharmacovigilance experts demonstrate how our expertise, knowledge, and experience can contribute to the protection of patients worldwide. However, how did these challenges impact pharmacovigilance in 2020, and what awaits us in 2021 and beyond? Our team spoke to Stefania De Santis, a pharmacovigilance professional with more than 30 years of experience and Director of Pharmacovigilance of seQure, to find out.

Pharmacovigilance teams across the whole world have a paramount task – collecting and analysing data, both from clinical trials and from the post-marketing settings, in order to monitor the safety of vaccines and drugs used against COVID-19.

We are there to make sure that risks caused by the drug once it goes into the “real world” are identified, properly managed, and communicated to all involved stakeholders.

We are talking not only about new treatments. Drug repurposing gains a lot of attention too. If before it was mostly occasional, in 2020 many companies launched targeted research to explore new potential uses of their drugs. Pharmacovigilance plays a big role in this research and European Medicines Agency has also drawn additional attention to it. In June 2020, EMA added nine additional active substances (chloroquine, darunavir, emtricitabine-tenofovir, filgrastim, ivermectin, nitric oxide, oseltamivir, prednisone, and ritonavir) which are being investigated as potential treatments for COVID-19, to the list of active ingredients used for MLM literature screening.



# NEWS INSIGHTS



Know the full range of symptoms of COVID-19.

The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include loss of taste or smell, aches and pains, headache, sore throat, nasal congestion, red eyes, diarrhoea, or a skin rash.

Stay home and self-isolate even if you have minor symptoms such as cough, headache, mild fever, until you recover. Call your health care provider or hotline for advice. Have someone bring you supplies. If you need to leave your house or have someone near you, wear a medical mask to avoid infecting others.

If you have a fever, cough and difficulty breathing, seek medical attention immediately. Call by telephone first, if you can and follow the directions of your local health authority.

Keep up to date on the latest information from trusted sources, such as WHO or your local and national health authorities.

If COVID-19 is spreading in your community, stay safe by taking some simple precautions, such as physical distancing, wearing a mask, keeping rooms well ventilated, avoiding crowds, cleaning your hands, and coughing into a bent elbow or tissue. Check local advice where you live and work. Do it all.....WHO