

Coronavirus – your questions answered



Q. What is a coronavirus?

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19.

COVID-19 is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

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Q What is the industry in Europe doing to help in the fight against the coronavirus?

As an industry #WeWontRest in fighting the COVID-19 pandemic and preventing future outbreaks. Our first thoughts are with all those affected by the coronavirus pandemic. As an industry we are committed to working collaboratively across the research and healthcare communities, utilising our world-leading science, people and resources to tackle this outbreak. Our aims in this time of public health crisis are to; ensure the safe supply of medicines to the patients that need them, research and develop new vaccines, diagnostics and treatments for use in the fight against COVID-19 and partner and support organisations on the ground to fight against COVID-19.

Q. Where do I find accurate information on the coronavirus outbreak

There are a number of sources of accurate and up-to-date information on the coronavirus outbreak such as the [World Health Organisation](#) and the [European Centre for Disease Prevention and Control](#). Health advice should be accessed from national authorities or your health provider.

With the volume of COVID-19 content on social media, always remember to check the source(s) for reliable information.

Q: Are there any vaccines for citizens or treatment options for patients with COVID-19?

There are no currently approved vaccines or therapeutics to prevent transmission of, or treat, the COVID-19 virus. However, approved treatments have been used to alleviate symptoms and address complications of patients. EFPIA members are working around the clock to find vaccines, diagnostics and treatments to use in the fight against coronavirus

There are several ongoing clinical trials (82 clinical trials planned or pending worldwide on 16 March 2020), with three already occurring in the [European Union](#).

Q. What is a vaccine? And how do they work?

¹ <https://www.who.int/news-room/q-a-detail/q-a-coronaviruses>

A vaccine is a biological preparation used to produce or improve immunity against a particular disease like COVID-19. By inoculating killed or weakened disease-causing microorganisms (or crucial fragments, products or derivatives) the production of antibodies is stimulated. If and when the immune system encounters the disease-causing microorganism, it then itself prevents the disease through reacting rapidly and effectively.

The human immune system is a system of biological structures and processes that protects us against diseases by recognising germs that enter the body as foreign invaders (a.k.a. pathogens). These are referred to as antigens, a term which stands for “antibody generator”. When antigens invade the human body, the immune system responds by producing protein substances called antibodies and highly specific cells that can fight the invading germs.

Immunity is the body’s successful defence against a pathogen. When a sufficient number of antibodies has been produced by the body to fight the disease, immunity results, providing protection against the disease for many months, for years or even for a lifetime. If a person later comes into contact with that same pathogen again, the immune system will be able to quickly produce the same type of antibodies preventing the disease from developing or decreasing its severity and eliminating the pathogen from the body. Through “immunological memory”, it is estimated that the immune system can remember or recognise and effectively combat hundreds of thousands, possibly millions, of different foreign organisms.

Vaccination involves the introduction of a limited quantity of a specific disease antigen into the human body stimulating the immune system just enough to produce the amount of antibodies needed while not causing the disease.

Q. How are vaccines developed?

Vaccine development is a complex and time-consuming process that differs from the development of conventional medicines. Indeed, vaccines are intended for use in healthy individuals as a preventive measure whereas conventional drugs are aimed at the treatment of a condition. Vaccine clinical trials focus on demonstrating efficacy and safety which implies that a higher number of subjects will be required than for traditional drug trials.

Before a vaccine is licensed and brought to the market, it undergoes a long and rigorous process of research, followed by many years of testing to comply with stringent regulatory requirements.

Q. How long does it take to develop a vaccines?

Normally, the period for vaccine development is 12 to 15 years.

Q. Why are some media stories reporting that vaccines could be available in around 1 year?

EFPIA medicine companies and vaccine developers have deep scientific knowledge gained from decades of experience with similar viruses such as MERS, SARS, influenza, HIV and Hepatitis C. This knowledge dramatically improves our likelihood of success in developing an effective vaccine and identifying existing treatments for those infected. EFPIA member companies are now working around the clock to use this knowledge and any likely vaccines or medicines in development can be used in the fight against COVID-19.

Q: Are biopharmaceutical companies developing treatments or vaccines to address the crisis?

Yes, there are significant efforts underway to diagnose, treat and prevent infections from the virus. Companies 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.

Others are researching vaccine candidates and undertaking inventories of research portfolio libraries to identify additional potential treatments for R&D. Companies are also exploring ways to leverage existing technologies that provide the ability to rapidly upscale production once a potential vaccine candidate is identified.

A practical example of this radical research collaboration in action is the [Innovative Medicines Initiative's Call 21](#). It brings together world-leading scientists and researchers from industry and academia to accelerate the production of diagnostics and therapies for use in the fight against coronavirus.

Q: What other ways are companies supporting the fight against COVID-19?

EFPIA member Companies are committing millions of euros in direct monetary and in-kind contributions to support organizations at the heart of the crisis who are able to have an immediate impact for infected patients and communities.

A variety of crucial supplies including advanced surgical equipment, antibiotics, disinfection equipment, vitamins, protective clothing, goggles, masks, gloves and more have also been donated. In addition, antibacterial medicines that are approved to treat secondary infections such as pneumonia are being donated. You can find a host of examples [here](#).

Q: Is biopharmaceutical industry collaborating or coordinating with government agencies?

Companies are collaborating with EU and global public health authorities including the European Commission, the European Medicines Agency, the Innovative Medicines Initiative, Member States and their authorities.

Q: What are the risks of drug shortage caused by the coronavirus?

From the latest information received from members by EFPIA, there is limited immediate risk that COVID-19 would impact manufacturing and supply of branded medicines in Europe in the short term.

With Europe now at the epicentre of the coronavirus pandemic, there are perpetual challenges in getting medicines to patients across Europe, challenges that EFPIA member companies are meeting head on. These include logistical issues where shipments of medicines, vaccines and semi-finished products across Europe are becoming increasingly difficult to organize. There are demand pressures on some treatments used to manage the symptoms of COVID-19, these pressures can be exacerbated by unilateral decisions by Member States. In addition, there can be supply challenges as a result of failure to manage 'panic' buying of prescription medicines at the pharmacy level. Another emerging issue is the reduction in air traffic leading to less capacity to move medicines and materials around Europe and beyond. Addressing this issue requires coordination between the European Commission, Governments, air carriers, logistics operators and industry to ensure that we can continue to produce and ship medicines to where they are needed.

Today (23 March 2020) stock levels of medicines and manufacturing cadence are being maintained. The situation remains fluid, a pandemic of this scale contains inevitable uncertainty, but at this point EFPIA members do not anticipate impacts to their supply chains unless disruption due to the COVID-19 outbreak is sustained over several months.

Members continually monitor their supply chains and contingency plans as well as liaising with the Commission, the European Medicines Agency (EMA), Member States and their Competent

Authorities to address issues as they arise with pragmatic approaches that put patient needs first. At the same time, researchers from across our member companies will continue the quest to find diagnostics, vaccines and treatments to address the crisis.