OPPI

Note on Novel Coronavirus (2019-nCoV) outbreak

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"***We need our collective knowledge, insight and experience to answer the questions we don't have answers to, and to identify the questions we may not even realize we need to ask***."

- Dr Tedros, Director General, World Health Organisation

The research-based pharmaceutical industry is fully supportive of efforts that will ensure the scientific community can respond quickly to the challenges the novel coronavirus (nCov-2019)presents. As a science-driven industry that aims to address some of the world's biggest health care challenges, the research-based pharmaceutical industry clearly has a role to play in developing new and improved medicines and vaccines to help respond to this epidemic. R&D biopharmaceutical companies with potentially relevant knowhow have teams of scientists checking their libraries of potential assets that could fight coronaviruses.

COVID-19

The COVID-19 virus is a new pathogen that is highly contagious, can spread quickly, and must be considered capable of causing enormous health, economic and societal impacts in any setting. It is not SARS and it is not influenza. Building scenarios and strategies only on the basis of well-known pathogens risks failing to exploit all possible measures to slow transmission of the COVID-19 virus, reduce disease and save lives.

For example, COVID-19 transmission in children appears to be limited compared with influenza, while the clinical picture differs from SARS. Such differences, while based on limited data, may be playing a role in the apparent efficacy of rigorously applied non-pharmaceutical, public health measures to interrupt chains of human-to- human transmission in a range of settings.

The COVID-19 virus is unique among human coronaviruses in its combination of high transmissibility, substantial fatal outcomes in some high-risk groups, and ability to cause huge societal and economic disruption. For planning purposes, it must be assumed that the global population is susceptible to this virus. As the animal origin of the COVID-19 virus is unknown at present, the risk of reintroduction into previously infected areas must be constantly considered.

China's experience strongly supports the efficacy and effectiveness of anchoring COVID19 readiness and rapid response plans in a thorough assessment of local risks and of utilizing a differentiated risk-based containment strategy to manage the outbreak in areas with no cases vs. sporadic cases vs. clusters of cases vs. community-level transmission. Such a strategy is essential for ensuring a sustainable approach while minimizing the socio-economic impact.

COVID-19 is spreading with astonishing speed; COVID-19 outbreaks in any setting have very serious consequences; and there is now strong evidence that non-pharmaceutical interventions can reduce and even interrupt transmission.

However, to reduce COVID-19 illness and death, near-term readiness planning must embrace the large-scale implementation of high-quality, non-pharmaceutical public health measures. These measures must fully incorporate immediate case detection and isolation, rigorous close contact tracing and monitoring/quarantine, and direct population/community engagement.

Studies can be prioritized in terms of the largest knowledge gaps that can be most rapidly addressed to have greatest immediate impact on response operations and patient management. This suggests prioritizing studies to identify risk factors for transmission in households, institutions and the community; convenience sampling for this virus in the population using existing surveillance systems; age-stratified sero-epidemiologic surveys; the
analysis of clinical case series; and cluster investigations.

Industry perspective

From our industry's perspective, there are three reasons to feel cautiously optimistic that the scientific community can respond quickly to the challenges this epidemic faces. Firstly, rapid access to the virus can speed up the process of kick starting the search for solutions, secondly, there is global recognition, funding and structures in place to share the burden of R&D. Last but not least, there are tried and tested sharing platforms in place for influenza that can be leveraged.

For example, the GISAID Initiative, set up twelve years ago has played an essential role in the sharing influenza virus sequences to help researchers understand how the viruses evolve, spread and potentially become pandemics among the WHO Collaborating Centers and National Influenza Centers. This open access platform, partly funded by the private sector, is going to play an important role in centralizing the collection of the novel coronavirus sequences and will be critical in speeding up the sharing of information among scientists as well as public health authorities. This includes streamlining the use of existing networks to improve response, such as Global Initiative on Sharing All Influenza Data / sharing data & clinical trials outcomes.

The speedy sharing of the 2019_nCoV pathogen sequence, followed by the declaration of the novel coronavirus as an international emergency and the convening of an R&D Forum, should further galvanise global collaboration with the private and public sectors as required for timely development of vaccines and treatments. R&D biopharmaceutical companies are already engaging with existing networks such as CEPI (Coalition for Epidemic Preparedness Innovations) and Europe's IMI (Innovative Medicines Initiative). In addition to R&D efforts, many research-based biopharmaceutical companies with a presence in China are donating funds, medicines, diagnostics and medical protective products.

Accelerating research and innovation for COVID-19

Going forwards, it will be crucial that the WHO continue to involve researchers, government, industry and coordinate efforts to help make informed decisions on how best to prioritize and collaborate on a shared research agenda for this virus. Speed and coordination, evidence-based response, involvement of those who already have the knowledge and expertise (in particular scientists on the front line in China), avoiding duplication, are all going to be paramount to ensure that lives will be saved and the spread of virus would stemmed and if possible be stopped.

The longer term research agenda should not detract taking the necessary immediate steps to contain the COVID-19 outbreak and support first-line responders while vaccines are being developed & therapeutics are researched. The declaration of the novel coronavirus as an international emergency signals the fundamental need for epidemic preparedness. This should further galvanise global

collaboration with the private and public sector required for timely development of vaccines and treatments.

As a science-driven industry that aims to address some of the world's biggest health care challenges, the research-based pharmaceutical industry clearly has a role to play in developing new and improved medicines and vaccines to help respond to this epidemic. All information on the member companies involvement in countering the COVID-19 can be accessed on this link: https://www.ifpma.org/wp-content/uploads/2020/02/IFPMA-Members-involvement-in-countering-the-novel-coronavirus-2019-nCoV.pdf

Scientists checking libraries of assets - From the outset of the epidemic, member companies have reviewed their drug and vaccine portfolios to see if there is any research that could be of help. This analysis involved scientists assessing the companies' libraries for potentially useful assets that could help with the development of new or repurposed treatments or vaccines to fight against the novel coronavirus.

Relevant assets include diagnostics and biomarkers, approved therapies or compounds in development which could be repurposed for use in treating patients with the coronavirus. In addition, member companies are undertaking to identify any ACE inhibitors, protease inhibitors or immunotherapies that could be relevant in the context of novel coronavirus.

Vaccine and treatment development underway:

Treatment Development

As of March 2020, there are at least: 14 companies with a medicine in early phase research, 4 companies with a medicine in Phase I of development and 3 in Phase II, and one company has a medicine in Phase III trials. Listed below is a snapshot of the different areas of research focused on finding a new treatment.

- AbbVie announced it is partnering with global authorities to determine the effectiveness of HIV drugs in treating COVID-19. AbbVie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention, National Institutes of Health and the Biomedical Advanced Research and Development Authority to coordinate these efforts.
- Eli Lilly and AbCellera (Canadian biotech firm) have entered into an agreement to codevelop antibody products for the treatment and prevention of COVID-19. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.
- EFPIA is working with the Innovative Medicines Initiative (IMI) on potential actions to support collaborative research programs in order to fast-track the development of therapeutics.
- Gilead is working with the Chinese health authorities to set up clinical trials to test the effectiveness of an experimental antiviral (remdesivir) aimed at treating Ebola and SARS.
- Johnson & Johnson, in partnership with the Rega Institute for Medical Research, University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19 that could contribute to providing immediate relief to the current outbreak.

- Pfizer announced that it completed a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses similar to the one causing COVID-19 in cultured cells. Pfizer is engaging with a third party to screen these compounds under an accelerated timeline and expects to have the results back by the end of March.
- Pfizer also outlined a detailed 5-point action plan to battle COVID-19. The plan includes a commitment to sharing its clinical development and regulatory expertise to support other smaller biotech companies that are screening compounds or existing therapies for activity against the virus causing COVID-19.
- Regeneron Pharmaceuticals announced an expanded agreement with the U.S. Department of Health and Human Services (HHS) to develop new treatments combating the novel coronavirus
- Regeneron Pharmaceuticals and Sanofi SA are racing to launch clinical trials exploring whether their arthritis drug could treat symptoms of the novel coronavirus infections.

- Roche's Actemra was approved by China on March 5 to treat Covid-19 patients with lung complications. Roche has donated nearly $2m-worth of Actemra to China to help the country manage the COVID-19 outbreak". Actemra has been on the European market since 2010 for treatment of several kinds of arthritis.

- Takeda announced that it is initiating the development of a drug to treat people infected with the novel coronavirus. The experimental drug would be derived from the blood of coronavirus patients who have recovered from the respiratory disease. In parallel, Takeda is also exploring whether currently marketed and pipeline products may be an effective treatment option for infected patients.

Vaccine development

While vaccines and small molecule treatments are approved through different regulatory pathways and their development programs vary, they generally both must complete three phases of clinical trials. However, there are differences in the data required to show the safety of vaccines and the size of clinical trials for vaccines relative to small molecules.

Experts are hoping it will take as little as 12 to 18 months before there is a vaccine available. This is a best-case estimate that assumes one or two of the first few vaccines that enter development will be successful. Typically, only approximately one in ten experimental vaccines make it all the way through to regulatory approval. Therefore, the more companies taking different approaches to find a vaccine, the more "shots on goal" and significantly greater chances of success.

- CEPI and GSK will collaborate to help the global effort to develop a vaccine for the novel coronavirus. GSK is making its adjuvant technology available to support rapid development of candidate vaccines and is working with The University of Queensland, Australia.
- CSL Limited partnered with the University of Queensland's COVID-19 vaccine development program. They will provide technical expertise as well as a donation of Seqirus' proprietary adjuvant technology, MF59®, to their pre-clinical development program.
- GSK announced it would partner with the Chinese biotech company Clover Biopharmaceuticals. Under the partnership, GSK will provide Clover with its proprietary adjuvants – compounds that enhance the effectiveness of vaccines

- Johnson & Johnson expanded its collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of U.S. Department of Health & Human Services (HHS), to accelerate development of a potential novel coronavirus vaccine.
- Pfizer and BioNTech have entered into a partnership to jointly develop BioNTech's mRNA-based vaccine candidate BNT162 to prevent COVID-19 infection. The collaboration aims to accelerate global development of BNT162, which is expected to enter clinical testing by the end of April 2020.
- Sanofi announces it will work with the U.S. Department of Health & Human Services (HHS) HHS to develop a coronavirus vaccine.

Diagnostics

Rolling out diagnostics to detect whether patients are genuinely infected with the new coronavirus is a key step in preventing or slowing its spread. However, the rapid spread of COVID-19 has drastically increased the demand for testing kits around the world, especially in the United States and Europe, and governments are trying to ramp up their testing capacities.

- Roche announced that the FDA issued an Emergency Use Authorization for its diagnostic kit cobas® SARS-CoV-2 Test, advancing coronavirus testing to meet urgent medical needs. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity.
- Takeda is partnering with public entities and other pharmaceutical companies through the Innovative Medicines Initiative (IMI) in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19 as well as inhibitors to help prevent future outbreaks.

Source:https://www.ifpma.org/subtopics/novel-coronavirus-covid-19-industrys-rd-efforts/?parentid=268

Pharmaceutical manufacturing supply chain

OPPI and its member companies are monitoring the coronavirus situation, globally. Member companies are consistently and diligently monitoring the supply chain for medicines both at their own sites and for their suppliers globally. Currently, member companies have inventory in India which will cover close to three months. At this moment, there is no need to panic.

Recent News from India

Helpline Number for corona-virus : +91-11-23978046
Helpline Email ID for corona-virus : ncov2019[at]gmail[dot]com

Latest updates are available on the link provided by Ministry of Health: https://www.mohfw.gov.in/

OPPI will continue to monitor the situation as it develops and will update this information accordingly. Last updated: 17 March 2020

Some useful links

- WHO:
  https://www.who.int/

- John Hopkins University: https://qz.com/1814380/interactive-map-from-johns-hopkins-shows-coronavirus-in-real-time/
- OPPI: https://www.indiaoppi.com/wp-content/uploads/2020/03/Revised_Corona_ad_Eng.pdf
- IFPMA https://www.ifpma.org/subtopics/novel-coronavirus-covid-19/?parentid=268