IFPMA Members involvement in countering the novel coronavirus (2019-nCoV)

The spread of the novel coronavirus epidemic is a major public health threat for all affected countries; and is of particular concern for those countries with weaker health systems who could be disproportionately impacted.

The R&D biopharmaceutical industry has welcomed the decision taken by the World Health Organization (WHO) on 30 January 2020 (IFPMA statement) to declare a public health emergency of international concern and reflects the serious nature of this public health threat. The industry is fully supportive of efforts that will ensure the scientific community can respond quickly to the challenges this epidemic faces. 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.

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.

Sharing the novel coronavirus (2019-nCoV) virus sequence

The rapid virus sequencing by the scientific community has allowed researchers to characterize and begin to understand the new threat posed by novel coronavirus (2019-nCoV). "Open Access" data sharing channels are the backbone to securing a response capacity, and have proven their worth with influenza networks.

The Global Initiative on Sharing All Influenza Data / GISAID Initiative, an open access platform partly funded by the private sector, has an important role to play in sharing of the first genome sequences of the novel coronavirus, and centralizing the collection of the novel coronavirus sequences, which is critical in speeding up the sharing of information among scientists as well as public health authorities.

Accelerating research and innovation for novel coronavirus (2019-nCoV)

The R&D biopharmaceutical industry (IFPMA and its members) is deeply concerned by the novel coronavirus (2019-nCoV acute respiratory disease) epidemic. Outbreaks of novel virus infections for which there is no known effective antiviral therapy present a serious threat to public health.

Currently, there is a focus on prevention and controlling the spread of this novel coronavirus, as there are no specific treatment options available for this particular strain of the virus.

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.

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:

- 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.
- Chinese regulators have recommended an HIV treatment (lopinavir/ritonavirus) development by AbbVie as a potentially effective drug for treatment of the novel coronavirus and clinical trials are currently being set up.
- Johnson & Johnson has announced that it has begun to develop a vaccine for the novel coronavirus.
- Regeneron is development a treatment for the novel coronavirus using a class of drug that has boosted survival rates among Ebola patients (REGN-EB3 – a cocktail of three monoclonal antibodies).

Companies & associations engaging in R&D collaboration – R&D biopharmaceutical companies are part of a wider research community which is collaborating to fast-track the development of therapeutics and diagnostics for the coronavirus to complement the ongoing global activities on novel coronavirus vaccines.

Collaborating in this way has the potential to accelerate development of resources to tackle this outbreak. It enables networks of centres of excellence that can deliver real impact and create a preparedness infrastructure which can be mobilized for future outbreaks.

R&D collaboration underway:

- 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.
- IFPMA is contributing funding to ensure the Global Initiative on Sharing All Influenza Data / GISAID Initiative has additional resources to support sharing the new coronavirus sequence.
- EFPIA is working with the Innovative Medicines Initiative (IMI) on potential actions to support the collaborative research programs in order to fast-track the development of therapeutics.

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Support for public health emergency in China

Across the R&D-based biopharmaceutical industry, the first concern is for those affected by the recent outbreak of the novel coronavirus (nCov-2019).

In addition to monitoring the spread of the coronavirus in China, IFPMA and its member companies are working with their teams on the ground, and with the Chinese authorities to ensure people can get access to screening and healthcare. They are constantly reviewing how we can be most supportive during this outbreak; including ensuring that patients can continue to have access to the medicines they need.

IFPMA member companies with operations in China are responding to the Chinese government's calls for drug makers to maintain or even increase their supplies to help the country throughout this public health crisis.

Member companies are consistently and diligently monitoring the supply chain for medicines both at their own sites and for their suppliers globally. This activity is an integral part of a company's business continuity plan that is set up to deal with exactly these kinds of scenarios. These plans include critical inventory at distribution centers outside high-risk areas as well as working with external suppliers.

Providing support on the ground:

- Johnson & Johnson has provided boxes containing laboratory-based investigations to the Chinese Centre for Disease and Prevention, which includes drug-screening for antiviral properties against the novel coronavirus
- Pfizer has made cash contributions to its global NGO partners who have shipped supplies to hospitals in China.
- Roche donated diagnostics tests, medical supplies and financial support.

Pharmaceutical manufacturing supply chain

IFPMA and its member companies are monitoring the coronavirus situation in China closely.

Currently, member companies are not aware of any near-term impacts on the availability of medicines and vaccines. The companies are continuously monitoring and proactively handling the situation as it's developing and do not expect any long-term impact on the availability of medicines and vaccines, unless disruption due to the novel coronavirus outbreak is sustained over the next several months.

R&D biopharmaceutical companies are working proactively to prevent and mitigate potential shortages through close coordination with national regulatory authorities and other global stakeholders, including the World Health Organization.

IFPMA will continue to monitor the situation as it develops and will update this information accordingly.