IFPMA Covid-19 Update - 1 May

Top news:

- COVID-19 remains a public health emergency of international concern, as WHO accepts Emergency Committee's recommendations
- WHO and European Investment Bank sign memorandum of understanding to strengthen efforts to combat COVID-19, malaria and antimicrobial resistance.
- Moderna enters manufacturing deal with Swiss firm Lonza, aiming for a billion COVID-19 shots a year
- African CDC chief raises concerns over lack of testing on the continent

GLOBAL RESPONSE

- **UN**: UN chief calls for 'solidarity, unity and hope' in battling COVID-19 pandemic. António Guterres, UN Secretary-General, ran through the multiple ways the Organization is working to combat the virus on the ground and said that a new UN policy report would be launched today to advise how best to protect older persons, along with an analysis of COVID-19 consequences for persons with disabilities. He maintained that a smart recovery from COVID-19 would help steer the world onto a "safer, healthier, more sustainable and inclusive path".
- **WHO**: WHO and EIB strengthen efforts to combat COVID-19 and build resilient health systems to face future pandemics. The work will focus on 5 areas of work, including COVID-19, AMR, UHC (more below under WHO).

ACCESS AND IP

- **BMJ**: Covid-19 vaccines: global access means having enough, Seth Berkley, CEO, GAVI, argues that to ensure equitable access to a COVID-19 vaccine, one solution would be a covid-19 Advance Market Commitment (AMC), to make sure that when vaccines are licensed the capacity is in place to rapidly manufacture and distribute the billions of doses needed. The ultimate aim of a covid-19 vaccine AMC would be to increase the chances of success, accelerating the availability of the most suitable candidate vaccines by sharing the risks associated with investing in some vaccines that may end up not making it. The best way is if there is a global political commitment to set aside national vaccine strategies and treat covid-19 vaccines as a global public good.
- **Business Day**: Gilead is likely to announce voluntary license agreements with several Indian manufacturers to allow them to produce generic versions of remdesivir. Among the companies that could sign partnership deals are Cipla and Dr. Reddy's Laboratories. Indian Council of Medical Research (ICMR) had hinted that if the medicine proves effective, and if cost effective versions of the medicine can be made available through Indian generic companies, then it can be considered for treating COVID-19 patients in India too.

R&D AND CLINICAL TRIALS

- **CGTN**: Over 130 virus therapies under investigations, says pharma group. Unprecedented efforts to collaborate across the pharmaceutical industry have significantly accelerated the search for safe and effective treatments for the novel coronavirus, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) said.
- **New York Times**: How long will a vaccine really take? In this opinion piece, the NYT asked vaccine experts how we could condense the timeline and get a vaccine in the next few months instead of years. The article visually summarizes which companies are working on

clinical trials, the probability of success at each phase of research and how factories are being prepped now.

- **FT**: Dozens of existing drugs being tested as possible virus treatments. Researchers from University of California, San Francisco, and their colleagues in New York and Paris, have narrowed down an initial list of 69 potential drugs that could be repurposed to treat coronavirus, including over-the-counter medicines for allergies and coughs and a cancer treatment, in a pioneering project examining how the virus interacts with the human body.
- **Lancet:** Considering BCG vaccination to reduce the impact of COVID-19. Randomised controlled trials are underway in the Netherlands and Australia to assess whether the BCG vaccine reduces the incidence and severity of COVID-19 in healthcare workers. However, until these trials are complete, Dr Tedros, WHO DG, and the lead investigators of these trials, lists reasons why it is important to adhere to WHO's recommendation that the BCG vaccine is used for COVID-19 only in randomised controlled trials.
- **FierceBiotech**: Retrospective study from China finds that COVID-19 patients had remarkably low T-cell counts in their blood and had sky-high levels of some pro-inflammatory cytokines such as IL-6—which Roche's Actemra targets. Actemra has previously shown promise at controlling potentially life-threatening cytokine storm in COVID-19 patients in China and France, and Roche is running a large phase 3 to confirm its effectiveness in treating patients with COVID-19.

MANUFACTURING & SUPPLY

- **Bloomberg**: Moderna and Lonza Group sign deal for 1 Billion Covid-19 doses a year: the Boston-based mRNA player, which has the most advanced US vaccine in the clinic, announced a deal with Lonza creating a 10-year alliance on vaccine production. The Swiss chemical and pharmaceutical company will ramp up output of the proposed vaccine, with the first batches to be produced in the U.S. in July.
- **STAT News**: Gilead faces remdesivir production challenges. After preliminary positive results of a U.S. trial of remdesivir, Gilead Sciences reportedly now faces the challenge of scaling up production of a drug the whole world may want, STAT explains. But some of the substances used to make remdesivir are scarce, and the company wants to be careful not to disrupt its own supply chain.
- **FiercePharma:** COVID-19 restrictions send generic drug shipping costs through the roof, as average shipping costs have jumped by 224% as the pandemic added new kinks to the global drug supply chain, a survey from the Association for Accessible Medicines (AAM) found. The article also says a potent mixture of patient and channel stockpiling and manufacturer "allocation" measures will drive generics pricing upward in the short term, and could have a "lasting positive impact" on the industry in future quarters.

REGULATORY

- **EndPoints**: After NIH trial, EMA begins rolling review for remdesivir, setting up potential authorizations in US and Europe. A day after the NIH released positive results from their trial testing remdesivir in COVID-19, the EMA has announced the start of a rolling review process for the drug. With an FDA decision expected to arrive in the coming days, the news sets the stage for the Gilead antiviral to become the standard-of-care for the deadly virus in both the US and Europe.
- **FiercePharma**: Indian pharmas call on FDA to perform 'virtual' facility checks during COVID-19 inspection lockdown in order to "ensure the continuous supply of much-needed drugs in the United States," according to a letter from the Indian Pharmaceutical Alliance

(IPA). Among the alliance's members are India's largest drug manufacturers, including Cipla, Cadila, Dr. Reddy's Laboratories and Abbott India.

IMPACT ON BIOPHARMACEUTICAL INDUSTRY RESULTS

- **PharmaPhorum**: Merck & Co has lowered its full-year revenue and earnings estimates because of the impact of COVID-19 on its business, which is focused on products administered in hospitals. The company's business is heavily reliant on its big cancer blockbuster Keytruda (pembrolizumab), which is likely to be disrupted by the impact of the pandemic. Fewer patients will be able to visit their hospitals or clinics to receive their drugs, which could impact on sales in the coming months.
- **PharmaPhorum:** AstraZeneca maintains 2020 guidance as Q1 sales grow despite pandemic. China has been an important market for AstraZeneca and despite the pandemic revenues continued to rise there during the quarter. AstraZeneca is also testing two of its already-approved drugs as potential treatments for COVID-19.
- **PharmaPhorum:** GSK starts 2020 on a high, but warns of tougher times ahead. GlaxoSmithKline saw its sales surge in the first three months of the year, with the coronavirus pandemic giving its pharma and consumer health units a lift and vaccines emerging largely unscathed. GSK chief executive Emma Walmsley said a slowdown in vaccine sales is expected for the second quarter, but whether that continues throughout the remainder of the year will depend on how long it takes to return to some degree of normality.

COVID-19 & AFRICA

- AllAfrica: African Union Raises U.S.$25 Million for COVID-19 Response Fund and an additional $36.5 million to the Africa Centres for Disease Control and Prevention. The continental body also set out an intensive lobbying of the international community, including the international financial institutions, for a comprehensive, robust economic stimulus package for Africa.
- Devex: Low coronavirus testing in Africa leads to blind spots. With less than 500 000 people test – on a continent of 1.3 billion people, access to diagnostics is one of the three critical areas the Africa CDC chief identified the region needs right now, followed by personal protective equipment and commodities for case management, such as ventilators and oxygen equipment. Although limited, efforts are also underway in Africa to test certain candidate therapeutics against COVID-19. There are about 18 clinical trials on this in Africa, most of them in Egypt.
- ReliefWeb: African Union to distribute more COVID19 supplies to its member states after receiving the third consignment from the Jack Ma Foundation

WHO - COVID-19 UPDATE, 1 May

Statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of COVID-19 here

- Dr Tedros reconvened the Emergency Committee under the International Health Regulations to review the evolution of the COVID-19 pandemic. The Emergency Committee unanimously agreed that the outbreak still consists a public health emergency of international concern.

Statement made by Dr Tedros here

- Dr Tedros announces a deepening our the WHO's relationship with the European Union, signing an agreement with the EIB on five main areas of work:
    - A new EU Malaria Fund to address market failures in developing more effective vaccines, drugs and diagnostics for malaria
    - Working on a fund to foster the development of new innovative antibacterial treatments– investment in antibiotic development has continued to decline. "Very few new antibiotics are in the pipeline. Most of them offer little benefit over existing treatments, and very few target the most critical resistant bacteria", Tedros says. WHO and EIB now are in discussions with potential investors and other stakeholders on this initiative.
    - Strengthen primary health care and build resilient health systems, working to urgently to invest in health infrastructure & health workers in 10 countries in Africa & the Middle East
    - Exploring how the EIB could support the COVID-19 supply chain system
    - Study market failures in other areas of public health to examine how innovative financing could help overcome investment barriers and increase access to lifesaving products and services