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Tumor-Agnostic First In England As NICE Reverses Vitrakvi Rejection

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The UK health technology assessment institute, NICE, has reversed its preliminary rejection of Bayer's Vitrakvi (larotrectinib), making the cancer drug the first histology-independent treatment to be made available for use on England's National Health Service.

NICE changed its mind about the drug after Bayer dropped the price for the product.

Vitrakvi will be made available to patients via England's Cancer Drugs Fund for treating advanced neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumors, the institute said in a final appraisal document (FAD) published on 21 April. The CDF provides interim funding for promising new treatments, via managed access arrangements, while further evidence is collected to address clinical uncertainty around a product.

As noted by NICE, histology independent medicines, like Vitrakvi, are "an exciting new development in the treatment of cancer." These cutting-edge therapies can be used to treat tumors with often rare genetic mutations regardless of where in the body the tumor originated.

The NHS added that that Vitrakvi was a "game-changing" cancer therapy that could be used to treat hundreds of people a year. The product "can be used against a wide range of cancers and could offer hope to patients with rare forms of the disease that may previously have been untreatable," it said.

NICE's FAD recommends Vitrakvi for the treatment of advanced NTRK fusion-positive solid tumors in adult and pediatric patients, if the disease is locally advanced, metastatic or surgery could cause severe health problems, and if they have no satisfactory treatment options. According to the NHS, NTRK gene fusions occur in less than 1% of the common solid tumors such as lung, colorectal and breast cancers and are much more common in certain rare cancers.

ADDRESSING CLINICAL UNCERTAINTIES

NICE initially turned Vitrakvi down in January, after deciding that the price Bayer was asking for the drug was too high for it to be considered cost-effective. *(Also see "Bayer's Efforts To Pioneer Tumor-Agnostic Market In Europe Held Back" - Scrip, 17 Jan, 2020.)*

There was also uncertainty in the clinical evidence as Vitrakvi has not been compared with other treatments, the institute said.

"The company has since submitted a new price which now means patients can access larotrectinib through the CDF while further data can be collected to address some of the clinical uncertainties," NICE said.

Staff at NICE have previously recognized that there are challenges in assessing the clinical and cost effectiveness of histology-independent treatments – which are also known as tissue-, tumor- or site-agnostic cancer drugs. In a study published last year,

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Part D Plans Want A Preferred Specialty Tier, But Not The Limit To Generics And Biosimilars
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Payers say Part D plans should have flexibility in determining which drugs to place on a preferred specialty tier, while manufacturers oppose the notion of a second specialty tier altogether.

New Filings At The EMA
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DOJ OKs Supply Chain 'Control Tower' Collaboration Against COVID-19 Drug Shortages
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AmerisourceBergen, McKesson, Cardinal and others can help FEMA deliver hydroxychloroquine and manage critical-drugs supply chain without running afoul of US antitrust law.

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they said that post-authorization data collection would be needed. *(Also see "Site-Agnostic Cancer Drugs: HTAs Will Need Post-Approval Data" - Pink Sheet, 3 Jan, 2020.)*

The clinical evidence for histology independent medicines "is usually based on extremely small sample sizes, requiring novel approaches to testing them in clinical trials and translation into models of assessment for potential value in NHS practice," Meindert Boysen, deputy chief executive and director of the Centre for Health Technology Evaluation at NICE, said in a statement today. "We're therefore pleased to be able to recommend larotrectinib for use in the Cancer Drugs Fund while more data is collected on its clinical effectiveness," Boysen added.

Bayer welcomed NICE's recommendation, saying it would "allow clinicians, for the first time in England, the opportunity to offer adult and pediatric patients with TRK fusion driven cancer a therapy that targets the specific driver of their disease." TRK fusion driven cancers can occur all around the body, commonly in rare tumor types with potentially unsatisfactory treatment options, such as surgery, chemotherapy and radiotherapy, the company observed.

Bayer noted that histology-independent treatments had been "called out by NHS England Chief Executive Simon Stevens at the 2019 NHS annual conference as a class of cancer medicines to be fast-tracked in a similar manner as CAR-T cell cancer therapies."

The charity, Sarcoma UK, also welcomed NICE's decision. "With novel treatments few and far between, larotrectinib is a welcome addition to the available therapies for sarcoma as well as to treat other tumor types, like lung and colorectal cancer," said the organization's policy and public affairs manager, Bradley Price.

CONFIDENTIAL DISCOUNT

The cost of Vitrakvi is £5,000 ($6,157) per 100ml vial of 20mg per ml oral solution (excluding VAT; £15,000 per 30-day supply), although Bayer is making the drug available to the NHS with a discount that is confidential. According to NICE's FAD, the drug will be available as hard capsules (25mg and 100mg) to be taken orally twice daily. Bayer's commercial arrangement comprises a simple discount patient access scheme and a managed access agreement including a commercial access agreement, the institute noted.

NICE's FAD for Vitrakvi has now been sent to consultees who have until 6 May to consider whether they wish to appeal against it and/or notify the institute of any factual errors. The expected final publication date is 27 May.

NICE APPRAISING RIVAL PRODUCT

Vitrakvi received a conditional approval in the EU in September 2019, for children and adults with TRK fusion driven cancer.

The product is also approved in the US, Brazil and Canada. Bayer said that other filings in other regions are underway or planned. In January, NICE said it was also appraising another histology-independent treatment, entrectinib, made by Roche. Entrectinib, which is approved in the US under the brand name Rozlytrek, is not yet authorized in the EU. A marketing application for the product was accepted for review by the European Medicines Agency early last year and is still being evaluated. *(Also see "New Filings At The EMA" - Pink Sheet, 17 Apr, 2020.)*

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REAL-WORLD EVIDENCE ON COVID-19:
US FDA Approaching With 'Sense Of Urgency'

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The COVID-19 pandemic is forcing the US Food and Drug Administration to step outside its comfort zone when it comes to using real-world evidence to inform rapid regulatory decision-making and clinical trial design. This experience could have a potentially lasting and positive impact on the agency's view of the utility of RWE to support – or even guide – drug approvals and labeling expansions beyond the context of the current public health emergency.

The agency is trying to leverage existing real-world data sources, such as electronic health records, to quickly assess the impact of potential therapeutic approaches as well as the downstream effects of the disease itself, Principal Deputy Commissioner Amy Abernethy told a webinar sponsored by the Duke-Margolis Center for Health Policy on 20 April.

"Within the context of COVID-19, we've got this urgency to learn what we can as soon as we can, and that means that we need to be learning from the patients that are receiving care right now and trying to understand how do we apply that as quickly as possible," Abernethy said.

> "We're really in the setting where we need to figure it out right now and acknowledge that this may take us out of our comfort zone."
> – FDA's Amy Abernethy

"It certainly takes us out of our comfort zone at FDA, where we usually contemplate very careful work that has been carefully thought through and vetted, and we've also really thought through the precedent of what happens when we make a decision on real-world data," she said. However, in the context of COVID-19, "we're really in the setting where we need to figure it out right now and acknowledge that this may take us out of our comfort zone."

FROM STEP-WISE APPROACH TO A 'SENSE OF URGENCY'

With its release of a real-world evidence framework in December 2018 and initiation of numerous demonstration projects, the agency has taken a step-wise approach to exploring how RWE can be used in the drug regulatory context. *(Also see "Real-World Evidence: US FDA Framework Emphasizes Data Fitness And Study Quality" - Pink Sheet, 9 Dec, 2018.)(Also see "RWE: Comparators, Therapeutic Area May Be Key For Trial Replication" - Pink Sheet, 14 Oct, 2019.)*

Yet, the agency has remained cautious about the utility of RWE, particularly from observational studies, to support efficacy claims given concerns about data quality and reliability, methodological issues and transparency. *(Also see "Real-World Evidence: Sponsors Look To US FDA Drug Reviews For Potential Pitfalls" - Pink Sheet, 7 Oct, 2019.)*

However, the morbidity and mortality resulting from the SARS-CoV-2 virus could mark a turning point in how the FDA approaches RWE.

In response to questions from the *Pink Sheet*, the FDA said the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are using existing RWD sources and initiatives to assist with COVID-19, while the Office of the Commissioner is coordinating agency-wide initiatives to develop novel data and analytical solutions to address urgent questions related to the disease.

In the postmarketing space, the FDA is using RWD for COVID-19 natural history, drug use and shortages, and treatment impact studies through the Sentinel System of distributed data networks. In addition, the FDA is working with the Centers for Medicare and Medicaid Services to apply rapid analysis of Medicare claims data to support the agency's mission.

The agency also pointed to the CURE ID app as enabling clinicians to share their real-world experiences treating patients with COVID-19. Although there was only limited use of the app for reports on the novel coronavirus a month ago, activity has since picked up. *(Also see "Coronavirus Hasn't Sparked CURE ID Physician Social Network Interest" - Pink Sheet, 17 Mar, 2020.)* As of 21 April, there were 23 case reports, 77 discussion posts and 323 clinical trials listed on the site.

Abernethy said the agency is approaching RWE on COVID-19 "with a sense of urgency"

The pandemic is "a story that keeps changing," she said. "So rather than sit around and wait until we learn how to use RWE and make some of the hard decisions, one of the approaches that we've taken right now is to start learning from the data that are currently available, and what does that teach us about what decisions we can confidently make with the data that are available as well as what do we need to do in the future."

THREE BUCKETS OF QUESTIONS

Abernethy said the agency is looking to RWE to answer three buckets of critical questions (including epidemiological, treatment, safety and operational) related to COVID-19:

- Questions that can be answered within two weeks because the data are available;
- Questions that can be answered within three to 12 weeks with available data that require some clean up or new analytic techniques; and
- Questions that are going to take more than three months to answer.

"By dividing the questions in that way, what it's allowed us to do is figure out what data sources are already out there and how can we start to put them to bear, and also figure out how do we practice answering the questions," she said.

Having a list a questions matters because it tells the agency what variables are needed and what kind of work needs to be done, she said. For instance, there needs to be agreement on common data elements in RWD sources, and these same data elements should be incorporated into clinical trials to enable a future comparison between the RWE and traditional clinical trial evidence, she said.

REAGAN-UDALL STEPS UP

Identifying key questions and core data elements is at the heart of a new initiative launched by the Reagan-Udall Foundation and Friends of Cancer Research.

The COVID-19 Evidence Accelerator provides a venue for major data organizations, government and academic researchers, and health systems to gather and design queries that can be quickly turned around and their results shared.

"Since the beginning of the pandemic, data scientists around

the country have been engaged in an intense effort to capture real-world data and rapidly deploy data analytics to help answer key questions related to the management of COVID-19 patients," the Foundation said in announcing the program. "While over time each of these individual efforts will likely develop into valuable insights, by banding together we can collectively accelerate and maximize the utility of this information in the near term."

> "It's not a true definitive trial, but it just gives you a kernel of knowledge to say are these things actually working the way you hope they are, or are they not and should we be looking in a different direction." – Cigna's Steve Miller

The group is developing a set of common data elements that can be uniformly embedded into data collection efforts to allow for rapid aggregation and analysis.

THE 'BUBBLING UP' EFFECT

The FDA has been trying to organize different data streams – such as through the Sentinel network, pharmaceutical companies and other data holders – into a series of critical categories "where ultimately the results then bubble up and get merged together in ways that we haven't historically thought about," Abernethy said.

"What we've been thinking about is how do we bubble up the information coming from all of these different areas and start to put it together to look for consistent findings that provide enough signal that we should get it" to the White House Coronavirus Task Force, the Centers for Disease Control and Prevention and the National Institutes of Health, she said.

Those findings also will inform the next set of critical questions that needs to be answered.

"I think part of the challenge here is recognizing that the questions are going to keep coming, and so we not only have to develop systems to answer those questions but also systems to rapidly say here's the next thing we need to know," she said.

HYDROXYCHLOROQUINE AS A RWE PLATFORM

The widespread use of the antimalarial drugs hydroxychloroquine and chloroquine as potential therapeutic agents for COVID-19 has provided a jumping off point for various RWE initiatives.

"We've used this critical question around hydroxychloroquine as what I call the platform for figuring it out," Abernethy said. "Practically speaking, hydroxychloroquine is being prescribed by many physicians in America outside the context of a clinical trial. So that means the patients are receiving hydroxychloroquine or not, and their care is being picked up within the electronic health record."

Querying different datasets about treatment patterns, safety concerns and potential effects with hydroxychloroquine "will teach us what datasets make that possible, how can we standardize the questions in the common data elements, what results do we find reliable and compelling enough, and also replicable enough against different datasets, that we can actually answer potentially questions around hydroxychloroquine with confidence but also then use that same platform approach for other questions," Abernethy said.

The use of hydroxychloroquine with or without azithromycin versus control among hospitalized COVID-19 patients is the focus of the first parallel analysis project by Reagan-Udall's COVID-19 Evidence Accelerator. This project will involve collaborators repeating analyses in parallel, using different analytical techniques and data sources, to characterize: the COVID-19 patient populations treated with the drugs; nature of the treatment; safety signals; comparative effectiveness on key outcomes; potential predictors of treatment safety and effectiveness; and validation of a COVID-19 risk stratification score.

Payers also are turning to RWD to probe questions about the utility of hydroxychloroquine. Steve Miller, chief clinical officer at Cigna Corp., told the Duke webinar that payers are pooling their claims data to look at off-label use of hydroxychloroquine, chloroquine and other approved drugs that may have utility in treating COVID-19.

For example, insurers are using a case-controlled approach to look at whether hydroxychloroquine provides a prophylactic effect against COVID-19 among rheumatoid arthritis and lupus patients who were already using the drug to treat their underlying conditions.

"It's not a true definitive trial, but it just gives you a kernel of knowledge to say are these things actually working the way you hope they are, or are they not and should we be looking in a different direction," Miller said.

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Sarah Karlin-Smith contributed to this story.

NIH Partnership To Pick COVID-19 Therapeutics For Clinical Trials; Results Anticipated By Summer

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A public-private partnership launched by the National Institutes of Health is evaluating promising COVID-19 therapeutic candidates to come up with a short list of those to test in existing clinical trial networks.

NIH announced the partnership, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTV), on 17 April. It includes 16 biopharmaceutical companies, NIH, the US Centers for Disease Control and Prevention, the Office of the Assistant Secretary of Preparedness and Response in the Department of Health and Human Services, the US Food and Drug Administration, and the European Medicines Agency.

At a same day press briefing, NIH Director Francis Collins said the collaboration emerged from a 3 April meeting with the R&D heads of the largest pharmaceutical companies and government leaders. The industry members of the partnership include GlaxoSmithKline PLC, Johnson & Johnson, Merck & Co. Inc., Novartis AG, Pfizer Inc. and Sanofi. (*See list.*)

While companies have established other consortiums to work together on accelerating the development of COVID-19 therapeutics and vaccines, the NIH initiative appears to be broader in scope and include more government involvement.

Collins said there has been a need to develop a pathway to get promising compounds prioritized and into clinical trials. "I have asked the group to do so in such a fashion that by the summertime, let's say June or July, we would have trial results beginning to appear" that would show which compounds are actually working, he said.

LATE PHASE THERAPEUTICS, REPURPOSED MARKETED DRUGS

The partnership has formed four working groups: a preclinical group to standardize and share preclinical evaluation methods; a group to evaluate and prioritize therapeutic candidates to move into clinical trials; a group to connect existing networks of clinical trials to build capacity; and a group to advance vaccine development.

Biopharma Teams Up With NIH

Companies participating in the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership:

- **AbbVie**
- **Amgen**
- **AstraZeneca**
- **Bristol-Myers Squibb**
- **Evotec**
- **GlaxoSmithKline**
- **Johnson & Johnson**
- **KSQ Therapeutics**
- **Eli Lilly & Co.**
- **Merck & Co. Inc.**
- **Novartis**
- **Pfizer**
- **Roche**
- **Sanofi**
- **Takeda**
- **Vir Biotechnology**

A steering committee is to be established to set criteria for and rank potential candidates submitted by industry partners for clinical evaluation.

Collins said the committee will put "at the top of the list" candidates that have the greatest chance of being effective and safe and can be manufactured and scaled. He said they may look at three categories of therapeutics: small molecules that can interfere with viral load, monoclonal antibodies, and immune suppressors.

Asked about the initiative, Sanofi explained that the first wave of candidates to be selected for clinical trials will be existing marketed drugs that can be repurposed and those in late phase development. The emphasis will be on drugs that are not already being tested elsewhere. Platform clinical trial designs will be created to test them in existing clinical trial networks.

Collins said the support for the partnership was inspiring. He said he had heard the head of a major pharmaceutical company say, 'if we do the prioritization and if my competitor's candidate compound looks like it's the most promising, I'm glad to have them use my clinical trials network to test it.'"

MASTER PROTOCOL TRIAL DESIGN

As for trial design, the group is looking at a variety of master protocol options. Collins said they have discussed having a common control arm for multiple therapies so half of the participants do not receive placebo.

"Everyone agrees a master protocol structure where you are testing multiple therapies simultaneously is probably the only way to do this efficiently and where you can add or drop arms as they succeed or fail," David Wooley, senior VP of research partnerships at the Foundation of the Na-

tional Institutes of Health, said on the press call. He noted that these master protocols likely are going to have to address the different patient populations as how a trial is run differs according to what stage of disease is being addressed.

The group is also doing an inventory of existing trials. Collins noted that NIH enrolled 800 participants in its trial of Gilead Sciences Inc.'s remdesivir while only 500 were needed for it to be powered. He said one question is whether a particular trial network should be adapted to test a different candidate therapeutic in such a situation. *(Also see "COVID-19 Study Of Gilead's Remdesivir Using Ebola-Style Adaptive Platform Trial" - Pink Sheet, 17 Mar, 2020.)*

OTHER COLLABORATIONS

Collins compared the new initiative to the Accelerating Medicines Partnership (AMP) established between NIH and life sciences companies in 2016 to identify and validate targets for therapeutics. That partnership is focusing on four disease areas, Alzheimer's disease, type 2 diabetes, autoimmune disorders of rheumatoid arthritis and lupus, and Parkinson's disease, and looking to add schizophrenia. *(Also see "NIH Eyes Expansion Of US FDA Partnerships To Gene Therapy" - Pink Sheet, 15 Oct, 2019.)*

While AMP took a couple of years to get off the ground, Collins said the COVID-19 partnership took a couple of weeks to set up. It is being coordinated by the Foundation for the National Institutes of Health.

Several other collaborations have been formed to tackle COVID-19. Last month, a group of 15 life sciences companies established a consortium to accelerate the development, manufacture and delivery of vaccines, diagnostics and treatments for COVID-19. As a first step, they agreed to share their proprietary libraries of molecular compounds that have shown some degree of safety and activity with the COVID-19 Therapeutics Accelerator established by the Bill & Melinda Gates Foundation. *(Also see "Coronavirus Update: R&D Starts, Product Delays, Continuing Collaboration" - Pink Sheet, 29 Mar, 2020.)*

Collins noted that there is cross representation between the industry consortium and NIH's partnership.

INTELLECTUAL PROPERTY AND PRICING

Consumer and patient groups expressed concern that the partnership does not address pricing of potential COVID-19 treatments.

Peter Maybarduk, director of Public Citizen's Global Access to Medicines Program, said it is somewhat encouraging that NIH will coordinate an effort to share information and research methods. But he said, "NIH should announce clear standards for pricing and insist on the open licensing of patents and other exclusivities, in exchange for royalties to patent holders, so that researchers can quickly draw on the most recent science and technology and ensure a robust supply of affordable medical tools."

In a 16 April letter to Collins, Maybarduk asked him to commit to nonexeclusvie licensing of treatments and vaccinces. "At minumum, you should require manufacturers benefiting from federal funds to commit to reasonable pricing," he said.

Patients for Affordable Drugs said it is glad the federal government is directing billions of taxpayer dollars to find treatments and vaccines for COVID-19. "But since taxpayers are investing extraordinary amounts to lead the development of COVID-19 drugs, our investment must be accounted for when the time comes to set a price," the group said in a statement.

It noted that from 20-27 March, the Biomedical Advanced Research and Development Authority (BARDA) awarded J&J, Regeneron Pharmaceuticals Inc., and Genentech Inc. a collective $721m in government funding for COVID-19 research. And on 16 April, it awarded Moderna Inc. $483m for COVID-19 vaccine development.

Asked about the issue of IP and pricing on the press call, Collins said he expects companies to retain existing IP claims on their compounds. He stated that NIH has not tried to tackle the issue of pricing. Where we've tried to do that, he said, "the collaboration has ceased."

Several organizations and academicians have been calling for COVID-19 related IP to be made available either through compulsory licensing or a voluntary commitment by companies. *(Also see "As Calls For Patent Sharing To Fight Pandemic Intensify, Manufacturing May Be Bigger Issue" - Pink Sheet, 19 Apr, 2020.)*

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US FDA Greenlighting Dozens Of New Trials For Coronavirus Therapeutics

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The US Food and Drug Administration has substantially increased the number of potential coronavirus treatments being tested in less than three weeks, and saw a more than 10-fold jump in the number in planning stages. The agency's Coronavirus Treatment Acceleration Program (CTAP) reported that as of 19 April there were 72 active clinical trials for therapeutic agents and another 211 development programs in the planning stages. Center for Drug Evaluation and Research Director Janet Woodcock also tweeted that as of 16 April, 45 products were in active clinical trials, which suggests that many products are being studied in multiple clinical trials.

The products in active trials has ballooned since the 31 March announcement of CTAP's creation – but is dwarfed by the increase of products in development. The program had already been running for several weeks, and 10 potential therapies were in clinical trials and another 15 were in the planning stages by then. In less than three weeks, the total number of potential therapies in clinical trials increased 350%, while the number of products in development planning stages increased 1,307%.

The *Pink Sheet*'s coronavirus pipeline tracker offers details on therapeutics and vaccines in pre-clinical as well as clinical development stages. Woodcock, Center for Biologics Evaluation and Research Director Peter Marks and FDA Commissioner Stephen Hahn also wrote in a post on the FDA website that they anticipate clinical trial results soon for a variety of products and will act quickly. "When we do [receive data], we intend to use a flexible and innovative approach," they said. "Once we observe favorable results, we intend to be very proactive about patient access."

Indeed, the remarkable movement of products into development phases appears to be the result of the FDA's devotion of substantial resources to the coronavirus outbreak and the search for potential treatments. CTAP also offers sponsors expedited timelines for protocol assessments and physicians faster responses to expanded access requests. *(Also see "Coronavirus Sponsors Should Get Responses To Regulatory Requests Within One Day, US FDA Says" - Pink Sheet, 31 Mar, 2020.)*

The Pharmaceutical Research and Manufacturers of America called the number of trials taking place "noteworthy," adding that despite the upfront costs and risks, "there are significant efforts underway by PhRMA member companies who are researching and developing new potential vaccines and treatments and testing existing medicines." A Biotechnology Innovation Organization spokesperson also said the figures confirm the industry's unprecedented effort to eradicate the virus.

BEST PROPOSALS WILL BE CONSIDERED FIRST

The agency has received 950 inquiries and proposals for potential coronavirus treatments as of 16 April and is "quickly triaging a second wave of potential products," based on scientific merit, Hahn, Marks and Woodcock wrote. "The strongest proposals will go to the front of the line," the post stated. *(Also see "US FDA Coronavirus Response Features Three-Step Triage Process For Inquiries" - Pink Sheet, 15 Apr, 2020.)*

"Our overriding objective is to find effective medicines that don't cause more harm than good as soon as possible," they said.

Woodcock also tweeted that soon the CTAP website will include "guidance to clarify FDA's scientific and regulatory expectations" for coronavirus product development. More detailed information about "CTAP procedures and timelines" also is expected, according to the program website.

The FDA has published dozens of guidances in order to expedite coronavirus therapies and other problems arising because of the pandemic, including recommendations for clinical trial conduct *(Also see "For COVID-Impacted Trials, Investigators Should Practice Remote Assessments Beforehand, US FDA Says" - Pink Sheet, 19 Apr, 2020.)*, convalescent plasma development *(Also see "US FDA Sets Convalescent Plasma Access Recommendations For Coronavirus Patients" - Pink Sheet, 16 Apr, 2020.)*, and compounding. *(Also see "US FDA Clarifies Compounding Policies On Interstate Distribution, Drug Shortages" - Pink Sheet, 8 Apr, 2020.)*

CORONAVIRUS FOCUS SOON MAY TAKE TOLL ON FDA

While the FDA works to increase the potential shots on the goal of developing a coronavirus treatment, the massive effort soon may begin to take its toll on the portions of the agency still conducting regular business.

Hahn warned on 16 April that the agency soon may begin missing user fee goals, in part because it is working at full capacity and cannot expect to maintain current performance level indefinitely.

The FDA told the *Pink Sheet* that work on non-coronavirus applications may be affected "by an inability to conduct pre-approval inspections," although workarounds are possible.

Hahn also said that any increase in drug shortages or supply disruptions would require a reprioritization of work. *(Also see "US FDA May Start To Miss User Fee Deadlines" - Pink Sheet, 16 Apr, 2020.)*

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Medicare Will Boost Physician Reimbursement For Sharing COVID-19 Clinical Trial Data

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To receive the Medicare credit, clinicians must attest that they are participating in a COVID-19 clinical trial and report their findings through a clinical data repository or clinical data registry.

The Centers for Medicare and Medicaid Services is providing a financial incentive to clinicians participating in a COVID-19 clinical trial to report scientific findings to a clinical data repository or registry.

CMS announced on 21 April that clinicians participating in the agency's Quality Payment Program (QPP), including physicians, physician assistants, and nurse practitioners, can earn credit in the program's Merit-based Incentive Payment System (MIPS) by sharing clinical trial data, which could increase the amount of Medicare reimbursement they receive.

"At the direction of President Trump, CMS is supporting efforts of researchers to obtain solid, actionable data to accelerate the development of new treatments and our understanding of the coronavirus," CMS Administrator Seema Verma said in a release. "Today's action encourages clinicians to report data that will help us monitor the spread of the virus, find innovative medical solutions, and unleash scientific discovery as we seek to overcome this terrible disease."

In order to receive this credit, clinicians must attest that they are participating in a COVID-19 clinical trial using a drug or biologic to treat a patient with the coronavirus infection and report their findings through a clinical data repository, such as Oracle's COVID-19 Therapeutics Learning System, or clinical data registry, for the duration of their study.

The US Department of Health and Human Services announced on 20 April that Oracle was donating its learning system, an online platform designed to collect real-time COVID-19-related medical data from doctors and other clinicians, to the department.

"Oracle's platform will help give us the ability to see real-time information about the patient impact of possible therapeutics around the country, which is critical to combating COVID-19 and reopening the American economy," HHS Secretary Alex Azar said in a release announcing the donation.

Separately, the National Institutes of Health has issued COVID-19 treatment guidelines for healthcare providers that are being constantly updated as new clinical data is accrued. On 21 April, NIH announced that a panel of US physicians, statisticians and other experts developed the guidelines based on published and preliminary data and the clinical expertise of the panelists. The guidelines focus on antivirals and host modifiers and immune-based therapies and include recommendations on the use of concommitant medications.

Each recommnedation includes two ratings that indicates the strength of the recommendation and the quality of the evidence that supports the recommendation. The guidelines state that there is insufficient clnical data to recommend either for or against using cloroquine or hydroxychloroquine or the investigational antiviral remdesivir for the treatment of COVID-19. Except in the context of a clinical trial, the guidelines panel recommends against the use of hydorxychloroquine/azithromyicn because of the potential for toxicities.

CREDIT WOULD BOOST IMPROVEMENT ACTIVITIES SCORE

Trial sponsors and principal investigators currently submit information about clinical studies to clinicaltrials.gov, a clinical trials registry run by the National Institutes of Health's National Library

of Medicine. They generally submit information to the website when the studies begin and update it as the studies proceed. The registry does not contain information about all clinical studies conducted in the US as some studies, such as observational studies, are not required to be registered.

CMS believes its initiative could speed up the process of sharing clinical trial data.

"Having clinicians use an open source data tool to submit their findings will bring the results of their research to the forefront of healthcare much faster, leading to improvements in care delivery and the ability to treat COVID-19 patients," CMS said.

CMS's Quality Payment Program, established under the Medicare Access and CHIP Reauthorization Act of 2015, is an incentive program to reimburse eligible clinicians based on quality and value of performance. One of the ways clinicians can participate in the program is through the Merit-based Incentive Payment System.

The performance of MIPS-eligible clinicians is measured through the data clinicians report in four areas: quality of care; promotion of interoperability; activities to improve care processes, patient engagement and access to care; and cost of care. The measurements of these areas make up a final score that determines payment adjustments to a clinician's Medicare reimbursements for certain services. The payment is sent to the clinician's practice.

CMS said clinicians who report clinical trial data will automatically earn half of the total credit needed to earn a maximum score in the MIPS improvement activities performance category, which counts as 15% of the MIPS final score.

CMS COVID-19 ACTIONS

CMS's offer of a reporting credit follows its efforts to get universities and academic hospitals with in-house laboratories to report their COVID-19 diagnostics test results to HHS. Last month, Verma and Vice President Mike Pence sent a letter to nearly 4,700 hospitals requesting them to send their de-identified COVID-19 test data results daily. *(Also see "US VP And CMS Chief Urge In-House Academic Hospital Labs To Share COVID-19 Data With HHS" - Medtech Insight, 31 Mar, 2020.)*

CMS has taken several actions in response to the COVID-19 pandemic. In March, it issued an interim final rule that will allow for Medicare reimbursement of infused or injected Part B drugs administered at home as long as a physician or practitioner is supervising with telecommunications technology. *(Also see "Part B Drugs At Home: Medicare Policy Responds To COVID-Driven Access Concerns" - Pink Sheet, 5 Apr, 2020.)*

And last week, the agency announced that it would pay nearly twice what it usually does for certain laboratory assays using high-throughput technologies to rapidly diagnose the COVID-19 virus, increasing reimbursement from $51 per test to $100. *(Also see "CMS Doubles Up On Test Reimbursements, Will Pay Labs $100 Per Test For COVID-19 Clinical Diagnostic Assays" - Medtech Insight, 15 Apr, 2020.)*

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COVID-19:

UK Sets Up Key Vaccine Taskforce; Funds 21 New Research Projects

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The UK government has set up a new Vaccine Taskforce to accelerate the development of a coronavirus vaccine and has also announced that 21 new coronavirus research projects are set to benefit from a share of around £14m ($17.4m) in government funding.

In a statement on 17 April, the government said that the Vaccine Taskforce, which includes representatives from government, academia and industry, will "support efforts to rapidly develop a coronavirus vaccine as soon as possible by providing industry and research institutions with the resources and support needed."

This includes reviewing regulations and scaling up manufacturing, so that when a vaccine becomes available, it can be produced quickly and in mass quantities.

The 17 April statement also said that the 21 new research projects to receive funding include those relating vaccine and therapy development, the first clinical drug trial in primary care, and studying epidemiology, disease transmission, behavioral interventions and policy approaches to COVID-19.

The taskforce is also working closely with the BioIndustry Association (BIA), which recently set up an industry-led group to accelerate vaccine development and manufacturing.

The BIA said that its vaccine manufacturing group would "consider any COVID-19 vaccines or therapies which emerge, regardless of whether the vaccine or therapy is UK or internationally based and look to help where it can."

It added that the government's latest moves would "help accelerate the manufacturing capacity and capability of the UK and support vaccine candidates and other COVID-19 therapies, which are needed in this global health crisis."

FIVE STRANDS OF VACCINE TASKFORCE ACTIVITY

The new Vaccine Taskforce, which is up and running, is key to coordinating efforts to rapidly accelerate the development and manufacture of a potential new vaccine," according to business secretary Alok Sharma.

It is being led by chief scientific adviser Sir Patrick Vallance and deputy chief medical officer Jonathan van Tam. Its members include UK government adviser on life sciences Sir John Bell, as well as AstraZeneca and the Wellcome Trust.

The Vaccine Taskforce, according to the government, will focus on five strands of activity including:

- Supporting the discovery of potential coronavirus vaccines by working with the public and private sector, rapidly mobilizing funding, supporting leading academics and identifying ways to fast-track clinical trials.
- Preparing the UK as a leader in clinical vaccine testing and manufacturing, working with companies already at the forefront of vaccine development.
- Reviewing government regulations to facilitate rapid and safe vaccine trials.
- Developing funding and operational plans for the procurement and delivery of vaccines.
- Building on the UK's research and development expertise to support international efforts to find a coronavirus vaccine.

The BIA said that its industry-led vaccine manufacturing group, which it established in March, would work alongside the government's Vaccine Taskforce.

This vaccine manufacturing group is a collaboration of the public sector, private sector companies, academia and universities. It is chaired by Ian McCubbin OBE, former VP for global manufacturing and supply at GlaxoSmithKline.

Its short-term aim is to "accelerate UK manufacturing capacity & capability to produce Xm doses of vaccine," the BIA said. Its long-term aim is to "create a UK capability that can deliver 25 million doses in 24 weeks by 2023." The BIA noted that its group has been working closely with Oxford University and Imperial College London "to assess supply chains and understand what they require to scale and rapidly deploy their vaccines."

According to the government, establishing its Vaccine Taskforce is part of the UK's wider efforts to support and accelerate the development of a vaccine for coronavirus. "This includes the UK already pledging £250 million from the government aid budget, the biggest donation by any country, to the international programme to develop a coronavirus vaccine under the Coalition for Epidemic Preparedness Innovations (CEPI)," it said.

FUNDING FOR NEW RESEARCH PROJECTS

As for the 21 new research projects, they are receiving £14m from a £25m government research investment that was announced in February. Altogether 27 research projects have received a share of the £25m investment; the first round of projects were announced on 23 March. *(Also see "UK Attacks Pandemic With Funding For Drug And Vaccine Trials" - Pink Sheet, 27 Mar, 2020.)*

The new research projects to receive funds include vaccine developments by Imperial College London and Public Health England.

> "A public/private group is chaired by Ian McCubbin, former VP for global manufacturing and supply at GlaxoSmithKline.

Imperial College London has developed a promising RNA vaccine, the government said. The funding will enable to the researchers to take the vaccine "through GMP [good manufacturing practice] manufacturing, testing in animal models for safety and efficacy, regulatory and ethical approval, and, if that's successful, a phase I clinical trial in healthy human volunteers."

Public Health England is developing an animal model of SARS-CoV-2 virus infection in non-human primates, which can be used to test if new vaccines and therapies are effective and safe. "This will enable researchers to address concerns that vaccines that enhance the immune response could potentially worsen COVID-19," the government said. Another project by Public Health England that is receiving the new funds concerns the development of a new antibody that could offer protection against infection and disease progression of coronavirus.

Also being funded is a clinical trial that the University of Oxford is conducting. This trial is initially testing whether the anti-malarial drug hydroxychloroquine can reduce the need for people to go to hospital or speed up their recovery. The study, called PRINCIPLE, is the first clinical trial in COVID-19 patients consulting in primary care, the government said. It aims to recruit over 3,000 people, and has been designed to be flexible, so new suitable treatments can be added into the trial when these become available.

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Africa Proposes Joint Coronavirus Clinical Trial Reviews

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Medicines regulators in various African countries are to expedite the approval of coronavirus-related clinical trials by streamlining national procedures and setting up an online platform for the joint review of trial applications. The move is expected to result in 15-day reviews for proposed studies of novel products for COVID-19.

The move comes as the World Health Organization warned that as of 16 April, just over two months after COVID-19 was first detected in Africa, the disease had spread to almost every country on the continent, resulting in nearly 17,000 confirmed cases and around 900 deaths.

As in many other countries, African regulators see the expedited review of drug and vaccine trials as a key component in the fight against the coronavirus pandemic. At present, regulatory agencies and ethics committees in each African country review trial applications sequentially and without oversight of each other's inputs, which "results in inefficiencies and delays in providing a final response to the sponsor," according to the WHO.

Under an agreement reached at a recent virtual meeting organized by the WHO and the African Vaccines Regulatory Forum (AVAREF), regulators and ethics committees across the continent will be able to combine their expertise to conduct joint reviews, although each country remains responsible for granting the actual trial approval.

AVAREF is an informal capacity-building platform set up by the WHO in 2006 that brings together African regulators and ethics committees and aims to improve regulatory oversight of clinical trials in Africa. It is also one of the technical committees of the African Medicines Regulatory Harmonization (AMRH) initiative, which is taking steps to strengthen and harmonize regulatory practices and build up an African Medicines Agency. *(Also see "New Deal To Boost Progress On African Medicines Agency" - Pink Sheet, 19 Nov, 2019.)*

The new cooperative approach proposed by AVAREF has already been successfully applied to vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia and Ebola, and has been extended to other therapeutic interventions. "Importantly this process retains country specific requirements so that participating agencies do not compromise protection of its citizens by a top-down approach," the WHO declared. "A timeline of 10 working days is suggested for processing of clinical trial applications via the joint review pathway where the product is already registered for other indications, and 15 working days for novel products," it added.

Given the COVID-19-related restrictions on face-to-face meetings, the AVAREF member states will set up an online (SharePoint) platform for joint reviews of proposed trials for therapeutic, diagnostic and preventive interventions related to the pandemic.

National regulatory authorities, ethics committees and targeted ethics review boards in participating countries will post their queries online for real-time responses from sponsors/applicants, while the AVAREF secretariat will convene and coordinate virtual meetings for participating countries to conduct joint reviews of clinical trial applications on COVID-19.

Virtual meetings will also be used to discuss how regulators and ethics committees can better prepare for and respond to the COVID-19 pandemic. Regulatory authorities and ethics committees can use a separate platform (MedNet) to share information on planned or ongoing clinical trials in their countries.

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UNECA REPORT

Meanwhile the United Nations' Economic Commission for Africa (UNECA) has published a report urging RECs to set up joint reporting mechanisms on the availability of medical supplies and production facilities that could be accompanied by "commitments to expand production, with clear mutual agreements to export to each other." It says a number of African countries, such as Egypt, Mauritius, Morocco, South Africa and Tunisia, "already have medical supply capacity that can be expanded through collaboration."

In addition, UNECA has called for African governments to be given "emergency exemption" from intellectual property rights on COVID-19 medical supplies to support domestic production, "in particular for pharmaceuticals."

The report says that while the World Trade Organization's decisions on trade-related aspect of IP rights (TRIPS), allows producers in developing and least developed countries to make versions of patented drugs, "what is further required is the expedited sharing of novel patents, design schematics, and industrial techniques."

It has identified a range of priority products as requiring IP derogations, including medicines shown to have "some curative benefits, including antivirals," as well as inexpensive ventilators and rapid testing kits, medical consumables, and effective disinfectants and sterilization products.

REGIONAL SPREAD

In its 16 April report, the WHO said that while South Africa has seen the most severe outbreak of coronavirus in sub-Saharan Africa, "West and Central Africa are of growing concern," with Cameroon having more than 800 confirmed cases, and Niger, Cote d'Ivoire and Guinea reporting a "rapid rise" in numbers over the previous week.

"Eleven out of 17 countries with more than 100 cases of COVID-19 are in West and Central Africa," said Dr Matshidiso Moeti, the WHO's regional director for Africa. "We are working with the governments to better understand what is happening on the ground, but this is worrisome as countries in these subregions often have particularly fragile health systems."

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Global Regulators Explore Alignment Options During COVID-19

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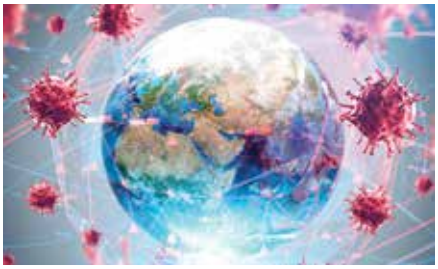
As drug regulators around the world explore ways to deal with the COVID-19 pandemic, they have agreed to hold bi-weekly meetings to exchange information and build synergies to speed up the development and approval of medicines and vaccines, and to look at ways to avoid medicine shortages.

At the first such meeting on 16 April, organized under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), global regulators discussed ways to align their regulatory requirements and policy approaches to respond to the pandemic.

Representatives of more than 20 medicines regulatory authorities as well as experts from the World Health Organization acknowledged the importance of regulatory convergence as well as allowing flexibilities to facilitate the development, evaluation and availability of medicines to treat and prevent COVID-19 infection.



At the meeting, the regulators exchanged information on various accelerated regulatory measures implemented in different countries and agreed that regulatory rules should be applied with greater flexibility during the pandemic to facilitate development of potential COVID-19 treatments and secure continued supply of medicines.

In addition, ICMRA members stated that ensuring the continued availability of medicines, in particular those used for treating COVID-19 patients in intensive care units, was of critical concern. Different countries and regions have adopted different approaches to dealing with medicine shortages. The EU, for example, has launched a new fast-track system to monitor the availability of medicines to treat COVID-19 patients that initially focuses on medicines needed in hospital intensive care units. *(Also see "EU Launches Fast-Track Monitoring Of Crucial COVID-19 Drug Shortages" - Pink Sheet, 21 Apr, 2020.)*

On the development of new medicines to treat or prevent COVID-19, regulators reiterated the need to prioritize large COVID-19 clinical trials and to align common study protocols. Large randomized controlled studies are regarded as the best way to collect robust evidence to determine which investigational agents or repurposed medicines are safe and effective. *(Also see "Regulators Insist On Large-Scale Trials For Coronavirus Treatment Candidates" - Pink Sheet, 9 Apr, 2020.)* Regulators also said it was important to discourage the conduct of multiple underpowered studies that could compete for essential resources.

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With Eye On China, India Tightens Foreign Investment Vetting

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India has tweaked its foreign direct investment (FDI) rules, amid concerns that unprecedented stress as a result of the coronavirus pandemic could expose domestic firms across sectors to opportunistic takeovers and acquisitions.

The new norms, widely seen as targeted mainly at China, essentially require nations that border India to secure government approval prior to investing in India in sectors where such investment is permitted.

"An entity of a country, which shares land border with India or where the beneficial owner of an investment into India is situated in or is a citizen of any such country, can invest only under the Government [*approval*] route," the revised regulations from India's ministry of commerce and industry state.

While no specific reference to China was made, there is little doubt that the changes are meant to safeguard key Indian assets from any corporate adventurism from the country against the backdrop of COVID-19. Media reports of the People's Bank of China raising its stake in one of India's largest private banks, HDFC, and China-backed funds scouring for investment opportunities in India amid plunging valuations, have only added to the overall nervousness.

CHINA SEES 'DISCRIMINATORY PRACTICES'

The new rules also specify that a citizen of Pakistan or an entity incorporated in that country can invest only under the "Government route" in sectors/activities "other than defense, space, atomic energy and sectors/activities prohibited for foreign investment." They further clarify that the transfer of ownership of any existing or future FDI in an entity in India, "directly or indirectly, resulting in the beneficial ownership falling within the restriction/purview" of the revised norms, will also require clearance from the Indian government.

The corresponding existing FDI policy applied to investments from Bangladesh and Pakistan, and while the new norms expand the scope to China, Nepal, Bhutan and Myanmar, they realistically appear targeted at the might of China.

That message was evident when the spokesperson of the Chinese embassy in India tweeted that the country's investment supports India's "industry development, creates jobs and promotes win-win cooperation. Our companies actively help India fight COVID-19. Hope India revise the discriminatory practices and foster open, fair and equitable business environment," Ji Rong said.

India has rebutted China's claims however, indicating in local media reports that the new measures will not curb market access or national treatment; in fact there is constant reference to how China hasn't really provided Indian IT and drug firms unfettered access to its own market.

But Amitabh Kant, CEO of NITI Aayog, a policy think tank of the Indian government, sought to soothe frayed nerves and was reported as saying that India welcomes investments from China and that the country will have to play a major role if the Indian economy has to grow. "No need for any country to overreact," he was quoted as saying.

STRONGER GOVT OVERSEER ROLE APPROPRIATE?

While the changes in FDI policy are not pharma-specific, experts in the industry are keeping a close eye on things – some are endorsing the government approach while others are a little concerned India may have just plunged into an unnecessary controversy.

Ranjit Shahani, former vice-chairman and managing director of Novartis India, noted that in these times of turbulence "the card deck has been reshuffled" and predatory acquisitions are "certainly a possibility" in a free market. "For India this could become particularly sensitive if China has access to any strategic assets, critical technologies or sensitive national data," Shahani told the *Pink Sheet*, referring to the large number of Indian "unicorn" companies now funded by Chinese investors. The term typically refers to private startups valued in excess of $1bn.

While no specific reference to China was made, there is little doubt that the changes are meant to safeguard key Indian assets from any corporate adventurism from the country against the backdrop of COVID-19.

The ex-big pharma executive believes that in the current environment, it is appropriate that the Indian government has a stronger overseer role in the approval of transactions.

Some investment bankers said that India could see some impact on early-stage funding as there are several Chinese venture capital firms operating in the space. "By that logic, health tech funding could get partially affected," one told the *Pink Sheet*.

The banker does not anticipate any impact on pharma funding, at least for now, simply because there has been no large Chinese company investing in the Indian pharma sector except in a 2017 deal involving Fosun. The Chinese group snapped up a controlling 74% stake in India's Gland Pharma Ltd. for over $1bn, though the deal had its share of tense moments and Fosun tweaked the original transaction. *(Also see "Fosun Tweaks Gland Deal Amid Limbo In India" - Scrip, 18 Sep, 2017.)*

Specifically for the pharma sector, under the existing policy, up to 74% FDI is permitted under the automatic route in brownfield pharmaceuticals, though government approval was required beyond that threshold.

For greenfield investments, 100% FDI was permitted via the automatic approval route in the pharma sector; but the latest FDI changes will mean investments from nations that share a border with India will need a round of vetting, unless exception are put in place.

DOESN'T STAND TO LOGIC?

But some pharma industry experts in India are questioning the need for apparently hurried FDI restrictions at this juncture.

"It doesn't stand to logic. We need funds and ideally this wasn't the time to create additional confusion," one industry veteran told the *Pink Sheet*, adding that the globalization versus localization debate was also generally becoming "confused" in the current scenario.

The executive added that there was currently a "lot of rhetoric" everywhere and that most investment fund managers were adopting a wait and see approach. "We should permit FDI, we shouldn't debar someone investing in a plant in India – they can't shift the plant out of the country," the person explained partly in jest.

China is estimated to have made cumulative investments (across all sectors) in excess of $8bn in India as of December 2019.

There is also some concern on how far countries should push China in the current global situation. In the Indian pharma context this is perhaps more complex, given that around 68% of active pharmaceutical ingredients by value are sourced from China. In some cases, the country is the sole or key supplier of critical intermediates and APIs including digoxin, losartan, metformin, glimepiride, isoniazid and streptomycin.

EXISTING INVESTMENTS UNAFFECTED

Meanwhile, existing China investments in India are unlikely to face any enhanced scrutiny in India, at least going by what some experts say.

The investment banker quoted previously said that conglomerates like Fosun are seen as critical investors - the huge Chinese group also has a venture capital fund - and that it is "unlikely the Indian government would 'mess around' with their past investments."

Ex-Novartis India boss Shahani had similar views, underscoring that Indian firms that already have Chinese funding are unlikely to face problems, as these investments make strategic and financial sense for the Asian giant.

"Round tripping via Hong Kong - in the old days the Mauritius route was used - as a channel by foreign investors to fund in India could be an option, even though Hong Kong does not share a border with India," Shahani said, but predicted that "this loophole too will be plugged."

He also doesn't see China resorting to any immediate retaliatory measures against the new Indian FDI measures. "They have so far leaned on the discriminatory aspect but are unlikely to invoke the World Trade Organization. In any case there were no big strategic investments planned in China by any Indian major," Shahani noted.

Several major Indian drug firms including Sun Pharmaceutical Industries Ltd., Cipla Ltd., Glenmark Pharmaceuticals Ltd. and Dr. Reddy's Laboratories Ltd. have recently outlined broad plans to tap into the Chinese market or expand there amid favorable regulatory reforms, and hopefully India's new FDI approach will not have any ramifications on these efforts. *(Also see "Indian Firms May Want To Slow March Into China" - In Vivo, 20 Nov, 2019.)*

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NOTE: The FDA is not expected to announce new advisory committee meetings during its current freeze on in-person meetings due to the COVID-19 pandemic.

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