To: 5.1.2e [5.1.2e @minbuza.nl]; 5.1.2e [5.1.2e @minbuza.nl]
From: 5.1.2e)
Sent: Tue 4/20/2021 7:13:31 AM
Subject: RE: POLITICO Pro Morning Health Care: Action on obesity — EU affairs ministers to talk coronavirus — Health and climate
Received: Tue 4/20/2021 7:13:31 AM

Dank, er wordt nu trouwens met onze vaccin gezant ook in NL behoorlijk wat op poten gezet in deze richting zo krijg ik de indruk.

Van: 5.1.2e < 5.1.2e @minbuza.nl>
Verzonden: dinsdag 20 april 2021 08:39
Aan: 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e < 5.1.2e @minbuza.nl>
Onderwerp: FW: POLITICO Pro Morning Health Care: Action on obesity — EU affairs ministers to talk coronavirus — Health and climate

Helemaal onderin een inkijkje in de Britse HERA incubator. Geeft bij mij het beeld dat we met de EU al weer achterlopen op de Britten. Maar dat is misschien ten onrechte.

From: 5.1.2e < 5.1.2e @minbuza.nl>
Sent: dinsdag 20 april 2021 07:04
To: 5.1.2e < 5.1.2e @minbuza.nl>; 5.1.2e < 5.1.2e @minbuza.nl>; Functionele emailadr < 5.1.2e 5.1.2e @minbuza.nl>; 5.1.2e < 5.1.2e @minbuza.nl>
Subject: FW: POLITICO Pro Morning Health Care: Action on obesity — EU affairs ministers to talk coronavirus — Health and climate

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From: Morning Health Care Europe
Sent: Tuesday, April 20, 2021 7:00:58 AM
To: 5.1.2e
Subject: POLITICO Pro Morning Health Care: Action on obesity — EU affairs ministers to talk coronavirus — Health and climate

[View in your browser or listen to audio]

By CARLO MARTUSCELLI

with Helen Collis, Jillian Deutsch, Mark Scott, Karl Mathiesen, Hanne Cokelaere and Helen Fessenden

PRESENTED BY

SNEAK PEEK

— MEPs are launching interest groups to push obesity up the Brussels agenda.

— **Documents seen by POLITICO show the U.S. has played a more significant role** in the EU's vaccine supply than previously thought.

— **EU affairs ministers are set to discuss the pandemic,** including vaccine certificate plans.

Welcome to Tuesday's Morning Health Care! Pfizer, Sinopharm or Moderna? We're not talking about vaccines — but the different jab-themed sweets that are being sold in one ingenious Hungarian patisserie. The desserts are filled with different types of jelly based on which vaccine they are meant to represent, and are topped by a decorative syringe.

Reuters has the story here.

Get in touch: 5.1.2e @politico.eu, 5.1.2e @politico.co.uk, 5.1.2e @politico.eu, 5.1.2e @politico.co.uk and 5.1.2e @politico.eu. Tweet us @deutschjill, @hcollis, @carlomartu and @ashleighfurlong

DRIVING THE DAY

'OBESITY IN THE BACKSEAT FOR TOO LONG' SAY MEPS: It's high time that the European Union takes a stronger stance on obesity, according to MEPs marking the launch of an interest group on the disease today.

Meet the chair: Danish MEP Pernille Weiss, of the European People's Party, said in a statement that the pandemic had shown Brussels how critical it is to strengthen health resilience throughout the bloc.

"Policymakers and all parts of society cannot fall into the trap of doing business as usual," Weiss explained, noting that 60 percent of Europeans live with obesity or pre-obesity. The MEP said that it was key to address the condition like other chronic diseases, with a focus on prevention, treatment and long-term management.

Getting the word out: The interest group said that it aims to get more people to understand obesity as a non-communicable disease, getting the conversation to move "beyond prevention." It also will advocate for the creation of a framework for obesity, complete with national plans, data collection and the creation of obesity centers of excellence.

Portugal's Sara Cerdas, a doctor and MEP for the S&D, is vice chair of the obesity interest group. As she notes, obesity must be addressed as well as a "chronic relapsing disease" and that it's essential to have clear guidelines in place.

"The EU can add value by working on a framework for national plans on obesity as we have done for the other major chronic diseases — now is the time to act," said Cerdas.

Don't miss the talk. Starting at 2 p.m. MEPs from the interest group and other speakers will be holding a launch event which includes representatives from both the World Health Organization and the Commission.

VACCINES

J&J DAY (AGAIN): The European rollout of the Johnson & Johnson vaccine looks likely to get back on track this week after the company paused its rollout last week following blood clotting concerns in the U.S. (refresher). This afternoon, the European Medicines Agency will make a decision about whether it's safe. It's quite likely that the regulator will give the vaccine a thumbs up in all adults like for Oxford/AstraZeneca — but we'll see if countries actually use it the same way. France already said it will only use the vaccine in people over 55.

NEVER EZ FOR AZ: Speaking of AstraZeneca, documents seen by Jillian and Belgian magazine Knack show that the EU's shortage of Oxford/AstraZeneca doses all comes down to a lack of drug substance — or vaccine liquid — made in the EU. The company sent substance from a plant in the American state of Maryland to make up for some of the shortfall. Although it was not nearly enough to plug the gap, the shipments show the U.S. has played a more significant role in the EU's vaccine supply than previously thought. More here.

CUREVAC VAX EDGES TOWARDS SWISS MARKET: German biotech CureVac has filed initial data for a marketing authorization of its mRNA COVID-19 vaccine in Switzerland, launching a rolling review. Regulator Swiss Medic said Monday it was the fifth COVID-19 vaccine to be reviewed, noting the timing of its decision would "depend on the completeness of the data submitted by CureVac and the results of the clinical trials, and cannot therefore be predicted."

CureVac announced last week during its 2020 full-year results that it anticipated data from its Phase 2-3 trial in the second quarter, with complete filing and regulatory decisions also in Q2. The European Medicines Agency began its rolling review of initial data from the Bern-based company supporting its mRNA vaccine candidate on February 12.

Competition: While CureVac has been investigating the potential of RNA vaccines (and treatments) the longest, it has been pipped to the market post by neighboring BioNTech, in Mainz, as well as U.S. biotech Moderna. But CureVac's jab also has benefits: It can be refrigerated for three months and doesn't require sub-zero storage like the others; it also contains the smallest amount of active ingredient of any of the mRNA vaccines, potentially making production faster.

VIENNA PULLS THE TRIGGER ON SPUTNIK: Austria will go through with the purchase of 1 million doses of Russia's Sputnik V vaccine. News site Vienna.at reports that the announcement was made by Chancellor Sebastian Kurz on Monday. But the government said it will probably wait for the European Medicines Agency to first approve the vaccine. Last week, Sweden and Finland said they were in talks to buy the adenoviral shot.

So far … so good? The Russian vaccine has displayed an almost incredible efficacy rate of 97.6 percent, according to an announcement from the Gamaleya National Research Center. You can see how the numbers were calculated — and decide whether or not you trust them — in the press release here.

TWO DOSE OR NOT TWO DOSE? Spain's government is considering delaying plans to administer second doses for the BioNTech/Pfizer and Moderna vaccines to give more people their first shot, reports El Mundo. The idea is to follow the successful examples of the U.K. and Israel and grant at least partial protection to as much of the population as possible. The Spanish newspaper reports that following the plans, which will be voted on by the country's Public Health Commission later today, people will receive their second dose within 56 days of their first — up from the three to four weeks currently recommended.

Mix-and-match: Meanwhile, the country's health ministry announced it's starting a clinical trial to assess the BioNTech/Pfizer jab's use as a second dose for people who have had a first shot of AstraZeneca.

"So far there is no clinical data on their possible combined use," notes the ministry. "Joint use seems possible and even desirable."

PUBLIC HEALTH

EU AFFAIRS MINISTERS TO TALK COVID COORDINATION, AGAIN: European Affairs ministers are meeting informally today and an update on EU coordination on pandemic-related issues is on the agenda. That's an occasion for ministers to talk about the state of play of the pandemic — a broad umbrella topic that covers everything from vaccination to travel.

Travel is (still) a hot topic: Expect the EU's plan for a so-called "digital green certificate" to restart travel to come up. It's not just the ongoing work on the certificates that's keeping the subject of travel high up the agenda: The presence of virulent mutations, particularly Brazil, is provoking fears that they could undermine efforts in the bloc to get the pandemic under control.

Coordination calls: There are fears that those variants could prove the latest challenge to the bloc's hopes to restart travel. Last week, Belgium's Mobility Minister Georges Gilkinet called for a European, coordinated approach on the Brazilian strains of the virus to "prevent a patchwork of 27 different national measures." The call for stronger coordination is also shared by other countries, including France.

Work in progress: The plea was on the agenda of Monday's integrated political crisis response (IPCR) meeting. Among the asks is a request for the European Center for Disease Prevention and Control to provide a joint map covering the presence of "worrying variants" in third countries to build on to strengthen a common approach EU countries agreed earlier this year, an EU diplomat said. The hope is that today's debate will give a "political impetus" to the proposal, the diplomat added.

Not just Brazil: The U.K. added India to its "red" travel list Monday over concerns about a new COVID variant, first identified in India.

FACEBOOK DOES IT AGAIN: We're more than a year into the global pandemic — you'd think the world's largest social network would have cracked misinformation by now. A new report out this morning from campaign group Avaaz outlines how the tech giant is twice as likely to remove or label COVID-19 misinformation posts (those already flagged by outside fact-checkers) in the United States than false material aimed at EU users.

"Facebook hasn't improved its ability to detect misinformation," Avaaz campaign director Luca Nicotra told POLITICO. "It's incredible. It's under so much pressure, but it hasn't had an impact on Facebook to detect misinformation." Not surprisingly, the tech giant disagrees, telling us it's removed millions of COVID-19 misinformation posts and that it's working with national public health bodies to promote legitimate information.

It's worth noting that Avaaz's sample size (137 misinformation posts, across English, Spanish, Italian, French and Portuguese) is relatively small. But the group found that Facebook took action on a mere 31 percent of Italian-language COVID-19 misinformation posts (again, those already been flagged as false or misleading) compared to 74 percent of similar English-language material in the U.S — not a good look by anyone's standards.

Avaaz, too, has a mission. Nicotra told us he wants the upcoming Digital Services Act to push harder for Facebook and other social media companies to disclose how effective their misinformation work is, as well as provide outside groups with larger datasets to keep them accountable. "Our policy ask is for the European Commission to force these companies to disclose more information around misinformation," he said.

CLIMATE

COVID-19 AND CLIMATE COLLIDE: Welcome to the age of "compounded crisis," the World Meteorological Organization (WMO) said on Monday as it released its annual state of the climate report for 2020 — one of the three warmest years on record. It was also a year when the pandemic and climate change piled atop one another, hampering humanitarian responses and deepening human suffering. More than 50 million people worldwide were impacted by this double blow, the report said.

Pile on: In the Pacific, lockdowns led to delayed recovery operations for nearly 100,000 displaced people after April's Cyclone Harold, one of the region's strongest recorded storms. Evacuation centres in the Philippines were forced to operate at half capacity after Tropical Cyclone Vongfong in May. The storm also damaged the only COVID-19 testing center in the Bicol region, home to nearly six million people.

Greta steps in: COVID-19 is also hampering political efforts to slow climate change. The COP26 U.N. talks have already been delayed by a year, and access for diplomats from 197 countries to the meeting in Glasgow this November looks shaky given the uneven vaccine rollout worldwide. Swedish climate activist Greta Thunberg has zeroed in on that unfairness, saying she won't attend the talks while vaccines aren't universally available. On Monday she doubled down, gifting €100,000 from her foundation (which collects the teen's prize money) to the World Health Organization's COVAX scheme. "We can no longer separate the health crisis from the ecological crisis," said Thunberg.

AROUND THE BLOC

NI OFFERS JABS TO YOUNGER ADULTS: Northern Ireland opened up its COVID-19 vaccinations to some 35 to 39-year-olds on Monday, the first part of the U.K. to officially do so. The early rollout applies only to a large vaccine center in Belfast. Appointments in community pharmacies will be made available to this age group later in April "as vaccine supplies permit," according to a statement from the Northern Ireland Executive. Northern Ireland follows the advice of the U.K.'s Joint Committee on Vaccination and Immunization (JCVI).

CORONAVIRUS IN IT FOR THE LONG HAUL: The president of Germany's Robert Koch Institute has warned that we will have to get used to living with the coronavirus, reports Die Welt. Lothar Wieler, a veterinarian by training, said that the virus' ability to infect a large number of different animals will ensure that it keeps circulating. The RKI president said that it was important for health reasons that animal breeding and trading be brought under control.

WHAT WE'RE READING

Next-generation COVID-19 vaccines are supposed to be better. Some experts worry they could be worse, via STAT.

The Guardian breaks down what we know about the Indian coronavirus variant so far.

The U.K.'s health service rolls out an online quiz to help men at risk of diabetes get treatment, also from the Guardian.

COVID-19 infections in the U.K. have reached a nine-month low, writes New Scientist.

The U.S. Food and Drug Administration has ordered a contract manufacturer for the Johnson & Johnson vaccine to stop making doses until it can finish its inspection, reports our U.S. colleague Sarah Owermohle.

The U.K.'s Centre for Process Innovation wants to make sure we're ready to handle coronavirus variants, and it's gearing up to help drugmakers use mRNA vaccines to do that. Helen Collis has the story here.

POLITICO PRO ARTICLES

Documents: Oxford/AstraZeneca vaccine shortfall due to production woes in EU

Inspections show no drug substance came from the UK.

— By Jillian Deutsch

The EU's shortage of Oxford/AstraZeneca vaccines in recent months came down to simply not having enough serum — and even a significant amount sent from the U.S. couldn't make up the shortfall.

While a Belgian subcontractor making the serum or "drug substance," was fulfilling its contract with AstraZeneca, another plant in the Netherlands wasn't producing enough to be included in the company's application for approval to European regulators at the end of December, according to EU documents seen by POLITICO and the Belgian magazine Knack.

With so little drug substance coming from the EU, AstraZeneca turned to its U.S. plant in Maryland to make up the difference.

"The most important quantity" of drug substance came from the American plant, owned by Catalent, before being put into vials in Italy in a process known as "fill and finish," the documents said, detailing inspections in January and early February of three AstraZeneca plants in Belgium, Italy and the Netherlands that produced vaccines for the EU.

The documents don't specify how much drug substance actually came from the U.S. — one EU official said it was more than half of what formed the EU's Oxford/AstraZeneca vaccine supply at the time. They also don't state how many more shipments have arrived from the U.S. since early February.

But they do reveal that the U.S. has played a more significant role in the EU's vaccine supply than previously thought.

It's a point that has sometimes been muddied by conflicting statements from EU officials.

European Council President Charles Michel wrote in March that both the U.K. and the U.S. had "imposed an outright ban on the export of vaccines or vaccine components produced on their territory." But European Commissioner President Ursula von der Leyen has said there has been a "seamless" flow of vaccine products with the U.S.

In light of the role of the Maryland plant, the documents shed light on why von der Leyen took a softer approach to the U.S. when the EU threatened to cut off vaccine exports to countries that didn't send vaccines in return — a threat primarily pointed at the U.K.

The documents also confirm that the relationship between the EU and U.K. hasn't been reciprocal: "Nothing" in terms of drug substance "has been received" from the U.K., which has three AstraZeneca plants of its own, they state. However, a portion of what the Dutch plant was making by early February was still slated for export to the U.K., although it remains unclear how much.

AstraZeneca didn't respond immediately for comment to POLITICO.

Production squeeze

The January inspections are just one part in the ongoing story of the bitter dispute between the European Commission and AstraZeneca, which exploded in late January when the drugmaker announced it wouldn't deliver tens of millions of promised doses to the EU. That announcement prompted EU officials to all but flat-out accuse the company of sending EU-made vaccines to the U.K.

At that time, a team of EU officials, including three Commission staff members and nine national inspectors, were sent to investigate the European plants to see what was causing the massive shortfalls and assess whether AstraZeneca was making its "best efforts" to fulfill its contracts, as its CEO insisted.

The documents, obtained by Knack via a freedom of information request and analyzed with POLITICO, are based on two meetings between the team members on January 29 and February 5. They found that, based on AstraZeneca's existing supply chain, the company simply couldn't deliver.

"According to our knowledge, the firm AstraZeneca is not able to honor the quantities defined in the contract with the European Commission and with the schedule defined at the origin," the inspectors wrote.

"Today the only solution would be to import more Drug Substance batches from" the United States, because "some capacity" for fill-finish is always available at the Italian site, they added. They also confirmed plans to get drug substance from other countries, including South Korea and China.

It's a far different picture in the U.K. — where more than half of Britons vaccinated have gotten the Oxford/AstraZeneca jab — or the U.S., where the vaccination effort is racing along so quickly that some U.S. officials say the country probably won't need to authorize the AstraZeneca jab at all. In theory, that should free up more vaccine substance for the EU coming from Maryland.

But even if there is an influx of U.S. supplies, it remains unclear whether the drugmaker can meet its deliveries to the EU, coming on top of a huge shortfall in the first quarter, when it delivered only 30 million doses rather than the 100 million promised.

At this point, AstraZeneca plans to deliver another 70 million doses in the second quarter, totaling 100 million doses by July — just a third of the 300 million doses it promised when the contract was signed in August 2020.

The persistent delivery delays, along with safety concerns over the jab's side effects, have seriously undermined any chances that the EU will sign future contracts with the Anglo-Swedish company. Instead, the Commission is turning its attention to mRNA vaccines, having just agreed to buy 1.8 billion more doses from BioNTech/Pfizer.

Drug substance

The components that form one vial of vaccine are often produced at different locations around the world.

In the EU, AstraZeneca makes drug substance at two subcontractors: a Belgian plant originally owned by Henogen but bought by Thermo Fisher Scientific in early 2021, and another, Halix, in the Netherlands. The substance is then sent to a plant owned by Catalent in Anagni, Italy, to be put into vials. Another site, the AstraZeneca subsidiary MedImmune, does the "batch release," or quality checks, before the vaccines are sent to a Belgian distribution site.

The company also has three plants in the U.K.: Oxford Biomedica and Cobra Biologics both make drug substance, although Oxford Biomedica is the only U.K. site approved to send substance to the EU. Wockhardt carries out fill-finish in the U.K. and another plant in Germany, owned by IDT Biologika, has confirmed it has also done fill-finish for doses heading to the U.K.

Shortly after AstraZeneca announced the EU shortfalls in January, CEO Pascal Soriot said the issue was at its Belgian drug substance plant. But these documents contradict him, detailing instead assertions from the company and EU officials that the plant was meeting its contractual obligations. "Henogen has fulfill[ed] [its] contact with AZ," the inspectors wrote. "We cannot expect more efforts from them."

The company also added a new and "more efficient tool" to that site, which was expected to ramp up manufacturing by February 6, the report said. That plan may have been a reference to the expectation, laid out previously by an EU official, that the site would go from making about 4 million to 8 million doses a month.

By contrast, the Dutch plant did not produce much drug substance in 2020 when the company submitted the vaccine for approval in the EU, the documents suggest. It had an initial contract to make drug substance for Oxford University's clinical trials in April 2020, but did not sign another contract with AstraZeneca to make vaccines beyond clinical trials until early December.

According to European Medicines Agency information last December, Halix "has been removed as a … manufacturer from the dossier and will be added later in Q1 2021," they state.

The likely reason for the suspension was that the plant wasn't "ready" to produce enough drug substance, the EU official said. "If they haven't manufactured enough, then they can't meet qualification status."

By February 8, however, the Dutch plant seemed to be producing substance. The inspectors wrote that it was going to the U.K., most likely a fill-finish site in Wales, and to Italy. More shipments to the U.K. were expected, with the inspectors writing that the production of substance was "completed" and "shipment" of some substance to the U.K. "is anticipated."

However, the Commission's export controls appear to have kept the substance in the EU. International Market Commissioner Thierry Breton said after a March visit to Halix that nothing had been sent from that plant to the U.K. after the export controls were implemented in late January. By that point, the plant was able to make around 5 million doses a month. It was approved to make drug substance for the EU at the end of March.

Amid the production squeeze, the inspectors wrote, a "more sustainable" solution than relying on the U.S.-made drug substance could be adding more drug substance producers, possibly from South Korea's SK Bio. They also noted that another application is pending, most likely with China's WuXi.

Since then, AstraZeneca has submitted a request to have SK Bio added to the company's EU conditional marketing application, which would allow the EU to use vaccines made at the site, the EU official said, adding that the application is still pending with the EMA.

Fill-finish

It was the inspection of the Italian fill-finish plant run by Catalent that showed that the bulk of the vaccine substance arriving there actually came from the Maryland site — and confirmed the absence of shipments from the U.K.

Belgium and the U.S. "are the only ones to supply" drug substance to Italy, the inspectors noted.

The number of doses filled at the Italian plant was expected to decrease in 2021, as Catalent was also slated to fill the Johnson & Johnson vaccine. That order was to take priority over Oxford/AstraZeneca, which would move to "a less powerful, slower line" at a certain point. (The date for that switch in the document is redacted.)

AstraZeneca has since inked more contracts to do fill-finish elsewhere in the EU. It signed a contract with Universal Farma's Insud in January, and in early February, inspectors said the company had received the "frozen bulk" and planned to do batch validation in March. And under the just-announced partnership with Germany's IDT Biologika, the plant would do the fill-finish for at least 10 million doses.

The Italian site, meanwhile, also filled substance that came from SK Bio, but that was then sent to "non EU markets," the documents noted.

After fill-finish in Italy, the next step is sending the vials to AstraZeneca's subsidiary, MedImmune, in the Netherlands to do "batch-release," or quality checks. From there, the doses are sent to a distribution site in Belgium. Notably, the documents make clear that nothing from that Belgian site has been sent outside the EU.

"After verification, they [have never exported batches] to countries out of EU," the inspectors wrote.

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UK ventures into mRNA vaccines manufacturing

The Centre for Process Innovation will help speed up production of mRNA vaccines against new variants.

— By Helen Collis

The U.K. is gearing up to manufacture vaccines to target new coronavirus variants using the latest mRNA technology.

The Centre for Process Innovation (CPI), a not-for-profit that brings together academia, businesses and funders to commercialize innovations, is partnering with vaccine makers to accelerate and scale up production of messenger RNA jabs designed specifically to prevent disease from a novel coronavirus variant.

Although the World Health Organization and global public health bodies have yet to select the variant of concern to be the target of the next generation of vaccines, the CPI is already shoring up its supply chains to ensure that when that decision is taken, everything is in place to hit "go" on manufacturing, starting with clinical trials.

POLITICO spoke with Dave Tudor, managing director of the Medicines Manufacturing Innovation Centre at CPI, on how to secure mRNA supply chains, and what we can expect from the U.K., which is making its first foray into manufacturing new mRNA vaccines through the work of the CPI.

This interview has been edited for length and clarity.

How long has CPI been working with the pharmaceutical industry?

Since about seven years ago, when the government invested £2 billion to create a catapult network for high-value manufacturing. There are seven organizations just like CPI, as part of the High Value Manufacturing Catapult (HVMC).

What has your role been with the government's Vaccine Taskforce?

Ian McCubbin was leading manufacturing supply for the Vaccine Taskforce. He asked if I would be involved in the manufacturing supplies subgroup of the task force. I've been helping Ian and that team look at the whole manufacturing supply strategy of vaccines.

At CPI, we were asked to partner up with Imperial College London to try and push their mRNA vaccine technology and get that into the marketplace. I led the manufacture supply part of that work. Unfortunately, that vaccine didn't quite achieve the clinical endpoint that we were expecting, so it's gone back into the laboratory.

We're now involved in a strategy where we could support the Vaccine Taskforce on some future variants opportunities with the mRNA technology.

With the Imperial College product gone back into the lab, which RNA vaccines are you working on?

We've now stopped the work with Imperial and we're working with other companies that have mRNA technology. I'm not at liberty to say which ones. There are three companies with that technology: Pfizer/BioNTech, Moderna and CureVac. We're focusing on the ones that are approved.

Can you tell me what talks are happening?

We're looking at what's next with the mRNA technology. We're not trying to replicate what these companies are doing, but the science has come through at such breakneck speed we're looking at where we can enhance the science. So, for example, can we bring the temperature profile back to a room temperature stability?

The COVID-19 virus has accelerated RNA technology by about five years. This technology was around before the pandemic, but it was in its infancy. As a result of this acceleration, there are still lots of questions to be answered. And this is where CPI can play a significant role working in partnership with these companies to enhance the scientific understanding.

Is it specifically for optimizing and enhancing the technology that's out there, or is it also going to look at ramping up production to high volumes?

Both. It's trying to solve scientific problems but also give a rapid capability. If you look at the time scales that have evolved with the original variant, it's about 12 months for vaccine supply to come through. So what can we do to shave off three or six months from that time scale? That's where CPI can help.

In the event there's a new variant, we want to get the vaccine supply chain going faster, [with] CPI doing preparatory work to ensure that the clinical studies and scale-up of the vaccine is even faster than before.

Are your facilities Good Manufacturing Practices-ready (GMP) to do this work for U.K. and EU markets?

With government money five years ago, we built the U.K.'s National Biologic Centre in Darlington. The facility has been running for three years and it has a capability to turn its hand to any of the complex biological systems, gene therapies, viral vectors and others.

The facility itself was originally designed to be non-GMP, as a development incubator. But the money from the government for the Imperial vaccine has converted the facility to GMP. We are now operating under GMP conditions but we're about to be audited by the U.K. Medicines and Healthcare products Regulatory Agency in early May, and that should give us a GMP license.

So that would be the first GMP-compliant facility specifically for mRNA technology in the U.K.?

That's right.

Can you give me any timeline on what you aim to achieve and when with the mRNA work?

We'll be looking to manufacture some of the clinical trials material towards July and August. That allows the clinical evaluation to be done, and then the pharma industry to do the commercialization. We don't have any plans at this stage to make commercial material.

What's the capacity at the facilities? If there is a need to scale up, what could the center produce if it needed to?

One production line for RNA could produce 25 to 30 million doses a year, if needed. But CPI is not a commercial organization. Our remit is meant to be to drive the science and drive timelines for the government.

You're specifically focusing on new variants. Can you tell me how this is being done?

The Vaccine Taskforce will do this with support from the World Health Organization. We will be guided by the task force, and that will come from the research work on these variants.

Do you know which variants they are looking at?

I couldn't tell you because we haven't been told yet. There's lots of discussions about what the options could be.

How would you accelerate?

What's very attractive about RNA technology is that you can make some of the initial steps of it and freeze it, and it's stable. It's about early manufacturing at risk, and having real clarity on the supply chain end-to-end structure. It's about being prepared to take some of the early steps in the production process or the supply chain process, making those

decisions and making the material ahead of the event.

How much of that can you do if you don't know yet what the variant is going to be?

If you don't know what the variant is, unfortunately, you can't do any of the early make. The first thing that has to happen is the protein variant is converted to DNA and that's used to make the RNA. So until you know the variant, the clock doesn't start on early manufacture. [But] you can get the supply chain design up and running, get all the parts of the supply chain connected and contracted and ready to go.

You're just waiting for that variant announcement and then you can go — and you think that's going to come any day?

I don't know. But I think it would be weeks rather than days or months. The U.K. will need to make that decision sooner rather than later.

How ready is that supply chain?

That supply chain is probably about 60 to 70 percent ready. But we are working furiously hard to get it fully ready — that is a big focus for the Vaccine Taskforce. And like creating every supply chain, there are some little bumps in the road, but I'm wholly confident that we can create it.

What are some of the biggest hurdles in the supply chain for you?

Getting long-lead equipment items we have to purchase. Some may have up to 16 weeks lead time. There are some very basic consumables that are used in the production process, and getting access to the consumables is relatively challenging. And then there's the whole contracting side of it. In the supply chain, there's no single organization that's going to do it all.

Can you give me any examples of long lead equipment?

Bespoke reactors. This particular RNA technology uses lots of smaller identical bioreactors as opposed to one big one. And that's about keeping the science the same, so nobody plays around with the bioequivalence. The bioreactor is incredibly important, and getting our bespoke bioreactors has a long lead time.

Some of the lipids that are used in the manufacture of mRNA vaccines are now made in Yorkshire. Is that part of the supply chain you're looking at?

For the RNA technology you need to encapsulate it into a lipid to get into your cells. Twelve months ago, the liquid supply chain only had about two or three very small companies globally. But that has now increased and there are companies in the U.K. that are making lipid, like Croda, and that's been a really positive thing. That has been an example where we've responded to a supply chain risk that we've identified 12 months ago.