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From: (10)(2e)
Sent: Thur 7/16/2020 4:15:59 PM
Subject: RE: POLITICO Pro Morning Health Care: Health ministers talk second wave — Groups angry with Gavi — Romania extends alert
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Zal ik doen in het ochtendberaad morgen, dank voor het doorsturen.

Groet,

(10)(2e)

Van: (10)(2e) <(10)(2e)@minvws.nl>
Verzonden: donderdag 16 juli 2020 12:38
Aan: (10)(2e) <(10)(2e)@minvws.nl>
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Onderwerp: FW: POLITICO Pro Morning Health Care: Health ministers talk second wave — Groups angry with Gavi — Romania extends alert

Als je de Minister informeert (zie mail (10)(2e) net over de PV tweets), dan is hieronder in het geel mogelijk ook nuttig.

Van: Morning Health Care Europe <(10)(2e)@politico.eu>
Verzonden: donderdag 16 juli 2020 07:01
Aan: (10)(2e) <(10)(2e)@minvws.nl>
Onderwerp: POLITICO Pro Morning Health Care: Health ministers talk second wave — Groups angry with Gavi — Romania extends alert



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By JILLIAN DEUTSCH

With Carlo Martuscelli, Ashleigh Furlong, Carmen Paun and Helen Fessenden

SNEAK PEEK

- Health ministers will discuss the second wave and pharma strategy today.
- Civil society groups said Gavi, CEPI and WHO are not including them enough.
- Wellcome Trust's (10)(2e) said coronavirus therapeutics have a long way to go.

Welcome to Thursday's Morning Health Care! Belgian Health Minister Maggie De Block [wore a face mask](#) with her face on it to raise money for charity — but [Twitter was more focused](#) on the, err, interesting look of them. (And Morning Health Care was most interested to see De Block is wearing them incorrectly in two of the photos.)

Get in touch: (10)(2e)@politico.eu, (10)(2e)@politico.eu, (10)(2e)@politico.eu, (10)(2e)@politico.co.uk and (10)(2e)@politico.eu. Tweet us @deutschjill, @swheaton, @carlomartu and @ashleighfurlong

DRIVING THE DAY

PANDEMIC PRESIDENCY GETS TO SHINE: The first informal health ministers' meeting under the German Council Presidency will take place today — and they have a lot to talk about.

Ball is in countries' courts: For starters, the Commission wants to talk about the second wave preparedness. When unveiling its new guidance document on preventing a second wave, both Health Commissioner Stella Kyriakides and Commission Vice President Margaritis Schinas were clear on Wednesday: Countries need to get ready.

“Europe must use this period of lower transmission rates to reinforce its preparedness and coordinated response capacity to counter further outbreaks of COVID-19,” the Commission wrote. “Time is of the essence to ensure that science-based measures are in place and have been stress tested to guarantee adequate implementation.”

A case in point: Countries have remained vigilant with travel guidelines and face mask requirements, but very few have placed orders for items the Commission secured via joint procurement.

Only five countries (Austria, Estonia, Latvia, Belgium and one undisclosed country) placed orders for masks; Latvia placed an order for goggles; Luxembourg for gloves; and Bulgaria for ventilators, according to a Commission official. Several countries also placed orders for lab equipment, but the official didn't specify which kind.

Kyriakides and Schinas stressed that the Commission is doing all it can within the current competences to ensure the EU does not return to large scale lockdowns. Read the full story about the second wave document [here](#), and expect to hear the Commission's choice words for member states today.

But the Commission isn't off the hook: Fifteen countries are pushing the Commission to give EU countries more of a say in the pharma strategy. The countries — notably the Netherlands, Italy, Malta and Spain — wrote that they want to see more cooperation between the Commission and member states, and that countries should be involved in setting the objectives and development of the strategy.

They also made it very clear: They want a “mutual understanding” of everyone's competence — “guaranteeing respect to the competencies of the Member States.” We're eager to hear countries mention this today.

Germany at the mic: The German Council Presidency will also get to shine light on its major proposals, most notably strengthening the European Centre for Disease Prevention and Control (which [Finland](#) said Wednesday that it supports). We're keen to hear whether Health Minister Jens Spahn will also be more optimistic about the possibility of striking a health technology assessment deal. Stay tuned — as we sure will be.

WHO

WHO REVIEW PANEL LOOKING AT NEW CONVENTION: Could a new international convention requiring countries to notify a disease outbreak as early as possible be on the horizon after the coronavirus pandemic? That's certainly one issue the independent panel set up to review the World Health Organization's response to the pandemic would be looking into, according to Helen Clark, one of the panel chairs.

Even as the U.S. withdraws from the WHO, “this panel will want to hear American views, regardless of the status of membership of the United States of America, and we want the truth out,” [Clark told CBS News](#) in an interview published on Wednesday. “We don't go in to play to one side or another, we will put the facts on the table for the international community,” she said.

VACCINES

THE BIG MANUFACTURING PUSH: In normal times, vaccine development is risky, but not “plan, build and pay for possible future manufacturing” kind of risky. Now, companies are having to carry out their manufacturing planning in parallel to developing a vaccine. And the chances are pretty slim that any one vaccine will actually make it. In our latest [piece on vaccines](#), Ashleigh looks at what Europe is doing to get on track with manufacturing and what challenges it still needs to overcome.

YOU GAVI BE KIDDING ME: A letter sent Monday by the Gavi Civil Society Organization Steering Committee [obtained by Morning Health Care](#) to the heads of COVAX joint procurement project begins with a “thanks,” but the rest seems to be saying “for nothing.” The scheme, spearheaded by Gavi, the Vaccine Alliance, aims to create a pool to jointly purchase a future COVID-19 vaccine. The NGO said that civil society has been shut out of the leadership for the scheme, and complained that this was “missed opportunity to harness the full value of [civil society organizations] for the COVAX pillar and Facility.”

According to the committee, civil society organizations are particularly concerned about making sure access to a future COVID-19 vaccine is possible in “fragile, impoverished, marginalized and the hard to reach populations — where government largely cannot or does not act.” It ends by noting that a number of Gavi board members had voiced their support for including civil society in the project at a recent board meeting.

ICYMI: 75 wealthy countries, including a number of EU countries, [signed onto](#) the COVAX Facility to jointly purchase coronavirus vaccines.

CORONAVIRUS

LONG WAY TO GO: Therapeutics are just part of the approach to tackling coronavirus “rather than the answer to everything,” Director of the Wellcome Trust Jeremy Farrar said during a Chatham House discussion on Wednesday. Huge advances have already been made, he noted, but there’s a “very, very long way to go.” Some of the areas where Farrar saw the greatest promise are with convalescent plasma and monoclonal antibodies. (The latter are neutralizing antibodies that have been cloned from recovered patients or created in a lab.) They could possibly be used as a treatment and prevention if proven effective.

Sidenote on immunity vs. antibodies: Asked about the effectiveness of these treatments given emerging evidence of antibodies waning in the blood, Farrar reassured the audience that immunity may in fact be a separate issue. “What that means for immunity is a very different question,” he said. “Although the antibodies may wane, we don’t know if that means you won’t have longer-lasting immunity.”

The tsunami of preprints: He also weighed in on the usefulness of having thousands of papers published before being peer-reviewed, as has been seen during the pandemic. Farrar said that “on balance” the positives “massively” outweighed the negatives, because they bring out far more data into the public domain.

THE KIDS AIN’T ALRIGHT: The European Academy of Paediatrics (EAP) has released a number of proposals for policymakers to consider that could improve children’s health during the pandemic. One key issue is that most data on the disease focuses on adults: “Policies centred on adult data, that don’t consider the best interests of the child, risk causing more harm to children than COVID itself,” Adamos Hadjipanayis, EAP President, wrote in a press release. You can read the proposals [here](#).

BLOOD CLOT PROBLEMS: Representatives in the hematology and patient safety field are ringing alarm bells that patients hospitalized with COVID-19 have a high chance of forming disabling or deadly blood clots. The condition, called venous thromboembolism (VTE), is caused when clots that form in the veins of the leg groin or arm get lodged in the lungs. The International Society on Thrombosis and Hemostasis and 70 organizations have released [a statement](#) calling on the WHO to create a system-wide approach to VTE.

AROUND THE BLOC

ROMANIA TO EXTEND STATE OF ALERT: The Romanian government is planning to extend the state of alert by 30 days, given the record-setting number of confirmed cases reported in the country over the past week, President [Klaus Iohannis](#) said on Wednesday. There will be no new restriction introduced, but also no new relaxation measures, he said.

MORE MONEY FOR FRENCH HEALTH CARE: French Prime Minister Jean Castex announced that France will invest an additional €6 billion into the country’s health care system, and take over €13 billion of hospital debt. (A good chunk of this money is expected to come from the EU’s recovery plan, should EU leaders agree to a deal).

BELGIAN ABORTION DEBATE DELAY: Belgium's debate on whether to relax its abortion laws will be delayed until after the summer break, according to [De Morgen](#).

WHAT WE'RE READING

A new study showed vigilant mask-wearing prevented a coronavirus outbreak, writes the [New York Times](#).

[Bloomberg](#) has a long-read on the vaccine front-runner from the University of Oxford.

Skin rashes could be added to NHS' coronavirus symptoms list, according to [the Times](#).

POLITICO PRO ARTICLES

Europe's challenge of a lifetime: Manufacturing enough coronavirus vaccines

—By Ashleigh Furlong

The chances are that most coronavirus vaccines under development won't work.

But even if one succeeds, there's another hurdle: It needs to have a manufacturing and supply chain poised to produce and distribute billions of doses around the globe — a feat never attempted before.

This reality is causing drugmakers to scramble to get their hands on any available capacity. Pfizer and BioNTech, for example, are manufacturing the actual drug substance in both the U.S. and Germany, with later manufacturing set to be done at another U.S. site and in Belgium. AstraZeneca, which is developing and distributing the University of Oxford vaccine, has signed agreements with multiple manufacturing partners across the globe, including in [Italy](#), the [U.S.](#) and the [U.K.](#)

But they can't get around the fact that vaccine manufacturing is an inherently risky venture, said Harris Makatsoris, professor of sustainable manufacturing systems at King's College London.

To start with, "you have one group working really hard, on one particular vaccine candidate [and] one particular technology, and that group might be attached to a manufacturer in some shape or form," he said. And this group needs to invest millions in manufacturing capacity specific to its vaccine, so "if it doesn't work, then you have a big problem."

There's also the issue that setting up vaccine manufacturing in parallel to vaccine development isn't how it usually works, explained Charlie Weller, head of the Wellcome Trust's vaccines program.

"You wouldn't normally set up a manufacturing facility ... until you know that your clinical data is safe and effective," she said.

But the pandemic has forced an urgent response, with facilities getting converted and supply chains secured, all at enormous financial risk. In light of these costs, some of that risk is being mitigated by advance purchase agreements, with countries [racing to agree to deals with the vaccine front-runners](#).

"It can take a decade to bring a new therapeutic or vaccine to market, and typically only one in 10 drugs that enter clinical trials make it to the market," said Suzanne Farid, professor of bioprocess systems engineering at University College London.

What's more, each vaccine developer works on the assumption that it may be the only one with a successful vaccine for some time, according to the Association of the British Pharmaceutical Industry's Bryan Deane.

"They're thinking large scale at the moment," he said. "Because you've got no idea how quickly the second, third or fourth [vaccine] ... would come through."

But there is another problem — vaccines have global supply chains with a relatively small number of large companies

that can deliver such vast quantities. One possible workaround, said Deane, is the creation of a “network of manufacturing sites around the world to help scale it up on behalf of everybody.”

Europe grapples with capacity

Given the dismal statistics on vaccine success, it's no wonder experts are pointing to therapeutics and contact tracing as [possible alternatives](#).

But countries around the world see a coronavirus jab as the great prize, which has led to vaccine nationalism as governments race to buy up future doses and ensure that they're made as close to home as possible.

Whether Europe is able to manufacture enough vaccine for itself is the “billion-dollar question,” said King's College London's Makatsoris, admitting that international suppliers for the entire manufacturing process are still key for Europe.

Even DG SANTE's outgoing director-general, [Anne Bucher](#), [admitted in May](#) that the vaccine production capacity in Europe wouldn't be enough.

“The current production facilities will be insufficient to meet all the needs at the European level and also worldwide,” she told MEPs, adding that the Commission is in dialogue with the industry to see how it could help boost production capacity in Europe.

Many vaccines, many (different) challenges

Back at the lab, it's the multitude of different vaccines that may pose obstacles in scaling-up. Both the traditional and newer high-tech routes face challenges.

“If you've got a vaccine that, for example, works similarly to a flu vaccine, and you've already got large-scale capacity to be able to do that, then that's a different scenario perhaps than if you're working on new technology,” said the European Federation of Pharmaceutical Industries and Association's Andy Powrie-Smith.

But the old-school methods often make it harder to ratchet up production. For example, some vaccines need vast quantities of animal cells in their production.

“There's a limited number of manufacturers that are in a position to grow animal cells at 2,000- or 5,000-liter scale,” said Udo Reichl, professor of bioprocess engineering at the Max Planck Institute for Dynamics of Complex Technical Systems. “Obviously, these plants are not sitting there and doing nothing. They're usually busy with other things.”

Scale-up and speed problems are mostly solved when using high tech so-called platform technologies, experts say.

“You have the same production process, and with the same process, you can produce virtually any vaccine,” explained Zoltán Kis, research associate at Imperial College London's Centre for Process Systems Engineering.

Some of the more promising vaccines use [RNA](#), and these platforms have many advantages, including great speed.

So what's the catch? This method has never actually been used to produce commercial vaccines.

There is another issue. These new technologies don't solve the dilemma of how to fill the vials at the same speed. Kis explained that it's “almost impossible” to fill the vials at the rate that the doses are produced, “even if you have a huge filling facility.”

But he and other scientists are coming up with workarounds. For example, rather than filling the liquid into tiny glass vials, it could be filled into bags, sort of like IV bags, but 200 doses at a time.

Another option could be multidose vials instead of single-use, which “can allow for more efficient production as they can be filled faster and stored more efficiently,” said Pam Siwik, Pfizer's new product lead in its global manufacturing and supply team.

The big chill

It's about more than just producing billions of doses. It's about ensuring that they get to the people who need them, which requires proper storage conditions, said EFPIA's Powrie-Smith.

Once the vials (or perhaps the IV bags) are filled, they need to be kept cold on their journey. Ordinarily, vaccines need to be held at a temperature of between 2 and 8 degrees Celsius.

Toby Peters, professor of cold economy at the University of Birmingham, calls this the "biggest logistical challenge we've ever faced."

Broken cold chains are one of the main reasons for vaccine wastage. Estimates vary, but Peters cites figures of up to 50 percent of vaccines globally going to waste. "They mustn't freeze, they mustn't get too hot, otherwise they lose their potency," he explained.

New technology RNA vaccines pose an even bigger problem, because there's no certainty as to how stable they will be. In a worst-case scenario, they might need to be stored at minus 80 Celsius at all times.

This setting is "not very convenient" for the many countries and places that "likely lack the basic infrastructure" to maintain this, Pfizer's CEO Albert Bourla admitted at a briefing in May.

That's why scientists like Peters are working hard to come up with solutions that don't cost the earth — literally and figuratively.

"Cold chain is energy-intensive — it uses refrigerants, which have a big global warming impact," he noted. "So can we do it in a way that harnesses other symbiotic processes or cooling systems?"

One possibility could be to tap into existing food supply chains, even using part of the cold storage facility at the back of a supermarket or an existing food chain logistics network.

But that doesn't solve the next problem: When the vaccine arrives at the clinic or hospital, there may not be enough syringes and needles available to administer the jab. It's something that Ian Lindsley, secretary of the European Biosafety Network, is worried about.

"Nobody in Europe seems to have got a grip of this issue," he said.

The EBN has written to the European Commission and others to ask for clarity on the situation, but has not yet received a response.

What if it fails?

In the end, even if many of the vaccine candidates don't succeed, the hundreds of millions pumped into manufacturing won't be totally wasted, argues the Max Planck Institute's Reichl.

"The companies are in a position to switch products if one approach isn't successful," he said.

One case in point is Pfizer, which admits its vaccine may not be the winner.

"If unsuccessful, we'll refocus as much of our effort as possible," said Siwik. In fact, it may even mean supporting another pharmaceutical company.

"Once any therapy or vaccine is approved, it will need to be rapidly scaled and deployed around the world," she said. "Pfizer is committed to using any excess manufacturing capacity and to potentially shifting production to support others in rapidly getting these life-saving breakthroughs into the hands of patients as quickly as possible."

Commission: Summer is for second wave prep — not vacation

—By Jillian Deutsch

The European Commission had choice words on Wednesday for citizens and countries two weeks before August holidays: Now isn't the time to let your guard down against the coronavirus.

"We do not have the right to say this is too much, I'm too tired, this is enough," Health Commissioner Stella Kyriakides said when presenting the Commission's [guidance](#) on a second wave. "This would mean giving up all the sacrifices that have been made."

Through large-scale lockdowns, European countries contained the coronavirus just in time for the summer, allowing people to plan vacations while they watch coronavirus spread in other regions — most notably the Americas.

But member countries need to get their acts together now, the Commission warned, advising countries to build up stockpiles of medical gear and boost health care capacity and testing, especially among vulnerable groups.

It also pointed to some worrying signs, such as localized outbreaks in countries like Spain, Portugal and Romania. And flu season is coming up, which already overloads health systems every year without any help from the coronavirus.

The Commission cited scenes from the spring — uncoordinated border closures, medical supply shortages and overloaded health systems — as a cautionary tale: Whether countries use this time to prepare for a second wave will determine whether the fall will become a repeat of this chaos.

"One cannot say that a second wave is inevitable," Kyriakides said. "We need to have joint actions, and we need to be vigilant" to avoid returning to general lockdowns.

But the Commission lacks a big stick: Both health and borders are largely a member state competence.

Kyriakides, flanked by Commission Vice President Margaritis Schinas for the presentation, argued that the Commission has done its part.

The Commission created rescEU stockpiles of protective gear and medical equipment; crafted a plan to advance purchase coronavirus vaccines; and launched five joint procurement efforts.

Moreover, some of the shortcomings have been due to the member countries, not Brussels. For example, only Bulgaria has placed an order for ventilators through the EU's joint procurement contract.

To better prepare for the fall, the Commission has asked countries to run stress tests of health systems and care homes. It has also asked member countries to report what their needs are for protective gear and medical devices, and at what levels their current stockpile are. They also need to secure flu vaccines and start immunizing.

The Commission's guidance on Wednesday highlighted a number of other interventions as well: Testing is "essential," as well as contact tracing and public health surveillance.

"Their rapid scalability is crucial to keep up with a possible progression in the pandemic and to avoid having to reinstate strict confinement measures," the Commission wrote in its guidance document.

Interoperability for contact tracing apps needs to be a "reality" so workers and travelers can cross borders, it noted.

But the Commission is still struggling to address big-scale problems, including the lack of comparable data between member states. Andrea Ammon, the director of the European Centre for Disease Prevention and Control (ECDC), [said on June 30](#) that countries' different and changing reporting methods were a problem when the agency tried to assess outbreaks across the bloc.

The Commission also wrote in its guidance document that the access to protective gear and medical devices was a "major shortfall" earlier in the pandemic.

"Despite some improvements, there are no indications that shortages of medical equipment have been fully resolved," the document read.

On borders, the Commission warned they should only be closed "where it is strictly necessary."

But when asked by POLITICO why only three countries are respecting the EU's external border guidance, Schinas said the Commission is "in the hands" of member states.

Paola Tamma contributed reporting.

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